NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION

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SPRING MEETING

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SUB-COMMITTEE SESSION

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STANDING SUB-COMMITTEE NUMBER 3

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Issue: *How can risk-based sampling most effectively be conducted in small and very small plants?*

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Thursday, June 16, 2005

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The Subcommittee convened in Conference Room 1061, South Building, United States Department of Agriculture, 1200 Independence Avenue, S.W., Washington, D.C., at 3:00 p.m.

SUB-COMMITTEE MEMBERS PRESENT:

GLADYS BAYSE
DARIN DETWILER
MIKE GOVRO
JILL HOLLINGSWORTH
CHARLES LINK

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

(2:48 p.m.)

MR. DETWILER: Somehow I'm your factilitator for the group and that's very cool. Let's do a very quick round the table for the purposes of recording and if someone didn't get who is who. First off, I'm Darin Detwiler and I'm from the Seattle Area. And I am one of the members of the National Advisory Committee on Meat and Poultry Inspection and we have -- let's start over here to my left, Dr. Dan Engeljohn.

DR. ENGELJOHN: Right.

MR. DETWILER: And you're Deputy Assistant Administrator with the --

DR. ENGELJOHN: FSIS, Office of Policy and I'm here as a resource to the committee, to answer your questions.

MS. HICKS QUESENBERRY: I'm Heather Hicks Quesenberry. I'm the Listeria Team Leader for Risk Aassessment and I'm here as a resource.

MS. KAUSE: I'm Janelle Kause. I'm the Director of the Risk Assessment Division of the Office

of Public Health Science in the Food Safety Inspection Service again as a resource.

MR. LINK: Charles Link, I'm with Cargill Value Added Meats.

MS. HOLLINGSWORTH: Jill Hollingsworth. I'm with the Food Marketing Institute. They represent the grocery stores.

MS. BAYSE: Gladys Bayse, Department of Chemistry from Spellman College in Atlanta.

MR. GOVRO: I'm Mike Govro with the Oregon Department of Agriculture, Food Safety Division.

MR. DETWILER: And we have some people, some familiar and some new faces in the back here, starting with Tony?

MR. CORBO: Tony Corbo from the Consumer Group Public Citizen.

DR. WENTHER: Dr. Jay Wenther with the American Association of Meat Processors.

MS. JOHNSON: Lavonne Johnson, FSIS.

MR. SHIRE: Bernie Shire of Shire and Associates. I'm a consumer group.

MR. DETWILER: All right. We are working

on -- we're at Tab 5, the Risk Base Sampling Issue Paper. And specifically, on page 2 we have four major questions, but question 4 does kind of break it down into four major subsections. Question 1, again, relating to risk-based sampling and really dealing with small and very small plants is, are there any risk factors FSIS presently uses in designing risk-based sampling, more important when addressing the concerns of small and very small plants.

Number 2, are there additional factors unique to small and very small plants that FSIS should consider in the design of risk-based sampling. Number 3, how can FSIS conduct risk based sampling more effectively in small and very small plants. And 4, what are examples of the unique business practices of small and very small plants that should be considered when designing and implementing risk based sampling for and then the A, B, C and D, including E. Coli 01757 in raw beef manufacturing, trimmings and ground beef, Salmonella in raw livestock and poultry product, Listeria monocytogenes in post-lethality exposed to ready-to-eat product and finally, Salmonella in

pasteurized egg products.

I wanted to really quickly in case -- hopefully, I'm not the only one that wanted to be clear on this, we're talking about small and very small plants. A large plant is defined as equal to or greater than 500 employees. Small is between 499 and 10 or greater than 2.5 million in sales and very small is less than 10 employees or less than $2.5 in sales. I kind of thought that was significant in terms of the way we're spelling this out. At this point, what I kind of thought would be a good idea to do since we have Dr. Engeljohn here, is not necessarily to have you go over everything you went over already right after lunch, but to kind of give us Reader's Digest primer again for what we're doing here today and kind of the purpose and leading into what exactly you want.

DR. ENGELJOHN: Okay, I think there are two parts to what I'd like to re-emphasize from the discussion just a bit earlier from the larger session. One is that the Agency has traditionally just had a random sampling program in terms of how we selected

plants that we would conduct our verification testing and we looked to make it more targeted in risk-based with the belief that there is a desire by establishments to have FSIS test less frequently in their establishment where possible.

And so in order -- if that is, in fact, one of the designs that the risk-based program should have it would be one for which the agency would have confidence that the establishments producing product with their controls in place would, in fact, have effective controls in place. So one is to help identify how we can begin more targeting testing as opposed to random testing. We started the process with Listeria and we've identified the factors that we used for the Listeria one right now, which is, in part, information based on the type of product produced and the degree of control that the establishment has. So those are the primary features there.

And we want to expand the programs for risk-based verification to include E. Coli 0157-H7 as well as Salmonella in both ready to eat products and

in raw products. So it's all the verification programs but we're focusing first on Listeria, then moving towards E. Coli. So those would be some of the primary points that I would have you consider in terms of how we design our programs. We are, in fact, going to test. We are -- we allot a certain number of samples each year, so the question then becomes how best to do that, what's the most efficient and effective way to utilize those resources and have an impact on public health.

MR. DETWILER: Thank you. When we look at the first question in looking at risk factors that are more important than others when addressing the concerns of small and very small plants, that's one category of information we need to come up with. Also factors unique to the small and very small plants that should be considered when designing this risk-based sampling, we need to come up with that group of information and then when we start being able to synthesize those two pieces there, looking at how can we more effectively conduct sampling in these two plants, that's one more question we are looking at

answering there, too.

Why don't we look at the first thing in terms -- the first issue of the risk factors and once we get some risk factors that emphasizes currently using maybe we can try to start identifying which of them are more important than others when it comes to these smaller plants. And this is where I don't really have any expertise.

MS. HOLLINGSWORTH: I have sort of a question, I guess, and a comment here. Dan, you had mentioned -- and if we just look at Listeria, which, as I understand it, is probably the current example of where you've done the most to look at using risk factors for sampling and you mentioned two things. One is the type of product and then the second one was what -- which of the alternatives they are using.

And I'm trying to remember, I don't know that I can do this off the top of my head, the USDA-FDA-CDC risk ranking risk assessment paper, didn't it identify five risk factors that should be considered? It was ability to support growth, frequency of consumption, do you remember? I can't remember off

the top of my head but there were five risk factors in that risk assessment. Is FSIS using those same five and then your others added to that or -- I'm not sure which risk factors you're using other than the two that you've mentioned.

MR. DETWILER: Go ahead, Heather.

MS. HICKS QUESENBERRY: Jill, I think, first of all let me just say I'm impressed because that's a big document, you've obviously read it but --

MS. HOLLINGSWORTH: Yes, me and two other people, I understand.

MS. HICKS QUESENBERRY: -- those risk factors were the risk factors that that assessment team used to decide whether a food was at high risk, medium risk or low risk --

MS. HOLLINGSWORTH: Right.

MS. HICKS QUESENBERRY: -- in contributing to a case of listeriosis.

MS. HOLLINGSWORTH: Right.

MS. HICKS QUESENBERRY: What we're doing at FSIS, is looking at the specific product that's produced under our regulation and looking at those

products how likely is that product to contribute to a case of listeriosis.

MS. HOLLINGSWORTH: Okay.

MS. HICKS QUESENBERRY: So there are two different -- two different assessments.

MS. HOLLINGSWORTH: Okay.

MS. HICKS QUESENBERRY: So some of the risk factors that the FDA/FSIS in risk ranking used are applicable here and some of them aren't.

MS. HOLLINGSWORTH: Okay.

MS. HICKS QUESENBERRY: The ones that we use were established in the 2003 FSIS Risk Assessment for Listeria in deli meat, okay?

MS. HOLLINGSWORTH: Okay.

MS. HICKS QUESENBERRY: And we did that because the risk ranking that we do with FDA identified deli meat as a high risk food. So then we wanted to understand why, what are the risk factors that make deli meat a high risk food, so that's where we came up with the idea of is this product post-lethality exposed, is it sliced, is it repackaged, is it peeled after the final cooking step? Yes or no?

If yes, is this product formulated with an ingredient that's going to retard the growth of Listeria should it be present during the shelf life? Yes or no?

Is this product treated -- after the slicing or peeling or chopping or repackaging, is it then treated again with something that's going to kill Listeria that would be present, yes or no? Does this plant have specialized sanitation? Does it have a program that is looking for Listeria and anhialating it if it's in that processing environment? Yes or no? Those are the primary risk factors, that kind across the board allocation of resources.

Then, within those categories, what's this plant's compliance history, what's the volume of production? Is this establishment adopting voluntary interventions above and beyond what FSIS considers to be good manufacturing processes? Those are the secondary ones. Does that answer your question, Jill?

MR. GOVRO: Can you expand a little bit -- would you like is to identify ourselves as we speak? Mike Govro. You talked about the compliance history and as a regulator who's worked in the field a long

time, that seems to be an area that's very difficult to quantify and I'm wondering if you could tell us how you do that and how you factor that in. I know the -- one of the biggest challenges for us in achieving consistency is achieving consistency from inspector to inspector, and getting apples and oranges or apples and apples to compare.

DR. ENGELJOHN: Well, from the perspective of compliance history, I think this includes information about sanitation findings, the NR's that are written for plans, whether or not there are FSIS positives found in the plant, that's the kind of information that is collected and so we realize that there are inefficiencies and some degree of non-uniformity by inspectors in terms of some of this information but collectively over time we believe this information serves as a useful indicator. So it is the results of our PBIS testing is part of what goes into the overall looking at an establishment as to whether or not they've had a history of non-compliance or not.

And I'm not sure how your algorithm fits

that in, but it's a factor in terms of the design of how the plant is selected then.

MR. GOVRO: Do you assign a number to it or --

MS. HICKS QUESENBERRY: Actually, there's two parts to my answer. The first one is that we're just beginning to do this. So what we're doing right now is looking at while the Listeria rules has been in effect, has this establishment complied with that rule. Yes or no, and that's judged by the presence or absence of Listeria in their final product in regulatory sampling. Eventually, Dr. Engeljohn is exactly right, what we'll do is we'll be able to incorporate a long history of compliance, all these -- basically ways of evaluating their HACCP plan. Our inspectors are charged with assessing that and then documenting non-compliance. So we have that in a big data base.

And also, as time goes by, we'll have accumulated more and more laboratory samples under this program. So there's a -- does that answer your question?

MR. GOVRO: Yeah, yeah, it does. It leads me t another thought though, if I can keep going. I might go over it again. One of the arguments that we get from industry as we talk about assessing fees which is directly related to where we expend our resources as a food safety agency, has to do with the firm's ability to provide technical expertise on sites. That is their level of technical knowledge and how that might effect how they go about producing the product. And obviously, large companies that have someone like Charles on board and then people at each plant who are involved in technical services, quality control, food safety issues, people with degrees and have worked in the field a long time, should be considered to have an advantage over those who don't. And I would think that maybe that would be a little bit difficult, more difficult than in the very small plants because you're not likely to see that level of expertise, but again, maybe that would be a factor that you would want to take into consideration, so technical competency.

DR. ENGELJOHN: And how just -- this is

Engeljohn with FSIS. Now, how do you assess that information?

MR. GOVRO: Well, we don't. At t his time, it was an argument that was brought forward by industry. We're currently in a big fight in Oregon over who should pay how much for their license fee and one of the points that was brought forward by the larger processors is that we have technically competent staffs and therefore, you should inspect us less and, therefore, charge us less. We kind of rejected that argument because we're down to such minimum inspection that we don't really feel like we can go any lower and the bigger plants take more time just because of their size.

But I understand their point, that they may be better able to address the technical aspects of food safety than a smaller plant.

MR. DETWILER: In the back, I'm sorry.

DR. WENTHER: This is Jay Wenther, just to address that, what are you going to measure, anything from have they actually taken a HACCP course or have they had the consultant write their HACCP course? Is

there someone still employed there at that business that has a HACCP certificate saying they went to the course? Have they been updated with the Listeria guidelines. Have they attended E. Coli workshops, Listeria workshops, that type of thing.

We have members, like you said, you mentioned all those people. QC who contract up to one or two people in the plant, I can see where they're coming from. We also have members that have an education in food science and technology that when they ask for a process authority and you ask what makes up a process authority, they come back and they say an education in food science or meat science. Does that automatically make them a process authority. There's really a hard measurement on that deal but I think with some of the classes that are out there and the availability of resources you've put together for the outreach program, that may be one point.

DR. ENGELJOHN: Okay.

MS. HOLLINGSWORTH: I'm looking over these questions and I'm just trying to organize my thoughts and one of the things that -- I guess what I'm looking

here is, I'm coming from the bottom question up and that is if FSIS has a limited amount of resources for sampling, just like a pot, and this pot can be used for sampling and how are we going to do that, I guess one of the first things that, as a public health agency, you would need to look at is what is the greatest public health risk that we can actually address.

And I'll use for example, and excuse me for doing this because this is a very sort of the CDC epidemiology approach which becomes very insensitive toward the individual but I'm just thinking here based on the information that we've gotten recently from the FoodNet site, where if you look at Listeria, they have what 2.8 cases per million and if we assume 25 percent of those result in a death, you're looking at less than one death per million, less than three episodes per million. Now, if you put that up against the numbers for Salmonella and E. Coli, and I can't do that math in my head, I picked Listeria because I could do it in my head, if you look at Salmonella, maybe one of the things you're going to have to look

at, although the rates of illnesses are clearly higher, I'm not sure about the percent of deaths or subsequent or sequelae illnesses, but it would seem to me the first thing you would need to do is look at those illnesses that you are trying to reduce or prevent from a public health standpoint and first quantify or risk-rank them, then once you know which pathogens you want to focus on, or what human illnesses really, then look at what food products can be most -- and I know we don't have a lot of attribution data, but what food products are most likely to cause that illness, and you risk-rank that and then you get down to what products are most likely to be produced and what facilities where that occurs.

Is that -- am I making sense there? I mean, it seems to me like we're starting with the plant, the small plant, when, in fact, that may not be the first thing you need to look at. You need to look start with the pathogen first and then work your way down to where can you get the most public health benefit from your sampling protocol.

MR. DETWILER: Did you want to say

something?

MS. KAUSE: Yeah, I'd like to say that, you know, actually, I do think it starts at a broader perspective. When they set the healthy people 2010/2005 goals, that's where it starts. So when we say it's risk-based and we're using risk assessments, it is to provide -- to have interventions in place that lead to a reduction to achieve those goals.

MS. HOLLINGSWORTH: Right.

MS. KAUSE: From a risk assessment point of view in thinking about should you go after Salmonella versus Listeria? Well, back in the early ?90s should we have -- you know, chased after 0157 versus other things? The risk that is chosen to be -- that we go after is publicly driven.

MS. HOLLINGSWORTH: Uh-huh.

MS. KAUSE: As a public agency, you know do --

MS. HOLLINGSWORTH: Is the pathogen of the moment, yeah.

MS. KAUSE: Yeah, I mean, it's also severity. I mean, you're comparing numbers but some -

- you know, X numbers of gastrointestinal illness for risk assessment, even if you have 100 of those, is that more important that one death of a child.

MS. HOLLINGSWORTH: Right.

MS. KAUSE: And these are value-ladened, so it's not that straight. So basically CDC sets the goals and as a regulatory agency, we're here to achieve those.

MS. HOLLINGSWORTH: Well, and I'm right with you there, and that was my point, I guess, is that if you look at the CDC numbers, if I can recall from memory, the industry or the government, whoever is taking credit for it, but the goal for E. Coli has already been exceeded or we've gone better than the goal. Listeria, you're what .3 or .2 or something cases per million off the goal. So I guess that's -- what I'm saying is that what's going to be used as a starting place for what you're trying to achieve if that is Healthy People 2010 then I think first you need to say, okay, here's areas where we've done well, and obviously what we're doing is working, so we don't want to back off on that, but here's areas where we

have to do more and so all of a sudden the risk that they present bumps up.

In other words, Salmonella, actually if you look at the CDC numbers, should be considered a higher risk issue for the Agency than E. Coli and Listeria. Now, I don't know as a personal individual I'm comfortable with that, but if you look at Healthy People 2010, I think that would be your logical conclusion, or am I missing that?

DR. ENGELJOHN: No, I would just say, Jill, that's an excellent point and the Agency does, at this time, use Healthy People -- I'm sorry, Healthy People 2010 as its guide. And you're right, we do want to insure first of all, that we're having a system designed to address that. The small plant issue is on the table simply because again, who we regulate is a factor that there are more small plants than there are large ones and so we made the decision at this point and you certainly can give us feedback that you think maybe instead of doing 10,000 Listerias you should do 5,000 of them or substantially less there and substantially more with -- that certainly is

something that you can recommend to the agency to consider.

We've put in place the programs that we have now because those are the resources we have determined that we're going to do based on previous years. So the real issue becomes how do we divert those with small plants having special consideration in what we do just so we have that there. So that's the purpose there and you're right, it's -- we are concerned more about the pathogen than we are whether or not you're a large or small plant. There are just so many small plants that we have a special need to insure we're not overwhelmingly just focusing on them. I think that was the issue. We wanted to have a plan in place to insure that we're addressing the issue.

MS. HOLLINGSWORTH: And I certainly -- unless there may be others here who feel a lot more confident in their knowledge of risk assessing, mine is not great, I would be -- speaking for myself, I can't imagine we'd give you anything even close to a recommended number. I guess what I'm looking at is just sort of a process of how do you prioritize which

things you're going to assess before you get to that, so how many samples do we take? I mean, that's to me way down the line, way beyond our expertise, but I keep going back, too, to that real simple formula. I've only taken a minimal number of risk classes and I remember the first thing I ever learned is there is two things you look at, and that is, what is the chance of exposure and what is the outcome if you have that exposure. And that's sort of, I guess, the simplest version of risk there is.

And so maybe that gives us a starting place, like if you're looking at small and very small plants, what is the chance of exposure either to the product or from the product to the customer and I guess that would be a volume issue.

MS. KAUSE: And that's in the model.

MS. HOLLINGSWORTH: And then what is the outcome if there is exposure and I guess that's the concern about the public health outcome, do you give Listeria more weight than say Salmonella given that you have a higher rate of death?

MR. LINK: This is Charles Link. Just to

comment; I think initially we've got to look at the risk of exposure, I guess, not the severity because we all kind of know maybe that if you get a 157, it's going to be different than if you get a little Salmonella, but just looking at this risk-rank or, I'm sorry, the alternatives of Grade 2B, 2A1 and sanitation as a start, it's easy to say well, sanitation is most risky if you don't do other things on top, but has the Agency looked at the sanitation programs the companies have and what their finding through their sanitation programs and you can have one, but it may not be worth beans, you know.

One of the big differences, probably in larger and smaller and very small plants is just how much one actually tests. You know, I don't know what the right number is, but if you test three surfaces versus 25 surfaces, does it really make a difference? Statistically, I don't know, but what are the sanitation programs, what do they look like, what are they looking for, what are they finding? And if we're finding, you know, a lot of positive hits, but we're treating it with some antimicrobials ORK, I'm not sure

that's the right answer. I guess you've got to start with a strong sanitation program and I guess that's why it's on there.

If you do it right, to your point earlier, you can pretty well sleep at night. Sleep better if you do a few more things, I guess, but so I don't know if the Agency has looked at and I couldn't sit here and say, we'll one percent positive hits is the right number of .2 or 5, but it may be a way to kind of identify where you think the risk might be. If a plant is higher than the other, maybe that's where you ought to go look. And I think most people are sharing that data now with --

DR. ENGELJOHN: Yeah, and I think that's a good point in terms of consideration the Agency can go back and do is, analyze the data that we have thus far in the plants. We have -- as I tried to mention before, we have what the plants have given us on the form and then we have what they have in their HACCP plan which is the rationale for why they're doing what they're doing and I think the perspective that the Agency has is that often times there isn't a rationale

for why they chose the numbers that they did, the frequency of testing, for example, other than it's what the Agency had in its compliance guideline.

And I will say that we are intending to look at those plants that have had positives in the FSIS program what was it that they had in terms of the design of their program so that we can at least come up with a list of features that may be similar in plants in terms of the design of the programs that may give an indication that these are the things you might want to tend to if you want to enhance the control you have in place. There's always this issue about we know that the testing in and of itself isn't the answer. You know, the frequency of testing we concluded is not indicative of how effective your program is but it's how you've designed your program to prevent contamination to begin with is part of that issue.

And so we don't have an effective means to actually quantitate that. We know what the plants say they're doing in terms of the number of testing and we're considering factoring that in to our decision

making but we also know that that may not have a science basis.

MR. LINK: You mean testing product or --

DR. ENGELJOHN: Or contact services.

MR. LINK: -- or contact services.

DR. ENGELJOHN: And the goal from the Agency is, whatever we look at, I think we would want to say we want to encourage the testing and we want to encourage the finding of positive. The issue becomes what did you do when you found the positive and addressing the positive is the behavior we want to reinforce as opposed to finding the positive and then that being a target, that isn't what, I think we want to do in terms of a program. We want to encourage that.

MR. LINK: Yeah, you need to encourage finding them because otherwise, I mean, you can design your program not to run, you know, so you need to encourage, okay, great, you found it, now what are you doing is the next step.

MR. DETWILER: Go ahead.

DR. WENTHER: I was just addressing his

question. You need to encourage them to find it and we've had plants that have gone above and beyond just to find out they get beat over the head when they find a positive because then everything comes crashing down on them. They were trying to be proactive and it becomes an ethical issue whether you want to find it, an ethical issue of okay, if I do find it, now what's the Agency going to do? Are they going to help me along with this or are they going to bash me over the head because we found it?

MR. DETWILER: Dr. Bayse?

MS. BAYSE: Gladys Bayse. I'm not sure that this is the right place to bring it up, but if I understood Dr. Engeljohn's, what he mentioned earlier, did I write this down correctly that with the small and very small and by defining that by number of employees, I know we all kind of said, yes, it should be done really by volume rather than that, is it right that you said 80 percent of the products from small and very small plants come from 20 percent of the establishments? Was that -- something like that?

DR. ENGELJOHN: Yeah, again, I think if it

was for Listeria, it's probably a different number than that. But just in terms of getting it into your head as to there are substantially larger number of small and very small plants as defined in the HACCP category that produce a rather small amount of product and it's a small amount of establishments that produce a large amount and that's the concept.

MS. BAYSE: And if you spoke about how that's factored in or if you've tried to do that with what you've started with, if you mentioned that, I missed that.

DR. ENGELJOHN: Well, the issue becomes one of when we report back to the Small Business Administration or to the Office of Management and Budget or in our yearly congressional reports, we have to -- we do have to turn in a report on how we've addressed issues related to small business and small business to us is defined by our regulation which is the HACCP categories, but we've tried to provide refinement to that so that you may, in fact, be a small plant, but you're producing an extremely large amount of product. Well, so our goal is to be able to

provide clarity, ?Here's what we've done and how we're addressing small and very small plant issues?, by regulation and by definition of the categories that Darin mentioned, you know, the 500 or more employees or fewer than 10 employees, those categories, but then base our decisions preferably now on those factors that would discern the exposure and volume is one way that we're doing that. We're just not aware of other features that may, in fact, be good things to use to make those discernment.

It's -- we talk about small and very small plants from perspective that by the HACCP categories, they're defined by regulation and we have to report out on our activities related to that. How we design a risk-based program doesn't necessarily have to be based on large, small, very small. And we'd like to do that by factors that actually have more of an impact on public health since those weren't designed to actually do that. They were actually designed to look at the issue of economic impact.

MR. GOVRO: Mike Govro. Getting back to questions 1 and 2 which as I understand it, which of

the factors that are currently in use are more important in the small and very small plants and are there any other factors that should be considered; when I think of the four that you have listed here, type of control measures, product type, compliance history and volume of production, everything that I can think of that you might want to consider could be included in those and I would say that the compliance history sort of encompasses a lot of things we've talked about like how much does the plant test in-house, what is their sanitation program, how well is it monitored, how effective is it, that sort of thing. So let me just throw this out there maybe as a discussion point.

I would say, I can't think of anything for small and very small plants that would be any different. But I would assume from what you've stated up here in the purpose part, that you believe that there is a higher risk with the small and very small plants when you talk about their unique considerations, low volume of production, production specialty items, just in time processing, dependence

on external sources, limited use of new technology, et cetera. So I guess maybe the one thing that I could say that might help you in dealing with the small plants, would be that the more detailed characterization of the data you can provide, probably the better information you're going to get. And it's going to be more useful data. I mean, you can take a sample and characterize it as sample number 1 take on, you know, such and such date at such and such time, but you know, the more you can characterize the source of the ingredients that went into it, how large a batch it was part of, you know, just everything associated with the product, the more useful information you're going to get.

MS. HICKS QUESENBERRY: Heather Quesenberry. We do get source of the product, ingredients and on the sample collection form, there's a place for the inspector to make notes about any specific conditions that are present at the time of collection.

MR. GOVRO: Do you direct them to note specific types of things, or is it just kind of up to

them to --

MS. HICKS QUESENBERRY: There are, if I'm not mistaken, 36 specific questions that we ask them when they collect a sample.

MR. GOVRO: That's pretty detailed.

MS. HICKS QUESENBERRY: Things like, time of day --

MR. GOVRO: Ambient temperature?

MS. HICKS QUESENBERRY: All those kinds of things. And then we give them as much room as we can spare to give us anything else that occurs to them that's particular about that sample. So I agree with you.

MR. LINK: Part of what I struggle with is trying to look at Listeria and try to determine where you should focus your efforts and I start asking questions regardless of the plant size. I mean, I guess I have a hard time segregating that out, but and you've got to start with raw materials. You've got to look at your ovens and what kind of ventilation process does the plant have on their ovens, so that we know what cooks, sanitation programs, the elevation

of the inhibitors we're putting in that it really works, post-pasteurization, that we're really maintaining temperature and time and things said we were going to do. And everybody is trying to do this. I assume the very small plants may not be able to afford to buy a post-pasteurizer, I understand that and so they may choose a different route, may do batch pasteurization in an oven and that's fine, but how do they validate that, do they have the records, the data to support what they're doing?

If they do and everything is in place and maybe you go to the next guy that's not doing that, so that's where you focus your efforts, but just to say, ?Well, this guy does less volume, therefore, or more volume I should go in there because there's more of a chance?, well, yeah, there's more product but it depends on how well their systems are working, really, because every day is every day and you just do whatever. I don't know. I just have a hard time trying to decide that big plant, small plant, very small plant. If whoever is doing it has got a system and is validated and it's working for them, you've got

to find those that aren't.

MS. HICKS QUESENBERRY: I think you raise a good point and the only time that we do go to the bigger guy first is when all those other things are the same, when the processes are the same. And --

MR. LINK: And the difference is volume.

MS. HICKS QUESENBERRY: That's right. And as far as how effective is this system, well, first we have an inspector there. And you know, we trust that our inspectors are evaluating the systems, have evaluated their HACCP plans, have evaluated that their oven temps are reaching the proper kiln and secondly, I'm excited about next year we're planning to do checklist for our inspectors so that they can actually -- we have self-reporting information from all the establishments that say we're doing this. This checklist will allow us to verify that that is actually happening and give us greater confidence in the effectiveness of those systems.

MS. HOLLINGSWORTH: I guess one of the things that, it seems to me if what the Agency is trying to do, though, is to determine sort of, if you

will, from a headquarters level, here's this model and what can we plug into it that we have -- information we have access to when we set up our sampling plan? Although it would be nice if you could have all this individual specific information about, you know, how well do they clean everyday, I don't know how you're going to get that information to put it into a model to come up with a big nationwide sampling plan. So I guess what I'm wondering is what information does the Agency have readily available that it can plug into a model because you can come up with great things to assess, but if you can't get the data, what's the point?

And I guess I'm sitting here thinking about what kinds of things can you actually get your hands on to put into a model and I guess it would be things like the size of establishment, based on your HACCP definition, maybe we could, I don't know, list those or something or make a whole big list here of what you have available, size of plant, volume of product, I'm sure the Agency still collects volume of product, types of product, at least in some kind of

categories like ready to eat versus raw ground beef type of categories and then I don't know what's on the PBIS, I'm not close enough FSIS inspection reports any more to know all this stuff, but I would assume you have some kind of access to data on how many NR's they have or deficiencies or who -- what kinds of problems they've had with sanitation. If that information is readily available, then I think it becomes a useful tool to plug into a model. And maybe that's -- it would seem to me we would almost have to know what information you have or can get your hands on before we can say, ?Okay, now, given this list of information you have, that you can use to model? -- and the same thing about do they use post-lethality or what are they doing, then you can look at which of the list is perhaps -- should be or should not be weighted more or less for a small plant.

But I think you -- or we would even have to know what information do you have.

DR. ENGELJOHN: Right, and I think, you know, that's a good point, Jill, and I would just say, you know, in all fairness, I don't think we're asking

for the specifics though, because I know you don't necessarily have it, although if you had it, that would be really good.

MS. HOLLINGSWORTH: If I had it, I'd be selling it.

DR. ENGELJOHN: But I did try to point out earlier, you know, the Agency at one time did have access to more information we did collect. Back in the ?80s, we collected a lot of really specific information about what's produced and how much. We don't actually have those approvals any longer, so w don't -- we know what's in our PBIS system in terms of the plant profile, what products, what HACCP category and things like that but actual volume of production we don't have.

And on our sample request forms, for 0157 for ground beef as an example, the inspector makes an estimate. He provides a range of what has been produced, I think in the last week or last month, I can't remember but it's just a range of time, just to give us an estimate. And so we don't actually have the type of information we think that would be

helpful. We thought and we tried to correct that in the Listeria regulation by actually getting OMB approval to collect specific information from the plants.

So for Listeria, we do have the information the plant provides on what they produce, how much they produce and how effective they think their program is, how frequently they test and how effective they think their sanitation is. So we think that that was an important first step at getting at some of the issues that the plant has that could be used in terms of how we weight which plants we would go to.

So for Listeria, it will be an interesting exercise for us to see how effective this information is in terms of designing a program. And if it is effective, then we'll continue to collect the information and refine it as we need to. I think the real issue that we have is, is there a sense that you may have that this is actually the type of stuff that you should be collecting and should pursue approvals to get that same kind of information for the other

program areas, like for poultry slaughter. I mean, we don't collect information about what interventions are used and volume and those kind of things there either. But if we believe that that could, in fact, be helpful to the Agency, it would be something that we would intend to pursue provided that we actually use the data.

I mean, the real issue is we can't collect data just to collect it. We have to have a purpose for it. We believe that that probably would be helpful information to design risk based verification. We started it with Listeria and we'd like to pursue it elsewhere but I think one question we would have is feedback from you as to whether or not you think that's a prudent way to go, because we don't actually have it. Again, it's the inspector making a decision about what's in the plant's program but we don't actually collect that information routinely.

DR. WENTHER: Jay Wenther. I would think that you'd have to -- the data you're talking about the PBIS system you're talking about, I would think you'd have to look at that very carefully to you being

from -- I'm sure you deal with a lot of NR's around different plants. You see a lot of --

DR. ENGELJOHN: I see that a lot.

DR. WENTHER: But there's different, I would say levels of NR's, whether they're actually food safety related, they're not in compliance but it is directly a food safety issue. One guy has rust on a nail, the other guy forgets to take lethality temperatures. There's different levels but an NR is an NR is an NR at the end of the day. One thing when you talk about volume of production, you might want to think about or add into when that volume actually occurred. We've got guys that pop up in October and they're producing 50,000 hams in three months and they're done. So the volume thing, you have to kind of space out. Is it an intensified volume or is it over the entire year, and you look -- I don't know if distribution has ever been looked at. Small and very small, recognizing what we're looking at, their distribution is two counties versus 20 states, is that ever going to be taken into account or is that -- should be taken into account.

DR. ENGELJOHN: I think it's a very good point. From my perspective, for E. Coli 0157-87 presently we collect supplier information so that, if, in fact, you have a positive, and we find out who were the suppliers and I think we are interested in whether or not there's a greater risk if you have multiple suppliers of source materials versus single source in terms of for a number of reasons. But I think -- I don't know as if we've considered collecting information about distribution and geographical distribution but that sound reasonable. I don't know from your perspective, Jill, with the food establishments that you have, is that -- I mean, I don't know.

MS. HOLLINGSWORTH: Well, I'll tell you the one thing that strikes me and because it's a current issue that we're dealing with, and that is in the CDC data there is a significant difference in the cases of Campylobacter in the East Coast versus the West Coast. And I think that serves as a good example of where distribution and differences in handling in fact, probably would totally impact your risk. Your

risk actually on the West Coast is different than your risk on the East Coast. You're far more likely to be exposed to Campylobacter, have the disease if you live on the West Coast and so I think there the question would be, and why is that and so there you have to look at things like distribution and differences in practices.

My personal opinion is it's entirely based on state law with temperatures. And so there's a situation where those kinds of factors, I think, make a big difference when you're looking at how would you do your sampling. I mean, again using Camplyobacter, if you were going to do sampling for Camplyobacter, it seems to me it would make far more sense to be weighting your sample to the West Coast facilities versus the East Coast because your risk is greater out there. So I do think you have to take those other kinds of issues into account and I guess that's where I was going with the whole idea of if you're going to try to come up with a model that you can plug things into, there's probably a whole laundry list of different things that you would have to consider, can

we get this data and then where do we put it into this model to determine how we adjust our sampling levels. And I think developing that list is useful. I guess, if I understand what you're asking us is, do we think there are some things on that list that are more or less important for a small facility and I know we haven't quite gotten around to answering question yet, but maybe -- we always spend time, it seems, getting them framed up, but I --

MR. DETWILER: Well, you wouldn't want to go straight to answering a question without coming up with all the factors behind it, wait a minute. Now that we wrote all the answers, let's start over again.

MS. HOLLINGSWORTH: Yeah. We've done that many times. We've debated for four hours and then wrote up the answers in 20 minutes. So I guess in my mind I'm still trying to get that clarified. Is that what you're trying to ascertain or have us help you with, is do we feel that there are those things that may or may not be more important in a model if you're looking at all these criteria because of the uniqueness of a small plant?

DR. ENGELJOHN: That's ultimately the question, is the differences between small plants and others, yes.

MS. HOLLINGSWORTH: And it would seem to me that you almost might eventually somewhere down the road, end up with a matrix of all these factors that you want to include in your model or to plug in and then weight them, this factor is more important. If it's a big plant, this factor is more important, if it's a small plant kind of thing.

MR. GOVRO: Yeah, just to clarify, I think I'm understanding the question. Any risk factors FSIS presently uses in designing risk-based sampling more importantly when addressing the concerns of small and very small plants, does that mean more important than in large plants?

DR. ENGELJOHN: Uh-huh.

MR. GOVRO: Okay. As opposed to compared to each other because you're already broken them down into first tier and second tier as I understand them. So --

DR. ENGELJOHN: And again, getting back to

the issue, the Agency is interested specifically in -- we're going to have a risk-based program and everybody is included in it, but we want to have some special considerations for those things that we're looking at for small or very small plants. So that's why the focus of is there things in particular we should probably pay attention to that we have not.

MS. HICKS QUESENBERRY: A good example, I think of what Dan's talking about and what you mentioned in the back, I'm sorry, I don't remember your name --

DR. ENGELJOHN: Jay.

MS. HICKS QUESENBERRY: Jay. Seasonality production, right now, our risk base verification sampling program knows when a plant is in production and when it is not. So we're able to take that into consideration and we are asking plants next year to tell us not only that they operate for this number of months and this is the poundage, but which months, exactly those happen so that we can look at an annual forecast, not just on a month-by-month basis are they producing. So that's one of the kinds of

considerations that we need to take into account for small and very small plants.

You know, an organization like Cargill doesn't have that problem, or doesn't present that challenge because you guys have a more uniform kind of production.

MR. LINK: We do, but we still see seasonality differences not in Listeria but in the 0157 for example certainly --

MS. HICKS QUESENBERRY: I'm sorry, I don't mean in prevalence of pathogens, I mean in how much product you're sending out the door.

MR. LINK: Oh, no, yeah.

MS. HICKS QUESENBERRY: Yeah, whereas small businesses do.

DR. ENGELJOHN: Yeah, I think on that issue, this is Engeljohn, if we know there are seasonal effects with the prevalence of the pathogen, then absolutely, we are -- we take that into account now, such that we double the number or we significantly change the frequency or the numbers of samples that we would collect in the period of time

where there's high prevalence, so we -- that's part of what we try to do if we know that there are seasonal differences.

MR. GOVRO: Mike Govro. I'm just going to throw out an answer for question number 1 and then I'll let you all argue it out -- argue me out of it.

DR. ENGELJOHN: What is question number 1?

MR. GOVRO: Question number 1, are there risk factors that FSIS is using that are more important in small plants and very small plants than in the larger plants. And I'm going to throw out the answer no. I think when you look at all of those things, they're all important whether you're a small plant, a very small plant or a large plant. You may look at them a little bit differently as you try to design your sampling program but those seem to be the elements that are -- I mean, seasonality applies to a big plant as much as a small plant. You may see it more in smaller plants but it's still an important factor.

The time of year when you sample and the ambient temperature is an important factor. It's

going to give you maybe different results at different times but it's still as important in a large plant as it is in a small plant. All of these things that we've talked about that we can roll up into the phrase of compliance history and the sanitation program and all this sorts of things as important in small plants as in larger plants. So unless -- can you argue me out of that?

MR. LINK: No, I'm not going to try to. I guess the only thing that might be different and I think Jay brought it up, the distribution discussion and maybe it's just very small plants and not small, because small is a really huge category, but you know, if I'm going to the next county or if I'm going from cross country, different considerations, shelf-life weighs in. I may only need two weeks if I'm going to the next county. I might need 60 days if I need to put it anywhere else and distribute to a huge chain retail establishment or something. So there's differences there. I don't know if that's something that needs to be --

MR. DETWILER: Well, it sounds almost like

it's not so much that it changes his answer of number 1 but it goes into number 2 in terms of those additional factors unique to the small and very small, and it also sounds like it's more so that it pertains to the very small than to the small because of the range of the small plants, that the very small plants because of the time and duration to its -- for its distribution and how wide is its distribution and its seasonality, might play more a factor for the very small, but I don't think that changes that issue of the answer to number 1 being no.

MS. HOLLINGSWORTH: Yeah, if I'm following, Mike, what you're saying, it's that some factors may have more weight than others but whether that factor is applied to a small or a large plant is not the issue. If volume of product is important because that has to go to exposure, then it's not volume is more important in a small plant versus a big plant is that the volume is a factor that has to be weighted

MR. DETWILER: Exactly.

MS. HOLLINGSWORTH: And more product

that's produced say using a single source of material that was contaminated is going to produce a larger amount of contaminated product and result in a larger exposure, therefore, a greater risk, but that could be equally true if that product was produced in a small plant or a large plant. Is that what -- and the same thing with the distribution. The longer a product is held, the more shelf-life time is has for growth, the further its distributed may be all factors, but whether that product originated from a small plant or a big plant is not the point.

MR. DETWILER: Yes.

MS. HOLLINGSWORTH: Is that -- Okay, and I can agree with that because I do think things like volume matter but it's not a matter of is it the volume, of the big plant or the little plant, it's how much of this product did you produce and therefore, how much exposure is there.

MR. DETWILER: So just to recap, I have so far, as some jotted notes here, the answer to question number 1, we have so far is, no, that all factors are equally important. They may be looked at differently

between large and small plants, such as seasonality but equally important, some factors may have more weight than other factors, but again, all factors apply in terms of all large -- I'm sorry, well, to large, small and very small plants.

MS. HOLLINGSWORTH: I can't think of a factor that you would consider in one size plant versus another. I mean, it would be -- I'm trying to think here. I mean, it's the exact same factors, the volume, the season, the distribution, the type of product, the type of processes, all that long list we talked about, once you have that list, it's the same for a small or --

DR. WENTHER: What about in-house versus brought in product? What I mean by that is there's a guy that -- a small guy that slaughtered his own steers and also brining in raw materials versus a guy that does not slaughter any more and he's just bringing in boxes of materials with USDA marked inspection already on it.

MS. HOLLINGSWORTH: And I think you're right, that factor but whether it's a small plant

doing that or a big plant is not the issue.

MR. LINK: I mean, we have plants that -- I mean, we don't kill a thing. It all comes in and referring to the small plant category, but it's a huge plant. It kicks out, you know, millions of pounds a week of hamburgers, you know, but it's a small plant. And so you look at that and you -- I'm looking at that, yeah, okay, there's a factor there. Raw materials coming in, so we've got supplier programs, loading and sub-loading testing, a lot of things in place to kind of guard against problems, but it's a factor.

MR. DETWILER: Are those plants kept as small plant?

MR. LINK: Pardon me?

MR. DETWILER: Are those plants kept at small plant?

MR. LINK: Well, the difference is numbers of bodies, right?

MR. DETWILER: Yeah, so just like --

MR. LINK: Yeah, it's automated.

MR. DETWILER: Yeah, just like you've seen

that guy on Star Trek going on the away mission? You know, he's --

MR. LINK: No, no, I mean, it's automated, so you're kicking a lot of volume out but it's small because there's no bodies.

MS. HICKS QUESENBERRY: And that illustrates the value of having this based on production volume and not on number of employees who stand in the plant.

MR. LINK: That's right.

MS. HOLLINGSWORTH: Is your HACCP categories a combination of employees and dollar value and/or employee or dollar or --

DR. ENGELJOHN: Only in the very small, the large it's just -- more than 500, small it's fewer than 500 and more than 2.5 or more than $2.5 million, so small is fewer than 11 I think or 10 employees and do not produce greater than $2.5 million. So that's how the HACCP categories are. So really it was distinctions made from the census. I mean, it's what the Small Business Bureau had designed in terms of looking at impact. So it's -- really, again, it's

more based on features that are separate and aside from what actually happens in the plant.

MS. HOLLINGSWORTH: So you could have a facility that is enormous and extremely automated and it would still fall into the small plant category.

DR. ENGELJOHN: It could, absolutely, in fact, it does. And so from the purpose of the Agency, there are a couple choices. One is we could get rid of the HACCP designations which is how we phased in HACCP, you know, that was part of that consideration, and change how we consider our impact on the industry by these other considerations. We don't do that right now, but it certainly could be where we could go in the future. But we think in terms of public health, that's what we should be doing is basing it on those factors that effect risk as opposed to what size category the Small Business Administration classified you as.

MS. HICKS QUESENBERRY: It makes some sense when you think about the impact on a business to think about the number of employees and it also makes some sense to think about production volume when you

think about exposure to consumers and that's really what the Agency is doing simultaneously. When we look at economic impact looking at is this a small business, is it a very small or a very small plant, and we were sampling, we were looking at how much product is going out the door to consumers.

DR. ENGELJOHN: See, I don't know whether -- again, I think you come up with an answer to number 1, but if you were talking about issues for number 2, again, trying to get as some of the issues just raised is -- does a larger plant have greater turnover of employees and is that a factor that may, in fact, effect sanitary dressing on the floor as example, versus a small plant, a very small plant that has the same employees there are often from the same family that that's all they do, you know, there may in fact be really economies generated by not having high turnover. And just simply the fact that you have slower turnaround, you know, that may be a business issue for you but you also have the quality that's there because you have employees that have been doing it for the last 30 years.

You know, those, in fact, may be factors that could and should be considered. We don't consider them now but they -- if there was a way to do so, it would be something we could pursue.

MS. HOLLINGSWORTH: And actually, it could work -- the fewer employees a large plant has, could actually reduce their risk because they've taken on a lot of human error kinds of issues if everything is automated. So the whole idea of a small plant has a few people and there's greater risk there may, in fact, not hold up at all.

MR. GOVRO: I wonder if you could develop -- Mike Govro, develop some sort of ratios in terms of volume of product versus number of employees or another measure, how many steps to the process, how many pieces of equipment does it touch or get moved from one to the other to the other, increasing your chances of exposure to a pathogen. I'm kind of thinking out loud right now, but it seems like there might be some other things that you could look at that -- you know, it sounds that we're all a little bit uncomfortable with those three size categories as

being significant in any way and there are so many other things like distribution, sanitation programs, number of employees, turnover, I mean, that's a great one, characterize the training that the employees get.

MS. HOLLINGSWORTH: Sort of off the record, I guess, we have -- retailers have an audit program for suppliers and when we were trying to determine how we would assess the need for how many auditors and how much time they had to spend in a facility and how much they were going to charge to do an audit, we started out using FSIS' criteria and we abandoned it. It just didn't work. Now that was different because it's a lot of FDA regulated products, too, but if you start looking at produce facilities where they're growing a product, they have 6,000 employees in August and 12 in December.

We tried to base it over a 12-year cycle or a two -- we just got rid of it, we just couldn't do it and it's all done now on sales -- volume of sale.

MR. DETWILER: So I have turnover of employees, ratio of -- I like this one, the ratio of volume of product to employee -- not employee number,

employee numbers, differences in geography. We also talked about seasonality before. Is that still something we want to put for number 2, seasonality or we're not thinking that's really a different initial factor?

MR. LINK: I think it's -- is it Heather, I want to get it right?

MS. HICKS QUESENBERRY: You mean seasonal production, right?

MR. LINK: Exactly.

MR. DETWILER: I'm sorry, seasonal production.

MR. LINK: If you run six months out of the year, what six months are they and does it matter. If it's in the summer, maybe you want to be in there.

MS. HOLLINGSWORTH: But I think to question number 2, again, going back to Mike's point, there's a lot of factors that could be considered in maybe not only the ones that FSIS is using but even look at some different ones or weight them differently, weight some more important than others, but to the question of are there factors that are

unique to the plants that are small or very small, I thought we were saying no, that it's the same factors, they're not unique. We send --

MS. BAYSE: Well, the risk factors are the same, I think, in number 1.

MS. HOLLINGSWORTH: Right.

MS. BAYSE: Did we say -- did we agree on number 2?

MS. HOLLINGSWORTH: Well, I guess that was my point. Number 2 says, are there additional factors.

MR. GOVRO: And again, we came up with some other things to think about but I'm not sure they should be considered unique to small and very small plants.

MS. HOLLINGSWORTH: Right.

MR. DETWILER: It's -- one thing that keeps coming back to me is that I sat on a panel with King County, which is basically Seattle and the area there and they're talking about some of the more ethnic stores that they provide for different basic customers but in trying to deal with the economy, they

expand a little bit since they have some of the equipment. They also might do ground beef in addition to very limited cultural things and that I remember then telling me at this meeting, I remember then saying that that was one of the things that the smaller establishment -- they did have some problems in terms of dealing with those very unique, you know, smaller, usually family owned what do you call that, a rare -- a rare market, more of a rare --

MS. HOLLINGSWORTH: I niche market.

MR. DETWILER: Exactly, a niche and that over the last 30 minutes is one thing that I keep thinking. I don't know if that would be something a large plant would be as much as in terms of where it is actually something as being seen as unique to a very small plant because you wouldn't have it causing the same problem.

MS. HOLLINGSWORTH: Well, I think Darin, that's a good point in that -- but again --

MR. DETWILER: Ultimately you're right.

MS. HOLLINGSWORTH: Whether a big plant is making a meat product or a little one --

MR. DETWILER: Whether -- big plant would be the same thing.

MS. HOLLINGSWORTH: But you're right, it does tend to be that small operators tend to look for a product or something that makes them unique. That's how they compete with the big guy.

MR. DETWILER: Right.

MS. HOLLINGSWORTH: They compete by making something different or unique and maybe that does in some ways increase their risk because there is less knowledge or experience with making that product, handling it. There's not as much technology available for doing post-processing maybe of a particular product. So I think there are some niche or unique products that present greater risks. Again, I don't know if that matters what size facility they're being made in, but you're right there are --

MR. DETWILER: Well, their argument though, is you would not find that niche in --

MS. HOLLINGSWORTH: In a big plant.

MR. DETWILER: Yeah, exactly, you would not find that in the large plant. But ultimately, in

terms of the factors, the risk factors, it's a moot point to say that it's any different if it was large, small or very small.

MS. HOLLINGSWORTH: Right.

MR. LINK: Something just popped in my mind that might be a little different, big, small, is on some of the interventions that people employ, if it's freezing, for example, to get to -- does it matter if you freeze it on site or if you freeze it at a warehouse somewhere three hours away. If you're using high pressure, does it matter if you do it in your own plant or if you take it 10 hours away and stick it in a pressure vessel? Does that really matter?

MS. HICKS QUESENBERRY: That kind of takes us back to the issue of distribution that was brought up earlier and the thing with distribution is besides the self life issue, is you think about time and temperature during that distribution and that's an additional handling step and what you get into there is actually an issue of compliance. You know, it theoretically shouldn't matter if the product is

shipped an hour away or a week away if it's handled properly during this. And so what you end up with is this issue of distribution and the compliance during that distribution.

MR. LINK: I understand that but I think to Jill's point and if we go back no the Campylobacter discussion, you know, if I'm taking raw poultry to 26, 28 degrees, and distributing it fresh and I'm in California and I think I don't know what that means. I'm thinking 36 is fresh, so I've created a different situation and I'm in compliance but I've created a different -- I don't know.

MS. HICKS QUESENBERRY: That would be something like the voluntary measures that we talked about before where an establishment goes above and beyond what the basic minimum good practice is and that's where you have to -- where we're excited about the ability to assess the individual relative risk of one establishment's practices and processes to another's.

MS. HOLLINGSWORTH: Yeah, I mean, it would be sort of interesting if there were some software

developed where a company actually fills out just fields and then automatically it ranks that based on criteria that have been preset in this software program, you know, where you just ask the company to fill out this series of questions and they do a whole bunch of things and fill them all out and then when it's done, it sends back to FSIS some arbitrary number like this is an A23946 facility based on all these things they've told you but that little code means something to FSIS as far as how many times do we sample this facility and for what?

DR. ENGELJOHN: And so that's -- quite frankly, that's exactly where we are trying to go is to -- as we can identify those things that matter whether or not, here's a minimum level of what we consider to be industry good manufacturing practice, where this is the bar that's set for most plants and then there is others that exceed the expectation and here are the factors that may impact that, that's ultimately what we're trying to do is come up with that -- what we call a checklist to say here's some features that we want feedback from the inspector on

and, again, do they have these practices, do they have real shelf-life data as opposed to a computer modeling their program and that type of thing.

And then that ultimately would segregate right now plants for Listeria anyway into one that exceeds expectation versus meets minimum but doesn't go over this threshold. So that there are, in fact, distinctions made within the alternative. That is, in fact, what we're trying to do, starting with Listeria but ultimately we would do with Salmonella, depending on do you control from that hatchery all the way through slaughter, what comes to the slaughter house and the intended use of the product? Well, those all would be features, hopefully that ultimately would impact on one of those decisions as do we target it or not, you know.

MS. HOLLINGSWORTH: And if that's the concept, then I guess it goes back to our original point and that is when you're answering those questions, I don't think it matters really how your plant is categorized according to HACCP; it's how you've answered those questions. What are you doing

and how are you doing it and how much of it are you doing.

MR. DETWILER: Okay, Jill, based on your concept of this A236 kind of thing, would there then be the idea of going well, we've got this data and what do you know, here's another A236 and so what is it that's common between these two A236. We don't just say that they're both small or they're both very small. We can actually get more specifically targeted and say that these both have a seasonality issue that's the same or they both have a turnover of employees issue that's the same and now we can look at either training outreach or difference in inspection criteria that's very much more specifically targeted to not just a small, very small or a regional but specifically on that idea of what are those various weighted factors that they have in common?

MS. HOLLINGSWORTH: Right, you're right, I think it's a good point, if we make up this theoretical thing were you have these A23 plants and if you went to them or just looked at their size, you might think, why would they be sampled the same, but

if you looked at the processes they have in place, and the kind of practices and the kinds of operations that they're -- whether they're sampling or not sampling, what they're producing, how much of it, if they have unique niche products, that's what they're going to have in common, not how many employees they have or how big or small their building is.

MR. DETWILER: Right because what happens then is I tend to think that there's some plant that they would fill that out once and they might never change. They would always be that A236, that a year or two down the road, they're no longer an A236, they're something else, so if we can identify maybe, in terms of certain factors, what is it that would change, then that would be the kind of thing we need to look at in terms of what are those factors that would make those small or very small plants differ and I do see the idea of turnover employees, the ratio of product to employee quantity, the region geography and the seasonal production as being those kind of things that could change, you know, even if the ownership of the plant does not change.

MR. LINK: It could be volume of sales, now I can afford to do things I couldn't do before.

MR. DETWILER: Exactly, or we have this new deforestation law that requires me to not be able to have this and the zoning changed and now we have to focus on this and therefore, the place where I was getting my product has changed or, you know, there are many factors that could change. The seasonal production and the distribution of geography.

MS. HOLLINGSWORTH: Even formulation, I mean, if you're making a product that has a certain pH and your high on the list for Listeria sampling and suddenly you've reformulated it and you now have a very acidic product with a very low pH, your need for Listeria sampling is going to probably totally change.

And we've seen that even with non-meat products. I mean, we've seen a real change -- and I'm getting off the subject here -- but in the industry that produces salads, deli salads, they've just gone to acidifying the stuff and now the whole food code is going to change because they've got the pH so low on that stuff. So it's like, you know, the product, the

formulation.

MR. DETWILER: Mike and then Gladys.

MR. GOVRO: I was just going to say, it sounds a little bit like we've gone through question number 3.

MR. DETWILER: Way to go, Mike.

MS. HOLLINGSWORTH: Thank you, Mike.

MR. GOVRO: Unless Gladys has more to add, it sounds like what we're focusing in on is just refining the risk criteria and maybe being able to create categories or scores or something that would allow you to focus your sampling on those with the highest risk and again it sounds like we're still sort of shunning the size categories as really being significant, although there may be differences in what you see in those risk categories from size to size.

MS. BAYSE: It was about the same comment. We've sort of talked now about performance evaluation and if we have the spreadsheet whatever, Jill's with blocks in it, then when something changes, now you should be able to -- yeah.

MS. HOLLINGSWORTH: In the interest, I'm

sorry.

MR. DETWILER: I'm sorry, Jay?

DR. WENTHER: I'd just ask the question, how come a niche market automatically makes it a risk to the product because I could think the other way, too, a niche market would make it a non-risky product? I think ground beef, as I said, I grind five boxes, 20 boxes of beef. I bring it out of the freezer on Monday, I grind it on Tuesday and I sell it Tuesday afternoon. I don't know if that's quite as risky as something that's got 60 days of shelf life.

MR. LINK: I don't think that implied it was more risky. It was just a factor to consider.

MR. DETWILER: Yeah, the reason they had brought it up in King County was that they were talking about the inspectors went to this one restaurant and that a meat processing plant in the back for this one cultural group and they were surprised to find love goats walking around and apparently that's what they do. They -- it's that short of a duration, a farm to table and --

DR. WENTHER: Well, I don't know that

niche markets are risky but I think there's some that aren't risky even -- I didn't want this to just be all they --

MS. HOLLINGSWORTH: No, I think the idea is it needs to be one of the factors looked at.

MR. GOVRO: And that probably goes under the characterization of product type and --

MR. LINK: Can I jump off in the weeds a little bit? This concept of 1A, 2B and 3, now there's four, do you or does the Agency see an alternative to formulation better than host pasturization or vice versa or are they equally as wonderful as far as you're concerned?

DR. ENGELJOHN: Well, I would say when the risk assessment was done, it was the combination of a post-lethality treatment and preventing growth as being the most effective way to address Listeria throughout the shelf life of the product. And so if you're only treating something post-lethality but it would allow growth and if there's low level contamination in the shelf life long enough, well, it could, in fact, create a hazard on down the road. So

I don't know as if there's a distinct way to discern how much risk is different between the two. It's just that it's the combination of barriers is what's more effective than --

MR. LINK: No, I understand that. I just -- if I were to choose one or the other and alternative 2, which would be the most effective, I guess in my mind, which would be better and I'm kind of looking like the formulation -- because, you know, if you've got a good sanitation program, chances of surface contamination are pretty minimal anyway but I just wondered -- I didn't know where you were on that. Is one better -- is there some hierarchy on --

DR. ENGELJOHN: I would say for the moment the way the Agency is looking at it, it is. How the establishments are, in fact, verifying that they have an effective program and you know, we do have a concern that some establishments may have just added antimicrobials but not necessarily at a level that's effective. That's a concern to us and so when -- taking all things into consideration, if, in fact, they're effective, obviously having sanitation which

is a necessary thing to begin with, in preventing its growth would be something I think would be highly desirable.

MS. KAUSE: This is Janelle. Just to add to that, you can always go to the website and look at the 2003 FSIS' Listeria risk assessment that's been extremely peer reviewed according to OMB guidelines and cleared through OMB, it's the only one that's been cleared through OMB to date and they actually give you the differences overall but on top of that is exactly what Dan said, you know, you may be doing one of those interventions but how effective is it to say, ?I did it?. You know, you can add it at a level that was going to make much difference.

MR. DETWILER: Very true.

DR. ENGELJOHN: The only issue that I don't think that's been talked about much and it's talked about and you can make a decision about how you want to recommend back to the Agency but I do think it is important that the agency consider the establishment's documentation, their own data and a way to figure that into -- if a plant has lots of data

and it's reputable data, or they have ongoing data not necessarily lots of it but they have good sound data to support their program, that there needs -- or there could be a means by which that gets factored into the overall decision such that it's not just the Agency's data that's driving but there's the encouragement, like we said on Listeria in particular, an encouragement to have data designed to find the problem and then data to demonstrate its fix, should probably carry some weight over having no data or insufficient data to make those kind of determinations.

MS. HOLLINGSWORTH: I think even in previous discussions and committees we've always come back to that point of can you make having data and giving it to the Agency an incentive and not a risk?

DR. ENGELJOHN: Right.

MS. HOLLINGSWORTH: And that's tough. I mean, it is tough. The other thing I was just going to throw out and I thought it was interesting when your comments -- when you made your comments and toward the end how there seemed to be sort of a

concern or maybe even a misunderstanding about looking at small plants differently. I think with this type of approach, where you're looking at all these factors on a matrix that are weighted but they're not weighted for whether or not the factors are in a small facility or a large facility, I think it certainly also goes to address those concerns that the Agency does not give perhaps bias or preferential treatment that allows one plant more latitude to be a little less safe than another and I think this concept wipes out that whole fear or concern that that could happen.

MR. LINK: Is part of our discussion -- I'll save the questions and answers but just in terms of where these folks and their attention whether it's Listeria, Salmonella in poultry or eggs, when you've got limited resources and I think Jill pointed out, they're talking about 0157, already where we're supposed to be and still making progress with regards to the 2005/2010 goals really close on Listeria, not quite there yet. Salmonella is still kind of out there a little bit but we don't really know if it's meat, poultry or if it's alfalfa sprouts or something

else. But is that part of what we need to be talking about or am I really in the weeds now?

DR. ENGELJOHN: You guys have the ability to decide what it is you want to talk about.

MR. LINK: We can talk about whatever.

DR. ENGELJOHN: I mean, that's what you can decide, do you want to go in that direction.

MR. LINK: Part of it is, okay, if I'm going to look for Listeria, what do I need to think about. If it's 0157, there are a different set of factors, I think. If it's Salmonella, it's something completely different again because they are completely different processes and different sources and things of that sort. And really, we're kind of focused on Listeria but touched on other issues and I don't know. But then I wonder how much effort you really ought to be putting on 0157 given where we are today and maybe we're in a maintenance mode as far as you're concerned there and not so much the Salmonella where we ought to focus a little more attention. I don't know. I'm thinking that way.

MR. GOVRO: Related to that, I think it's

really important that we get the -- what's the word I'm looking for, I'm having a brain freeze right here -- attribution data, in terms of the illnesses and try to make a determination whether these products, meat and poultry products, are where the overall resources of the food safety machine get focused. You know, the -- and I appreciate that if you reduce the amount that's in the source, then you will reduce the number of illnesses. I think that's a straight correlation, but there are so many other factors that influence it. For instance, with Listeria, we see a lot of Listeria cases at least in our part of the country that has had a large influx of Hispanic population in recent years in the production of illegal queso fresco cheese which is a raw mile fresh unpasteurized cheese, a lot of cases. We are estimating that there is more illegal queso fresco sold than legal queso fresco sold, and so I think the attribution is just really essential, that we determine where to look and that's going to drive overall where we should place our resources in food safety.

Maybe it should be consumer education.

Maybe it should be food worker education. Maybe it should be inspection at the food service level. So I think that's an important point with regard to which particular organisms we look at and how we view that data.

MR. LINK: And on the Salmonella side, just a similar argument, we've looked at on farm data pretty extensively trying to understand what's going on in farming and looking at the stereotypes of Salmonella. We don't find the same stereotypes in plants that we find on the farm, interesting enough. And then I think what we've finding in the plant typically aren't pathogenic strains but and I know that sometimes there are obviously, but at some point, do we need to look at Salmonella and focus in on these are the strains that are the problem, all the rest of them are not a problem.

You know, because I guess there's a finite number of pathogens within the Salmonella family. We're going after positive/negative and if it's there we'll go nuts, trying to figure out how to get rid of it and a lot of times it doesn't matter anyway because

it's not a pathogen.

DR. ENGELJOHN: But I would say on that issue -- this is Engeljohn -- is that one thing that we are looking into is methodology can be a factor being the one that we're looking at right now, with the other advisory committee but we do have a need to insure that our methodologies aren't selecting for certain pathogens in the medium that we use to find pathogens in the products that we regulate.

The medium may, in fact, be selecting for certain strains and this would be the incubating media that we use in the lab, such that the strains that are causing people to get sick may, in fact, be there on the plate but they don't grow well and the other ones do. And so those are the kind of issues we need to make sure that if in fact, people are getting sick from these particular pathogens, and we're not finding them on the products, that, in fact, we know they're not on the products and so there are a number of issues we need to answer there as well.

MS. HOLLINGSWORTH: I think back to Charles' point, maybe in this concept of developing

sometimes ultimate software where you just plug in this information, I think there almost needs to be probably two separate components of what data is going into that decision tray, if you will. One set of data is all the information that the plant supplies you; their volume of product, their processing activities, if they're testing all these different factors that we talked about, and then I think on the other side, the other pieces of data that need to be put in are things like how common is that pathogen or how much disease results from that pathogen, what is the morbidity/mortality rates for that, all that human public health kinds of information also needs to be plugged in because you're right, I mean, there's no point in putting your resources into testing for a pathogen that no one is getting sick from. So clearly that second component, the public health component, I'll call it for lack of a better term, needs to be added into the model along with all the industry information when you're trying to assess what are your real risks and where you really put your resources for sampling, if, in fact, your goal is to lower food

borne illnesses in the human population.

MR. LINK: Part of that, you know, is back to this are we on cruise control on 0157. I don't think that we are but from an Agency perspective, maybe you back up and say, ?Yeah, I want to keep my hands on it, my finger on the pulse, but I ought to put more effort on identifying in the Salmonella world where we ought to be working.

MS. HOLLINGSWORTH: Have a maintenance level versus a reduction level.

MR. LINK: Yeah, I mean, once you're there, you're there but --

MS. HOLLINGSWORTH: Then you've got to maintain that.

MR. LINK: I know, and that's why you've got to keep your finger on it. Do you go aggressively after 0157 and you know we're well ahead of goal at this point and focus our effort somewhere else? I don't -- until we found Listeria, if you know -- I mean, if we had the attribution that we knew that, hey, do you know what, we're close but the reason we're not over the hump is because of cheese, you

know, it would be nice to know that.

MS. HOLLINGSWORTH: Well, if they could take out the cases, even the cases they know about, that occur from non-commercially produced products, that would be way below the Healthy People goal. The problem is the non-commercial products are incorporated in and there's nothing FSIS and FDA are going to do in the industry to effect that. I mean, that's strictly public education. There's nothing you can do to change that as an industry.

MR. DETWILER: I also agree in terms of the fact that if you look at the forces and the various factors at play here, I mean, if it was, we could limit it down to a few, this is why we have the E. Coli or the Salmonella or whatever, that would be great, but unfortunately it's so fluid and to say we'll focus on this, who's to say that's going to change, like you were saying here, six months a year down the road or in this part of the country versus this part of the country, like you were saying.

It almost seems like the factors that we've looked at weighing them that they don't really

have any difference whether it's small, very small or large. But looking at some different factors but at the same time, not just looking at the pathogen of the day but looking at here are some standards and we've got some more interesting data that says maybe we need to go look at this as well and that, you know, three weeks from now it might be completely different. So I don't know if specifically we would relate it to any one or two pathogens based on any factors as in the long range the prudent thing to do. That's just my ramblings.

So for number 3, just trying to move on, keep with the list here, I have down for number 3, refining the risk criteria, creating categories or scores but not necessarily focusing on plant size. Was there any more specific verbiage that you wanted to include that we had not already included in our responses to numbers 1 and 2?

I did include for additional factors that idea, I think it was Dr. Hollingsworth and her -- I'm sorry, it was someone -- about the amount of ongoing good and sound data. I'm sorry, someone over here

said that. That might -- maybe being another factor to look at, a small plant that never has any data might be something you'd want to keep your eyes on more than a plant that has a lot of very good sound, ongoing data and they are proactive in looking at their own factors there. Was there anything else for question number 3 in terms of anything else for sampling more effectively?

MS. HOLLINGSWORTH: Darin, is it -- I guess what I'm seeing is, I'm not even sure that you have specific answers any more for 1, 2 and 3. It's like here's our one big answer to that whole block issue.

MR. DETWILER: Yeah, but then again, to some extent, the questions are not very unique in and of themselves, because look at our answer number 1 and then saying that, no, all factors are equally unique, but then question number 2 is what are additional unique factors? We're saying still no, there's no unique factors but here's some additional factors that are not unique but need to apply to the large, small and very small that could be looked at in terms of

coming up with your A236 kind of categorization or scores, if you will in trying to avoid just the focus on the plant size.

And then we had listed the few additional factors to look at but that they were not -- again, these are not unique factors to the three different types of -- these are just additional factors to consider.

MS. HOLLINGSWORTH: You know, it would be sort of interesting if you had your criteria and could plug information in to see if, in fact, for example, very small plants all tend to fall into one category because they do have factors in common that large plants don't have, but you wouldn't be sorting them because they're small. They would have to fall out into one category because either they don't collect data or they don't use post-lethality treatments. They end up falling into the same category together anyway but it would be interesting.

DR. ENGELJOHN: Yeah, I -- I mean, again, it's -- the issue is the Agency's looking to start capturing differences and then trying to see if, in

fact, the outcomes of the plants are different and whether or not we can attribute food borne illness to anything in particular. All those things are trying to mesh together and so the -- it just gives us direction to just continue to do that.

DR. WENTHER: There's different tiers I'm looking at, too, when you talk about just because they have -- they may all have the same 50 components and they all say the same thing but when you break those components down, just because one company uses lactate and the other one does, too, the level of lactate will then break it down even farther and it just keeps on tiering it down. So it's not as simple as then we're going to clog everybody down and they're all going to be the same again. I don't think it will ever get to be the same, because now the customer that we deal with is --

DR. ENGELJOHN: I can tell you this; we did try a couple of years ago, when we were starting to look at how we could do Salmonella testing for raw product differently, we looked at the plants that had failures of the criteria for the Salmonella programs

and we looked at plants that didn't -- did not fail and rarely, if ever, had positives to try to see if there were differences in terms of the written programs that they had and the reality is, the written programs are the same, but the commitment by management to the programs were different. But how you capture that is difficult.

You know, again, a small plant that has a commitment to -- they may do it slow and they may do -- you know, do it infrequently but they still may, in fact, have better dressing procedures, you know than an automated system and you know, consequently, there simply are differences, simply because of just how they conduct their business. But there also is a commitment to making things happen versus one that doesn't. You know, how we capture those things, that's the hard part.

MR. LINK: One factor we hadn't mentioned and I'm not sure if anybody believes this to be a factor or not, was geography. And I'm sure in my mind that it matters.

MR. DETWILER: You mean not the

distribution geography but physically where it is.

MR. LINK: Where they are.

MR. DETWILER: Yeah.

MR. LINK: Where you are.

MR. DETWILER: I think there's a big difference between places depending upon where exactly they are. I'll put that down.

DR. ENGELJOHN: What do you mean by that? I mean, we -- I can -- do you mean like what we said with jerky as an example, that if you're in a high altitude area, that may be something you need to consider in terms of cooking temperatures may be more difficult to achieve a level, a falsity at a higher elevation than one at sea level as an example.

MR. LINK: That's a good example. I think just being in a warmer climate makes a difference for Salmonella for example or 0157. If you're in Texas instead of Pennsylvania, you may see a difference.

DR. WARD: And that's where the animals are slaughtered or reared or both.

MR. LINK: Reared and slaughtered.

MR. DETWILER: Do you know what else I was

thinking when you were saying that? One of the things that popped into my mind is, if you're a small plant in the Eastern part of the United States, you got much less distance to a much greater percentage of population than if you're in you know, the Midwest.

MS. HOLLINGSWORTH: Wyoming.

MR. DETWILER: And it might take you a lot longer and you have to go a lot further to get to the same quantity of customers you want to get to. So it's not necessarily big city/little city or rural or urban, but you know, proximity to your basic customers that could effect that as well.

MS. HOLLINGSWORTH: Well, if you start looking at factors like humidity with Listeria it seems to us we find more environmental Listeria particularly in the Southeast. I think it might be related to humidity. Everything is always wet and they're always blowing air conditioning all the time.

MR. DETWILER: I'm going to be a facilitator here and say we've been here for two hours and maybe we should take a break for a little bit and if anyone disagrees --

MR. GOVRO: Yeah, and I mean at some point probably when we come back, we ought to think about getting a report written.

MR. DETWILER: Yeah, just don't forget what room we're in. They all look the same on this floor. Yeah.

DR. WENTHER: Just one question before you break, is this something, Dan, that we're going into, I mean, the system on the grade, the concept is on the grade, it's been talked about for years. Is this something that's going to maintain for years? And what I mean by that is, they say we're there with E. Coli, we've made the 2010 goal in 2005. When it hits 2010, then what, is it going to lower even farther and then we're going to back up and now we're going to be addressing E. Coli again because our goal is -- are we still going to maintain it? Is it something we can achieve or is it different -- you can't foresee the future, but different Administrations have different objections for this, accomplish what you need to get done for moving to that system?

DR. ENGELJOHN: Yeah, I mean, in all

fairness, I don't have an answer to the question but in terms of the strategic planning by the Federal Government we do, for public health, use 2010, Healthy People 2010, so we'll at least know until then we have some goals to work towards, and the goal is to not meet them but to exceed the goals. And there will be efforts made to reassess where we need to go beyond 2010. Whether or not it will be continued lowering or in the case of 0157, and I certainly don't know the answer to this but again, there's been significant progress made within raw beef products but there hasn't been a focus in Healthy People 2010 by the water or other areas that contribute to that disease. So the focus may be on a different product.

There still may be a goal there to be achieved and it may not specifically identify raw ground beef the next time. It may, in fact, identify another vector that needs to be controlled.

MR. DETWILER: All right, let's get back in 10.

(A brief recess was taken.)

DR. ENGELJOHN: I'm not trying to put

words in your mouth but from my perspective, the -- what has been talked about by this group is there are a number of things that should be taken into account, much if not --

MS. HOLLINGSWORTH: Beyond these five.

DR. ENGELJOHN: Beyond these things and much of which the Agency does not have access to, has access to the information but we don't collect it and that by -- the establishment providing the data, could and should be used to help factor in how the Agency does its verification program which to me, means that it would be prudent for the Agency to identify those things that could be used in a matrix type of thing to use in its decision making which would come from the establishments themselves.

And that would give, in essence, us one direction which would be to pursue a means by which we can capture that information.

MR. GOVRO: If you need to pursue that permission, then you should. Some of the things we may have talked about today might be things you could observe in terms of their sanitation program and that

sort of thing.

DR. ENGELJOHN: And we do that now and it gets into the issue of we, the government, has this information but there needs to be a way to take -- for the establishment to get credit for the good things that they're doing as opposed to just an opinion by the Agency and we did that in Listeria by creating a data request form that we would update it regularly. As the establishment changes its process, they can submit new information which may, in fact, put them into a lower risk if we're rating establishments based on relative risk and that should be a good thing.

The problem is, is that we -- it would be helpful to have from the committee a recommendation that that should be something the Agency pursues.

MS. HOLLINGSWORTH: Well, again, I guess I sort of -- thinking here of my future career, perhaps, I'm going to be a millionaire and write this software, it would seem to me that -- and I know, Dan, you referred to like a checklist. I guess I see it sort of as a series of questions that can be provided to the industry to fill out and even very small plants

that might not have the wherewithal to download a form and fill in, you know, data fields, even the inspector could have that information and sit down with the client management and say, ?Let's see how many of these questions or this information we can fill out?.

There may be some small and very small plants that either aren't going to know or even if they're unwilling, I mean, you're not going to hopefully mandate this, that they're going to say, ?I don't know?, or, ?I don't want to put that information in?, in which case there would be a default which might automatically mean they're going to be ranked as a higher risk and sampled more, so it's to their advantage to give you all the information you need but they fill in this information about how they operate and what they do and what they produce and how much and things like that.

I would also say, though, I feel strongly that in addition to that industry component, we also need to go back to this other idea that side-by-side with that needs to be this public health set of information that needs to be added to the matrix.

DR. ENGELJOHN: Yeah, in fact, when I wrote that down, Jill, I wrote down, there's the need to have input of plant data provided by the plant as one category that fits into this. There's the need to have the risk information which is the public health information, the morbidity, mortality, some factoring in of that and then the third component being that the FSIS data, since you've got those three pieces there, probably that feed into an algorithm or something.

MS. HOLLINGSWORTH: Exactly.

DR. ENGELJOHN: But that would be helpful but from my perspective coming from this committee, it would be especially helpful to have a recommendation back that the Agency should pursue obtaining this kind of information.

MS. HOLLINGSWORTH: And Charles, as a person who's going to be in a company or in a plant that's going to get these questions to answer, does that seem like something reasonable to ask a company to do if, in fact, the answers -- first of all, it's going to give you a chance to explain yourself to the company, but then that will also be a basis for

determining what gets sampled in your facility and how frequently.

MR. LINK: And especially if you tell me if I don't fill it out and they're going to be all over me.

DR. ENGELJOHN: Or again, if we told you if you met this threshold, you're in one category of higher likelihood of being tested frequently versus in this if you meet these criteria, you have a lower likelihood, that type of thing. So that's it's incentive based to do what you can within your resources.

MS. HOLLINGSWORTH: And I think the whole idea of giving companies incentives for sharing data is built into a process like that with the idea of if you're not filling out certain fields or providing information, there are defaults. The problem is the defaults are not an incentive, providing the information is an incentive.

MR. LINK: I'll tell you what the problem, the immediate problem that I see is because the USDA is asking for it and we give all that data, it becomes

public domain and the next thing we know you've got this list of plants and the first thing -- I go back to this -- do you remember the Salmonella deal that got published in the paper and one of our plants was in the Filthy Five.

MS. HOLLINGSWORTH: Yeah.

MR. LINK: You know, and that was not good news. It's not there any more, but, you know, that's the kind of thing that would inhibit this type of sharing. You know, I don't know if it's something that USDA can do or do through a third parties to get the information but not have -- somehow not have it available to them.

DR. WENTHER: That's the first thing I was thinking of because, I mean, FPA did a seminar on risk-based inspection and data sharing and that was one of the biggest things, all big industry and all industry wants the data sharing but they want to know how the data is going to be used and they do not believe it should be out there in the public domain where everybody can use it against everybody to then muddy the waters with that data and I believe it's

going to take data to get there.

To use this old grid system like you're talking about makes sense but to have that out there and to really put it out there, it's tough.

MS. HOLLINGSWORTH: And saying it's a trade secret or protected under FOYA might not be enough but it might be the kind of thing where the Agency could decide to let this out as a contract or a grant to a university or some other private entity and then what the Agency gets back maybe is not the individual pieces of data but the categories or where plants fit in, in a testing scheme, if that's the only way to protect the privacy of it, but I agree, I think the Agency needs to consider that because chances are a lot of people may just say, ?Just put me in at the default level and I'll take the heat, but I'm not going to tell everybody in the world everything about my plant?, and that will be an issue.

MR. LINK: You just don't want to read about yourself in the paper.

MS. HOLLINGSWORTH: Yeah, especially -- and that much data and information is so likely to be

misrepresented and misunderstood.

MR. LINK: And the problem is, if you do that ranking then you've got these plants that fall into this other category as default. They're the first ones that are going to be on the front page, ?What's wrong with these guys?, you know?

DR. ENGELJOHN: But the reality is, is that the Agency's testing program is, in fact, going to need to identify which plants to target and that's just how it is and so there are going to be those categorizations of the plants so the question then becomes what other -- what data is absolutely necessary to get you for the agency to be -- where the benefit of providing it outweighs the risk that you have otherwise.

MS. HOLLINGSWORTH: Well, and I think, too, a lot of it might be in the explanation, if it's clearly understood and the agency does a good job of communicating the fact that a plant may be in a category to be tested a lot, because they make a lot of product and a lot of product that is a challenge to make because it can, in fact, if made badly or in

appropriately, could cause illness.

DR. ENGELJOHN: Sure, and those are -- I think that could be part of your recommendation going forward is for the Agency because we're suggesting moving forward with risk-based approach, which may in fact, segregate plants or products into categories, it's critical to have a communication plan developed around that, and that's something that I think you should recommend, so that we don't not do that.

MS. HOLLINGSWORTH: Yeah, I mean, the whole thing might be to find a whole other way to categorize so that the terminology isn't high risk and low risk which sounds bad, ?I am a high risk plant?, when in fact, it might be that you have some of the safest product in the country but it's because of what you're making and how much of it you're making.

DR. ENGELJOHN: The inherent --

MR. GOVRO: FDA characterizes the firms on their official establishment inventory as high risk, low risk, allergen.

MS. HOLLINGSWORTH: Right.

MR. GOVRO: And I don't know, and they've

been doing it for a long time.

MS. HOLLINGSWORTH: Of course, you know, even now they're looking at rechanging all of their inspection reports to get away from the use of the word, critical, because then people think, ?Oh, my God, you have a critical violation therefore, you have good contamination?, but in the Food Code a critical violation means something that could result in a hazard and it's not quite understood that way. So they're changing the names, just to get away from the words.

DR. ENGELJOHN: I think that's an important point to bring up and if we don't capture it in your recommendation coming forward, we may not get that addressed. In other words, remember to capture that, so that would be an important --

MR. DETWILER: I'm sorry.

MS. HOLLINGSWORTH: We'll tell you in a minute. Tell us when you're ready --

MR. DETWILER: I'm just trying to process what we've got here.

MS. HOLLINGSWORTH: Okay.

MR. DETWILER: So we'll have a first draft.

MS. BAYSE: You may not want us to talk. With the FoodNet surveillance, I don't know enough about that. It's reported illnesses but do they track back to try to -- and is there a way for Jill to fix her matrix so it's compatible with their software?

DR. ENGELJOHN: Yeah, I think, ultimately, Gladys, will fit in in the sense that there are only a certain number of states involved in FoodNet right now, volunteer states.

MS. BAYSE: Oh, yeah, I forgot about that.

DR. ENGELJOHN: And -- but those states have directly tied into the clinical illness, a means by which food is better attributed, so that there is, in fact, more close ties in those particular establishments. I would just suggest at the moment just, you know, just another issue the Agency is working on, again, is we think that we, in fact, will have the issues related to Listeria well under control through the procedures we have in place through our regulation, but that just deals with post-lethalics,

post-product. We do have a concern about product at retail, which is an issue for which I know Jill has a lot of concern about, where we're going to with that particular program, but the issue becomes if, in fact, getting back to this maintenance issue, if we think we got things under control in the federal and state plants is that the focus may need to switch to retail if, in fact, public health benefits can be gained by refocusing there. But there are a lot of drawbacks to going to retail that have a program which you have to take into account which is you first have to establish that the problem is generated there as opposed to came in with a product. And so -- but we have a FoodNet project -- there's a -- there are certain FoodNet states right now involved in a Listeria program that we're monitoring at retail to see if, in fact, there's better information we should be basing our public health risk-based decisions on. And if so, if we made a focused attention there with our risk based program would that impact public health?

And if so, then that may shift our resources to start looking there. But we would

certainly want the data to support changing how we view that first, but FoodNet is more directly tied to the food because there's a more direct means to try to get back at attribution.

MR. GOVRO: Mike Govro, in case we're still on the record. It seems like regardless of what we do try to focus the sampling into the correct places, what's really going to drive it or should drive it in the future to a large extent is going to be sampling history and regardless of what category somebody falls in, if they fall into a category over here that says, ?Gee, we don't need to sample these guys very much?, but nevertheless in the limited amount of time, limited number of times that you do sample them, that they're positive every time, I would think that they would then fall into a different category.

DR. ENGELJOHN: Yeah, Mike, I think that's a really good point is -- and again, I do think we should give credit to the plants particularly if they have data to support what they're doing and we have our own historical data to rely upon. I think what

that gets at is another level of the Agency looking at how the plant has designed their program. If the program by the plant is designed to find low level contamination with high confidence, that's distinguished differently than a plant that may just be testing once a quarter or once a month, just because, not really designed to find the problem. There should be credit given to that and there are means to verify that that is, in fact, working.

But I would also point out that just so you know in the current E. Coli 157-87 program, the Agency had made the decision about the fact that if a retail grinder is only grinding product that comes from the federal plant, that presents a different risk scenario than a grinder who grinds in store trim and that that should be a consideration as well, so that if there's the opportunity to test it in the federal plants, that's one consideration about do we test on down the line. I think also one thing that should be considered and as you suggest is, how frequently has those suppliers been tested and if they haven't been tested in awhile, then maybe there should be tests

done intermediary. So those are the kind of things that we're certainly looking into when we design this program, to take all those things into account.

DR. WENTHER: I would think the more data you get the longer you continue with the sampling program, the better you're going to get at going after the ones where you're likely to see a problem.

DR. ENGELJOHN: Yeah, well, that's one of the reasons why with the Listeria program right now and I know Jill in particular asked this question earlier and the answer was confusing that I gave, but we do intend to have a discernible difference in the frequency in Alternative 3 versus Alternative 2 versus Alternative 1 plans. And right now, there is a distinction between those three alternatives but all three are being sampled at a very high rate.

Ultimately, that will likely change such that it will be allocated to the highest risk but all of this historical data we're generating now for Alternative 1 and Alternative 2 plans will be captured, which we wouldn't get otherwise if we only tested them infrequently. So we think there's a

benefit right now to have the high level of frequency in all three categories even though it's at different levels as a historical basis.

DR. WENTHER: When you're talking about the risk and everything and you're talking about small meat processors, I find it very difficult to put my hands around the fact that these small meat processors are making 50 different types of meat products, two of which fall into the high risk categories of either frankfurters or deli products and then we have all the rest of them that are in there, when you talk about how many times you sample, is that ever going to take into consideration because we'll never get out of all Alternative 3 because some of the options aren't available to them to get into Alternative 2. Take for example, scrapple in Pennsylvania. You can't have approval without tasting it. Most people are saying they don't want to because it changes this and that. They've always got excuses and reasons.

If then never get out of Alternative 3 and they make 50 different products and all of them except for two or three are in Alternative 3, is there still

going to be that same frequency or --

DR. ENGELJOHN: Well, maybe I'm not understanding the question as fully as I need to but if all the products -- a number of those products all fit within -- they're Alternative 3 but they support growth, and we would consider all those to be -- that's -- when we pull a sample, all those fit within that, so it's not like each one of those products has an opportunity to be scheduled separately. It's part of the process and by alternative. Does that get at the issue?

DR. WENTHER: Yeah, I'm just trying -- when we filled out that reports, when the reports came through and they've got products in every category, some of them do and it's difficult to find out -- they think they're going to get sampled less because they've got two products in Alternative 3 and all the rest of them are Alternative 2. I just wonder how that all calculates out. I assume it's extremely difficult for you. You just send out a memo and say, ?This product needs to be tested?.

DR. ENGELJOHN: Yeah, well, ultimately the

goal will be is if there are ways to discern that the alternative to product, any of it, doesn't get cross-contaminated with those from Alternative 3, then we would look at them as entirely separate entities.

DR. WENTHER: Right.

(Whereupon, at 5:08 p.m. the above entitled matter concluded.)