UNITED STATES OF AMERICA

DEPARTMENT OF AGRICULTURE

NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY

SPRING MEETING

FRIDAY, JUNE 17, 2005

The meeting came to order at 8:30 a.m. in the USDA South Building Cafeteria Conference Room, Mary Cutshall, Moderator, Presiding.

PRESENT:

DR. BARBARA MASTERS	ACTING ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE
MARY CUTSHALL	MODERATOR
DR. GLADYS BAYSE	MEMBER
DR. DAVID CARPENTER	MEMBER
DR. JAMES DENTON	MEMBER
MR. DARIN DETWILER	MEMBER
MR. KEVIN ELFERING	MEMBER
MS. SANDRA ESKIN	MEMBER
MR. MIKE FINNEGAN	MEMBER
MR. MICHAEL GOVRO	MEMBER
DR. JOSEPH HARRIS	MEMBER
DR. JILL HOLLINGSWORTH	MEMBER
MR. MICHAEL KOWALCYK	MEMBER
DR. CATHERINE LOGUE	MEMBER
MR. MARK SCHAD	MEMBER

C-O-N-T-E-N-T-S

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

(8:44 a.m.)

DR. MASTERS: Rumor has it that we had good fruitful discussion as usual last night. I hear some of the groups deliberated well into the evening. So I appreciate as usual the hard work that always goes on.

As I said yesterday, I'm always amazed how we give you these questions, and you go off and you have these deliberations, and I always think, what are we going to see tomorrow? And you always come back, and you always have these nice, thoughtful, well laid out options and deliberations for us. So I look forward to hearing those this morning.

I apologize. The good-new-bad-news of having the worst-case scenario of being here yesterday. I thought it was a small room. I thought it was the heat. And I apologize, by being here my bosses know where I'm at, and I couldn't even sneak out gracefully.

So I apologize that I had to depart yesterday a couple of times, and I appreciated Dr.

James being able to step in.

So I do plan to be here this morning to hear the reports. But just as a recap for those of you who weren't with us yesterday, we're going to be hearing back from our groups.

We're going to hearing back on three issues that we presented to the committee. And the subcommittee report outs are going to be on new technology.

In particular, we're looking at - we have been working at getting new technology. And we've got some that we've gotten back, and we're going to be getting more.

And we're looking in particular how to transfer that new technology, and how to get it out to the small and very small plants in particular.

The second group that is going to be reporting out, we in particular want to make sure on test-and-hold on the guidance material on how to get that out to small and very small plants in particular.

And then finally on risk-based sampling, the question we posed to the subcommittee was, how

would we best do that, and in particular, to small and very small plants?

And we shared with that group how we've been approaching that for Listeria monocytogenes, and we wanted to look at going beyond that, and we posed those particular questions to that subcommittee, and we're looking for some guidance and feedback on how we could approach that for small and very small plants.

So that's what we'll be hearing back from the groups this morning. And so with that, we'll get back to the groups and hear some feedback from the deliberations that we had yesterday.

So thank you.

MS. CUTSHALL: I would like to start with subcommittee number one. And I believe, Mr. Elfering, that was your group on how we're going to look at new technologies for small and very small plants.

MR. ELFERING: Well, Dr. Masters, after that introduction, I hope we live up to having the thoughtful presentation.

We had first thought that the best way to do this was just to have everybody call Mary Cutshall,

and she could get all the information out.

But knowing that Mary is only one person, we decided that maybe we needed to look a little bit further.

I'd like to thank the committee, first of all, Dr. Denton. And we had - where is all our committee members? Mike and Catherine - who else was on the committee last night? I think that's probably pretty much it. Oh yeah, Dr. Leech.

And we also had some representation from Bobby Tippens and Miguel Castellanos, and Dr. Patel, Dr. Syed, and also Andrea Warfield from American Association of Meat Processors.

They also provided some guidance and some good forethought and information.

I think one of the things that we looked at first of all is probably using the onsite inspectors as using them to get the initial information out. And this would be both FSIS inspectors and from state inspection programs.

After that we will be looking at utilizing country extension agents. And actually we should

probably change that to county extension educators, because that is really is more their - the focus of their positions is education, and that's truly what we would be looking at.

I think there needs to be a strong emphasis on simplicity for these small and especially very small plants.

For example the sanitizing handle that we discussed yesterday seemed to be a pretty inexpensive piece of equipment that could be easily assembled, buying the materials at a local home store. And that certainly is something that a very small plant would be able to utilize. And with no additional training or special training.

Again, what technology could be adopted by certain plants? Very small plants certainly are not going to be able to use technology that has been developed for very large processing plants.

But I think we have to identify the technology, or at least the FSIS needs to identify the technology, and then apply it where it best fits, if it applies to the small plants, or very small.

And I think the focus on these is having first of all the outreach to clients. Building an element of trust I think is an important part. And then also the technology costs.

So then with that sort of a preamble, we get to the questions themselves, and the best way is to get the information out is, first of all, we have to identify the audience. Who are they? Who are the various small and very small plants?

And I think that we'd be able to do that either getting information from the performance-based instruction system, or through district offices, and also from state directors.

We'd also be able to identify those facilities through trade organizations, country extension educators, and also technology providers.

Also being able to use USDA ARS and universities to be able to not only be able to identify who some of these facilities are, but to assist in doing some of the - a lot of the education.

If we go to the second page, for those of you who - I believe you have a copy of the report -

the information should be available on the web, CD ROM, directly from FSIS, and state programs.

But it could include -- Dr. Leech brought this up, in a lot of these small communities that have small town newspapers are willing to print just about anything someone gives them, especially if it comes from an agency, or especially from county extension.

So that would be another method of being able to get information out.

An up-to-date resource website, and I do applaud USDA, because they really do keep their website up to date, and that needs to continue.

I think it really has to be consistent, having the same information from USDA, and also state inspection programs. So that it's a good consistent message, because there are times when some of these facilities eventually go under federal inspection that had been under state inspection or vice versa.

Dr. Patel I think brought up possibly - or Dr. Syed brought up a technology weekly report that is information that is disseminated to district offices.

DR. SYED: District offices and --

MR. ELFERING: So that would be also another method of getting information out.

The district office role would be getting that information to front line supervisors, inspectors in charge, and also consumer and safety inspectors.

The next question is, how does FSIS present scientific information? It has to be simple, powerful messages in layman's terms. You have to have resource contact information, and then also, have research demonstration with colleges and universities.

One of the things perhaps for future cooperative agreements, collaborators should be required to assist in disseminating the information on their new technology, so that that would actually be part of their grant proposal that they're submitting is, they would have to demonstrate how they're getting that information out.

And then also to communicate the new technology to inspectors, more as a benefit in helping them make their job easier.

And I think that we talk that the information has to come as directly to the inspector

as possible. I think that people are always going to probably take information perhaps from their supervisor rather than from the administrator. So it needs to trickle down to that supervisory level to really make it that this is something not only for food safety, but can help the inspector do their job much better too.

The last question is, how does FSIS access the very small establishments that don't belong to a trade organization?

I think some of the things, first of all, that's why we thought first, the front line inspector can get the best information out, and they can get it to every plant regardless if they belong to a trade organization.

One thing, we could provide this information to other inspection agencies. Have it posted on state or university websites, information with county extension agents; and I think also, to include the HACCP coordinators in contacts that every state has a HACCP coordinator and contact.

One thing that I kind of skimmed over a

little bit on this is should this - and maybe we talked about this - should this be focused only on plants that are under continuous inspection? Or should this information also be going out to those who are operating under custom exemptions?

We kind of looked at this as not necessarily an inspection issue but rather a food safety issue. And also some retailers, there are retail operations that produce a considerable more amount of product than very small plants that are under continuous inspection. And if we would be able to identify some of those and get the same information out to them, especially when it comes to, some of these stores may have a central kitchen where they produce sausage products and then distribute to their other retail stores which are exempt from inspection.

We do have a footnote on there that FSIS should utilize the existing information to assess technological needs. You already have the technical services center that I'm sure many calls come in from plants that want to know if there is some technology available, if there is any kind of a log kept on what

kind of technology is really needed out there.

Plus I'm sure that there's trade organizations that have come to FSISes wanting to know what technology is available for these very small plants to accomplish certain things.

And any other information that's gathered by the agency, to be able to utilize what you've already gathered.

So I would leave the rest open for comments from the rest of the committee.

MS. CUTSHALL: Do we have any comments or questions from the committee on the first report out?

Dr. Harris.

DR. HARRIS: Just very briefly.

First thing, I did not receive copies of the first two reports. I got the subcommittee on risk-based sampling, but I didn't get the other two.

But my question is, the state HACCP coordinators - and this is probably more a question for the agency than it is this subcommittee - but is that group, is there ongoing communication between the agency and that group? Or is - I don't hear much

about it on a day-to-day basis, so I guess I'm curious, is that thing being maintained fairly current and in an ongoing dialogue back and forth?

MS. CUTSHALL: The answer to that is yes. We generally tend to have conference calls with all the contacts and coordinators, including the district managers, and federal-state relations staff here in Washington, usually on a quarterly basis.

We send out invitations, we send out an agenda, we ask for issues that different contacts or coordinators may have, and we try to keep an open dialogue.

We also, whenever we have a series of workshops or any of that type of thing, we also have a conference call. We usually do a mass mailing to let them know what we have, make sure they have that information.

We try very hard to make sure that those contacts and coordinators be maintained on an ongoing basis.

And if there is anything that we can do that you could suggest to make it better, we would

certainly be glad to do it.

DR. MASTERS: Mr. Finnegan.

MR. FINNEGAN: Yeah, one thing that worked good for us was, when big issues come up like the BSE, and the initial start of HACCP was at an awareness meeting. And there was kind of a form, I remember some kind of a form where the inspectors - now this was just under inspected plants, state and federal - where after the awareness meeting had to sign off on them, and then we know that that plant got all this information, and that it was clearly authorized.

Wasn't there some kind of a form, don't you remember, called the BSE - the SRM's.

DR. MASTERS: Barb Masters, yes.

At the time we did the BSE, we had our inspectors in charge work with the plant and just had the plant memorandum of the interview that they had in fact discussed that information to ensure that there was that exchange of information.

MR. FINNEGAN: That seemed to work very well. That way we knew that everyone of our plants at least had that information.

MS. CUTSHALL: Mr. Alfred.

MR. ELFERING: Yes, I was going to add to Joe's comments, I think one of the things with the HACCP contacts and coordinators, if they start getting this information, it's going to get them more engaged in the whole process too. Because I think the more information you can get out to them on new technologies is going to be beneficial to them. And they are going to feel like they - as a HACCP contact or coordinator, I think sometimes they think they've been lost. And this would help get them more engaged in the process.

MS. CUTSHALL: Okay, thank you..

Dr. Masters.

DR. MASTERS: Did you all talk - I like the idea of the small town newspaper. But did you all talk in any specific detail about what that article might be? And did you give any thought to how that article might be presented as far as, would it be an article that would demonstrate like, going into the sanitizing halo (phonetic), obviously it's a real-life technology, but what would that article look like in

your subcommittee's mind to how it would attract the business person to actually read the article and know to get to that technology?

MR. ELFERING: Yes, I think one of the main things that we talked about, and I think the more we talked the one group that came up almost each and every time was extension educators.

And I think every extension educator that has a newspaper column that they submit to local newspapers. And I think that's right where it could come from. It could be included in their either weekly or monthly column.

DR. LOGUE: And remember one thing, remember Catherine, though, you want that simple message going out there, so that's the kind of thing that maybe somebody like that will do better.

MS. CUTSHALL: Thank you. Are there other questions or comments on the subcommittee's report out?

MR. ELFERING: Did we live up to the standards, that's what I would like to know?

MS. CUTSHALL: I would actually like to

answer the question as well. I appreciate your comments, Kevin, on trying to keep the contact coordinator network viable, and I would ask the subcommittee if they have any suggestions in addition that would help us ensure that not only do we have an existing contact coordinator network engaged, but how we could draw in additional people. I would certainly love to hear your comments on that.

We've tried a number of things just to get people engaged, and get new people engaged. If you have any suggestions for us, I would certainly love to hear those as well.

Dr. Harris.

DR. HARRIS: One suggestion that I might make is, rather than limit these kinds of discussions to the state coordinators, maybe you develop an informal email network of interested people, let's just say, in maintaining an ongoing - if you get something interesting, something you can share with the rest of the group, almost maybe even like a list-serv situation so that it's not just limited to one or two people per state.

MS. CUTSHALL: That would be great. How could we find those people initially who would be interested, and how could I get the word out to say, if you'd like to belong to this email group or initiation group, let us know?

I know Kevin says my name is bandied about everywhere. Maybe not enough.

DR. HARRIS: I think most interested people do read constituent updates, and a little blurb in there might be a good way. If you've got an interest here's a contact.

MS. CUTSHALL: Thank you. Appreciate it.

Any other comments? Questions? Okay, thank you very much.

We're going to move on then to subcommittee number two. And Mr. Schad, if you would like to discuss your report out. I actually sat in the group on the subcommittee's deliberations.

(Simultaneous voices.)

MS. CUTSHALL: Mr. Schad did tell me he was not a fan of long meetings, so we have to make sure that they reach consensus as rapidly as possible.

MR. SCHAD: Well, again, first of all, I would like to thank the subcommittee for their work. That was besides myself, that was Mike Finnegan, Joe Harris, David Carpenter and Sandra Eskin. And also, besides, as a catch-all, Charley Gioglio sat in on the discussion, what's involved in the discussion.

First of all what we did is at the subcommittee, because some of us had read the industry and the agency guidelines before. Some of us had not. Joe gave us an update or a synopsis of the industry guidelines, and then Charley helped out and gave us an FSIS synopsis. So we were all kind of on the same playing fields. We were all getting started with the same amount of knowledge or update.

After that we were assigned with four questions for the subcommittee, but the questions were so interwoven that we decided that basically there was really just one question to answer, and that was, are we in the subcommittee going to ask for guidelines? And if so, which ones are we going to recommend?

So basically we ended up with this recommendation. The subcommittee recommends that,

first of all, FSIS refrains from issuing its own hold and test guidelines at this time, but instead, review the industry guidelines to ensure that they conform with the applicable laws and regulations and policies.

DR. ESKRIN: It should be test and hold, not hold and test.

(Laughter.)

DR. ESKRIN: It's test and hold, not hold and test, in that first bullet. And there should be a period at the end of that bullet. Anyway.

MR. SCHAD: The second bullet reads, industry issues and guidelines. After FSIS completes them, and he works with the agency to ensure widespread distribution of the guidelines, especially to small and very small plants.

And as a suggestion or ways of disseminating this information, industry associations, universities, EIAOs, and directors of state meat and poultry inspection programs should be involved in that dissemination process.

FSIS should monitor the effectiveness of the industry guidelines on an ongoing basis, taking

any appropriate action in response to the findings of the evaluations, raising for recommendations for improving the guidelines informal agency action.

And on that last point, if I could just kind of explain more what the discussion there was. It was a thing I was kind of concerned about. I was kind of wanting the agency to kind of look at the - assume that we're going to go with the industry guidelines, kind of grade how industry was doing on an ongoing basis, and give feedback to the industry, and give them the option of maybe they could tweak the guidelines to make them work better, and not let set a certain date, okay, if it's not working at this date, therefore, we need to take agency action.

And then there was also discussion of what we really mean by informal agency action. And we're not saying there necessarily that we're talking about formal rule making.

MS. CUTSHALL: But it could be.

MR. SCHAD: But it could be. But there was quite a discussion on that.

FEMALE VOICE: Does anyone have anything

to say about that?

DR. HARRIS: Not at this point.

MR. SCHAD: So that's pretty much what we came up with.

DR. ESKRIN: I just wanted to follow up on what Mark just said. Again, when we have discussions in the subcommittee about sort of - the question I'd ask I think to the whole group yesterday, and asked again, was, what is the agency's position? Do they have the authority to mandate if they so chose test and hold guidelines?

And the response is, yes, but it would require a notice and comment rulemaking proceeding.

And I can support this recommendation with the idea that if the guidelines don't work that rulemaking option remains out there.

And we did talk about the issue of how the ongoing evaluation should be conducted, or should there be some sort of periodic report. I think at this point we really have to leave it open to the agency and see when the guidelines themselves get distributed, and given some time to work.

But the idea being, it's not going to be open-ended in terms of evaluation..

MS. CUTSHALL: Dr. Harris.

DR. HARRIS: I would like to comment, but not probably on what you thought I was going to.

Regarding the dissemination part of this, and how to best get this information out to small and very small plants, we copped out on that one.

We thought that the new technology group was going to be talking a lot about disseminating that anyway, so we thought we might piggy-back along with some of their work, and we assumed that they would come up with some outstanding recommendations that could be applied to this one as well.

MS. CUTSHALL: Thank you.

Dr. Hollingsworth.

DR. HOLLINGSWORTH: Just an idea that I had. I was not on the committee, but I'll throw it out for consideration. And that is, whichever guideline is used, and if we're using the industry one, which by the way I think is really a nice piece of work they put together, I wonder if it might be

useful for the agency to come up with a very short, even if it's on a card, that just said, since they are all pre-notified when a sample is being taken, at the time of prenotification, that every facility is given some type of a little reminder card that would just say, remember it is in your best interests to make arrangements to hold the product that we are going to be sampling tomorrow or the next day or whatever, and on the back just have a few bullets about how maybe to proceed to hold, and then say, for more information see this guideline.

So that every time you sample - or a company knows they're going to be sampled, they would have a constant reminder that they should consider holding it.

MS. CUTSHALL: Thank you. Mr. Kowalcyk.

MR. KOWALCYK: Yes, Michael Kowalcyk. I was not on this subcommittee either. And I had a couple of questions. Going into the presentation we saw yesterday by Mr. Gioglio, about 20 percent of the samples roughly, that was his quick estimate, were not held.

Did the subcommittee discuss any of the issues that surround that figure as far as are there certain types of plant that are more likely not to hold product because of their size and location? And what can FSIS do to make it so that it is more manageable for them to hold product? And how can the guidelines be set up to assist those plants?

Because it seems to me without looking at any hard figures, but my gut tells me that a recall costs a heck of a lot more to a company than the agency than arranging for holding product. And you know, public health issues aside, which is the ultimate concern, the financial impact on that organization if they have a recall I imagine would be much more significant than holding the product.

And also I'm wondering if the subcommittee discussed issues as far as what new technology there is. And this kind of flows with Joe's comments about sending information about new technology, as far as testing is done, and what types of technology is out there for more rapid testing that would give you a result that would tend to be negative quicker, and

that the agency is confident in as to the science.

I'm not necessarily saying that you've got to test very quick, that you're not comfortable with the methodology. But I'm just wondering if those issues were discussed on the subcommittee.

MR. SCHAD: That was kind of a long question so I'll try to do the best I can. We discussed that as far as what are the problems going to be, or what are the biggest problems with not holding the product. And it really is on fresh ground beef. That's the tough one. Especially for small, very small plants.

It's their niche. They take an order, they go to work early that morning, they take an order, and that product is delivered the same day. And a lot of times it'll be consumed by noontime.

And like I said, that is their niche to be able to sell this very fresh ground beef. And in that situation I had come up with an answer on really how to hold that product.

If I could make another comment here, and I don't know whether it's helped you out or not, Mike,

a lot of the success - in my opinion, a lot of the success on whether this works or not is the agency and industry working together, like Jill said, about maybe on something like Jill said about maybe a card or something.

The communication needs to get down to the IIC that the plant is entitled to prior notification. And I'm not sure this is the agency's responsibility, or it's the industry's responsibilities, but it is in the best interests of the plant to hold the product, not only from a safety standpoint but from a business standpoint.

Is there something I didn't answer?

MR. KOWALCYK: No, that helps. Those are certainly issues that I think are important that I think needs to be addressed. And I don't think Dr. Hollingsworth's comment about that through the inspector, some type of notification form. And to your point about some of the small processors were - if that product is going to go out because they have no place to store it, and it's consumed the same day, to me one of the other issues that came up was making

sure that the plant being tested is aware of where that lot came from.

A lot of these grinders are getting raw product from several suppliers, and if product cannot be held, there is some means for the agency to efficiently track back that product.

There are instances where small plants get burned because there is a disconnect there, and time goes by and you've got a serious problem.

MR. SCHAD: And I think that's where prior notification is the key, not to give the plants an option to change their process or anything like that. Just so they can minimize the number of suppliers in any particular instance so if there was a problem, if they had two suppliers or five suppliers or something like that.

It did come up in the subcommittee, at least I brought up the question, should we take the time on class night to look at the industry guidelines as something we can make better? Like right now, and we decided that was outside the realm of what we could do.

But as to why we did have some discussion, we would like an ongoing feedback from FSIS, how are we doing? Are the number of recalls going down, and are they going down significantly.

DR. MASTERS: And this is Barb Masters, and I want to comment a little bit to what Mr. Kowalcyk is commenting on.

And I have not looked at the industry guidance material, but something we encourage the industry as they're putting this together, and something we've commented on for a long time, because this is of significant concern to us, and something we will be evaluating very closely, because we do have means to put out notice and comment in rulemaking, and we'll do that if need be.

Because this is something that we have to be looking at as a means of addressing public health.

Something we ask them to look at in particular with a small, very small plants is, there are ways for them to address this. We do provide prior notification. That is part of our way of notifying the plant we're going to take a sample.

Suppliers is the way that we are looking at ground beef in particular when we look at ground beef. If we had to look at - if there was a positive sample, and we looked at the need to notify a plant that they asked them to volunteer to recall that product, we would be looking it from the supplying establishment or producer.

What we encourage them to do is look creatively - and that's my understanding of what the industry tried to do in putting together their guidance material - could they work collaboratively if they had an order that they needed to fill, to work collaboratively to have somebody else help them fill that order so they can hold that product and not lose that customer base?

And those kind of creative means to ensure that they can hold that product, those are the kinds of things we've asked them to do with their guidance material.

Because we believe that they have to have means to maintain their customer base, and to maintain the public health and food safety in this country.

So that's what I'm hoping is addressed in the guidance materials.

MS. CUTSHALL: Mr. Govro.

MR. GOVRO: Just a minor grammar suggestion here. I think - correct me if I'm wrong - it should read that FSIS - the subcommittee recommends that FSIS refrain --

MS. CUTSHALL: Yes.

MR. GOVRO: And then on the reviews in the second line, that should also read, review. And under the second bullet, it would be issue.

MS. CUTSHALL: Right.

MR. GOVRO: Issue.

MS. CUTSHALL: Right.

MR. SCHAD: This question is for Dr. Masters. I'm not sure I understood what you were saying. Are you talking about using like another process in place to fill an order? I heard that before. I'm just speaking as an owner-operator, as far as an option, that would be like the very bottom of the list. That's like asking a competitor to oversee it.

DR. MASTERS: I'm only encouraging you to consider all viable options to ensure that you can maintain public health and integrity and ensure that you're not shipping adulterated products into commerce, and that we will allow you the option to put guidance material out there - and I don't know what's in it. I'm just asking you to ensure that you're considering all options.

We'll evaluate the effectiveness of those options, but we are looking to see that those options are effective. And I'm just saying that I know there are some ways to do that, and that's one of the things that we said might be effective.

MS. CUTSHALL: Mr. Elfering.

MR. ELFERING: Maybe just to add to that, one of the things that we've encouraged our clients, and most of them do this, is, if we take a ground beef sample, and they all decide that they're going to make that into patties and freeze them. And then they take other source materials to fill their order for that particular day.

So what they do is, they automatically

switch, freeze it, and that way they hold the product until we get the results.

DR. MASTERS: And we've had some suppliers who say we only have one source, so if you only have one source, then we're just saying, that's the only source material you have, then we're just asking folks to look at all viable options.

MS. CUTSHALL: Do we have any other questions or comments on the report out from the second subcommittee?

I thank you, Mr. Schad, and I thank the second subcommittee.

We're going to move right along to the report out from subcommittee number three, which is chaired by Mr. Detwiler and they had some very spirited discussions, so I think you will find their report quite interesting.

MR. DETWILER: For subcommittee number three, this is Darin Detwiler, first off I'd like to thank the great talent and expert showmanship of Dr. Gladys Bayse, Mr. Michael Govro, Mr. Charles Link, and Dr. Jill Hollingsworth.

And I'd like to thank Dr. Engeljohn and Heather Quesenberry and the other fine people, and good handful of other people that were in the room with us.

Initially, too, we thought this would be one of those things we'd be able to come up with a quick response. But unfortunately, the high level shall I say caliber of the people in that room prevented us from being brief.

And I was only the facilitator.

The task of this subcommittee was to provide guidance to the FSIS on how to more effectively develop risk-based verification testing programs addressing the unique considerations associated with small and very small plants.

Question number one was, are any risk factors FSIS presently used as in designing risk-based sampling more important when addressing the concerns of small and very small plants?

While the FSIS recognizes that small and very small plants present unique considerations, this subcommittee believes that all five risk factors

presently used in designing risk-based sampling, such as the type of control measures, product type, compliance history, validation systems, and volume of production, apply to all plants regardless of size.

So technically the answer to question number one is, no.

Number two, are there - number two - well, unfortunately, this is where the educator steps in. If you want more detail on the response, don't ask a question that the answer is either yes or no.

Number two, are there additional factors unique to small and very small plants that FSIS should consider in the design of risk-based sampling?

The subcommittee also believes that there are a number of factors which need to be taken into consideration beyond the five that are already in use. Additional factors are not necessarily unique to small and very small plants when the FSIS designs a risk-based sampling system, but instead, provide a more targeted focus for a data collection analysis.

Such factors could include, but are not limited to, employee turnover, ratio of number of

employees to volume of production, number of production steps, seasonal production, amount of ongoing good sound data collection by the plant, a niche or cultural specialty related to the product or the process employed, and finally, physical geography such as altitude, climate, humidity, and distance to customer base, et cetera.

So the answer for number two is yes, kind of.

Number three, how can FSIS conduct risk-based sampling more effectively in small and very small plants? One suggestion by the subcommittee as a way that FSIS can conduct risk-based sampling more efficiently in all plants, not just in small and very small plants, but in all plants, is to refine the risk criteria by creating categories or scores that utilize the above additional risk factors.

This new set of factors should not focus on plant size, but rather on weighted risk factors including data from the industry - that being plant-specific data; FSIS including sampling results and generic industry data; and the CDC, that being public

health data.

This will ensure that the agency uses a complete set of risk factors to develop verification protocols.

Question number four: What are examples of the unique business practices of small and very small plants that should be considered in designing and implementing risk-based sampling for - and then four different pathogens are listed.

The subcommittee is not necessarily aware of any unique business practices of small and very small plants that relate to specific pathogens. Rather, the subcommittee recommends that the agency focus on risk sampling related to pathogens of public health concern.

The agency should consider the inclusion of an expand list of factors. To further implement this more targeted sampling, A, the subcommittee urges the agency to seek approval to obtain additional information from all plants in order to more effectively focus its risk-based sampling efforts using an expanded quantity of risk factors such as

those listed earlier.

Likewise, there needs to be a system in place to maintain the confidentiality of the information collected. For example, the FSIS should consider data acquisition through a third party or a land grant university.

B, create a communication plan to ensure a clear understanding that the data collection and even the risk category of an establishment is not an indication of compliance or a lack of compliance, but rather, the overall categorization of a set of risk factors for analysis and sampling frequency consideration.

For example, a plant might require a higher frequency of sampling because of the type and volume of its product, even though it has an excellent history of food safety compliance.

C, FSIS and CDC should continue to pursue attribution data through Food Net to aid in targeting resources, to ensure pathogen reduction/control and improvement in overall public health.

And finally D, FSIS should focus resources

on the pathogen of most public health significance. Using health people goals will allow the agency to identify where to focus its efforts on sampling for pathogens.

Two levels of sampling could be established, for example, at the maintenance level, where a healthy people goal is achieved, and a higher level for pathogens that have not met the goal reduction.

And with that, we submit our paper for risk-based sampling.

MS. CUTSHALL: Thank you, Mr. Detwiler.

Are there any questions, comments? Dr. Harris?

DR. HARRIS: First, I want to compliment you guys on doing a very thorough job. You've got some excellent information in here.

I do have a question for the subcommittee, because I'm assuming that as you developed these lists that there was significant discussion.

I'm curious as to how the agency would or could consider employee turnover relative to a risk-

based sampling program, and how the agency would even have an idea about a company's employee turnover.

And maybe more specifically, how employee turnover might be related to the risk.

MR. DETWILER: If anyone on the subcommittee is willing to comment on that, I greatly would appreciate that at this time.

MR. GOVRO: This is Mike Govro.

The reason we thought that might be an important consideration is that employee turnover is usually related to less experience on the job, the need for more training, and that might affect the procedures that take place at the plant.

So that might affect the safety of the product produced.

In terms of how the agency would get that data, that was one of the things we had a discussion about and made a recommendation in number four that the agency would need to request permission to collect that sort of data, and this would I grant you probably be problematic, and you might get some push back from the industry about that type of information.

So this was sort of a brainstorming list of things that might be useful in focusing the sampling, and not necessarily something that we'd be able to do. Kind of a wish list, maybe.

DR. HARRIS: I guess my comment to that is, I don't necessarily disagree with what you've said, but it's a fairly complex issue, and day to day turnover - take a large processing plant, especially a large slaughter fab plant, they may be turning over 25 - 30 employees a day. And generally I would say almost without exception those are not going to be employees that are in food safety critical positions.

Obviously everybody has a role to play in food safety. I'm not saying they don't. But the guy who's working in the tripe scalding room probably is not as critical to the overall food safety as the HACCP coordinator.

So I think employee turnover is just a difficult thing to get your arms around, I'm a little concerned that we are asking the agency to try to incorporate that into their risk assessment.

DR. HOLLINGSWORTH: If I could add a

little bit more to that, one of the things that brought that particular item up was a discussion about the general assumption by some that small or very small operators don't have as good or as efficient a program as a big company.

And what we were saying is that it may be just the opposite. What we were trying to capture there, and one of the things that come out in details, we actually talked about the plants being allowed to give FSIS information about its profile. And one of its own profiles might be, we're a small family owned company. We have the same employees here for 10 years. They're highly trained, highly experienced, and that might actually give you a tick more for less risk as opposed to a big company that says, we have continuous employment turnover. We have 2,000 employees, and then you don't the little tick for the extra reduction of risk.

So it was more looking at a company's profile that they provided to help give them maybe a little advantage or incentive when it came to looking at how risky was their operation.

MS. CUTSHALL: Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk.

I like Joan would like to compliment the subcommittee on a really thorough report. It covered a lot of things I had questions about when I left yesterday.

In the last bullet point you discuss two levels of sampling, and I think that's a very good idea. Also, did the subcommittee discuss the current sampling that's done on a random basis where the agency randomly selects establishments to do the verification testing.

Is the thought here and I don't know if the subcommittee would want to add it, as far as maintaining that sampling regimen? Because in my experience, in my profession in economics, and database marketing, it's very nice to have a control to compare against when you're developing some type of model when you're using data.

So did the subcommittee discuss that as far as maintaining a certain level of random sampling so that they have a snapshot in any given year of what

is going on across the industry, and then they can compare that to what their finding is, the prioritization through the risk model?

MR. LINK: Charles Link.

We did talk about that. I think one of the - when you look at the public - or the healthy people goals, the first thing that pops out is there were about seven goals that have already been achieved or below target, and the Listeria goals are really close.

And one of the things you talk about is, well, why isn't it below? And it may be a number of factors not related to meat and poultry.

But we were looking at it, as long as you're get to set two levels, one a kind of a maintenance level, do you keep the same level of testing or do you back it off a little bit, but somehow you've got to keep your finger on the pulse of what's going on. You can't just walk away from it. You've got to kind of keep a maintenance level of testing so you know.

But rather than maybe given the limited

resources, limited funds, you should spend more time and effort on a different area than ones that hardly meet those basic goals.

So you couldn't walk away, and that's why we had those two levels, kind of a maintenance level, and then more focused.

MS. CUTSHALL: Mr. Elfering.

MR. ELFERING: I just had one question on the number of production steps and how do you address - I mean are they critical issues or just the numbers of steps in production?

In most cases I would think that very small plants would probably have more steps in their process than a large processing plant. Does that necessarily make the product at a higher risk?

And where do you - ten production steps, if you have ten it's a higher risk product rather than if you have only five? I don't know how you would be able to identify that more production steps would be higher risk.

MR. GOVRO: Mike Govro, to answer your question, we were really just throwing out ideas about

things that might prove useful in determining ways in which product becomes, or has a high risk of becoming contaminated.

So an operation where product is moved from vessel to vessel through various machines, handled by different people, is something we thought could contribute to higher levels or higher chance of contamination of a product, and that would be something that would be worth looking at.

And sort of in response kind of to all three of the last three questions, we recognized that the best information that the agency will have in order to focus its sampling in the future is going to be the sample results it gets as it continues through a more focused sampling program, and that the agency is going to learn which operators, which types of operations, will be - have a higher need for sampling.

And the more it characterizes the data that it collects, the better chance it's going to be to hone in on different things that are contributors.

So again, this was sort of a brainstorm list, and we would assume that the agency would take

this as that, and if they move forward with this, would we find this in a much more scientific process.

MS. CUTSHALL: Mr. Detwiler.

MR. DETWILER: Also on that same note, one thing that didn't come out too clear to use Dr. Hollingsworth, her idea about a profile, part of this more targeted - larger set of risk factors to more target the focus of the agency would be to almost create this idea of a profile that is beyond the categorization of large, small and very small plants; that we might be able to take, for instance, like we're saying with seasonal production or number of production steps or even physical geography and find that it's not so much that here is this situation, here is what the epidemiologist is telling us, here is what the reports are in terms of an outbreak or whatever, or a condition, but we need - and say that this is a small plant problem.

But we might even be able to say, isn't it interesting that it happened to plants that fell within this physical geography characteristic, or that fit in with this - and we can actually more

specifically be able to look at a targeted profile, and rather than just putting it into the three categories of large, small and very small.

Again it wasn't so much that we were trying to say that it's a rating or a ranking or anything that is to the idea of it's in compliance or lack of compliance, but the idea of more specific targeted information that would allow - and I don't know if we would necessarily even say that here's like a cutoff of production steps, but maybe we can look at a range of, I don't know, low, medium, high production steps, and that we can see a trend and ones that are specifically high, number of production steps, rather than just large, medium and small plants.

MS. CUTSHALL: Dr. Hollingsworth.

DR. HOLLINGSWORTH: I just wanted to kind of circle back to Michael's question. Because I'm not sure we fully answered your question or that issue.

And that was the idea of, should the agency also, in addition to risk-based sampling, continue a separate program of random sampling as a base to compare to? And actually, we talked very

quickly about random sampling, but we tabled it, because our charge was just to do risk based.

So I think it's an idea that the agency would have to consider and probably more for a statistician to discuss, whether or not random sampling still needs to be done to some degree as a baseline to compare the risk sampling against.

But we only did the risk sampling.

MR. SCHAD: Do we have other questions or comments on this particular issue?

Dr. Masters.

DR. MASTERS: Just one more question on your list of factors. On the yes kind of answer, you talked about most of them now in a little more detail, but just to make sure I'm getting the thinking on all of them, since we've now asked about most of them, on the amount of ongoing good sound data collection by the plant, were you getting at there more on the validation that they have or on their own sampling that they're doing or both?

MR. DETWILER: Both.

MS. CUTSHALL: Just for the record, the

answer was both.

Any other questions, comments on the report out of the subcommittee number three?

Well, I would like to thank all the subcommittees and the committee as a whole for a very productive day and a half. You did a lot of good work. You had wonderful issues.

You've come back with some things that we as an agency can really take to heart and put to use.

Personally, from my perspective, I come away from this meeting looking at the fact that I'm probably going to have a whole lot more work for my staff. I'm not quite sure I'm going to give out my phone number to anybody who doesn't have it yet. But no, you can always contact me.

And I do appreciate the hard work and the dedication of the committee, and I had the opportunity, as I said, to sit in on two of the subcommittees. And I think that they just did a fantastic job, and I appreciate that very much.

I did step aside, and did not see anyone registered for public comment. So that being said, I

would like to turn it over to Dr. Masters. And again, you've just done an incredibly efficient job. It's a beautiful day outside, and you may have a little bit of time to enjoy it before you catch your planes back home.

So Dr. Masters.

DR. MASTERS: Dr. Elfering - Mr. Elfering asked for a verification subcommittee when he reported out, but I'll speak for all three subcommittees. All three of you lived up to my expectation.

I think you did incredible work. And again, I'm always impressed at how you leave, and there's all this deliberation, but then you always managed to bring it together, and give us just incredible recommendations.

And at the front end, I indicated the work that we're trying to do to make sure that you get your materials up front. And I think that that has really contributed to the value that you give us in your deliberations.

And the thing that I'm trying to do on the back end is to make sure that we don't just get this

and walk away, and then a little bit before November, make sure that we get it out again.

What I'm trying to make sure that we do is to make sure that when this meeting is over, as Mary says, I'm looking to see all the work I have. That's because when we leave this I'm making sure that we take this material, and you saw all my notes, we have meetings shortly after this. And I get the staff together to say, what did we learn, what are we going to do with this information, and how are we going to use it as an agency.

That's because we do take these recommendations very seriously. And we look to see what value we gained, and what information we're going to use as an agency.

These meetings are not just to get together for a one-time sake. This is valuable information to our agency, and we take these meetings very seriously.

So when Mary says that, she says that very seriously, because we take this information to heart.

So there are a lot of meetings that follow

this meeting. For us to take the information and determine what we're going to do with all the information we've gained, so there is the post process.

And then we're beginning to start to do the prework for the next meeting. So we've already talked about what we're going to do for November, and then there will be a lot of wo0rk after this meeting to figure out what we're doing to do with all the valuable information we've learned at this meeting.

So I'm trying to work from both ends to make sure that we're not only getting ready for the next meeting, but to make sure we're using all the information we learned at these meetings.

Because there is no value for you to come to do all this work if we're not taking the information you give us and use it in a very useful way.

We're also trying to make sure the issues we bring to you are issues that we believe are issues that are pertinent, valuable and useful to the agency.

And hopefully you saw that at this

meeting. I think all three issues are very timely. I think they're practical. And I think they were somewhat interrelated.

I think Joe said he took it as a cop out. I think it was not a cop out; I think it was by design that issue number two was related to issue number one.

And I do believe we'll find that the guidance material, that the recommendation you gave us, and if that's the way we proceed, that whatever recommendation we use, we'll use the means that we learned from number one to use that as a way to get the guidance material out to the small and very small plants.

So that was by design that we thought we could put those together and find ways to get that material out to the small and very small plants.

We're trying to get better at putting all this together, and it's been a big challenge, and the staff has stepped up to the challenge, and you guys have more than stepped up to the challenge.

So you guys deserve a big round of

applause for the work you've done, so thank you.

(Applause.)

DR. MASTERS: And I appreciate all the hard work that you do, and you don't just do it here, you come prepared for the meetings. And that's important to the good work that you do.

So thank you very much, and hopefully you'll continue to see the same kind of issues facing you, and you'll continue to do the same kind of work.

So as Mary said, you have a pretty day to try to take advantage of it. And again, I heard you had a good place to stay for those of you who got to stay in the hotel, and thank you for enduring the accommodations here for the meeting room.

And Sandra, I know you said you came to close this. And you didn't get to stay at the Willard, but you know - oh well.

DR. ESKRIN: I was on time this morning.

DR. MASTERS: So was I. That's a record, we're both on time.

So thank you all very much.

MS. CUTSHALL: I have one more thing to

put before the committee before you go. Dr. Masters mentioned a November meeting. I have two sets of dates that I'd like you to write down, and if you would get back to Ms. West next week on your availability on either November 8th and 9th or November 15th and 16th.

If you could back to us next week on what your availability is on those dates, we'd appreciate it.

DR. LOGUE: Would you like us to email Sonia?

MS. CUTSHALL: If you would email Sonia, I would appreciate it.

DR. LOGUE: I think the committee would like to acknowledge Sonia's help again.

MS. CUTSHALL: I think that that would be a wonderful thing, and thank you for going on the record and recognizing Sonia.

And I'd like to thank Sheila Johnson as well, and the other members of my staff who helped escort you in, and always seem to do a lot of work behind the scenes that doesn't always necessarily get

acknowledged. So thank you very much.

Have a good day, and thank you all.

(Whereupon at 9:48 p.m. the above-mentioned proceeding was adjourned.)