UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE
ON MEAT AND POULTRY INSPECTION

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FALL MEETING

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TUESDAY,
NOVEMBER 15, 2005

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SESSION OF STANDING SUBCOMMITTEE NUMBER 1

The breakout session commenced at 4:11 p.m. in Room 0161, United States Department of Agriculture, 14th and Independence Avenue, S.W., Washington, D.C., Michael Kowalcyk, presiding.

PRESENT:

MICHAEL KOWALCYK	Safe Tables Our Priority
MARY CUTSHALL	Director (SIPO)
JAMES DENTON	University of Arkansas
KEVIN ELFERING	Minnesota Dept. of Agriculture
DAN ENGELJOHN	Assistant Director (OPED)
MIKE FINNNEGAN	Montana Dept. of Livestock
EVE HUBBARD	FSIS
CHARLES LINK	Cargill Value Added Meats
CATHERINE LOGUE	North Dakota State University
BARBARA MASTERS	FSIS
RICHARD RAYMOND	Undersecretary for Food Safety
MARK SCHAD	Schad Meats, Inc.

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

(4:11 p.m.)

MR. KOWALCYK: Okay. I guess for the transcribers I think it might be useful for us to go around quickly and everybody introduce themselves. My name is Michael Kowalcyk. I'm with Safe Tables Our Priority.

DR. DENTON: James Denton with the University of Arkansas.

MR. ELFERING: Kevin Elfering with Minnesota Department of Agriculture.

MR. LINK: Charles Link with Cargill.

DR. RAYMOND: Dr. Raymond with FSIS.

MR. SCHAD: Mark Schad with Schad Meats.

DR. LOGUE: Catherine Logue, North Dakota State University.

DR. ENGELJOHN: Dan Engeljohn, FSIS.

MS. CUTSHALL: Mary Cutshall, FSIS.

MR. FINNEGAN: Mike Finnegan, Montana.

DR. MASTERS: Barb Masters, FSIS.

MS. HUBBARD: Eve Hubbard, FSIS.

MR. KOWALCYK: Okay. We've been asked by

the agency to address questions regarding the inspection and the paradigm of risk-based inspection, and the first issue from Mr. Derfler's presentation discussed the deployment of resources. And there are specific questions with -- specific questions regarding four elements of the risk-based approach.

They are: attempt to align resources not only with what needs to be done -- example, appraisal of the carcass at slaughter, visiting establishments once per shift in processing -- but also level of risk-based on consideration of hazards presented by type of product and production process, consideration of how likely it is that hazard will be manifested in a plant, significance of effects of hazard if realized, and, lastly, ongoing assessment of establishments, food safety system, including interventions and testing.

The first question posed to us is: what do we think of the four factors that have been highlighted? And I guess I'd like to open the floor to discussion on those four factors, so we can brainstorm a little bit about what our position as a

subcommittee should be with respect to those four factors.

MR. LINK: Well, I had a question on the second factor. It talked about consideration of how likely it is a hazard would be manifested. How do you do that? I mean, is that I guess based on -- you know, I've heard talk of the hazard coefficient and different things.

I mean, how do you decide because I'm producing a ready-to-eat product that I'm likely to have a problem? Is it based on I'm using -- it's alternative 3, therefore, I have a higher risk? Or if anything is alternative 1 -- I guess, is that what we're looking at, or is there some other factor in there that you're considering when you try to decide if this hazard is likely to manifest itself?

MR. SCHAD: See, to me, that's based more on your food safety system than necessarily the product you're making or the type of process.

MR. ELFERING: I think it can be a lot of variables as well. I mean, you can -- you're going to have a higher risk. If you're making manufactured --

the end product is the same exact product. But if you're bringing raw ingredients into a plant in making the end product, or if you're bringing already-prepared products into the plant, you know, the risk is going to be different. So I think there are so many variables.

DR. LOGUE: Well, one thing -- one thing maybe we should consider is, what kind of risks do we want to look at here? I mean, we can talk about everything, but maybe we need to narrow the focus. Do we only want to just focus on it in terms of pathogens that would cause illness to humans versus something like BSE versus -- I don't know. Maybe we should narrow it to one thing.

MR. ELFERING: Animal pathology versus --

DR. LOGUE: Well, I think --

MR. LINK: I mean, you've got allergenic ingredients that you may use when you're not --

DR. LOGUE: I know, but we're not going to be able to cover all of these.

MR. LINK: No, I guess --

DR. LOGUE: So maybe we should define what

we want to look at.

MR. LINK: These four areas are pretty broad. I guess maybe we're digging in where we shouldn't be. I don't know, but -- I mean, because there's a lot of -- when you look at hazards, it's more than listeria, certainly.

DR. LOGUE: Yes. But, I mean, we could almost put all of the pathogens together versus something like a BSE. See what I'm saying? Maybe we should focus on, what will be the primary thing? And right now I would say to you maybe pathogens would be a bigger thing to look at than anything else, because they cause the most illness.

MR. FINNEGAN: The thing is is that the plants themselves, in their HACCP plan, they've addressed their hazards. They've already addressed their hazards that will -- is it likely to occur. So are we coming from FSIS, or are we looking at -- coming with our own hazards, or --

MR. ELFERING: I think it depends on the process, though. In a slaughter plant they don't necessarily -- they have not addressed every hazard in

a slaughter plant. They're not looking at the animal pathology and all, but they would be doing a hazard analysis on any process product.

DR. LOGUE: And they may not be able to find allergens in it.

MR. ELFERING: Well, they would be addressing that in the HACCP plan as well.

DR. LOGUE: To some extent, but --

MR. ELFERING: Well, they have to. Anything that's a hazard that's reasonably --

DR. LOGUE: Okay.

MR. ELFERING: -- likely to occur. And they have to address it.

MR. FINNEGAN: And they have to be pathogenic-specific. That's how we've addressed our hazard analysis, where you've got to -- well, what bug are you chasing? I mean, no sense chasing E. coli 1574, a ready-to-eat product, because you're going to cook it at 145 degrees. That doesn't make sense to do that.

DR. LOGUE: I don't know. I thought we could make it a little bit more focused, but maybe

not.

MR. LINK: Well, if you look at the question -- I mean, are these four areas adequate, probably they are. I mean, you know, they're going to look at the hazards that are there, consideration of risk I guess --

DR. DENTON: They do cover a wide range of issues there, and I think that's probably in the best interest of the subcommittee and the agency is to keep it as broad as we can, because if we get too specific, we're going to get bogged down in the details with regard to how we would actually deploy those resources.

I think just thinking in terms of what the particular type of product is, and the process used, is enough to make a judgment based on historical information that has already been collected by the agency, as well as what's out there in the scientific literature that we could make the decision that we wouldn't be looking for something like O157 if somebody is making jerky, as opposed to somebody that's making ground beef patties.

MR. FINNEGAN: Right.

DR. DENTON: So it's going to be product and process specific with regard to any particular pathogen that we look at. So I think that they've probably defined that pretty well by saying that it's a hazard that's presented by the type of product and the production process associated with that. That's one man's opinion.

MR. FINNEGAN: Okay. I agree it would have to be also species-specific.

DR. DENTON: Yes. I made a note in the margin "species."

DR. LOGUE: All right. Well, then, are four points enough? Do they cover it? Sounds like --

DR. DENTON: And the next one gets at the heart of the issue is the likelihood of the occurrence. I think that's an appropriate thing.

MR. LINK: Is that -- I don't know. I guess I -- that's where I started this whole conversation, because I was asking, how do you figure that out? Are you doing that based on our hazard analysis, or based on your own food safety assessment

of our hazard analysis?

Or, to your point, because I've got -- I've got ready-to-eat products, I've got raw products coming in, I've got -- there's all kinds of opportunities for a cross-contamination issue, or whatever, I guess somebody has got to make a judgment on that.

MR. ELFERING: Well, even --

MR. LINK: I'm getting in the weeds again. I shouldn't --

MR. ELFERING: Well, no. You've got so many different types of processing facilities. You may have facilities that all they do is do portion control cutting, and they're not doing any cooked product. Some of them grind. A lot of them don't anymore. A lot of these portion control operations don't even grind, because they don't want the risk.

MR. LINK: Right.

MR. ELFERING: So, to me, that's a very low risk operation, much lower than a grinding operation. How do you put your arms around something like that, though, to try to break those down as -- I

mean, just as simple as that, grinding as opposed to not grinding increases the risk tremendously.

MR. KOWALCYK: I think to add to that, I'd be interested in learning if the agency has any hard data behind some of these factors as far as where you envision how resources could be deployed based on what you already know, and are there gaps there that you're looking to fill. Are you looking for guidance from us as to identifying additional factors beyond these? Has the agency done some work with respect to these factors already that we can talk about?

DR. ENGELJOHN: This is Engeljohn with FSIS. I would say that we haven't identified, other than going through the exercise of the June -- the last meeting, June 17th, where we identified for a ready-to-eat operation involving listeria, what are the factors that affect whether or not listeria is likely to be present.

So we have identified there those factors, and then the subcommittee provided additional things. But I think as you're pointing out, you -- it may be that this committee would come back to us and say

there needs to be more clarity assigned to, what do you mean by consideration of how likely it is to occur?

And you identified if you are -- if you have multiple suppliers, that presents a different risk maybe than if you control your own ingredients. If you further process it, that adds another component to it. So I think it's -- that's the kind of thing for which we haven't yet provided additional clarity, other than in the factors that we identified for listeria, and we had not identified additional things for O157 yet, as an example.

So, because we had a risk assessment on listeria, there were factors identified there that presents one product as being greater risk than another. Not doing a post-lethality treatment or not doing an anti-microbial intervention presented a greater risk than if you just relied on sanitation.

So we have scientific data for ready-to-eat products that are less exposed to the environment. But we haven't provided any additional documents that clarify this for every type of process that's out

there.

DR. DENTON: Particularly the raw products, I would think. Is that what you're referring to?

DR. ENGELJOHN: Yes. I'm saying we've put out generic models, HACCP models, and we've put out a hazard guide that identified the types of things that we think are relevant to processes. But I think the issue is here, are there other things -- construction as an example -- in a ready-to-eat operation provides an additional risk. So I think there's -- there is a need to articulate what cold be all of the possible things that affect risk in an operation.

DR. RAYMOND: As an example, though, we know that salmonella is seasonal. And after the hurricanes, we know the salmonella risk goes up. I mean, there are some things that we do know.

And, Barb, did we not have an outside --

DR. MASTERS: We had earlier, John, an expert elicitation, and that's what we talked about. You all had asked us for that information, and we had done -- the vision document was done on the earlier

expert elicitation on product and processes, and so we have that from earlier.

And so the agency has that information on products and processes, and that work has not been updated, and we're looking at updating that work. We're early in that process, looking at products and processes exclusively. But it doesn't take into consideration all of these questions.

MR. ELFERING: Have you analyzed data that you have based on regions of the country or anything like that, you know, looking at -- are you getting all of your salmonella performance standards, failures, in one part of the country as opposed to another, or --

DR. MASTERS: We had done some early work on that, yes.

DR. ENGELJOHN: When we constructed the national baseline -- in the early baseline students, they were designed to get prevalence in products, classes of products, over the course of time, so over the course of a year, in order to get the four seasons.

And then, after we conducted the

baselines, the other Advisory Committee, National Advisory Committee for Microcriteria for Foods, looked at the information to see whether or not there were, in fact, regional or seasonal effects. And so the recommendation back from that committee was, if you design future baselines, you must address region and season.

So we got guidance back from them as to how we should conduct future baselines to specifically address the issues, because we do have some processes that are only seasonal. Some -- this time of the year turkey production is higher than at other times of the year, and in the spring ham production. And other types of processes are higher.

So there are seasonal effects that go with various times of the year that -- that may present different types of need to conduct activities. So that's one of the things that could go into that category.

DR. LOGUE: Does that mean, then, with that new E. coli O157 stuff, that you've designed that with this in mind? Does that use sampling that you

wanted to do baseline --

DR. ENGELJOHN: Yes. The new baseline is designed -- the original E. coli O157 baseline is an example in ground beef, was done for only a nine-month period. This one will be for a full year at a minimum, in order to get the full gamut of production over a course of time.

DR. LOGUE: Okay.

MR. FINNEGAN: To get back to that question, are they appropriate elements -- like Kevin was saying, you take a small plant, and we've got a lot of them, they are strictly boning and grinding, and if that plant has finished their salmonella set without any big problems or any E. coli positives, does that inspector have to sit in that plant all day for eight hours? I don't think so. Not in a simple, low risk.

So in answer to the question, are they appropriate elements, the hazards would be appropriate on a basic operation that has had a pretty good record. And, you know, I know of several plants that fits that scenario, and the inspectors are there for

eight hours.

DR. ENGELJOHN: Could you clarify, is that slaughter or processing or both?

MR. FINNEGAN: Processing. Even some of -- a lot of our very small plants, they might slaughter one day a week. Then, the remaining four all they do is bone and break and maybe -- or maybe not. Like Kevin said, grind. In that basic type of plant hazards would come into play.

MR. ELFERING: Well, I think they are certainly appropriate. The only thing that I always cautioned about is what are real hazards and what are perceived hazards again, you know, and really, you know, is -- is salmonella in poultry, in raw poultry, is it a hazard? When you're not looking at campylobacter, which is much higher prevalence, are those really truly hazards?

I mean, are you ever going to be able to get them to the point where you're going to ensure that you have a much safer product? You might be able to reduce them somewhat.

DR. DENTON: You reduce them, but that's

the best you can do.

MR. LINK: And maybe that's one of the considerations is when you look at this, if you're talking salmonella in raw poultry or listeria in ready-to-eat products, maybe more emphasis is on listeria --

DR. DENTON: Absolutely.

MR. LINK: -- than on raw poultry. I don't know.

MR. ELFERING: And even with salmonella in cooked ready-to-eat products, I think most of the work that's been done with those is there is very little salmonella in fully cooked ready-to-eat product, at least of some -- I don't think we've ever had a positive salmonella. We've had positive listerias.

DR. DENTON: Nor have we in fully cooked product.

MS. CUTSHALL: Can I ask you a question for clarification, so that I'm sure I'm capturing the essence of what you're saying? You're talking about appropriate hazards and what are real and what are perceived hazards. And what I'm hearing you say is

that you really want to look at reduction or elimination and which can be the most effective for the appropriate organism of concern. Is that --

MR. ELFERING: You want a zero tolerance in anything that's fully cooked ready to eat certainly, but in a raw product that's not always achievable.

MR. LINK: I'd debate the zero tolerance thing with you, but that's probably outside the scope of this discussion.

PARTICIPANT: How late do you want to be here?

(Laughter.)

DR. LOGUE: This here -- I'm not looking into this as well. Like you said, salmonella is probably more common in poultry than it may be, you know, in pork or beef it's slightly less, but I don't know.

MR. LINK: So I guess I look to this thing that we've kind of beat it to death. But, really, you're looking at the hazards that are there, and to your point again, make sure we're looking at real

hazards. And if you're assessing the risk, the likelihood of severity of that hazard, I guess you've captured it.

And if you look at raw poultry versus ready-to-eat poultry and the different risks, different hazard -- so I guess it's captured. I don't know. I just -- I don't know if we need to, maybe to your point, Dan, clarify some of the language there. But I don't know if there's -- if we need extra points or not. I think these four pretty well. They're broad. They capture it.

DR. DENTON: They capture it. And, really, that last one, with the ongoing assessment of the establishment's food safety system, including intervention and testing, really kind of pulls it all together with regard to what the expectation is on the part of the establishment. I can't think of anything outside of this that jumps out at me that we could add that would improve this.

DR. LOGUE: And this would include new technology.

MR. LINK: I want to say that's why I look

at this a little bit, and I wonder if I -- if I've got two plants side by side, and one of them is doing a little bit better job with this number 4 point, maintaining and managing their system, that ought to be taken into consideration as to where you put your resources and how you look at that. So --

MR. KOWALCYK: I'd be hesitant -- I think the last point -- ongoing assessment -- is critical, obviously, to identify where problems could occur and how the agency reacts to that is key. I'm a little concerned that when you're talking about hazards that are more likely to occur than others, when we're looking at inspection where there's carcasses on the line, I don't want to open the door for -- I'm not comfortable with going down the way of not doing what's already doing now. I see this as something that it should be added to -- to make the inspection system more effective to result in a safer product ultimately.

DR. LOGUE: So you want to start with a certain standard, and then just keeping piling on on top of that. Am I right? Well --

MR. LINK: It sounds like a safe way for the work to be done.

DR. LOGUE: -- that's what you're saying, yes, whereas we're kind of thinking about maybe if this plant is always achieving, move that resource to something else. Isn't that what -- where there isn't a bigger deficiency, whereas you're saying keep this and add this on top of it all.

MR. ELFERING: But it's that and, you know, I know -- I understand the issues with BSE, and that the agency had to make some decisions on specific risk materials. But there is virtually no risk at all, so why do you -- why do you put all of your -- why do you put an emphasis on BSE when you may have a much bigger issue in the same facility?

DR. LOGUE: With O157 or something else.

MR. ELFERING: Right.

DR. LOGUE: Yes.

MR. ELFERING: I mean, especially in a lot of these plants there is a lot of -- cattle are all less than 30 months of age.

DR. LOGUE: And all the SRMs removed

anyway.

MR. ELFERING: Well, in most cases they are. They just do it, but, I mean, to me that's -- that's a waste of resources.

MR. KOWALCYK: I think that's to the perceived risk versus the actual.

MR. ELFERING: Exactly.

DR. ENGELJOHN: Just as a matter of clarification, when you said that from your perspective you'd look at layering on additional activities from the current, is the assumption that what the agency has in place with slaughter inspection now, which is presence -- any time slaughtering activity is occurring there is that putting of goal inspection of every animal and with -- and so that's one concept.

With processing we use another, which is that there is the daily activity. What -- that daily activity can vary, but we don't apply it the same in slaughter and processing, so that's the assumption you would go with, starting with that.

MR. KOWALCYK: Well, yes. And then, those

applications I'm assuming would not change for a slaughter plant and that processing plant. You're just looking for ways to allocate resources to address specific hazards.

DR. DENTON: And establishments that have a greater risk associated with their product than their process.

MR. KOWALCYK: Right. So it's more of an establishment level.

DR. DENTON: Establishment, and the product, and the process that's used. If you have a higher risk product, that's where you want to focus your energy.

MR. LINK: Maybe there's one more question. We were talking off the record earlier, but defining what inspection, as we were talking about deploying resources, do we need to define what it is they need to be doing, and what is the inspection -- to your point, I mean, can we do -- can you do something offsite, if you can access records or whatever?

DR. MASTERS: And that's really the next

question.

MR. LINK: Is that getting to the next question? Is that a segue?

DR. ENGELJOHN: And I think it's an important issue to address. Can it be done differently? Can inspection be defined differently for various aspects?

MR. FINNEGAN: One thing I might want to add to the last, question number 1, is hazards. You know, thinking of the small plants, the hazards are different in the very small plants. You know, the very small plants, most of it is manual labor as compared to machinery.

I know we have mostly very small plants, and I think that has to be taken into consideration, too -- the type of the process. I mean, for slaughter all of our guys use a cradle. They're hand-skinned and hand-viscerated.

DR. DENTON: Would that fall in the production process for these smaller plants?

MR. LINK: First bullet.

MR. FINNEGAN: Right.

MR. LINK: It's in that first bullet there.

MR. FINNEGAN: Right.

MR. LINK: Product and process.

DR. ENGELJOHN: And that's, I think, an important -- from the agency's perspective, I think we look to research to see who is doing what research on mapping carcasses. And I think if there were data available to show that in your case, small operation where it's hand-dehiding on a cradle, and you don't have the high line speed production process and the yanking of this -- the hide off by mechanical means, that you may, in fact, because of the process be able to create a cleaner product.

Your hazards may be different, or they may be located differently on the carcass. But I think that data would be an extremely important piece of information that if not already available could and should be one of the data types of things hopefully the other group may identify.

But you're right. The process, just by -- by volume or speed or just because it's --

MR. FINNEGAN: Mechanized or --

DR. ENGELJOHN: Yes, mechanized or not, may in fact make a big difference in terms of the likelihood or presence of various organisms.

MR. FINNEGAN: Right. good.

DR. ENGELJOHN: But because we talked about it here, I think it's -- then, that can add to the clarity of what that issue actually means.

MR. KOWALCYK: So we would -- based on that, we would add to that second bullet, based on technology, plant size, as examples -- technology utilized, plant size.

MR. FINNEGAN: Technology. Sure. Yes, that would -- that would fit.

MS. CUTSHALL: Do you still want to include product? You had mentioned product earlier.

DR. MASTERS: That's in there. I think the chart is -- they're back on the chart now, Mary.

MS. CUTSHALL: Oh, okay.

DR. MASTERS: Do you have your chart?

MS. CUTSHALL: Thank you, Michael.

MR. KOWALCYK: So are we comfortable with

-- are we comfortable with these four points, with that minor addition?

DR. MASTERS: You added species somewhere. Where did you -- where are you recommending to add species?

DR. DENTON: Probably the first bullet.

MR. ELFERING: I mean, I think actually Phil had that in his presentation. It's not in this text here.

DR. ENGELJOHN: Charles, just on that last bullet, on the ongoing assessment of the establishment's food safety system, you raised the issue earlier today about the value of that checklist and what its intention was.

And, really, that's an instrument that the agency came up with to try to get at the issue of, is the validation supporting a food safety system different in this establishment versus that one? Is this one based on real data? Is this one based on a little bit of data, but mostly computer modeling versus just the agency's compliance guidelines, with no actual data?

And that's part of the issue is: how do you define measurement of that ongoing assessment? And that's one way that we've looked at trying to get at --

MR. LINK: I didn't have a problem with the checklist per se, just that, you know, in the past, going back a few years I guess when we were first looking at listeria and trying to understand what alternative they were in and what interventions we were using in the plants, the inspectors were trying to fill out spec work and made a lot of mistakes, because they didn't have all of the facts and weren't able to really sit and discuss it with the plant.

And I just didn't want to revisit all of that, particularly if we're going to go through all this testing and come away with, "I'm not sure how they're doing. We're going to test them again."

Our goal is to provide -- when we collect information that we think makes a difference as to how we view your operation, it would be my hope that we -- we are, in fact, sharing that with you, so that you

know what information we're using.

So that if we come up with a score on that checklist, you would know that and have the opportunity to say, "But I have this data that you marked me down on. Here it is." You know, so that there is an interaction. It should be an educational activity to begin with. But in any case, it's a feedback loop that we're trying to build into the system.

DR. ENGELJOHN: And that addresses a concern, and certainly we'll do the -- we'll do it ourselves, so we're --

MR. LINK: All right.

MR. ELFERING: Do we want to add anything in here at all asking if -- directing the agency or suggesting that this would be done by developing a more in-depth profile to actually do this first initial hazard analysis?

MR. KOWALCYK: Profiling each plant based on product, plant size, technology, so --

MR. ELFERING: More in depth than what they have now. Now you've got, you know --

MR. FINNEGAN: Oh, I see what you mean, yes. Right now we have a profile set up to pick which codes you're going to use or you're talking about. Right.

MR. ELFERING: But have something more in depth, you know, of -- of that plant profile.

DR. ENGELJOHN: To capture these issues. I think that would be helpful.

MR. FINNEGAN: I think that would be a good idea. I do.

MR. KOWALCYK: As far as another possible addition would be utilization of public health data. We already spoke earlier about seasonality and greater sensitivity to E. coli or salmonella at different times of the year.

What can the agency do in the way of if the -- you know, utilizing outbreak data in a certain area -- you know, there are certain plants that distribute within that market, how can you direct resources to look a little more keenly for those indicator organisms or pathogens that are of interest? Is that something we would want to add?

MR. LINK: Well, we may be getting into the other subgroup, I don't know. But since you brought it up --

(Laughter.)

-- I think it's important, you know, we look at the data that the CDC has, or whatever. I mean, we need to get the attribution data. We need to understand what's really there. I know that the agency, when you're doing salmonella testing, for example, you're served like -- I mean, I don't know, when you look at that and compare it back to the pathogenic salmonella versus non-pathogenic, and is there really something of concern or not, or are we just finding bugs that are out there.

So if we're going to look at the data, we need to really look at it and understand what it's telling us.

DR. LOGUE: Well, you need to do more than just serotype it. You've got to do virulence typing if you really want to know everything. You've got to do Brown's genotyping expression studies, and not everybody is going to do that.

MR. LINK: No. I know. I mean, we find bugs on the phone we don't find in the plant, and we don't find at CDC, that they are saying make people sick. You know, I mean --

DR. LOGUE: Is it important or not? Is it an environmental strain? Is it a non-pathogenic?

MR. ELFERING: I think, actually, USDA has been doing a pretty good job using public health data. They certainly have -- we've had some good success with even having recalls initiated based on public health data, even just epidemiologically linked. So --

DR. MASTERS: I hear Michael suggesting that you try to tie the data back into how you deploy your resources, and the nexus is not made between column 1 and column 2 as the column exists. Is that what I hear you suggesting?

MR. KOWALCYK: Yes, I think with respect to that, yes. And that's I guess once the committees come together.

MR. FINNEGAN: I know one of the things that EIAO checks before they come for a review is

consumer complaints. You know, that would fit right into the --

MR. LINK: So is there I guess a fifth bullet point then? Is that what we're saying, data -- if that's microbial data, complaints, whatever, external data I guess.

MS. CUTSHALL: Is there something that's not covered in the data bullets that are there? One thing I heard you talk about that I didn't see, and I assume you're still talking about -- you're back to deployment of resources, charles?

MR. FINNEGAN: Yes, we're still there. We're still on that same one.

MS. CUTSHALL: No. I'm just clarifying. We had the recommendation to add based on technology, plant size, process, and we talked about species that may be wrapped into bullet 1. You also recommended to revise the plant profile to capture these types of issues, and you're suggesting, as a -- possibly a subset of that that seasonality and other data should be included as part of that profile?

MR. LINK: I was asking -- I guess I was

asking a question trying to get where Michael was going with the data, and is that a piece that -- I mean, it's all here, but it's not one of these four groups.

DR. ENGELJOHN: First of all, this has to be presented by the type of product and production process. It may lead back to what's the epidemiologies there, what does CDC say is -- these are the pathogens or the serotypes that are causing human illness, and then are those present in the operation? That would be maybe one way to look at the first bullet there.

MR. FINNEGAN: Actually, our group here, is it not, we're supposed to look at risk-based inspection, and the other group is going to look at the data, risk-based data.

DR. MASTERS: I'm just suggesting data -- I think Michael's point is, though, is there a question needed to make the nexus to all of their work to say, "How is the data considered by the other group used in making inspection decisions?" I think that's the question I hear Michael asking, not that we need

to get into data questions, but is there a nexus between all of the good work that they're doing, when you go to deploy your resources is there a nexus there.

Is that data they're coming up with going to be used to drive your inspection resources I think is what I hear Michael asking.

MR. KOWALCYK: Right. Because we're taking information about the plant, about their process, about their product and technology. It's just another element to add to that decisionmaking process, that we know there's something going on in the communities in a certain area. This may be the time for the agency to step up.

DR. ENGELJOHN: Or, as you were saying maybe that the agency may not have any data on plants in a particular region, and that may trigger, then, the need to collect samples in order to get that information. So that could be one way to tie those together.

MR. KOWALCYK: So I think it fits to add something of that nature to this.

MS. CUTSHALL: Well, I added something similar to what Barb said is the overarching question. Is there a way that you can make the nexus between deploying your resources and the data that's available and the data that's needed? Does that capture it?

I think you had started on work to be done.

MR. KOWALCYK: Do we believe that there are ways other than decision criteria to guide inspectors as they perform their activities? I guess one question that comes to mind from the presentation this morning is decision criteria was issued in 2003 to help guide inspectors. Has the agency looked back to see how effective that has been as a management tool?

DR. MASTERS: Phil talked about the FSIS Directive 5000, and it is somewhat of a decision criteria. It is a directive that gives the if/then type mentality, and we have done one effectiveness evaluation on that directive. And so he gave that as a model. That was the first directive that we put out there to help our inspectors understand rather than

just giving them a command. But give them the if this, then that.

And we did do an evaluation or -- yes, it was an evaluation, it was not -- it was just a questionnaire type of situation. And we did do an evaluation of that and got pretty good feedback on that directive, and the comfort -- our inspectors like having the if/then type directives put out there for them.

So we did do an effectiveness evaluation on that directive. And so that's the most that we've done in that area.

DR. ENGELJOHN: But a recommendation to continue that or ongoing would be helpful. So --

MR. KOWALCYK: Yes. I mean, if it seems that inspectors are receptive to that approach.

MR. FINNEGAN: I think they are. I mean, just other than just being -- and that's one of the problems is being a robot and perform -- perform, you know, where you put a little -- teach you to have a thought process. And I'm all for that.

MR. KOWALCYK: Being that this was one

directive, has there been any need to alter it? And if so, how flexible -- how flexible is it? I mean, is it, you know, a change comes, okay, the agency puts out an update to that directive, is there anything lost in that transition to "This is how it was done last week, and now this week we need to look at it this way"? Has there been any experience with that?

DR. ENGELJOHN: No. But I think the goal is, and as I had said, I think it's always important that we have built-in mechanisms to measure the effectiveness of the policy, particularly if there is a change. And so that's something that we have a need to have ongoing.

I did want to just raise one issue maybe for you to stimulate some thought on. I think the issue was raised earlier today about data, and it is the agency's belief that many operations collect an enormous amount of data, and they use that data to inform how they conduct their business.

And so one thing to consider in this particular question is: how does the agency use the industry's data? We don't collect that data and take

it back to the district office and summarize it. We look at it in the plant.

But we might consider, in looking at these questions, whether or not there's more work that the agency could or should be doing collaboratively with the industry, so that -- where the agency is, in fact, reacting to the data that the plant has on file, not necessarily just the agency's data.

I think there is a need to look at, what is the plant doing, and what is their performance in terms of how they react to their own data. So that could be something to think about it.

MR. FINNEGAN: The way I understand it is the -- as inspection, we can -- you know, if the plant shares their information with this, and if they get a positive E. coli, we don't even write an NR on that. Is that correct?

You know, I mean --

DR. ENGELJOHN: Well, the agency is --

MR. FINNEGAN: What I'm saying is we don't want to use the plant's -- if they're good enough to share records with us, to use it against them.

DR. ENGELJOHN: And I think that's an important -- and it has always been a concern of the industry is whether or not the agency would use the plant's data against the plant. And the agency's response hopefully has been, and will continue to be, that our goal is to look to ensure that you're -- you are, in fact, doing what you say your food safety system is designed to do, and that you're reacting to that data in a way that's protective of public health.

DR. MASTERS: So if a plant had a positive E. coli, and they took corrective actions and ensured the disposition of the product, and they took measures to prevent recurrence and did all of those things, then you're correct, an NR would not be written.

But if they said oops, la di dah, and that product got it in commerce, then we would write an NR.

MR. FINNEGAN: Right.

DR. MASTERS: And so those are the kind of responses that we're getting.

MR. FINNEGAN: Because they didn't do a corrective action.

DR. MASTERS: Right.

MR. FINNEGAN: Not because they got a positive --

DR. MASTERS: Got the positive in their system. Right.

MR. FINNEGAN: Yes, that's what I mean. If they're good enough to share records, you don't want to hold it against them.

DR. RAYMOND: I'm going to jump in. I mean, Barb answered most of it. If it was test and hold, and the product never got out, that's good. That's what we want.

But I'm going to compare that back to medicine a little bit. One of the reasons medicine isn't any safer now than it was 40 or 50 years ago is because doctors and nurses don't report near misses for fear they may be sued or something may happen to their malpractice insurance when an airplane pilot comes into Reagan out here, has a near miss, and they try to figure out what went wrong so it doesn't happen again.

And that's the fear in the practice of medicine where I come from is you don't want to report

it for fear it will be used against you. And that's something we have to work really, really hard on, so that there isn't that fear. And we have to make sure that it -- that it doesn't happen, that there -- you know, because they did the right thing, reported the near miss.

But, again, the plant that doesn't test -- says they tested but didn't test, and bad product went out there, you know, very definitely you've got a problem and you need more spec protection.

I don't know how we do that, but your point is well taken. It's a very serious concern.

MR. LINK: Yes. I think that's Sean's problem upstairs is getting data. People are just afraid to do it.

DR. DENTON: That's been the major obstacle.

DR. RAYMOND: I understand that fear is what I'm saying. Where I came from, I understand that.

DR. ENGELJOHN: But there's a tremendous amount of data likely there that would benefit both

the industry and the agency, and particularly may, in fact, help us to best use our resources and rely upon that data to a great extent. And that isn't necessarily occurring today, and I think that's really trying to get at that issue as well.

DR. RAYMOND: I mentioned a couple of times in my talk today -- communicate, cooperate, collaborate. But I didn't go into it, because I didn't have time. But one of my goals is to preach those three Cs repeatedly for the next three to four years.

Communicate is what we're doing here today. We're just exchanging ideas, and I trust that when you tell me something that you're telling me the truth, and you trust when I tell you something I'm -- when I tell you 14 people died today from food-borne illness, I want you to trust me. I want you to know that was good communication.

Cooperation is rolling up our sleeves and working harder together and, you know, sharing some information, that we row the boat together, that type of thing.

But collaboration is the goal. Collaboration is when you get a new product. Cooperation is you just keep this thing moving by we're going to talk more, we're going to spend more time, we're going to cooperate.

Collaborate is when industry might share numbers with us. They take a risk. Collaboration in that area is when we take those numbers and we say we're going to make a safer food product, then we take a risk, because if we don't then industry is mad at us because they -- they shared with us, and we didn't -- and the consumer groups are mad at us because we didn't produce a safer product.

We take a risk when we do that. The industry takes a risk when they do that. I think the consumer groups take a risk when they say, "We trust you to do that and do it well." They take a risk. That's what collaboration really is. It's -- but you've got to get those open lines of communication/cooperation done first through the open meetings, through the transparency.

And that's when we get to the tough issues

like sharing data, sharing information. That's the collaboration. It does not come easy. It has to get the better product, so -- off of my three Cs soapbox.

MR. SCHAD: I'd just like to emphasize that point again about -- about what you said, Barb, was I think there's a lot of plants -- I'm going to speak for very small plants here that -- that, I mean, I realize that just because something went wrong in their food safety system that's not necessarily -- well, I know I need to correct it, and inspection is not going to, you know, close me down or something. But I need to show them that -- here was a problem, this is how -- this is the corrective action we took, and then we go on from there.

But I'm not sure all very small plants quite understand that. I think they're still in the mindset, "Oh my gosh, something went wrong here." If I communicate that inspection -- I fear that if they communicate with the inspection, and I -- you know, I don't know the answer to that, but maybe there's some way that the agency can better communicate that to the small and very small plants, that, you know, a mistake

is going to happen or things are going to go wrong, but you have to take that corrective action. That's good.

And I think you'll get better sharing of data that way, if they know that.

DR. MASTERS: I think you're right, Mark. And Dan and I were recently at an outreach session and listening session in California, and we heard a lot of that. And Dan and I were both able to share that, and we're looking at ways to extend our outreach.

I think both Dr. Raymond and I say that we're both -- we recognize that for that industry leg of the stool or that industry leg to that infrastructure to be there, that we need to make sure that all of the food safety systems are designed, whether it's a small -- very small plant or a large plant, that they need to have effectively designed and implemented food safety systems. And so that's why we're really looking at reenergizing our outreach efforts.

DR. ENGELJOHN: I'll give you an example

of something where at one time we were presented with some information that we told the industry, if they would just find a way to capture that, we could probably begin selling a story differently about what -- what the public health systems are actually accomplishing.

We focus on what we found in the marketplace that was non-compliant. Or we -- we focus on -- because the data we have is about the non-compliances. We don't necessarily focus on the performed tasks that were done properly by the establishment. That isn't a focus that most people have.

But an example on E. coli O157H7, where industry now has in place their interventions and they're in essence putting in place a verification testing program that's sorting product. Product that doesn't meet the level of confidence they have that it doesn't have O157 is automatically being diverted to ready-to-eat operations, instead of going into raw products.

If we only knew how many pounds of product

was being diverted to that, because the food safety system caught it, that would be a tremendous story about the success of food safety systems. But all we really have in terms of the data the agency really reacts to is what failed.

So, I mean, just maybe something for you guys to be thinking about is, how do you capture the successes, and use that to show that the systems are working. Here is the small amount of failures that do get caught, but here's the really big savings, and here is why the programs are effective. They are actually doing this.

And I think we don't really have in place systems that are capturing that, and that's part of our inspection system. What can we be doing about our inspection system that maybe changes that focus, if you think that's an important thing.

MR. FINNEGAN: I do. I agree with you, Dan, on that. You know, I can remember what forms we used way back. There was a place for positive, you know, and now there isn't. It's all negative. So the way the Peebaes and everything is laid out, and I

agree with you there.

MS. CUTSHALL: Can I try and recapture what you've said? So I can -- I'm trying to -- you know me, Mary May I.

Okay. We talked about the first part of work to be done, and what I heard was some discussion about, you know, is the agency reviewing their decision criteria. We talked about continued evaluation. I think everyone is in agreement that the agency needs to do continuous evaluation of our decision criteria.

Michael, I think you talked about examining how flexible changes are to those to make sure that we can react. And then, under better ways to capture the successes, which is what I got out of the "don't necessarily focus on the negative," but if you do have something and you take appropriate corrective action, then you capture the successes.

Talking about why things are effective and providing better outreach were the three sort of pieces I got from your discussion. Is that accurate?

DR. ENGELJOHN: Yes.

MR. LINK: I think one of the issues I can sit down I think, Dan, with you and cover the table with, "Here's what we're doing." But do you think I'd do that with the IIC and the plant?

DR. ENGELJOHN: No.

MR. LINK: Because they wouldn't have the understanding that you do that, hey, this is data and this is good. This is a -- we call it this, and, you know -- because what I would get is the hammer, you know, and -- and that's not just small plants. That's all it was.

So I think maybe it makes your point on outreach, but outreach within the inspection circle to get that information down to the plant level, that to corroborate the -- collaborate and sit down and be able to share information and talk about what we're doing, why we're doing it, and exchange ideas ultimately is where we ought to be.

But we're just -- we're so far from that, I mean --

DR. ENGELJOHN: Charles, if I could maybe on that issue, is that as an example, just to get at

that very issue, the IKES, which many of you are familiar with, it's intended to be an instructional/ knowledge type of information-sharing process for the inspectors to go through these scenarios of "what if."

And an example could be to present what you just identified there, was that I'm the plant manager and I'm sharing all of my data with the inspector in charge of this plant. And walk them through the process of how they should or could react to that versus how -- what would be an inappropriate way to react to it -- is a way that we can impart information to the field force and to the small plants, or whomever else might be reading it, to try to get an understanding of the thought process.

And I think what you're suggesting is really a change in behavior. You have confidence you can share that with me, as you said, but not necessarily with -- and we need to change, we need to find a way to get at that. I do think that kind of gets at this work to be done. How do we change that mindset?

DR. RAYMOND: And maybe an idea -- just a

squirrely idea I just thought of, however, you know, there are certain things that probably deserve a bad mark. If you get enough bad marks, you get an extra inspector. But maybe there's a merit badge approach.

Maybe there are certain things we can identify that deserve good marks, and then the inspectors would be told if, you know, Cargill and Scott come up to you and says, "We tested and held and we got E. coli," that's actually a good mark. That's a plus, not a minus. And, therefore, you don't get -- I mean, they -- we have to teach them that that's a plus. And maybe that's -- maybe we have to identify some pluses along with just the minuses.

I mean, again, you talk about coming after just the bad stuff. What about the good stuff? What are the good things that help promote public health, public safety, that are being done in the plants that give them --

DR. LOGUE: Does that mean, then, you need a different kind of approach to training inspectors?

DR. RAYMOND: This would be something that --

DR. LOGUE: In other words, teach a different skill.

DR. RAYMOND: Which also I trust Dan, but I don't trust the inspectors working in my plant. Well, if the inspectors understood, here is a list of things that are actually good, they maybe look bad to you, but they're really truly good, because they did promote public health.

DR. LOGUE: Well, what about things that are not on the list? What about teaching them how the critical thinking skills that they have, certain degree of latitude where they can make decisions themselves?

DR. RAYMOND: We're definitely doing that. But that's one of the things that I think Charles is saying. He's a little bit leery of some of the critical thinking skills about they may bring the hammer, because their critical thinking skill may say it's time to bring out a hammer.

What we want to say is there's a few areas that are not -- they're off limits for the hammer. But we are definitely trying to -- I think we heard

that earlier today, maybe from Barbara Zimmerman, that we're trying to instill more in our inspectors, the latitude, rather than just everything is black and white, because it's not black and white in this world, and we are trying to do that.

MR. LINK: But see, maybe you ought to view it a little differently. That, you know, if I share with the inspector and their response is, "I'd better call the EIAO guys and bring them in," because I don't understand and here comes the cavalry, I should probably view that as a good thing, because now I can demonstrate that, hey, I'm okay, but this rarely works out that way. You know, but --

DR. RAYMOND: By the way, we're sending the cavalry, Scott and Mark.

(Laughter.)

MR. ELFERING: But, you know, everything, you know, you always hear about bad inspectors. You never hear about good inspectors. So maybe you need to look at the same thing for your inspection staff, too.

MR. KOWALCYK: I think this is also

important information that can be used in that ongoing assessment, whereas a plant has interventions that they're capturing positives and they divert them, so it doesn't get into the food supply.

While it's a positive that they did that, prevented that, it also gives the inspectors additional data for how they're managing their job at that plant, to say, okay, XYZ processor, their data show me that they're finding these samples, and they're diverting them away, which is a good thing.

FSIS testing isn't all the time, whereas a company with operations people there, they're probably doing a lot more random testing. So that data, I mean, it's in their financial interest to have a good system.

And using that information, although it won't result in regulatory action against a company, is additional data for that ongoing assessment, to say, okay, during May and June this plant tends to have higher levels or higher levels of positives, so the agency needs to e more aware of -- it may be viewed as a bad thing, I don't know, but it -- to me,

when we're talking about deploying resources, it's, you know, more likely to have trouble during this time of the year or during this shift or whatever.

So even that could even feed back into that first one as, you know, that continuing -- that continuous assessment.

DR. ENGELJOHN: But like you're saying, that plant is doing that level of testing, and you have confidence that you have -- you have a decision criteria that says, "I would have confidence in that system," that Plant B down the road doesn't have the same level of testing, and you have the same confidence.

That may be where our limited resources could go to take more samples as -- because they don't have as many in the plant. If you rely upon the plants, because you have confidence in them here, go take a sample there or maybe rarely do. But, I mean, that's sort of the approach I think that would be workable.

MR. KOWALCYK: Right. Whereas, you know, one guy who is getting a lot of samples, he is

diverting them away, but the other guy right up the road, during the same time of the year they're not testing. So it's a good indicator that there might be a problem there.

MS. CUTSHALL: You all keep circling around back to data. But to focus on some of the recommendations that you laid out for me, one of the next questions was, if you're aware of other/better ways to approach this aspect, cite the evidence that supports the approach.

And I'm trying to glean that. I'm hearing Michael saying, you know, we've got in-plant data that is giving us evidence that those kinds of things are happening, utilize in-plant data more.

MR. LINK: And maybe that's where -- I keep coming back to this we've got inspectors, and when you look at this statement here, basic procedures that just need to be done. Well, I don't know what those are necessarily, and I'm not sure that -- maybe that needs to be revisited.

What are those basic procedures that need to be done versus where should they be spending their

time? And maybe part of it is the inspecting plant ought to be looking at the data and understanding it and analyzing it and trying to understand, what is going on? Yes, I do see in August every year you guys have a spike or something.

But rather than doing something we think just needs to be done, whatever that is. And we're back to maybe redefining what inspection truly is and what those guys ought to be focused on. But maybe part of the work to be done is maybe really look at what -- how do you guys define inspection? What is it, and what do you see as those basic procedures that just need to be done?

DR. MASTERS: What do you see? And what do you see?

MR. LINK: I don't know. I mean, they go through their checklist, and they get this PBIS that says it's going to do these things, and they decide not to, they go do something else because they think it needs to be done.

DR. ENGELJOHN: What does the PC person in your operations do that tells you you've got to change

production today? Not what FSIS tells you, but in your operations, what kind of information do you and your supervisors react to to say, "We need to shift some resources over here to take care of this"? How do -- I think that's what we're trying to get at. What is it that you're --

DR. MASTERS: Your HACCP coordinator only has one thing he or she can do every day. What is it you're not willing to give up, Charles?

MR. LINK: My HACCP coordinator.

DR. MASTERS: Or your HACCP person.

MR. LINK: Well, they get through the paperwork diligently every day. I mean, that's -- they come in and they --

DR. ENGELJOHN: But what are they looking for? I mean, I think that would be very helpful in --

DR. MASTERS: Something above a threshold. They're looking for a spike.

MR. LINK: They're looking for any kind of mistakes on the paperwork. Did somebody forget to sign it? I mean, real simple things like that, to, "Hey, I had a problem. What did we do about it? Did

we react appropriately? Did we take preventive actions? Did we do all the things we were supposed to do?"

And if there's any question about it, then he waves a flag, we go out and we start finding people to find out what happened and where's the product, and etcetera. But -- and, you know, they're doing that anyway, but, I mean, every day somebody else is sitting there going through that, and looking for those kind of things. And we don't -- I mean, we do that every day.

DR. MASTERS: So you're looking for critical --

MR. LINK: Right, critical limits.

DR. MASTERS: I mean, you're not looking to see if somebody missed their records.

MR. LINK: Well, we'd like to, but we'll get an NR for that, and also we'll have a HACCP violation. So, yes, we make sure it's signed and make sure it's initialed or whatever, but yes.

DR. MASTERS: But if you only had one --

MR. LINK: Critical limits, yes.

DR. MASTERS: -- to the same that you -- you have --

MR. LINK: Did we do anything, critical limit-wise, yes. I mean, that's -- yes.

DR. ENGELJOHN: Or you pay a premium in terms of hourly wages, or if that person is good at doing some specific task that's -- that actually is going to save you money or --

DR. MASTERS: You don't want recalls. You don't want your product's name tainted, because children are getting sick from your product. What is it you want that person doing? Mark, do you want that person doing?

MR. SCHAD: The main thing is to make sure our critical limits are met every day.

DR. ENGELJOHN: On product that's going to go out the door.

MR. SCHAD: On product that's going out the door. That's the main thing we've got to do is make sure it meets the critical limits, and make sure there are pre-shipment reviews of it. You know, we're looking at it as critical limits when we do that.

DR. MASTERS: What about sanitation? Do you have --

MR. SCHAD: Sanitation and especially in the -- I'm not negating anything about the raw product area, but you're talking about tying the recall into the product name and all that kind of stuff, I'm worried about the -- we're packaging the finished product. That's my biggest concern on sanitation. To me, that's got to be perfect every day.

DR. ENGELJOHN: what goes in the package is in the package and it's labeled properly and it is -- if it was ready to eat, if you -- everything had to be done related to that?

MR. SCHAD: Yes.

DR. MASTERS: Do you do any product testing?

MR. SCHAD: We do product testing once a month for finished product testing, and food contact surface once a month.

DR. MASTERS: What about -- I mean, are those the kinds of things -- I mean --

MR. LINK: As a verification I guess or

validation that our sanitation program is working? I mean, do you think -- if you're talking ready to eat, I mean, yes, certainly we look at those results. And if we see -- if we see a positive in a zone 3, or anywhere, I mean, we're all over it trying to figure out what happened, why is it there. You know, we're trying to make sure it's gone.

DR. MASTERS: Those are things that you would see.

MR. LINK: Yes. And your inspector sees this, too, and --

DR. MASTERS: But we're just saying -- those, I mean, if -- if I -- if somebody just said, "Barb, you go off and design the system, and figure out what" -- if somebody asked me to, "Barb, go off and design the system," what are you not willing to give up?

MR. LINK: Yes. If I'm in the raw plant, you know, sanitation-wise, yes, we obviously -- we clean the plant, we inspect the plant, we find a piece of meat, and we -- we clean and sanitize and we fight over the measures and -

DR. MASTERS: If you give that up -- or what are you not willing to give up? When we say there are basic things that we believe are going to always be there -- are you going to always check those pathogen tests when you come in?

MR. LINK: Listeria, yes. On a finished product that's ready to eat, yes. If it's raw, I may not look at it today.

DR. MASTERS: Because you have time until tomorrow, right?

MR. LINK: I'll look at it tomorrow. And, really, on the raw products you're looking at more of a bigger picture than you are a sample that was positive for salmonella today, you know?

DR. MASTERS: But you're doing O157 testing.

MR. LINK: Oh, yes, on that. That's different, yes. Those we look at, and if we have any positives they go to the plants and they do --

DR. MASTERS: And would you be willing to give that stuff up? Do you believe that will always be --

MR. LINK: That's always there, but, you know, I'm back to -- well, I don't know.

DR. ENGELJOHN: It's objective data that you're relying on.

MR. LINK: Yes.

DR. LOGUE: It's got to be something -- it's got to be that threshold, something that will trigger something.

MR. LINK: Some of the stuff we do because there's regulatory requirements, and we do it. Some of it we do because we believe it actually makes a difference.

DR. MASTERS: And that's what we're trying to get at. What are those things you believe actually make a difference?

DR. ENGELJOHN: Even if we just consider that we remove our regulations, we finally went full-blown HACCP and we removed all of the regulations, and you rely upon what was important.

DR. MASTERS: What are those things you believe actually make a difference for public health? If Dr. Raymond and Barb Masters told you this morning

anything we do is to further protect public health and improve food safety, what are those things you do every day, Charles and Mark?

MR. SCHAD: Do I need to make a list?

DR. MASTERS: I think those are the things we're trying --

DR. MASTERS: I don't think my HACCP plan would be any different than it is now.

DR. MASTERS: But what are those things you do every day to further improve food safety and further protect public health? Those are the things we're trying to feather out from you to really make sure that our inspectors are doing those same kind of things each and every day.

Those are the things we don't want to give up. Those are the things we don't want to lose.

DR. RAYMOND: And if there is something you see that's just pure regulatory that has been fully --

DR. MASTERS: Yes.

DR. RAYMOND: -- for God's sake, let us know that, too.

DR. MASTERS: Yes. Those are the things that we're really trying to get at.

DR. RAYMOND: We'll put the resources where we need to put them.

MR. ELFERING: Well, I think one of the problems that I always see with an inspection is that you get inspectors that are not really seeing what the issue is, but just the black and white issues, that the pre-shipment review was initialed and not signed.

And I think that's what we always have to try to get away from is is -- you know, it's always good I think -- you know, if the plant is doing their pre-op sanitation inspection, and I think in PBIS you're looking at pre-op sanitation records almost ad nauseam, is that the issue, that they're keeping the records? Or is the issue keeping the plant clean?

So if the inspector is not seeing a -- if they are seeing an operation that is kept in good sanitation, is it so imperative to make sure that they have initialed their pre-op sanitation checklist?

DR. MASTERS: That's what we're trying to get you guys to start talking about, because --

DR. ENGELJOHN: And could it be a decision that you have a history of this plant, you know this plant, they always do it, or that's something they attend to and they -- and they place a value on it. But that particular day a new employee came in, because the employee that normally does it was sick.

Does that change your confidence -- should that change the agency's confidence in the product produced that day? If just that one employee who handled that one record that you find important didn't initial or sign the record.

MR. LINK: Only if it was like a cooking record.

DR. ENGELJOHN: But it gets into the issue of, what are the decisions that go around giving you confidence in the system, I think.

MR. LINK: So maybe part of the work to be done is, from an industry perspective, to maybe come back with a list of, hey, these are the top 10, top 25. The other thing --

DR. ENGELJOHN: These are the things we fire our employees for, these are the things that we

give them a bonus for if they catch and do, and that really truly is what you find to be of value that's protecting you as an industry. That would be extraordinarily beneficial to us, because that's what matters to you.

Now, we know that you do things for quality reasons, and you do things for public health. And it would be important -- most important for us to know what matters to you for public health that affects how you do your own employees if they do or do not do these tasks, and what are those tasks. That would be extraordinarily beneficial to us in this exercise.

MR. SCHAD: Okay. So you're saying like -- see, some of my employees I do not let them do sanitation, because they will not do a good job. So whether that was a plan of theirs or not, but they -- they don't get that job.

(Laughter.)

But other employees are very good at it, so those are the employees that do sanitation.

DR. MASTERS: So, in other words,

sanitation is important to you. I don't think anybody at this table would argue that sanitation is important in the production of safe products.

MR. ELFERING: But it's really of less importance from a HACCP standpoint.

DR. MASTERS: Well, I don't know that HACCP is really at the table. I think production of safe products is at issue, and I think the point you brought up is that initialed or signed, I would think it would be something we would want to spend less resources on. Is the plant clean or is the plant not clean is something we would want to spend more resources on.

Those are the kind of things that we're trying to feather out here.

DR. ENGELJOHN: That may be the threshold thing, like you say. They may or may not have signed it, but there's other evidence.

DR. MASTERS: Right.

DR. ENGELJOHN: What are those other evidence things that cause you to react differently.

DR. MASTERS: We want to spend more time

on clean versus dirty and less time on whether it has got Kay or Kevin Elfering.

MS. CUTSHALL: Well, what I hear you recommending as a subcommittee is -- and I don't think you're going to be able to do all those today, but one of the recommendations to the agency from the subcommittee is to possibly put together a group of industry folks. You may want to include some other folks as well.

But to go through and do that exercise and specifically focus on what are the top X number of things that are absolutely critical to you? What are the things that are nicer to do, and what are the things that sort of fall to the bottom when we talk about public health? Does that sound reasonable for a recommendation back to the agency?

DR. RAYMOND: I just have one question. I didn't quite catch Mary. You're going to ask the industry to do that, and then recommend to the agency, or the industry is going to do it and recommend it to the NAGB Committee?

MS. CUTSHALL: I think that's up to

however the subcommittee wants to make the recommendation.

DR. RAYMOND: Well, that's true. We ask them to decide. I would just throw out the suggestion that it shouldn't just be the industry looking at themselves. We need to have the employees and our public health advocates also either reviewing what the industry spends or whatever. Otherwise, it's not going to fly.

MS. CUTSHALL: Oh, no, I understand that. We wouldn't just take whatever these --

DR. RAYMOND: Okay. Well, we --

MS. CUTSHALL: -- thank you very much for --

DR. ENGELJOHN: Because the consumer advocates may, in fact, have a different perception of what they think is --

DR. RAYMOND: No, exactly. Exception sometimes is --

DR. ENGELJOHN: Yes.

DR. RAYMOND: And if we don't ask our workers who I think are the most important, they're

going to be madder than heck at us, and I don't blame them. They're in the plants every day, too. So, you know, I just -- industry may come up with a draft, and then it goes someplace else for consensus.

MS. CUTSHALL: How about if I word it this way, "List of industry-related top public health priorities, what they are, and who should participate in this process"?

MR. LINK: That's the recommendation we're going to put to the committee.

DR. ENGELJOHN: But, Mary, I think you said public health priorities, and I think the -- I think more practices in the day-to-day operations.

MS. CUTSHALL: So practices?

DR. ENGELJOHN: Would make it more clear to me as to what you're trying to say.

MR. KOWALCYK: I think the inclusion of -- what they see as the top priority versus in-plant.

DR. MASTERS: We talked about doing a focus group, so that may be something we could add to the focus group plan. Okay.

MR. FINNEGAN: But the very thing that

Kevin was talking about, just because some initials aren't signed, we're all -- the way the PBIS is set up, you're pretty much tied to that fact. Of course there's monitoring -- if they didn't monitor it right, you know, you get a demerit. That's the way the PBIS is designed.

You know, if there's no -- it's black and white. If you don't have the right monitoring, then there you go. NR.

MS. CUTSHALL: I'm going to facilitate a little bit, because I know he has to leave in just a few minutes. I don't know how much longer we can keep going. I don't know how much longer we can keep Dr. Raymond.

DR. RAYMOND: I was just going across the street. If you need me here, I'll stay. I was going to go over to the office and do a few things over there.

MS. CUTSHALL: Well, I was just going to throw out to the subcommittee -- I don't think you're going to get through all eight tonight. If you go through sort of the first couple, three, is there

another area of particular interest? Is there another aspect of inspection out of these eight that you feel particularly rises to the top that you want to deal with tonight?

MR. ELFERING: We want to look at all about, you know, the --

MS. CUTSHALL: I'm asking you all.

MR. ELFERING: The only thing I'm looking at is just the different procedures, the 70/30, the 30 percent of the procedures and that's on the work to be done. To be looking at readjusting that somewhat, and what is the 30 percent, is it all economic?

MS. CUTSHALL: It's like labeling.

MR. ELFERING: And is that something that you could --

DR. ENGELJOHN: Absolutely.

MR. ELFERING: -- put less of a priority on?

DR. ENGELJOHN: Yes. You could tell us what you think would be inappropriate.

DR. MASTERS: That is the intent. That is our -- as Mr. Derfler indicated, our traditional

approach was pure -- not pure as we know, but the intent is to move away from that to decision criteria. And any suggestion you have to us within the decision criteria would be helpful.

So, clearly, it is our intent to move away from that with the decision criteria. And that's why we're asking for your guidance on --

MR. ELFERING: Well, I still think that there are some economic issues that are always going to be of importance.

DR. MASTERS: Sure.

MR. ELFERING: But I think you could really eliminate the majority of that. I mean, you could look at maybe changing that to about five percent.

DR. ENGELJOHN: And that would be helpful. I mean, we'd still have some statutory requirements, but a recommendation back that -- clearly getting to a different focus would -- and ratio, even in -- and if ratio is even what you think should be done. I mean, and the issue really becomes, that's how we have the system basically set up in.

In a year's period of time, when you look at what is conducted in a plant, roughly 70 percent of the tasks performed are food safety related, and 30 percent are what we would classify as other consumer protections. So we're looking at changing that.

DR. LOGUE: Could some of that 30 percent actually be done electronically or through another method where they didn't have to physically be there? Then you have better devotion of time to more important things.

Because, okay, formulate economics regulatory -- maybe that is something that could be done online or -- I don't know. Is that one of those where it would fit there?

DR. ENGELJOHN: Again, it's where -- you're trying to get at the issue of defining what activity is for that, and we're -- we're more than happy to listen to or give back recommendations, if you could do it differently and this may be substituted for that.

MR. KOWALCYK: I mean, would the agency be in a position to specifically list out what those

procedures are currently? Out of that, what's approximately --

MS. CUTSHALL: Pretty much you can define O2, O3, everything but O4, and some of O5 sampling is food safety.

DR. MASTERS: And he's asking to help define that. These folks don't deal with our inspectors, so -- the O3 is our HACCP inspection procedures, and the O1 is our sanitation standard operating procedures, all the things they do for pre-op and operational. And then, our laboratory testing, which is under O5 inspection procedure codes, we'd actually pull out the sample inspection.

So our -- the other consumption protections is looking at labels, looking at the finished product standards in a poultry plant. It would be considered other consumer protection, looking at net weights, for example. So anything that we do that would be considered not to directly affect public health. But there are still regulatory requirements or statutory requirements for us as an agency to do those procedures.

DR. ENGELJOHN: As another example, our O8 tasks are our food defense tasks. We define them as other consumer protections. They're not defined as food safety. So they -- at the moment, they fall within that 30 percent. But we clearly are looking at a way to handle that maybe differently, so that we do put more emphasis there and less on the net weight in that type of thing.

MR. KOWALCYK: Would food allergens fall into that?

DR. MASTERS: Food allergens are addressed under HACCP. And so they are done under our O3 procedure codes. Most plants consider those in their hazard analysis.

MR. ELFERING: You know, what's always a little curious about allergens is they probably are the cause of a lot of recalls, but there really is very little food safety risk associated with allergens.

DR. MASTERS: Ask those of us that have food allergies and we might debate you on that, Mr. Elfering, but --

MR. ELFERING: Likelihood is small, but severity is --

DR. MASTERS: Exactly.

MR. ELFERING: I don't mean that it shouldn't be concentrated on. But, you know, if we really look at risk --

DR. MASTERS: But I think that gets into one of your earlier questions is, you know --

MS. CUTSHALL: I think you all commented on what really is risk, and what I'm hearing you recommend at this point is recommend to the agency to go back and look at that 70/30 and see, is there a better -- as you said, is there a better way? I don't think we can sit here at the table and define it should be 85/15 or 95/5, or whatever.

But I think that's the recommendation that I hear you making is that we need to revisit the decisions behind that decision.

MR. KOWALCYK: I think you would get buy-in from all parties if the agency can show hard data behind that as well as say, you know, it truly should be 85/15 and why, and what supports that. And we

should advise the agency that it needs to be supported by hard data.

MR. LINK: I'm sorry. While you're looking at resources, you need to get back to your process again, because I think you're back the other way on OCPs versus food safety with your inspection workforce in that regard, because OCP is pretty much what they're looking for.

I mean, obviously, they're looking for zero food safety hazards and that --

DR. ENGELJOHN: They're looking -- there is other suggestions there's -- you know, a ready-to-cook chicken carcass is expected to be free of feathers and free of bruises and free of lung tissue, and all those kind of things. And that all counts as OCPs.

To what extent do you change that, and I think we get the message we need to relook at that. And, as Michael said, and the agency probably should be presenting this committee with some information, some data, that we may have collected over time.

MR. ELFERING: Are you still doing any

economic sampling?

DR. ENGELJOHN: Again, that's a resource issue, which we discourage and we -- and we -- the agency direct what economic sampling should be done. And that also becomes one of, again, trying to define a level that gives us enough confidence that what is happening in the marketplace is, in fact, still being conducted in a way that misbranded product isn't out there.

So we do some, but to the extent possible the agency has directed the employees not to take an economic analysis sample and send it the lab, unless they are directed to do so, unless they just really have reason to believe that serious conditions exist, and then they would handle it differently.

MS. CUTSHALL: Okay. Is there any one thing that jumps out at you that you want to take on in the last little bit here?

MR. LINK: Are we going down this list of questions or this statement?

DR. MASTERS: Your choice.

MR. LINK: Okay.

DR. MASTERS: Your Chairman's choice.

MR. KOWALCYK: Well, the next one, which is the design of inspection activities, on the table it's number 4.

MS. CUTSHALL: Yes, on the table it's 4. On the list of questions, it's --

MR. FINNEGAN: I think we've talked about that quite a bit.

MR. KOWALCYK: Yes.

MS. CUTSHALL: So I can say that this is inclusive and other --

DR. ENGELJOHN: I think this issue here of evidence that the establishment is losing control, it just -- I'm just throwing out a suggestion for you to just think about it in terms of the issue of what we talked about a little earlier, where you come -- where it may be helpful if you and industry, as well as our own employees, as well as consumers, come back to us and tell us what do they -- what do you use as your indicators that your process is going out of control. That would be very helpful to us in the agency.

MR. FINNEGAN: One of the things that we

use is -- from the expression that salmonella is a raw product, we start getting up -- you know, half a dozen, five, four even positives, we sit down with the plant and we tell them, "Hey, you've got your -- you've got a good chance here of blowing it." That's one of the things that we use.

MR. ELFERING: I know there were some questions at one time whether or not FSIS was completing the entire set before they would discuss anything with the plant. Are they discussing it with the plant now, if they're getting -- if they would maybe get two positives in a row, would they discuss it with the plant at that time?

DR. ENGELJOHN: Yes. I think as a matter of fact, the agency published a Federal Register notice asking for input on it, is that should we, in fact, be telling -- giving the plants immediately their result as we get it, as opposed to waiting until the end of the set.

And we also got advice back from our national Advisory Committee for Microcriteria for Foods that it would be prudent for the agency to give

the results back immediately, so you can adjust your process as an industry.

DR. MASTERS: And I will tell you, during the hurricane, the plants that were affected down in that region, we went ahead and made the determination that it would be useful feedback to those plants. Because we anticipated there might be concerns with those plants in the hurricane-affected area, we provided that information to those plants down in the hurricane-affected area on an ongoing basis, and they found it very helpful.

And we have also, on a case-by-case basis, where the plant says, "We recognize this data will be FOIA-able once we request it," if they request that data, we will provide that data to them because they have found that useful to them. So shortly -- even though we haven't made a full-out policy decision to do that, where plants have requested it, we have provided it to them, and we did it on a plant-by-plant basis down in the hurricane-affected area.

MR. FINNEGAN: To even get back to the positive aspect, I mean, it's positive -- hey, here,

you've got four, you know, negative samples. You're doing good, you know.

MS. CUTSHALL: Just to jump in, this happened to us the last time, Dan. There's a graduate school class in here tonight that starts at 6:00. So if you've got -- if we could kind of wrap this issue up in like 10 or 15 minutes.

Something about this night, this time, this room, and the last time it was --

(Laughter.)

-- a Yugoslavian class or --

DR. ENGELJOHN: I don't --

MS. CUTSHALL: Language class or --

DR. ENGELJOHN: They weren't happy with us.

MS. CUTSHALL: No, they were rude. These people are a little bit nicer.

DR. ENGELJOHN: They were not happy. And we didn't know what they were saying, but they weren't happy.

MS. CUTSHALL: So we can -- if this is the one you want to focus on for the next 10 or 15

minutes, I can capture your -- I thought Dan was talking about, how should a system based on risk respond to inspectional findings. That's what I heard you all talking about, so --

DR. ENGELJOHN: I think one of the things we heard, then, was the agency sharing results.

MR. KOWALCYK: I think the one point in here in the approach -- evidence of good control will result in less intense inspection. I'm a little uncomfortable with that wording. Basically, I mean, I understand if you had a producer that there is evidence that they are out of control, they need more intense. But what does "less intense" mean? I guess maybe putting a definition over, you know, what does -- what does that mean per se?

MR. ELFERING: Drive by. No.

MR. KOWALCYK: But, I mean --

MS. CUTSHALL: You're on the record.

PARTICIPANT: That's Kevin Elfering.

(Laughter.)

MS. CUTSHALL: Really what I hear you saying, and I think I heard you saying it earlier, is

that one of the charges to the agency is to define what "less intense/more intense" means. Could mean.

DR. ENGELJOHN: And we are actually looking to you to say what do you think would be appropriate as well. I mean, if you have some ideas on that, that would be helpful to us. We can certainly identify what we think we could do within the resources that we have. Absolutely.

MR. ELFERING: I think other than less inspections, I don't know if you'd really be able to define what "less intense" would mean right now.

DR. ENGELJOHN: Well, I'll give you an example. I'll give you an example. For listeria, right now, just so you know for our -- our risk-based verification testing for listeria, our program has traditionally been we take one product sample. You may be producing all year long. We test you three times a year, and we take one product. That doesn't have a great deal of statistical confidence that you can build around that.

But we're also relying upon the day-to-day activity that the plant is doing. So we didn't design

it to be statistically-based.

But when we come in and do our risk-based verification testing for listeria today, we don't just take one product sample. We take multiple product samples. We take multiple food contact surface samples, and we take multiple environmental samples. So we're increasing the number of samples we take to try to have higher confidence that low-level contamination isn't there. So that's one way we could do it.

If, in fact, the plant had a problem, where there was an outbreak associated with that plant, we may in fact come in and take enough samples to have statistical confidence that once the corrective actions have been put in place we, therefore, have actually a statistical basis to say, based on the level of production, we've taken enough samples that we ourselves have confidence that the system has been corrected.

We're not trying to validate the system for the plant. We're going to rely upon the plant's data to demonstrate that they, too, have corrected it.

But it could be that we increase the level of testing or the numbers of tests that we take, or the frequency at which we take those tests, as an example. So --

DR. DENTON: Let me think out loud just a second here. We're talking about one company that's doing a very good job, maintaining good control of the process, and you have an incident in which that company is not doing a good job, and there is a demonstrated loss of control.

You're not going to add additional resources if you focus increased attention on the one that's performing negatively. You're talking a redeployment of your existing resources away from a plant that's doing a good job with more increased focus on the one that's not doing as good a job. Is that correct?

DR. ENGELJOHN: It could be more people, a larger team of individuals who have expertise in various aspects. If we look at the food safety system, deploying resources could mean additional testing resources. You know, so it's not just people being deployed to look at an issue. It could be

expertise kind of --

DR. DENTON: It's almost by default. If you're going to put increased attention on the one that is not performing up to the level of expectations, those resources have to come from somewhere. And so they're probably going to come away from the plant that's doing a really good job, because you feel fairly confident with that.

DR. ENGELJOHN: It is that.

DR. DENTON: And so you go with more of your resources on the one that needs the additional treatment.

DR. MASTERS: That was kind of my opening comment, which was I don't necessarily disagree with what Felicia made in her public comments. Sometimes we have to drive by and check the box to say we've been in a plant. If I'm going to say I've been in a plant, I'd rather review records where I have confidence and know that that plant is performing well, and to do it in a plant that I did it just because that's all I have time to do today.

I'd rather do it where I have confidence

in the system at that plant, and do it knowingly, and say, "I know that's what I'm going to do when I get there today," because I made the choice to do that today, rather than to say, "I made it there today. I met my obligation under the law," than to do it, which is what Felicia described accurately in her public comment -- I'd rather do it because I know that's what I have in my plan today.

Today I'm going to go to Kevin's plant, and all I'm going to have time to do when I get there today is to make sure -- you guys are going to -- critical limits are met, sanitation was done, whatever those really critical things are, that's what I'm going to do at that plant, because I know that they're a really good operator, a really good plant, and I have confidence in their systems.

Whatever those most critical things are, in my little bit of time that I'm there, those are the things that I'm going to look for, because I have confidence in that system.

DR. ENGELJOHN: Where they have demonstrated --

DR. MASTERS: I plan that today, and that's what I did when I got there -- my obligation.

DR. DENTON: That makes sense.

DR. MASTERS: So I don't feel confident with meeting the obligation either. I want to know that when I start my day. That's what I --

MS. CUTSHALL: Tell me what you all are saying to me. I'm hearing a lot of things.

DR. DENTON: It goes back to the discussion --

MS. CUTSHALL: I'm a minimalist.

DR. DENTON: -- right back to -- it's a difference in the language that's being used to describe. You're not necessarily rewarding a plant for being a good plant that's completely under control. By necessity, you're having to take resources away from that plant to address one that is not performing up to the level of expectation with regard to control of the process.

You're in a zero sum gain. You aren't going to add additional inspectors, and you don't have more money that you can spend on sampling. You reduce

one place and focus attention on another.

DR. MASTERS: But I still think it gets to a little bit what Michael was saying, is that you still have to define more and less intense, because what you're doing at the place that you're spending less time --

DR. DENTON: Needs to matter.

DR. MASTERS: -- needs to matter.

DR. DENTON: There needs to be a good --

DR. MASTERS: Well, and what you're doing when you're there needs to matter. I mean, I'd like to underscore a little bit of what Catherine said -- can we do some of that remotely? I'd like to explore what Cheryl said about, can we access the plant's data from the road?

If I could check my Blackberry and say, "Well, that plant had no positives today," and then I could look at their OCP data from the road, and -- what we do needs to matter.

DR. DENTON: It can really be explored.

MS. CUTSHALL: Well, now I captured some of that earlier. I captured --

DR. DENTON: Electronic data?

MS. CUTSHALL: I can't record more than one voice at once.

PARTICIPANT: Oh, we're out of control.

MS. CUTSHALL: I captured earlier the things about different ways that you could do things, if you can access things from the road using -- utilizing different technologies. What I've got here at this point is defining less intense or more intense could possibly mean defining resource allocation based on where the resources are deployed, and why and what those resources are.

DR. ENGELJOHN: But I think, Mary, just is everyone clear that resources doesn't just mean a human body.

MS. CUTSHALL: That's why I was saying why and what -- what the resources are.

DR. ENGELJOHN: It can be people. It can be --

MS. CUTSHALL: I'll just make a note.

DR. DENTON: But if we're focusing our attention on someone who is not performing up to

standard --

DR. MASTERS: Does anybody have any last-minute burning issues?

MR. KOWALCYK: I think we got through the first half of the list, and I think we're pretty much at our limit timewise here.

DR. MASTERS: We're talking about maybe giving it an hour in the morning to try to -- let folks try to -- and that will help us sort of put this a little bit better together and look at it --

MR. ELFERING: We don't want to try to finish any tomorrow? Because if we are, I'd like to make one suggestion, that we --

MS. CUTSHALL: You guys can go back to the hotel and work away. We'll be glad to transcribe everything first thing in the morning.

MR. ELFERING: The last question on the retail inspections, I really think you should utilize state programs in more -- more public health departments and retail inspections. There was a project a couple of years ago, when they first started the consumer safety officers, where they were going to

go out and do retail inspections.

And we actually started a process where we were going to train a couple of our inspectors to actually do exactly the same thing as the consumer safety officers were going to be doing. And I think that might be a good way to -- again, collaboration.

DR. ENGELJOHN: I think that's an excellent idea to maybe take up tomorrow.

MR. SCHAD: Kevin, how are we going to see that working in a plant that -- you know, like federally-inspected on a wholesale operation, and he's got a separate retail operation, how would you see that working? Do you think there would be some confusion there as far as the plant is concerned? One set of rules in the back and another set of rules out front?

MR. LINK: Not really. We already do that in -- like if we have a plant that's under -- that has a granted inspection, and then is maybe retail exempt --

MR. SCHAD: Yes.

MR. LINK: -- we've already got inspectors

going into the retail-exempt portion of the plant.

MR. SCHAD: Okay. All right.

DR. ENGELJOHN: And applying the food code.

MR. LINK: And applying the food code. And what we -- and likewise, we've already talked to the district office to maybe train the inspector to do the -- get some food code training, so that they would be able to do that.

DR. ENGELJOHN: I think that's a really good step to catch. Very good.

(Whereupon, at 5:45 p.m., the proceedings in the foregoing matter went off the record.)