UNITED STATES DEPARTMENT OF AGRICULTURE

NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION MEETING

Columbia Room
Holiday Inn Capitol at the Smithsonian
550 C Street, S.W.
Washington, D.C. 20024

Thursday, November 7, 2002

9:00 a.m.

Committee Members

DR. GARRY McKEE, Administrator
DR. GLADYS BAYSE
MS. NANCY DONLEY
MS. SANDRA ESKIN
MS. CAROL TUCKER FOREMAN
MR. MIKE GOVRO
MR. MARTIN HOLMES
DR. LEE JAN
DR. ALICE JOHNSON
MS. COLLETTE SCHULTZ KASTER
DR. DANIEL LAFONTAINE
DR. IRENE LEECH
MR. CHARLES LINK
DR. CATHERINE LOGUE
MR. MIKE MAMMINGA

Participants

DR. JIM DENTON
MR. BUD PAULSON
MS. CHERYL HICKS
DR. PHILIP AMAN
DR. WILLIAM CALLOWAY
DR. PERFECTO SANTIAGO
MS. JEANNE AXTELL
DR. ENGLEJOHN
MR. GIOGLIO
MS. LINDA SWACINA
DR. MURANO
DR. PIERSON
DR. WILLIAM JAMES
DR. KENNETH PETERSEN
MR. LAUREN LANGE

A G E N D A

A G E N D A

P R O C E E D I N G S

9:10 a.m.

Recap

DR. McKEE: Welcome back. I'm glad to see everyone back, especially with all the material that you had to cover last night and the activity that we had yesterday. And again, I appreciate all your efforts last evening on -- on the different topics that -- that you were addressing.

I think we've had some very good presentation and discussions. We'll begin today with the reports of the Standing Committee.

But I'd like to start with a presentation on behalf of FSIS and USDA. We have several people that will be leaving the committee. And those individuals -- one isn't back yet this morning.

What I'd like to do is to -- we have a certificate of appreciation and a presentation of a mahogany double pen stand with personal engraving.

This -- this is what it will be. I've got these in the box. And so what I'd like to do is to call your name and come forward and make the presentation to you.

Ms. Nancy Donley.

(Applause)

DR. McKEE: Dr. Daniel Lafontaine.

(Applause)

DR. McKEE: Dr. Michael Mamminga.

(Applause)

DR. McKEE: Mr. Dale Morse is not here, but he will be receiving one as well.

And we also have Ms. Carol Tucker Foreman. Is she here?

Well, thank you very much. You know, the committees are -- are dedicated, especially when you spend the evenings working on topics that will help us make decisions and strategy within the Agency. And it's an extremely valuable task for us to be able to have your input and your recommendations.

We have really appreciated the work and expertise you all have contributed to the committee. And the secretary has truly appreciated all of your invaluable recommendations as well. Your input has certainly been valuable to us.

As you know, we announced in the "Federal Register" this past August a solicitation for nomination for membership on this committee. We received so many applications from qualified candidates for these five positions that the selection process certainly poses a major challenge for us. However,

it's far better to select from so many talented individuals than it is being in a position where there are few to choose from. We expect to have a selection made by March 2003.

And I thank -- again, I want to thank those of you that are currently serving and those of you that are going off the committee for your dedicated service. Let's have a round of a hand for those that are leaving.

(Applause)

DR. McKEE: Okay. Thank you.

This morning what I would like to do is to start with the standing committee -- the Standing Subcommittee Number 1, which is Education and Training of the Field Workforce to Achieve a Public Health Vision. The leader is Dr. Daniel Lafontaine.

If you would like to start with your presentation?

DR. LAFONTAINE: Thank you, Mr. Chairman.

Briefing - Standing Subcommittee Number 1
Education and Training of the Field Workforce
to Achieve a Public Health Vision

DR. LAFONTAINE: I'm Dr. Lafontaine from South Carolina. And I was -- had the honor of chairing the subcommittee.

Before I get into the substance, I'd like to, first of all, thank my colleagues on the committee, Mr. Govro, Ms. Logue, and Ms. Eskin.

We even went high-tech, or low-tech if you want to call it, and Ms. Eskin was with our committee by phone last night because of another commitment. So that shows her dedication.

Also, we had good audience participation. Mr. Paulson and Ms. Hicks from FSIS were there to help us. And also, we had representatives from the inspector union and also the public citizen organizations. So we had a good, healthy group and discussion.

Also, one other introductory comment. Dr. McKee, we sincerely appreciate the opportunity to comment on this critical element in any organization. One way I like to put it is, and this is my own thoughts, training is certainly the bedrock -- or a bedrock of any organization. So we appreciate that opportunity.

(Slide)

DR. LAFONTAINE: We did address the two questions that were posed to us. And I guess we have those for everyone to -- to see on the screen here. So I will run through these fairly rapidly. And then if

there's -- I'll take question one and then question two. And if there's any comments from the committee members or -- the subcommittee or full committee, then we'll certainly entertain those.

The first question that we were posed -- well, first of all, the -- the issue is education and training of the field workforce to achieve a public health vision. So we're talking about that 80 or 90 percent of the -- of FSIS that is in the Office of Field Operations out there on the frontline doing the day-to-day work in the plants.

The first question was, what does the subcommittee recommend FSIS set as its top priorities with respect to education and training of its diverse field workforce, diverse being many different skill levels, many different types of responsibility.

(Slide)

DR. LAFONTAINE: The first question we asked was, does FSIS really know what knowledge, skills, and abilities, commonly known as KSAs, are required to perform the various job functions that its field force undertakes. In other words, a need -- needs assessment.

So we need -- we feel you need to define that or redefine it, if necessary, by doing a needs

assessment to determine what training is -- is needed to accomplish these KSAs.

The needs assessment should include input from the field workforce about the areas they feel they need more information or guidance. Also, don't forget in -- about the state programs. We're in this along with you, and we need to be included in that information-gathering.

So the bottom line there is, make sure you know what your -- what's -- what's needed as far as training.

Another key thing that -- we're not saying all these things aren't done, but it's kind of important to reiterate them.

After training, the Agency should test the participants to verify they've acquired the needed knowledge, skills, or ability. This information is also -- could be used to evaluate the effectiveness of training as an element of your ongoing quality improvement.

The third item was offered by myself and agreed upon by the subcommittee. We feel, Dr. McKee and leaders of FSIS, that the Agency needs to shift the focus of its training to provide more science-based training as appropriate at each level. We realize that

different jobs and skill levels need different parts of this.

But if you're going to be a public health agency, you need to have a good understanding of meat and poultry microbiology, especially those foodborne pathogens that we know are emerging. Biostatistics, if you're going to take scientific information and make valid assumptions. Food technology and -- and what's happening in the food safety interventions. And let's not forget about the basics. Cleaning and sanitizing and basic hygiene practices.

If I might digress for a moment, I've been with the state programs and in turn with the FSIS for almost 10 years. And I just haven't seen it happening. I know it's being integrated into certain training elements such as the consumer safety officers, but this is, we feel, needed across the board as you set your -- your game plan for the future to be a solid public health agency.

(Slide)

DR. LAFONTAINE: Also, the Agency should address the barriers to the delivery of training, such as the Agency requirement the more -- majority of its workforce be present on the production lines and wherever possible eliminate those barriers. And my

next comment kind of feeds into this.

The -- the Agency needs to figure out what funds you need to do your training plan and build a fence around those so it doesn't become a discretionary fund to use if all else does not go well.

More specifically, maybe a dedicated percentage of the workforce should be continually in training. This represents a higher level of commitment to education and training on the part of the Agency.

To give you a possible model to look at would be military training. The armed forces, we feel -- I feel personally, is probably the best in the world because of its bedrock of training. And in most of the services, they set aside approximately 10 percent of their personnel budget for having people in training rotation at any one time. And they do not touch that. So they have this -- a very -- and this ties in with, you know, obviously having enough people that you can release for training. So it's not only the training money but it's the -- the -- enough overhead as far as personnel so that you can actually rotate people and make them available, you know, for your -- your training game plan.

And then, a final comment for these new training initiatives such as CSO training. There was

also a supervisor's course started a few years ago that's a five-week course and a four-week scientific-based course for inspectors. From the get-go, we -- we would ask that at least a few slots be set aside for the state employees -- from the get-go. What's happened is, we kind of knock on the door and maybe a couple years later we start to get a -- a few slots to send people. And we're -- we have the same requirements and the same implementation needs, and we'd ask that as you look at this training situation that you include us in that initial allocations.

So let me stop here. This is question 1, which was, what are the top priorities. Any questions from the -- my colleagues? Dr. Jan? Let me get Dr. Jan first and then get you.

DR. JAN: Lee Jan, Texas Department of Health. I certainly have no argument with anything that you've presented. I think it's all right on target.

But I -- I think the Agency should consider that even before all these things are put into place, to consider starting with a more educated or a higher level of education of a workforce by requiring a college degree or some level of college. I think a public health agency -- I think the public expects that

the -- that the persons in that agency that are looking after them do have a higher level of education.

And -- and so I think if -- if that would become a minimum requirement. Now, it may not be necessary for first -- on-the-line slaughter inspectors where they simply do one task and that's slice -- and then they have oversight of some higher level people. Because I know college is not for everybody. But if you're going to move in the -- in the Agency -- move within the Agency and become a person that deals with these high level industries that -- being -- to produce a safe product, we have -- they have to have quality assurance people. Those people generally have a college degree. And being able to communicate with those people and not be intimidated, I think those people that are representing the Agency have to be at least equal to that level.

And so I think work that in and make that a mandate, at least at some level. Perhaps even consider -- and I don't know if there's a national registered sanitary and certification program, but I know each state has one. You know, perhaps require some certification of a sanitary status which would indicate that they have been capable of successfully completing an exam of -- of their knowledge and then be certified.

And most of those then do require a degree. But I think that's the thing I'd like to offer.

DR. LOGUE: Just one quick point. You see where you have that word, "with emphasis on foodborne pathogens for the microbiology"? You might want to consider changing that because that sounds exclusionary to the other aspects of microbiology. And you need another word, I think, there.

DR. LAFONTAINE: We'll work on that editorially.

Yeah, Mike?

MR. GOVRO: I just wanted to -- Mike Govro again. I just wanted to comment on what Dr. Jan brought up.

In addition to the possibility of requiring a degree, there are a lot of other models that are available out there. For instance, we -- at the Department of Agriculture, we require a sanitarian's registration. That does require a degree. There are also other programs, such as manager's certification, that is now required under the model food code. There are trainings that are given by training organizations that are certified by an independent third party so that they verify that the training meets the needs. And also, many states have food handler certification

so that someone coming into a job has to take a basic course.

And I think if you created a requirement such as that, you would find that there would be third parties that would step up and offer that training probably all over the country if there was a need.

DR. LAFONTAINE: Nancy? Ms. Donley.

MS. DONLEY: Thank you. Did the subcommittee at all discuss the idea of -- of looking at what level of field force is -- has the most impact on -- direct impact, I guess, if you will, or impact on -- on achieving public health and that -- or was any discussion on that there are gaps or -- or -- in this position or there's -- there's -- there's -- there's shortages here and that need addressing that would better benefit the public?

DR. LAFONTAINE: Let me answer your question this way. We did not specifically look for where the gaps were. But we indirectly addressed that by saying the very first step is to take a look at each of the job series and figure what the knowledge, skills, and abilities are needed in that job to execute a public health -- your public health mission.

So that -- in an indirect way, we did that very specifically as the very first step.

MS. DONLEY: Is there -- I guess, is -- is it -- would it be helpful if the Agency were to take a look at its field -- I'm wondering if the Agency took a look at its field force and says, okay, we -- in each category and we have X number here, X number there, X number there. And -- and underneath that classification there'd be thus-and-thus function. And -- and just kind of looking at the whole big picture to see -- we need more in this classification and less in this one. And -- just a suggestion.

DR. LAFONTAINE: Mike's going to answer that.

MR. GOVRO: Again, that goes to the needs assessment. And we felt we, as a committee, really couldn't answer what the Agency needs to do until they make that determination. And we've asked USDA if a needs assessment had been done and they said, no, really a comprehensive needs assessment hadn't been. And really, that's, I think, where you determine where you need to provide the training.

DR. McKEE: Do you suggest the -- the needs assessment include questions, a test kind of a thing? Or how -- how would you -- are you identifying the perception of -- needs themselves or are you looking at what are the weaknesses and do that through a testing kind of a baseline determination? Or what's your

recommendation there?

DR. LAFONTAINE: I'm going to start to answer that, and I'm going to let Mike embellish because he was the one opponent.

But what -- to put it in as simple language as I can, we are asking you -- the public are asking the field force to execute certain missions such as, does industry have an adequate HACCP plant, is there -- and are they implementing it properly. Do they have proper interventions to prevent foodborne pathogens from being in the product, whether it be raw in the case of 0157:H7 or, you know, listeria, salmonella -- salmonella.

So the point I'm leading up to is, when you're out there on the front lines talking to the quality manager or whoever might be involved in -- in this particular plant, do you have the knowledge, skills, and ability to execute -- to communicate effectively, to understand what's being said, to ask the hard questions. That's my view of a needs assessment of asking your workforce, what do you need to do what we're asking you to do.

Mike?

MR. GOVRO: I believe you're asking -- and correct me if I'm wrong -- how you would go about

making the determination of the level of competence of the field workforce with regards to how they compare to the knowledge, skills, and abilities that you defined?

DR. LAFONTAINE: Yes. I think it's probably two-pronged. And I'm thinking how we can do it possibly at one time. There's an issue of what -- I feel like I need to do my job but at the same time there may be issues that you don't know you need that we need to identify. And so how -- I guess the question is, that can all be done in a needs assessment. But maybe it's a combination of baseline testing information and a needs assessment by comment or perception as well.

MR. GOVRO: Right. I think you're on the right track there. And I -- I'm not a training expert, but the times that I've talked to training experts about the training I need to deliver to my staff, their first question is always, you know, have you done a needs assessment. And there are people who are very expert in that and I think could look at -- at your particular situation and advise you.

I don't know if you'd want to go outside or if you have people in staff. I was pretty impressed by the people at USDA last night. Mr. Paulson seems to have a good grip on it. So I would say, utilize

whatever expertise you can find.

DR. LAFONTAINE: Yes, Ms. Donley?

MS. DONLEY: One thing I -- I -- I think might be worth adding to this is, when it comes to education and training I think you need to have some sort of a feedback loop or some sort of an assessment done afterwards to see just how effective the training and education is so that there'd be some sort of a follow-up to see if it's translated into actual behavior modification.

DR. LAFONTAINE: We -- we touched on that briefly in this question by saying, you know, for those -- those critical training episodes, it needs to be tested. You need to -- you know, and of course, implied in testing is how effective is your training in accomplishing your training objectives. So we did touch on that.

And -- and the second question will -- will talk more about that also.

Yes?

MR. GOVRO: I was going to say, it's in the second --

DR. LAFONTAINE: Right. That's what I was saying. So we'll -- Nancy, we'll get to that in a little more depth in a moment.

Mr. Paulson or Ms. Hicks, do you have any comments on this at all? Oh, is there a question over here? Oh. Ms. Foreman?

MS. FOREMAN: Thank you. Carol Tucker Foreman with the Consumer Federation.

If you're talking about a vision of public health protection, I think you have to look beyond the questions that were raised with this -- at this meeting. So although you didn't ask, I want to talk about.

There are, as I see it, three major barriers to having a workforce that provides public health protection. One of them clearly is training. You've -- you're trying to address that. The second one, and I know you're aware of it, is the pay level, which connects to training in the federal system.

If you're at GS-5 -- you provided us with the salary tables yesterday. Twenty-five thousand dollars a year for a GS-5 employee, $30,000 for a GS-7 employee. Part of the reason that there are vacancies in places like the New York City metropolitan area is nobody works for that money. In -- no competent person can be hired for 25- or 30,000 dollars in Westchester County or in the metropolitan New York City area. We're -- we're still living with an assumption that

you're going to have people working who address the problems this industry as they existed 30 or 40 years ago, not today.

So you can't even get people you can train if you can't do something about the pay scale. It's a good salary out there maybe in rural Nebraska, but that's not where Albany's plants are.

The third one is attitude. And I've watched over the past several years since HACCP was implemented. It's not new. It's been going on -- well, it's been going on for a long time. It's gotten increasingly worse since HACCP has been implemented. An increasing level of hostility between the Agency management and the field workforce. I know some of that was there as long ago as when I was at the department. But it has just gotten infinitely worse in recent years.

And I -- I'd urge you, Dr. McKee, to -- to do everything you can to reach out here. As long as there is warfare going on between management and staff, the public won't be protected. I think it has become a barrier to public health. And as I said yesterday, I think the kind of language that was in that memo that was released is -- gee, I hope that's the worst of it. But it exists on a number of levels, and I do believe

that it is a serious barrier to public health protection. Thank you.

DR. LAFONTAINE: Ms. Hicks?

MS. HICKS: Thank you. What I wanted to add was just something that somewhat addresses what Nancy Donley brought up about taking a step back before we would do a needs assessment, but look at the complement of positions we have in the field and whether those are what we need and whether the duties that we have assigned to them cover all the bases. And as I mentioned yesterday, we're looking at the frontline supervisor jobs and what those need to be, and other things we're doing to fill in a gap.

I believe Dr. Johnson mentioned yesterday is we have compliance officers who have been split between the new organizations here and field operations. And so we're working on defining the job of the compliance officers that are left with field operations. And one of the things we want to do is train those individuals so that they can assist the districts with reviewing the corrective action plans that the plant submits so that can be turned around in a faster manner than it is now.

And so there are things along those lines that we're doing at this point.

DR. LAFONTAINE: If there are no further comments, we'll move on to the second question.

(Slide)

DR. LAFONTAINE: The second question was, what suggestions does the subcommittee offer concerning cost-effective delivery of training to FSIS's geographically dispersed workforce.

Before I get into the substance, you -- you will see some repetitive language in the second question. And what we did, we had two groups in the -- in the subcommittee write the report. And we consciously decided to -- to keep the repetition in there even though we -- I just wanted you to know we did recognize. You'll see some of the same words -- same ideas twice.

The report reads as, while the committee recognizes that FSIS endeavors to provide high quality and appropriate training for its entire workforce, the committee considers there are gaps in this training that need to be addressed. A needs assessment of the Agency's workforce must be carried out and the individuals identified who can determine gaps in the existing training.

The committee understands the resource constraints that are a contributing factor to these

gaps. And with that in mind, we recommend the Agency consider the following.

Training must result in learning. And this goes back to -- unless it's just general knowledge, it needs to be tested training so that there's an ownership in the process and a measurement, of course, how effective you're accomplishing your objective.

And we say that as -- I digress because in the distance learning that I've -- I shouldn't say distance learning. But the training that -- some of the training that I participated in, it's not tested. So it -- it -- it's fairly effective but it's certainly not honed in as it would if -- if the individuals were tested and held accountable.

The effectiveness of training, of course, should be balanced with the costs and benefits. What we're saying there is, you know, take a look at the various modes of training and, to the best of your ability, figure out what gets the job accomplished most cost effectively, which of course was -- was your basic question. So we're turning it around, saying that has to be a key element of this whole process.

We had quite a bit of discussion on the next topic. The -- the joint training of FSIS's inspection personnel and industry personnel should be encouraged

on appropriate topics. What we're saying is, if it's a purely technical issue where both parties need common knowledge of what we're talking about -- a food safety intervention would be a good example -- that would be an appropriate topic. Conversely, if you're talking about FSIS policy or enforcement, then that is not an appropriate topic.

But you can accomplish an awful lot when you train together, hear the same information, the same interpretations. It really helps the effectiveness of what you're trying to accomplish.

And another idea -- excuse me for a second.

(Pause)

DR. LAFONTAINE: Another idea is to consider regional training. And even went -- we went so far as to recommend district training officers. Your Agency is doing that now, and I'll just use the recent example of the IPS Biosecurity training where you had a two-day training block. You took facilitators to a central location to make sure they understood the subject material. The subject material was presented by, in this case, video tapes. But the facilitators were available to answer questions.

And then, in each district they reached out and found training locations -- and I was involved in

these firsthand in South Carolina, in this case with joint federal and state personnel -- and executed the training. And I thought it was quite effective.

And this answers the question of the diverse workforce and you can't -- you don't have the time or the money to bring everybody in for face-to-face training in -- in College Station. But you can have that face-to-face effectiveness by reaching out in your districts and then into subunits. So that's a -- a recommendation of the committee, that you give that a look-see.

The creation of district training officers or whatever title you want to call them is someone that has that as an integral part of their job description and responsibilities so that they're in the loop with the training center and other parties concerned on what's being developed, what the essence of it is, and that they know their -- they are -- he or she is responsible not only just to coordinate the training be done but to be actively involved in it, maybe even be a routine facilitator. So that you've got that cadre of folks that are accountable for -- for doing training or assuring that it's adequately executed.

I offer the example of state training officers. We have a system with our cooperative

agreement where the FSIS trains state employees so they can go back and be trainers at the state level for some of the basic requirements for accomplishing the mission. So you've got that kind of a system ready between us and between the states and -- and FSIS.

You can tell I feel very strong about that. I embellished on it quite a bit.

Consider alternative technologies for training purposes. The use of the land-grant colleges and their infrastructure should be considered. Those land-grant colleges and their extension services have communication nets to include Polycom and other current technologies out at the county level. So you -- you have an infrastructure in almost all states that you -- that you could possibly plug into so that you can better reach out to your workforce. In other words, work with the extension service and with these counties to -- to have -- to use their facilities and equipment for the ability to reach your workforce wherever they may be, in the middle of Texas or Kansas or wherever.

The next item that we suggest you consider is providing for interaction on the application of the training. And I touched on this already. Real face-to-face training is invaluable, especially when you have complicated or complex issues to work on or the

interpretation of what -- what this directive or this subject really means as far as the Agency's execution.

FSIS needs to consider options to address the recess -- resource allocation personnel to ensure the timely training and maintain necessary coverage of the inspection duties. One method of this is the team-based training approach. Once again, you see we're coming back to enough -- a structure that will allow you to dedicate on an ongoing basis what -- have workforce available so you can execute.

Finally, training is an important mandate of the FSIS mission. Commitment to training and the funds necessary to accomplish this mission should not be compromised by budgetary cuts. Touched on that earlier when the -- locking in or fencing of the funds. Put your game plan together, figure out how much you need and -- and lock in those funds so you can -- can do that month after month, year after year.

And the final comment is, who is out there to determine what training the inspectors need. We touched on that a couples times on needs assessment and figuring out what your gaps are, et cetera.

So with that, I'll ask the full committee and subcommittee to offer any additional comments.

Yes, Collette?

MS. KASTER: Thank you. This is Collette Kaster with -- Standard Farms. I think this is an excellent and very comprehensive list, and I'd encourage you guys to look very seriously at this. I really like the idea of the district training officers. I also like the idea of spreading this out, as we talked about yesterday, to other land-grant universities. Texas A & M is a great university but it's one of the harder and more expensive places to get to. And I know when our inspectors leave, it eats up quite a bit of time, including travel time. It's difficult for people to get down there. And there's a lot of other really fine institutions that could be included in this.

And the other thing I'd just like to add in here is something that does already happen on a lot of these trainings. But besides joint training, I'd also like to add a bullet point where we say that when appropriate, training materials are shared with industry. For example, the way that the CSO training was shared with industry, so that we understood the things that they were going to be looking for and could make sure that we made the adjustments that we needed to.

So I'd like to add that as a bullet point.

Thank you.

DR. LAFONTAINE: Yes, Ms. Tucker?

MS. FOREMAN: Carol Tucker Foreman with Consumer Federation. I have a couple of suggestions I'd like to make. Everybody knows that I have serious problems with the notion of joint training. However, Dan, as you -- as you started out, as you gave the examples, I was more comfortable with it. Could we include the examples in the bullet, please? So that --

DR. LAFONTAINE: Yes. I'll do that.

MS. FOREMAN: Thank you. That -- that -- that would make it a lot easier for me.

The second is, using the land-grant college training infrastructure strikes me as a good idea. As I was looking -- as you were talking, I thought, here we've got a force that we're really trying to get to look at their work in a very different way. It's a public health agency. FSIS hasn't historically been a public health agency.

I think it would be -- I think you could implicate that way of thinking in the Agency workforce faster and more successfully if instead of just involving extension if you were able to involve the public health community infrastructure of some of the land-grant colleges, if you would integrate some public

health people into this training. They do tend to look at things a little differently, think about it a little differently. And if you would entertain some reference to the -- the public health infrastructure there, I'd appreciate it. Thank you.

DR. LAFONTAINE: Carol, with the permission of the full committee, I'll -- I'll include that also. The -- words to the effect of, the public health infrastructure, giving examples of what we mean by appropriate topics for joint training, and also your comment about, continue to share the FSIS training materials with industry. So I'll put all -- integrate all three of those in, if it's -- if there's no objection.

Have some other questions? Mike?

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. One of the points that Collette brought up made me think of something. As I've tried to develop training in our agency for a shift over to the food code, I've relied on a lot of outside information that I've gathered from other agencies. One example is a guide that the Los Angeles County Health Department uses in explaining the use of their inspection form and their rules and regulations. And it puts it in -- it takes it out of the regulatory language that you find

in the rules and puts it in very simple, straightforward language designed to be comprehended by a lower level person, as you might find working in a food service establishment.

And I really find that to be an excellent document. And you might use that as a guide for how you could develop more information to get out to your field workforce and -- and the regulated industry as well.

But that brought me to the -- actually, the next point, which is there is a lot of information out there that has been developed by other agencies for the purposes of training. And I think it would be to USDA's benefit to participate with organizations such as the Association of Food and Drug Officials and find out what they've got available, what types of approaches they've taken, and avail yourselves of as much of that information as possible.

One of the things that AFDO is doing is -- is working on some collaborative efforts so that everyone is not reinventing the wheel separately and to try to -- it's called a States Helping States Program, and I think there may be information there that you could utilize.

DR. LAFONTAINE: Any other questions,

comments? Oh, Nancy? Sorry. Ms. Leech, let's deal with you.

DR. LEECH: Irene Leech. The first thing that I'd like to say is, thank you for the staff for having these here on our desks early this morning. I came in early and was able to read before the presentations, and that makes me a whole more effective than when I get the information after I sit down. So that was a big help this morning.

I would encourage you to consider ways to involve key consumer folks in some of the trainings and so forth as well so that everybody is brought along together. I think whenever parts are involved and parts are left out that it breeds mistrust and that kind of a thing. And I think we really need, with our food supply, to keep the public confident, need to be sure that we're bringing everybody along, particularly in the situations where we may consider new technology along the way.

So I know it's an expense, but I think key consumer leaders could be involved and that that might be a way to strengthen the whole system.

DR. LAFONTAINE: Let me make a follow-up comment. And I'll just go back to the land-grant college infrastructure and I'll use South Carolina's

example.

They are the individuals, in our state at least, that really are in touch with the consumers and the users as far as the food safety issue. So that's not exactly what you're talking about, but it's certainly -- my point is that if you -- if you do involve your extension folks, you're taking a giant step towards that -- that effort.

But I also hear what you're saying. You're talking about the next step of actual involvement of consumer organizations in -- in the training or what's actually being put out.

DR. LEECH: To give a further example of what happens on my campus, there really is no communication between consumer types like myself and our food science division. We're in different colleges, even. Even the nutrition people who do the food kinds of things are in a different college from our food safety people. And yes, they're extension, but they tend to have more connections with the traditional agriculture audiences than the average consumer on the street.

And that's why I think we need to ultimately be sure that we just keep people in the loop. And I know there's been some mistrust through the years, and so I think that's a little thing that can be done.

DR. LAFONTAINE: Ms. Donley?

MS. DONLEY: Thank you. This kind of is a general comment about education and training in general. And one of the things that STOP does, our organization does, is we are regularly asked to speak to various companies, organizations, trade associations. Basically, what we do at these -- during these speaking engagements is to empower the -- empower the audience. And we will have anyone from the highest level company executives down to the -- the bus boys, if you will, in a -- in the restaurant situation.

But our goal, our mission, is -- is to -- and particularly now that the Agency is making a very public stance towards going ahead to public health and safety, I think your inspection force needs to really know and understand how critically important they are and to be able to have some sort of an identity or a face or something in their minds to which they can say, yeah, I really am important, I really do need to do this job very, very well.

So I just would say that you need to have -- during all this is to have some sort of an empowerment message to give to them. Be happy to work with -- with FSIS in any way. You know, STOP will offer its support in any way we can on this.

Doesn't have to be your major, major -- major, major function, but just something that -- that reaches out to the inspection personnel and -- and gets them to buy into it and get committed to it.

DR. LAFONTAINE: Nancy, that's a -- a very pertinent and important suggestion. And I'll integrate something in here about the, using your words, the need to include an empowerment message.

Dr. Denton?

DR. DENTON: Thank you, Dan. First, I would like to compliment the committee on what I think is a very insightful as well as a very thoughtful response to these questions.

I don't want to belabor the point, but in thinking about what Carol mentioned earlier about including from the health side of the equation, I mentioned or referred to very generally yesterday our Food Safety and Quality Program. And as a point to follow up and reinforce that, I'm gratified to hear this because I think it validates the approach that we're taking just a bit.

One of the things that we looked at is a basic set of skills that we feel like people within not only the industry but within the regulatory community need. We looked at things like basic food

microbiology. We looked at things like statistical process control.

Some of the things that we looked at are outside of what we normally see in our College of Agriculture, Food, and Live Sciences. We actually dipped over into our College of Education in the Health Education curriculum for our modules that have to do with epidemiology and communicable diseases.

I think the more of this type of effort that we can have in putting in the expertise from the other areas, and it fits in with what you're saying about the extension service, we think that looking for the fundamental knowledge, wherever we find that, is going to strengthen this educational effort. We've worked very hard to put this thing together not only with three separate universities involved in it but looking beyond our traditional curriculum with regard to how we approach these types of things.

And I think that your recommendations should form a very important guidepost as -- as we move forward in this. Thanks.

DR. LAFONTAINE: Thank you, Jim.

Other questions, comments?

DR. McKEE: I'd just like to comment that I think the comments are exactly right. We need to have

the core public health disciplines within the public health arena. And we certainly need to have that incorporated as part of the training, whether it's technical and so forth, so that we -- we can start going in the direction that we understand that is. That includes epidemiology, communicable disease control, those kinds of things that are kind of -- that are basic to public health that we need to know how that -- how what we do in the inspection business fits into that.

And so certainly, that's an opportunity. We need to partner with -- with other folks in public health and schools of public health to do that. I think it's a good point.

DR. LAFONTAINE: Thank you, sir. You know, I'm going back and plowing the same ground again, but you need the basic knowledge and skills to execute what your mission is. And that's -- that's the first important and hard question. So we're saying the same thing.

Any other questions or comments?

(No response)

DR. LAFONTAINE: Okay. I will take these four items and integrate them into question number two and give it to our staff and support staff and then

we'll have a second version go out later.

Okay. Thank you, sir.

DR. McKEE: Okay. Thank you.

We have our -- we have a presentation for the -- the briefing on the HACCP-based Inspection Models Project, or better known as HIMP, right after our break. We will need to be right back on time at 10:30.

Before we go to break, I would like to make the presentation to Carol Tucker Foreman. We commented earlier about those leaving the committee and their dedication to the committee and the valuable work that they have done.

And Carol, I'd like to present you a -- this is a pen set that is engraved. And I believe everybody on the committee has spent two terms -- or three terms, which is two year each. That's a long time. Dedicated work, especially the evening work. And we certainly, again, appreciate it. So if you could come forward, Carol.

(Applause)

DR. McKEE: Okay. I believe we have refreshments outside the door -- are you finished, Dr. Lafontaine?

DR. LAFONTAINE: Yes.

DR. LAFONTAINE: And we will -- that'll give

us about -- a little over 20 minutes. So that'll make -- give us plenty of time to be back here right at 10:30. Thank you.

(Brief recess)

DR. LAFONTAINE: Okay. We can take our seats. It is 10:30.

We do have a long-distance presentation, and so it will be necessary to -- to start on time with that.

Briefing

HACCP-based Inspection Models Project (HIMP)

Introduction and General Status Update

DR. LAFONTAINE: This morning's presentation on HIMP will be facilitated by Ms. Jeanne Axtell and Dr. Perfecto Santiago, who have been the -- the lead individuals in the Agency on this project.

And Jeanne, if you would go ahead and start, why we'll do whatever we need to do on the electronics here.

MS. AXTELL: Okay. Thank you very much, Dr. McKee, and we thank very much the advisory committee for allowing us to come and brief you on the status of the HACCP-based Inspection Models Project, or HIMP it is -- as it is more commonly referred to.

This morning we would like -- we will be

presenting to you the results of the third party review of the HIMP data that had previously been collected by Research Triangle Institute, and to discuss our plans for the HIMP project.

At the last national advisory committee meeting in June, FSIS officials and the Research Triangle Institute project leader presented data that had been collected during the baseline and models phase of the project in young chicken plants. To say that the data presentation and the ensuing dialogue with members of the committee was lively would be an understatement.

At the conclusion of the June meeting, FSIS acknowledged that while the goal of HIMP remained solid, the Agency could and should do more to assure the public that their confidence in the Agency's decision-making based on the data from this project was well-placed. The quality of the data, what the data means, and how the data are communicated are critical issues for assuring public confidence in moving forward with the goal of HIMP. That is, modernization of inspection.

FSIS committed to having a third party review of the data that had been collected by Research Triangle Institute for the project after taking another

look at the data ourselves. And we acknowledged that the issue of increases in the recovery of salmonella during the course of the models phase of the project would need to be addressed.

With this acknowledgement, FSIS proceeded to an internal assessment of its management and direction of the project, what we have called assessing the current reality of HIMP.

With me today are individuals who represent the new face of HIMP. As you see represented on the panel here today, Dr. Lauren Lange from the Office of Public Health and Science; myself from the Office of Management; Dr. Perfecto Santiago from the Office of Policy; two field supervisors, Dr. Bill Calloway, Dr. Philip Aman; Dr. Kenneth Petersen from the Office of Field Operations in headquarters; and Dr. Bill James from the Office of Public Health and Science.

We represent executives from different program areas within FSIS and supervisors from the field at both the in-plant level and the circuit supervisor level of the organization.

FSIS is actively engaged in the HIMP pilot. It is our goal to bring the focus of HIMP back to the original intent of the pilot as stated in the June 1997 "Federal Register" notice which announced this project.

It was at that time and it remains today as the most ambitious and difficult undertaking for this Agency next to the implementation of HACCP itself.

With the implementation of HACCP underway, the HIMP proposal was designed to address the fact that under the carcass-sorting process, inspectors carry out certain process control activities that are not inspection activities and thus should be the responsibility of the plant under close FSIS oversight. This is consistent with the HACCP approach under which plants are responsible for the production of safe and wholesome products, including carcass-sorting process control activities. And FSIS is responsible for setting performance standards and ensuring those standards are met, thus assuring that no adulterated product leaves the plant.

With inspectors in these slaughter plants no longer carrying out activities that should be the plant's responsibility, FSIS believed and still believes that it can better focus on public health concerns.

FSIS believes that there are additional tasks within slaughter plants, such as verification of the zero tolerance standard for fecal contamination as well as sampling for pathogenic microorganisms and

verification of HACCP food safety systems, that deserve more focused attention than they have received. This would permit FSIS to focus greater attention on products after they leave plants and enter distribution channels where minimal attention is now paid. And opportunities do exist for improving food safety and public health.

This is where we began with HIMP. Over time we lost sight of the project's goals, but now we are back on track and intend to move forward.

Modernizing inspection is the goal and remains the goal for the Agency. It is about assuring that FSIS meets its food safety public health responsibilities.

The objectives of this project as outlined in 1997 we have reviewed over the last several months. We believe them to still be valid objectives for us to attain.

The first of these is that whatever new approaches we're looking at, that they do not diminish current food safety and consumer protection achievements.

Second, HACCP, other industry process control systems, and FSIS inspection activities, all three of these, are complementary and interrelated but they are

independent activities. Taken together, they enhance the safety of food and earn consumer confidence.

Third, resource redeployment of scarce inspection resources is essential to assuring food safety and consumer protection objectives throughout the farm-to-table continuum.

Those are the three objectives with which we began the project and the three objectives which we believe are still valid today.

To move forward with HIMP, we contracted with an independent third party since the meeting in June, the National Alliance for Food Safety, to review and analyze the RTI data and FSIS data. Today, the National Alliance for Food Safety will be presenting their findings.

Thus far in the pilot, we've seen that HIMP provides benefits to all stakeholders. It does result in safer, higher quality product for consumers. It permits industry greater control over the production process to meet food safety and quality standards set by the Agency. And it frees up inspection personnel to be redeployed to other areas of need.

We believe that in the last few years that we've been engaged in HIMP that we have accomplished what we set out to do, that there have been benefits to

consumers by FSIS's ability to focus its attention upon food safety concerns that otherwise would not have received the same level of attention.

Among the first 15 plants involved in the project, FSIS was able to successfully deploy 70 inspectors. These individuals were freed up to focus on other food safety concerns or were detailed into other critical slaughter vacancies within the local commuting areas of the HIMP plants to which they were formerly assigned.

FSIS has not had to request additional resources for program growth since fiscal year 2001 because this has been possible. In light of bioterrorism concerns that you heard discussed yesterday, having a flexible workforce that can be redeployed to areas of need will become increasingly essential.

At the same time, there have been benefits to industry. Participating plants have had the opportunity to redesign production practices, line configuration, and process flow and to introduce innoventions and interventions that would not have been possible with inspection personnel at fixed inspection stations midstream in the production process. Our inspectors, carcass inspectors, are now positioned at

the end of that production process prior to the chill plant.

Despite these benefits, there have been real and perceived problems with the project. FSIS has not been transparent in sharing data. And criticisms from many quarters have caused consumers to believe that products from HIMP plants are less safe than other products.

The project is not perfect. From our own assessments as well as those from outside groups, we've seen shortcomings in the pilot. As we move forward with the project, we will build on the important food safety gains that are already apparent and take the opportunity to address the shortcomings through ongoing evaluations.

We are at an important juncture in this project. We are working on strengthening the program and improving the benefits for all stakeholders.

At this point, I would like to ask my colleague, Dr. Perfecto Santiago, who has been co-leading this effort with me, to provide you a more detailed description of the sets that are underway today to address these shortcomings.

Dr. Santiago?

DR. SANTIAGO: Thank you. Good morning.

Like my senior partner Jeanne, I thank you for the opportunity to -- to speak to you this morning to share with you the initiatives we have taken to strengthen the HACCP-based Inspection Project for young chickens.

Being before you this morning is one of the first -- another first for me when I came to Washington in my -- after spending 32 years in the field, five years of that as a district manager with one key establishment under my jurisdiction.

As Jeanne mentioned, we know that HIMP is not perfect, and a few short comments that we must address as we move forward on this project.

We know that the set of procedures we are operating from in this project, called Draft 6, needs to be revised for clarity. We know that the inspection procedures are not being implemented uniformly in the 20 volunteer establishments under HIMP for young chickens. We know that the -- the normal supervisory structure in the management of this project. We know that we need to develop an enforcement strategy for non-compliance with non-food safety standards, also known as OCPs. And we know we need to review how we are starting HIMP establishments at the present time. Lastly, we know that we need to review our communication strategy with the industry and the

inspection personnel in the HIMP establishments.

To address these shortcomings, we have embarked on the following initiatives. Engaging the field supervisory structure. In the early stages of the pilot, HIMP implementation was managed by the New Initiatives staff in Washington. Technical advisors from headquarters were assigned -- HIMP establishments to provide direction on the implementation of the pilot.

While this arrangement worked well and probably was necessary in the early stages, disengaging the supervisory structure may have inadvertently weakened accountability and supervisory control.

As the role of the technical experts were gradually phased out -- advisors, excuse me -- it became unclear to the inspectors in charge of HIMP establishments where they may seek guidance and direction on implementation problems. Inspection personnel and plant management as well reported inconsistencies on directions being given by members of the headquarters staff. Procedures become unclear.

To address these shortcomings, the Office of Field Operations formally reengaged the supervisory chain of command in the management of the implementation of HIMP to establish clear

accountability and to strengthen supervisory control. Appeal procedures were also clarified.

The -- was reinforced in the last National Supervisory Conference in Dallas by Bill Smith and members -- members of the Office of Field Operations.

The second initiative we are taking here is to review and revise Draft Number 6. In response to the issues presented by HIMP establishments at the recent meeting with FSIS and as a result of our assessment of, as Jeanne called it, current reality, we -- in the HIMP procedures we are operating from to identify provisions or procedures that need clarification.

For example, in Draft 6, we are telling verification inspectors that when doing the eight 10-bird tests for Food Safety 1 and Food Safety 2, they should not score OCPs or -- defects but they may find against the plant's performance standards. In the OCP procedure further down this -- draft, we are telling verification inspectors to randomly select two 10-bird samples from the eight 10-bird sample sets for food safety and -- one and two and use that for OCP verification. Appearance of bias -- biased sampling is then most inevitable when these procedures as written are performed by our inspectors.

We will clarify this procedure in Draft 7. Possibly, -- a way that all food safety and non-food safety defects observed in an 80-bird sample are counted against the food safety and the non-food safety performance standards.

We do not anticipate major procedural changes, however, but all procedures in Draft 6 needing further clarification will be addressed appropriately.

We also intend to incorporate in Draft 7 all other minor revisions made to Draft 6 after it was first issued. We are actively soliciting input from inspection personnel and supervisors working in HIMP establishments in preparing the draft.

In addition to clarifying the procedures in the existing draft, we also plan to propose in Draft 7 an enforcement strategy for non-compliance with performance standards for non-food safety processing defects. Again, those we call OCPs.

We hope to develop an enforcement strategy that will provide guidance to inspection personnel using statistically based limits on how to determine when regulatory action will be taken. We expect Draft 7 to be completed by the end of this month -- the end of this month.

Another initiative we're taking is to conduct

sustained and vigorous correlation activities in the HIMP establishments. Reported inconsistencies on sampling and other procedures underscore the need for sustained correlation activities in HIMP young chicken establishments. Following the issuance of Draft 7, the Office of Field Operations is committed to conduct vigorous on-site correlation activities with inspectors and supervisors in the 20 HIMP young chicken establishments on the new procedures. They expect to complete this activity by the end of May 2003.

We plan to look at the existing staffing configuration as another initiative that was initially established for HIMP. We need to ensure that we have the appropriate level of staffing, including properly trained relief personnel, to conduct verification activities in HIMP establishments. The project has had time to make the necessary evolutionary changes. And roles and responsibilities are now better clarified for us to make this staffing assessment.

On communication, in the early stages of the project regular conference calls were made to inspectors in charge and supervisors of HIMP establishments from Washington, D.C. As the project matured, the -- became less and less frequent. The technical advisors from Washington, D.C. and the

Technical Service Center that were assigned -- initially assigned to every HIMP establishment gradually became less and less involved in the project. And that particular function has practically disappeared in the implementation strategy of HIMP at present.

We deem it critical at this stage of the project to ensure that effective communication is established between the now-engaged field management structure, the Technical Service Center, and the HIMP headquarters staff in the management of the project. As Draft 7 is implemented, we plan to -- the regular conference calls and explore other means of establishing effective communication with the supervisory structure of -- of those inspections in the HIMP establishments.

We are very confident these initiatives, when fully implemented, will strengthen the program, ensure the protection of public health, and maximize the benefits of all HIMP to all stakeholders. Thank you very much.

MS. AXTELL: Thank you, Dr. Santiago.

Now I would like to introduce two field supervisors who will share their observations from their perspectives on the HIMP pilot.

The first to speak will be Dr. Philip Aman, who is an inspector in charge at a HIMP plant. The second to speak will be Dr. William Calloway, who is a circuit supervisor with supervisory responsibilities for a HIMP plant within his circuit.

Dr. Aman?

Observations from the Field Perspective on HIMP

DR. AMAN: Thank you, and good morning. I'm very happy to be able to comment today on a project which I firmly believe in. My comments will be based on observations and assessments as a veterinary medical officer with 16 years of experience in meat and poultry inspection.

I'm currently assigned to a plant that slaughters young chickens, approximately 2 million a week. And at the end of next month, I will have just completed three years in this plant under the HIMP inspection methodology. Prior to that, I spent 13 years under -- in plants with the traditional inspection.

In my professional judgment, the HIMP inspection system is superior to the traditional inspection system. Given the choice of purchasing product for my 75-year-old parents or my 11-year-old son, I would choose to have product from a HIMP

inspection plant. Let me explain to you why.

In the traditional inspection, the inspectors, as you've already heard from previous comments, the inspectors were placed in the middle of the process, of the evisceration process, in fixed positions. They could only control what came to them at that point.

With the HIMP inspection method, we remove them from the middle of this process and place them at the end of the evisceration line where they are observing and inspecting those carcasses that have been sorted and washed and trimmed and are supposed to be ready to go into the chiller. At that point they are better able to determine what the consumer is actually going to get at the end of the process.

Not only that, but in the previous scenario and traditional situation, this inspector was pinned to the line for eight to 10 long hours a day in the same fixed position. With the HIMP, the inspectors are set up in a rotating pattern such that when one inspector leaves that line position, another inspector comes and takes their place, allowing that inspector to go into a different mode -- they're trained in all the modes -- where they will be inspecting carcasses. They will be performing all the other duties that were mentioned.

It allows us to reallocate our resources and better utilize our personnel resources to a much greater degree than we could ever do in a traditional plant.

I'm going to give you a snapshot view of what I've seen in the last three years in the plant that I've been in. That's what I can do today. And I want to give you some examples of what I've seen happen with their process.

Initially, this was a plant that had -- HACCP plant. Had an SSOP plant. It's meeting regulatory requirements. They went into the HIMP inspection system. And due to the HIMP, they were allowed to see some areas in their process that could be improved, and they took advantage of that.

For example, OCP-3, which is the -- one of the OCPs that we look at every day for ingesta, when they began under the HIMP system, because of the tightened performance standards -- and I can assure you the standards are tighter and they're harder to pass under HIMP than they are in traditional. Under this new tightened criteria, the plant was not able to meet this requirement on a daily basis. And they discovered that even though they had a good written plan for the field needs to meet this criteria, which primarily

consists of proper withdrawal, time of the feed, where it may be written that X amount of hours you withdraw the feed from the field. If you're a farmer and you are going to get up at 2:00 in the morning to pull those feeders and you know that no one is going to come to that farm and verify that you did that, the temptation would be to, what the heck, go ahead and wait until five or six and pull it.

But those two or three hours makes a vast difference on that flock when it comes to the slaughterhouse as to how it will process out and how it will score out on that OCP-3. The plant had to go back and start holding people accountable and verifying that those procedures were followed to the T so that they -- and at this point they have eliminated that problem.

Another example that we saw, as -- as the mission in the HIMP environment, we do closer scrutinize the product and we do take more sampling. And the numbers of non-compliances initially with the fecals did go up. Not the percentage of birds when you scale it out on percentage, but the numbers went up. The perception of this to the public is poor because they only see the numbers. They don't understand. And it's true that that would be the case.

But the plant did not want that perception.

And so they began to work on their process in that area. They began to better work on their equipment. The initial equipment that the birds come into that could cause fecal contamination of a carcass. They had to go to the field and make corrections.

I will say to you now that in the -- we are, like I said, almost into the third year. At the plant where I am, I could almost name on one hand the number of non-compliances that we see now of fecal contamination in a shift per month. And we're talking over 2 million chickens a month.

The other great improvement that I've seen at this particular plant is in the OCP-1 category, which is -- in a young chicken plant, the bulk of that is going to be airsacculitis. For all my career as a poultry inspector, veterinarian, in the winter and springtime is when we see those flocks primarily that come in with the airsac. And they are a processing nightmare for the plant and for the inspection team, whether you're on the traditional or whether you're under the HIMP, either one. But particularly in the HIMP.

Again, because of the increased or the tightened performance standards, this plant was not able to consistently meet those standards using the

normal routine as they did in the past. They had to address what flock -- they were using for these flocks before they brought them into the plant. And I can attest to you that in the last year and a half, I have not seen these flocks coming to the slaughter house. They have corrected this problem. And therefore, the OCP-1 issue has gone away.

So I think the -- the -- what I'm trying to say is that the -- in the environment of the HIMP system, it allows the plant to correct these deficiencies and improve their process.

The last comment I want to make, because when I told my inspection team that I was coming here to talk to this group, they told me before I left, Dr. Aman, please, please tell them that we do not want to go back to traditional inspection. Our job is more important. We feel like we're doing a better job for the consumer. And we would not want to go back to the traditional inspection. Thank you.

DR. CALLOWAY: I want to thank the committee for providing me the opportunity to come and give you my slant on HIMP.

As was noted in the introduction, I am a circuit supervisor. And for those who might not be quite sure on what that is, I'm responsible for the

delivery and implementation of inspection operations at the field level over a relatively large geographic area, mine encompassing Mississippi and south Alabama.

I have a fairly complex circuit. There are several different types of federally inspected establishments in my circuit, five of which are poultry slaughter plants, one heavy fowl plant, four young chicken plants, one of the young chicken plants being a HIMP plant.

I think for point of clarification, the HIMP plant in my circuit is not Dr. Aman's. He's not assigned in my circuit, although I'd probably let him work for me if he came down there.

So we are speaking about two separate facilities here.

I've been a circuit supervisor for about four and a half years, and so I've been a circuit supervisor for the entire time that HIMP has been implemented. I was an IIC for seven years prior to that, and four of those years as an IIC was in this facility that went to HIMP. So I have an approximately eight and a half year knowledge of this facility.

I don't pretend to be an expert on the big picture of HIMP. I can only give you a snapshot of one facility. And so that's what I'm going to try to do.

I want to try to touch on three points: the product that's exiting the facility, the company and facility itself and what HIMP has done to and for them, and what HIMP has done for the inspection personnel in that facility.

As to the product, I have to concur with Dr. Aman. And he's covered it in much more detail and better detail than I can provide you. I can relate to you that in -- in the major food safety categories of FS-1, septox; FS-2, fecal contamination; and OCP-1, diseased animals, there has been a significant reduction in this plant from the time that it was a -- under traditional inspection as opposed to its operating under HIMP inspection.

I firmly believe that the product coming out of this plant is of better quality and more wholesome now than it did when this plant was under traditional inspection.

As to the company and the facility, this is an old facility. It was built in the early 1950s. And the company is one of the smaller companies in the industry. To be quite honest with you, prior to HIMP and during the time pre-HACCP to HACCP implementation, this company was struggling. They were struggling financially and they were struggling meeting regulatory

requirements. And they selected to go to HIMP with the full knowledge that they were going to be held accountable to a more stringent regulatory standard, but they did it with the knowledge and the hope that by being allowed the freedom to reallocate their very limited resources that they could do a better job producing their product and also, at the same time, do a better job meeting regulatory standards.

And so we embarked on the HIMP road with this company, and it's -- it's had its rocky spots along the way. And they didn't immediately turn things around. They didn't have a lot of capital to invest into major renovations to immediately meet some of the changes that HIMP provided.

But I can report to you that as I sit here today that in the last year to year and a half, this company has been able to invest a significant amount of capital into replacement of equipment, to renovation of the facility. They have been able to install and implement an on-line carcass antimicrobial system. They have become competitive in the job market and have gone out and hired better-trained, progressive, proactive management. They have contacted and hired an outside consultant to come in and do a full audit on their HACCP and SSOP systems. And they have conducted

training for every supervisor in their plant in HACCP.

It is my opinion that had they remained under traditional inspection, these things, these improvements, all that went to better, more wholesome product, would not have been accomplished.

As to the inspection personnel in this plant, and I certainly don't sit here as a representative of the inspectors, particularly in regards to their working conditions. That's the charge of the NJC, and I respect that area.

I can relate to you individual conversations that I have had with the inspectors in this plant. They reiterate what Dr. Aman's inspectors have said. To the person, not one would go back to a traditional inspection. The inspectors believe they are doing a better job, that the plant is producing more wholesome product, and they are better serving the consumer in their role as HIMP inspectors.

I think as a significant sidebar to this, we have all seen and heard and read the reports that there is a crisis in the federal workforce. We have an aging workforce. A significant number of experienced inspectors are retiring and leaving the Agency each year. We have a subcommittee here, I believe, that's addressing some of those issues. It has been pointed

out that we're having difficulty obtaining qualified people and retaining qualified people.

If you think of what we have subjected these people to in a traditional inspection system where they are tied to the line for eight to 10 hours, that they can sit or stand only in one position, that they have a repetitive up-and-down and sideways head motion, a repetitive rotation of the wrists. We see a large number of traumatic illness-related cases of workmen's compensation associated with neck injury, shoulder injury, and carpal tunnel syndrome.

I can tell you, in this plant since they went to HIMP, those have gone away.

I can relate to you a story of two ladies in this facility. One is in her early 60s, one in her lat 50s. Both have in excess of 25 years' experience in inspection. Four and a half years ago they told me that they doubted they could last another year. I talked to them last week. They both told me they plan to work another five years and maybe longer if they can stay healthy.

If we can retain our experienced workforce and extend their life, their working life, then we have accomplished something and retained a major asset for the Agency.

In conclusion, I agree. I don't think HIMP is a perfect system. I do believe it is superior to -- to traditional inspection. And given the fact that it is driven by HACCP, it is forced to continually adapt and change to meet the requirements of HACCP. And therefore, the flexibility it gains from that provides not only that it meet the needs of the immediate time but also for the future.

I thank you again for this opportunity.

MS. AXTELL: Thank you, Dr. Calloway.

Introduction to Video Presentation

MS. AXTELL: We are at the stage now where we will be preparing to present to you the report of the National Alliance for Food Safety, which was the review of the RTI and FSIS data from a baseline and models phase of the project.

FSIS specified particular questions to be addressed through examining the data from the 11 plants that have been involved in the project from the beginning, from the 16 plants whose data was presented at the last advisory committee meeting in June, and from all 21 plants who have been engaged in the project at any point in time. When we met in June, we said 20 plants. The reason we're saying 21 today is that one had dropped out, one came on. And we had a plant enter

the project over the summer.

The questions that were posed to this third party review focused on the validity of study design and methodology that would permit an interpretation of the organoleptic and microbial data sufficient to assess the accomplishments of the traditional and HIMP systems. Again, this was a crucial question for the Agency since study design and methodology and a comparison of one system of inspection to another system of inspection was an inherent feature of the design of the project.

FSIS awarded the contract to the National Alliance for Food Safety. And a technical review of bids was submitted through the normal procurement and contracting process used by the federal government.

As with all outside contractors, the participants on the technical team identified by the National Alliance for Food Safety completed conflict of interest statements verifying their impartiality to participate in this review.

FSIS did not include in the contract a requirement to make an oral presentation of the findings from the review. Our requirement was simply to conduct the evaluation, to conduct the review, and prepare a written report of findings and conclusions.

When the Agency contacted Dr. Billy Marshall Hargis, the team leader, to request his availability to make a presentation to this committee, we found that Dr. Hargis had a previous commitment out of the country that precluded his being here today. Dr. Hargis has indicated that he would be available at some point in the future should the committee wish to have him present to address the work of the National Alliance of Food Safety directly.

What Dr. Hargis did agree to do is to tape the presentation he would have made had he been here. This presentation will run 30 minutes. It would be helpful to the members of the committee if you would follow his presentation with the copy of the report that was placed on your chairs or at your seats during the break. It has the cover sheet on it with the cover letter from the National Alliance for Food Safety.

MS. FOREMAN: (Off microphone)

MS. AXTELL: Ms. Foreman, Dr. Hargis was not able to be here, but Dr. -- but Dr. Patricia Curtis, who is another member of the team, is going to be available by conference phone. And following the running of the videotape, Dr. Curtis has agreed to be hooked up in order to answer the questions of the committee that they have at the moment with respect to

the work of the National Alliance for Food Safety on this review.

MS. FOREMAN: Carol Tucker Foreman from Consumer Federation. This is extraordinary. First of all, we've been here for two days. My tab number eight, which covers this material, is shockingly vacant. You walked in here with extremely detailed material. It was put on my chair while I was outside on the break. You do not have the author. You're willing to hook up one of the people by conference call.

It is clear that this presentation was brought to this committee in a way that makes it impossible for us to deal with it. And frankly, there are no data here. There are none.

So having said that, I want to be on record as objecting. I'll have some other things to say later.

MS. AXTELL: Thank you, Ms. Foreman. Your objection is on record.

We do want to proceed with the playing of the video. Again, there have been a number of technical difficulties this morning in trying to get all of this equipment connected properly and to assure that we could get the printing of the final report done. And

in fact, the copies of the report were not delivered until first thing this morning. I apologize to the committee for that, but we received the final version of the report only a couple of days ago.

We will proceed now with the video tape.

Video Presentation

DR. HARGIS: Hello. I'm Billy Hargis. I've seen a list of folks that are present here today. And I realize that I know many of you and I wish I could be here in person to see you and talk with you.

Unfortunately, none of our review team was able to be present for this particular meeting. It was very short notice. And I believe Dr. Curtis is going to be able to answer some of the questions by telephone some -- some time later after the presentation this morning.

As you know, it's my honor to be the lead person on this team to review the HACCP-based Inspection Models Project that we were granted by the National Alliance for Food Safety as a technical team, which of course contracts with FSIS for review of its projects.

The team consisted of some very well-known people: Dr. Pat Curtis, Dr. Mike Johnson -- Dr. Curtis is actually the professor and director of the Poultry

Product Safety and Quality Program in the Department of Poultry Science at Auburn University. Also, Dr. Mike Johnson, who's a very well known food microbiologist at the University of Arkansas in the Food Science Department. And Dr. J.D. Williams, who is a - biostatistician and is one of the best biostatisticians that I've ever known.

Also, myself. I'm presently a professor and director of JKS Poultry Health Research Laboratory at the University of Arkansas. My background is both in veterinary medicine and in research. Most of my research over the last few years has dealt with some work with antemortem intervention strategies and at the interface between pre-harvest and post-harvest intervention.

Do you want me to start -- okay. That's fine.

As an introduction, the National Academy and others have called for moving federal regulatory activity away from the traditional organoleptic inspection and toward a risk-based HACCP approach. In a subsequent report, the National Academy of Science has indicated that the mandatory inspection of all carcasses is an impediment to improving the safety of meat and poultry.

Arguments that have been made that sorting activities should appropriately be assigned to the plant under FSIS oversight to evaluate a model system of inspection operating under HACCP principles, the HIMP project was initiated to evaluate the ability of the HIMP models to improve the safety of processed animals and poultry.

As I mentioned, the present review has focused on the validity of study design and methodology to permit an interpretation of organoleptic and microbial data to assess the accomplishments of traditional versus HIMP systems. Our team reviewed the differences in food safety performance data between the inspection systems for young chickens using data from the Food Safety categories 1 and 2 and also microbial testing, as well as data from the other -- Other Consumer Protection categories, one through five.

The technical review team was selected by the National Alliance for Food Safety under contract with FSIS. And the review team consisted of nationally and internationally recognized experts, we hope, in the area of poultry microbiology, food safety, poultry health, poultry processing, and statistical evaluation. We reviewed the documents provided by FSIS.

The -- a group of documents, about eight

inches' worth. And I've given them here. We focused on the entire project, the original 11 plants that reviewed for both baseline testing and for models testing, as well as the replacement five processing plants that replaced the five plants that dropped out of the program. And we've also reviewed the FSIS data as well as the other reports and things that others have written about the data today.

As requested, the primary focus of this review was on the specific questions by FSIS. We'll go through these individually.

The first question was, does the design and methodology of the study permit an interpretation of the organoleptic and microbial data to assess the accomplishments of traditional and HIMP inspection systems.

Overall, the review team determined that the design and methodologies used allow for mutual comparisons of the plant that is measured under the two systems. The review team noted the enormous difficulties in accomplishing a comparison of this type under -- conditions and restrictions.

The primary -- design clause related to the fact that the baseline and HIMP system data were collected at two very different times, potentially

introducing unintended variables. However, when one accepts that the comparison is between these two systems at these times, then the data are indeed interpretable.

Large data sets collected on parameters not expected to vary substantially due to season or time are particularly comparable in the studies. However, an issue was raised with regard to the salmonella incidence data, that these data were collected under a very short time span for each of the systems evaluated.

As discussed in more detail in the report, the review team could not find any valid reason for discounting the data generated by the entire RTI -- RTI data set from the 16 plants under the traditional or HIMP inspection system. And secondly, comparison of the data provided from either RTI-generated data set does not alter interpretation of the data in a meaningful way.

Regarding geographic distribution, the review team noted that the -- area most represented, which was the southeastern United States, actually represents the area most responsible for approximately 80 percent of the young chicken production. And we didn't feel like that this was in any way a bias geographically for the design.

The size range of the selected plants were also representative of the majority of chicken plants. Now, I think the review team does recognize that extremely small plants might very well fall into a different category.

No reason was found for rejected the RTI-generated data based on statistical -- geographic bias, plant size bias, or non-completion of the study by five of the 16 originally selected plants. In fact, we think it's rather remarkable than 11 of the 16 originally selected plants are ready to complete the study. The design and methodology -- represent the best available choice for most of the plan that is measured.

However, the compressed time frame, only -- salmonella recovery data represent an exception to -- conclusion. And I'll talk about that just a little bit later.

Our second question that we were asked to address specifically was to evaluate and characterize the differences in food safety performance data for current inspection systems for young chickens using data from Food Safety categories 1 and 2 and microbial testing.

We found that there were clear and important

reductions in FS-1 and FS-2 defects, the food safety categories, that were attributable to the HIMP models system as compared to the baseline data. There were also clear generic E. coli reductions which were also attributed to the HIMP models system as compared to the baseline data.

The findings of the review team are generally consistent with those outlined by the RTI-generated manuscript which was published in "Journal of Food Protection."

Our third question was to evaluate the aggregate and individual establishment data by comparing the accomplishments of traditional and HIMP systems for the 11 establishments participating in both RTI traditional and RTI models sampling.

And so for this question we were focused only on the 11 plants that actually completed both phases of the sampling.

An apparent improvement in the average score was noted with -- process under the HIMP models system for Food Safety categories 1 and 2 and OCP-1 and -2. Consistent with these data and the numerical increase in the percentage of plants which met performance standards for these categories were noted for FS-1 and OCP-1, -2, -3, with no difference in the percentage of

plants meeting performance standards for FS-2.

The average score for carcasses processed under the HIMP models system was higher for OCP-3, OCP-4, and OCP-5. However, we also considered that there is a very real difference between statistically significant changes and those that are likely to be meaningful.

For example, the average score was reduced in the HIMP models group by 18-fold for Food Safety category 1 and almost five-fold for Food Safety category 2, almost three-fold for OCP-1, and almost two-fold for OCP-2. In contrast, the increase in average score in the HIMP models group was only 10 percent for OCP-3, 15 percent for OCP-4, and 44 percent for OCP-5 as compared with the baseline data.

It is also important to note that the Food Safety categories are considered to reflect much more important defects as related to product safety.

Overall, the review team considered these data to evidence marked improvement in the organoleptic defect scores of carcasses processed under the HIMP models system as compared to the baseline data collected under the traditional system.

Marked and significant reductions from generic E. coli recovery were reported in carcasses

processed under the HIMP models system as compared to those processed under the traditional or baseline system. However, a statistically significant increase in salmonella recovery from carcasses processed under the HIMP models system -- that was 9.2 percent -- was observed as compared to the baseline data, only 4.6 percent. This is again with the 11 plants that started and completed the study.

However, this observation was not consistent with the overall data of the combined 16 plants or with the FSIS data, and we'll discuss that in a moment.

Question Number 4. Descriptive analysis of individual establishment performance in traditional and HIMP systems.

A complete data set provided by the "RTI Individual Establishment Data" was available only for the initial 11 plants for most categories. But we certainly looked very hard at this data. Review of these data did not affect the conclusions apparent in the summary data for these 11 plants as discussed, with one exception, which I'll mention here in a moment.

There was no evidence that any -- that the summary data were unduly weighted by extreme variations with the exception of some very high individual salmonella recovery incidence numbers, particularly

with two of the plants in the HIMP -- operating under the HIMP system.

The aggregate analysis -- Question Number 5 was to look at the aggregate analysis comparing the accomplishments of the 16 establishments participating in the RTI traditional sampling to the accomplishments of the 16 establishments participating in the RTI models sampling.

And again, we did not -- we recognized that the model plants had made many, many changes. They are in fact a apple compared to an orange. And we -- we really struggled with the question but don't find any real reason to discard the data from the replacement five plants that -- that replaced those that dropped out of the study.

Very similar data, though, regardless of how you looked at it. Whether we looked at the 11 plants that both began and completed the study or the 16 combined establishments, we pretty much get the same data with one exception.

We saw significant differences again in issues of each of the organoleptic parameters evaluated, and this was expected because with very large data sets, very small differences, they're likely to -- statistically significant.

We saw apparent improvement in the average score with carcasses processed under the HIMP models system for Food Safety categories 1 and 2 as well as OCP-1 through -3. Consistent with these data, a numerical increase in the percentage of plants which met the performance standards for each category was noted.

As discussed above, average scores for carcasses processed under the HIMP model system were significantly increased by a small factor for OCP-4 and OCP-5 as compared to the baseline data. But again, these were small differences.

Overall, the review team considered these data to evidence marked improvement in the organoleptic defect scores of carcasses processed under the HIMP models systems as compared to the baseline data collected under the traditional system.

Marked and statistically significant reductions in generic E. coli recovery were reported in carcasses processed under the HIMP models system. And as with the 11 original plants, salmonella recovery was less noticeably but more crucially recovered from carcasses processed under the HIMP models system. As mentioned above, this observation was unexpected given the clear reductions in FS-1 and FS-2 scores and marked

decrease in generic E. coli recovery attributed to carcasses processed under the HIMP models system.

A pitfall of the microbiological data collected by RTI is the compressed time frame during the collection -- collection time. This is -- compressed into a six-week period per plant.

We know that flocks that have been identified as highly salmonella-infected antemortem -- in other words, hot flocks in the field. These birds have been associated with clearly increased carcass contamination at processing, and this is very well documented at this time.

The authors have good reason to believe seasonal and intermittent patterns of salmonella infection of broiler chickens may be occurring in the field. We certainly see this with a lot of plants, and there appears to be a -- in many reports.

With these -- considerations in mind, the authors suggest that salmonella data for this set of 16 plants are inconclusive and that more seasonally balanced data should be considered, as discussed -- as I will discuss in a few moments.

Our last question, we were asked to consider the additional data provided for this analysis, including the FSIS organoleptic and Pathogen Reduction

HACCP microbial verification data for young chicken establishments participating in HIMP and national salmonella Pathogen Reduction HACCP verification data for young chickens.

Our team focused really on the salmonella data. It's probably the most important. We did not have any specific information related to design or methodology, but I think it's pretty clear to the review team that it's pretty much the 21 plants that -- that continue to compare to the baseline data from these 21 plants.

The FSIS Pathogen Reduction HACCP data, current to September 30th, 2002, related to salmonella recovery from 21 establishments operating under the traditional system and 21 establishments operating under the HIMP models system were provided by plants and in summary form for review. These data reflect rolling consecutive sampling dates representing at least 51 working days which in fact translates to approximately two months.

Therefore, the potential effect of seasonal bias is reduced by this expanded time frame of sample collection as compared to the -- RTI-collected data for salmonella. In this case, the salmonella prevalence in sampling from plants operated under the traditional

system, eight percent, is not significantly different than the prevalence in samples from plants operating under a HIMP system, 8.2.

Furthermore, of the completed sample sets, 94 percent of plants operated under the traditional system and 96.9 percent of the plants operated under the HIMP system passed the testing criteria.

These data suggest that implementation of the HIMP system does not affect salmonella recovery frequency -- that these 21 plants operating under the HIMP models system be considered with a focus -- operating under the traditional system in the near future. This is really the only -- category that I think needs to be addressed, and the review team agrees with that statement.

The experimental design is generally appropriate for a field study of this nature. And the methodologies employed generally allow for interpretation and comparison of these systems. Overall, adoption of the HIMP models system has clearly improved certain scores related to the more important organoleptic parameters described as FS-1, septicemia and toxemia, and Food Safety category 2, fecal contamination, and has markedly reduced contamination of carcasses with generic E. coli as a generally-

accepted parameter related to plant hygiene and process control.

Adoption of the HIMP models system has also resulted in improvement of scores related to OCP-1, animal diseases, and OCP-2, miscellaneous conditions, and OCP-3, ingested contamination -- ingesta contamination. That has resulted in slightly increased scores for dressing defects, OCP-4 and OCP-5.

Salmonella recovery seems to be increased in plants inspected under the HIMP system when the smallest data set available was considered but less so when the larger data sets were considered, 16 plants. Although it can be argued that inclusion of the five replacement plants not included in the baseline study is a potential bias in the study, there are no founded reasons to exclude these plants from consideration.

While not impossible, the authors are unable to identify any -- any factor -- we can't -- we can't find any factors that we think would be associated with the HIMP system that could be responsible for increased recovery of salmonella. And the bottom line is, we don't really think that there is a significant -- a meaningful -- salmonella.

Seasonal or random influences affecting the salmonella data set collected in a single short time

frame may provide the best hypothesis for why we saw an increase in -- significant increase in salmonella recovery from the 11 -- original 11 plants operating under the HIMP system. This hypothesis is supported by lack of consistency of this data with the more recently generated FSIS data comparing the 21 plants under the traditional system and 21 plants under the HIMP system with data collected over an expanded time frame.

The authors strongly suggest that these data be carefully further evaluated and considered. And what we're talking about there is to, perhaps, look at the ongoing sampling to select appropriate control plants based on plant size and geography and make the comparisons with data that's already been collected.

Nevertheless, we feel that the data as presented would argue that implementation of the HIMP system is not contributing to salmonella contamination. Conversely, at this time there is no evidence that implementation of the HIMP system is reducing the incidence of salmonella recovery from chicken carcasses.

So it may not be all that surprising, if you look at the biology of salmonella. Where the bird comes into the plant, perhaps this -- salmonella incidence recovery.

In addition to these -- the authors also reviewed the Government Accounting Office document which commented on the results of this project in 2001. In general, we found the conclusions and recommendations of this report to be confusing, inconsistent, sometimes contradictory, and frequently inconsistent with the methodologies employed and data generated by this study. The bottom line is that we did not agree with the report at all. And we suspect that perhaps the people completing this report didn't really understand the restrictions and limitations of doing a field study of this nature.

The first -- this is a list of a few of the specifics. I pointed out that, quote, "The chicken pilot that the USDA designed lacks a control group." The principal criticism here appears to be related to the fact that multiple factors were simultaneously changed as the HIMP system was adopted. The review team believes that this criticism does not take into account the concept that it is in fact a system and that this -- that -- that's being evaluated and that constant adjustments to varying conditions is in fact the goal of a HACCP-based system. There are going to be multiple factors in terms of comparison.

If it is considered that systems and not who

did the inspections were compared, the controls are indeed appropriate for a study of this type.

The second major GAO criticism is, quote, "The plant -- the chicken plants that volunteered to participate in the baseline measurement phase of the pilot were not randomly selected, and they did not include plants from all chicken-producing areas or plants of all sizes." The plants -- end quote.

The plants selected represent the states supplying the majority of domestic chicken production. And the size range for the plants included in the study are representative of the majority of chicken slaughtered in FSIS-inspected facilities within the United States. We're basically not buying those arguments at all.

The third major GAO criticism of the study is the claim that, quote, "The pilot project's methodology did not take into account variables such as seasonal changes and plant modifications that could affect project results. For example, after the project began, many plants added antimicrobial rinses and washers, which usually reduce the levels of microbial contamination," end quote.

Indeed, seasonal related salmonella levels and compressed sampling times for microbial

surveillance could indeed be a factor limiting interpretation of this specific parameter. However, the addition of HACCP-based interventions during HIMP model implementation was in fact a goal of the study.

The fourth and final major GAO criticism of the study is, quote, "The pilot project did not include features of the modification -- modified inspection systems in Australia and Canada that would be important considerations in ensuring the successful implementation of a modified inspection system nationwide. For example, during the pilot project, USDA did not require the training of plant employees." While the review team does think that training is important and we do believe that FSIS should provide regulatory oversight and to require specific training for, you know -- but in terms of answering this criticism of the project, this statement in terms of no training is not consistent with the review team's understanding of HACCP training that was occurring prior to and during implementation of the HIMP models system. We know that there was a lot of -- of HACCP training that was going on out in the field.

Nevertheless, if training were inadequate prior to implementation of this project -- this is kind of an interesting observation -- this would serve to

enhance the relative effectiveness of the system and argue that improvements could be made with increased training.

So we're not completely buying the argument, but it would seem that that argument actually argues for the HIMP models system as compared to the traditional system.

Of special interest in the GAO report were the responses to the GAO's survey of USDA inspectors and veterinarians as related to this review. Of the 210 inspectors and veterinarians surveyed, 71 percent indicated that product safety was the same or better under HIMP -- under the HIMP system as compared to the traditional system. And 57 percent indicated that product quality was the same or improved.

The review team agrees with the majority of USDA inspectors in that safety and quality of young chickens inspected under the HIMP system was either the same or improved.

In final conclusion, the review team urges continued FSIS oversight and continuous reevaluation of HIMP is more broadly implemented. At this time, no convincing arguments were identified which indicates that adoption of the modified system under regulatory supervision would increase risk. And thirdly, the

authors find that there are several lines of evidence that strongly argue for process improvements from the consumer perspective as related to adoption of the HIMP system.

And that concludes our report. And as I mentioned before, I believe Dr. Curtis will be available to, hopefully, answer questions that your group may have for her with regard to the activities and findings of the review team.

Thank you very much for your attention, and it was an honor to do this. And I wish I could have been here in person to present this to you. Thank you.

Questions and Answers

MS. AXTELL: At this point -- call to connect Dr. Curtis. She had a time window open between 11:30 and 12:30. So we are -- we are attempting to -- to match her schedule with ours and being able to have questions from the committee directed to her. It will take a moment just to make sure that she can hear us.

(Pause)

MS. AXTELL: Dr. Curtis, this is Jeanne Axtell, one of the co-leaders of the project. Can you hear me from this point in the room?

DR. CURTIS: I can't hear very well.

MS. AXTELL: Okay. We'll come over.

(Pause)

DR. CURTIS: Yes, that's much better. Thank you.

MS. AXTELL: (Inaudible). And in addition, -- the advisory committee members here today, there are a number of FSIS and USDA officials. Dr. Murano. He is the undersecretary for Food Safety. And Dr. Pierson, the deputy undersecretary for Food Safety. FSIS administrator, Dr. Garry McKee. The associate administrator, Ms. Linda Swacina, and a number of other -- project officials.

Dr. Curtis, are you ready for questions? We have just completed viewing Dr. Hargis's video presentation.

DR. CURTIS: Okay. I'll give my best answer to the questions. Don't guarantee I can answer all of them, but.

MS. AXTELL: Thank you very much. First question from the advisory committee? Ms. Foreman?

MS. FOREMAN: Thank you. Can you hear me?

DR. CURTIS: I can, yes. I can hear you now.

MS. FOREMAN: Okay. The -- this is Carol Tucker Foreman with Consumer Federation of America. Dr. Curtis, I'm -- I'm looking at the language in this report, and I -- I've never seen a report, a scientific

report, that -- I don't understand the scientific nature of some of your language, and I'm going to give you some examples. You describe the study as, quote, "quite meaningful and useful," close quote, as having tremendous merit, as being a real-world comparison, these flags are possibly overcome by, and the -- determined but the methodology was generally appropriate.

I -- I don't find that to be quantifiable language. It doesn't seem quite scientific to me.

DR. CURTIS: Dr. Hargis put the report together. The exact language you would have to address to Dr. Hargis.

The general consideration that the committee had was that the report was looking at it from -- that the committee was looking at it from a practical study. It was -- you -- we felt you got much better results in a real-world situation as far as what was going to happen in the plants on a day-to-day basis versus what you would have if you had all the factors controlled like you would in a regular laboratory setting.

MS. FOREMAN: And that -- that accounts for "quite meaningful" and "tremendous merit." And I do understand that application, "real-world comparison. However, do I understand that you had nothing to do

with writing the report, you just did --

DR. CURTIS: We -- all the committee members submitted in their individual reports, and Dr. Hargis put them all together.

MS. FOREMAN: Well, I'd like to ask him questions but he's out of the country and the committee is unable to address questions to him. Thank you.

MS. AXTELL: Next question from the advisory committee? Ms. Eskin?

MS. ESKIN: Can you hear me?

DR. CURTIS: Yes.

MS. ESKIN: I was hoping you could address what was identified as, quote, "the primary statistical flaw in the data." Could you elaborate on that?

DR. CURTIS: That was Dr. William's comment. The -- the flaw that I'm aware of had to do with the condensed six-week collection of the salmonella tests and the fact that there was two years between the baseline and the data collection for the HIMP studies.

MS. ESKIN: I believe there was also some discussion of a lack of a control group. Was that also identified as a flaw?

DR. CURTIS: No. Not that I'm aware of. Dr. Williams may have identified it, but I don't recall that in our discussion.

MS. AXTELL: Thank you. Next question? Dr. Lafontaine?

DR. LAFONTAINE: Yes. This is Dr. Lafontaine from South Carolina. In your review of the GAO comments about training, if I understood your conclusions properly, in essence, you agreed with the GAO recommendation that there be -- for the plants that there be a baseline training so that they can adequately execute their mission. Is that a fair assumption or fair interpretation of what your group says?

DR. CURTIS: That's correct. We -- we support the training of the plant personnel. We think that could only improve the -- the effectiveness of the HIMP program.

DR. LAFONTAINE: I want to add an editorial -- not an editorial but an additional comment that I've made before. And that is, these plants volunteered, and so one would assume that they're proactive in what they do to include training. And I think it's critically important that if this is expanded to -- into any mode eventually that that be a clear-cut element so that all plants involved have a clear understanding that they have to have an adequately trained group of folks performing these

essential tasks.

So thank you for your comment.

DR. CURTIS: That -- that is -- that is what the committee supports, is -- is full training. They thought that based on the training they had -- the plants had put forth into the HACCP was much more than what was originally anticipated. They would anticipate that there would be significantly more training in the HACCP -- I mean, in the HIMP training as well.

MS. AXTELL: Thank you. Next question? Dr. Johnson?

(Pause)

MS. AXTELL: The delays you're hearing, Dr. Curtis, are people moving closer to this conference table so that you can clearly hear their questions.

DR. CURTIS: I appreciate that because some of them it's very difficult to hear.

DR. JOHNSON: Hey, Dr. Curtis. Alice Johnson with the National Turkey Federation. And I think we do want to -- thank you for setting up your schedule and doing this for us. I know it's a little hard to hear sometimes and hear the discussion.

I also think that we need to say "thank you" to Dr. Hargis for going to the effort to do it. It is regrettable he's not here, but he did put together a

good video presentation for us.

I just was wondering about some of the comments in the report. We talked about -- during the last advisory committee discussion, we had a lot of discussion over the 11 that were originally -- the 11 that -- the 11 that were originally baseline and then the information taken after HIMP implementation on the 16 plants, that there were -- the difference between the baseline that started -- the plants that started in the initial baseline and those that remained after HIMP implementation.

Can you make any comments on that?

DR. CURTIS: When we talked to the statistician about that, that was one -- one of the questions that we asked. And the conclusion was that, ideally, you know, it would have been great if you would have had all of the plants at the beginning and at the end. But in most biological studies you rarely have in a statistic set all of the things you started out with. So that was not as big an issue on this.

And we looked at everything. We looked at the 11 plants and we looked at the 16 plants. And it was the conclusion of the committee that that was not a problem with the study and the conclusions from that. The only issues that really come to question when you

looked at the 11 and the 16 plants dealt with the salmonella data. And then there were -- there were -- we had other comments to follow up with the salmonella data.

DR. JOHNSON: One more here. Somewhere in here, and I apologize because it was -- it was kind of -- you talked about one of the alternatives would have been -- at the project design would be to look at split lines.

DR. CURTIS: Ideally, that would have been a way to do that. But you're still going to have some changes if you're operating in a real-world HACCP system, as we all know, that if we recognize -- for a HACCP system to work when you recognize there's an issue, you correct that -- that problem.

So we think that there would still have been changes in a real-world situation with HACCP lines operating. You might have -- you would reduce some of the factors by having the split line operation, but you don't have enough of a split line operation possibility, we thought, to really get the job done as far as the research for -- for the HIMP study. We thought that using the different types of plants that were used added some validity to the study.

DR. JOHNSON: Thank you. I definitely agree.

It would be hard to say that a split line would -- would reflect the traditional --

DR. CURTIS: The other plants, yes.

DR. JOHNSON: Yeah, with the changes that we've already made with HACCP and the changes that just are inherent in the whole process.

DR. CURTIS: The committee thought that the additional plants that were added just added some additional support from the standpoint of how this would work in other types of plants and other types of situations.

DR. JOHNSON: Thank you.

And while I have the microphone, I did -- I think Dr. Aman and Dr. Calloway, we -- the committee would also like to thank you guys for trudging up to D.C. and sitting through this. So thank you very much for your remarks.

MS. AXTELL: Thank you, Dr. Johnson. Next question?

(No response)

MS. AXTELL: -- we have any further questions. And we think we are ready to move on to the next phase of the discussion.

So, Dr. Curtis, if you would like to say anymore to this that would be able to kind of -- issue

at the moment?

DR. CURTIS: I don't think I would be able to hear most of it based on what I've heard, so at this point I think I'll just hang up and -- and look for the minutes of the meeting.

MS. AXTELL: Thank you very much, Dr. Curtis. Again, we really appreciate the fact that you made time available within your schedule today and we do appreciate that Dr. Hargis took the time to put together the video presentation for the --

DR. CURTIS: Okay. And I know that Dr. Hargis spent many hours putting that together trying to get -- pre-guess what your questions might be and include them in the presentation. Thank you.

MS. AXTELL: Thank you again, Dr. Curtis.

DR. CURTIS: Bye-bye.

MS. AXTELL: Bye-bye.

Next Steps for HIMP

MS. AXTELL: In terms of the next steps for the HIMP project, I know there had been a great deal of concern expressed by the advisory committee at its last meeting in June with respect to the 11 plants that had been in the project from the beginning and the 16 plants whose data was presented at the last advisory committee meeting.

I wanted to advise the committee that the additional materials that were provided today are the summary data for the 11 plants that have been in the project from the beginning done in two formats. One of the packages says, "Aggregate Establishment Data." That represents the data summarized in the same fashion as the data provided at the last advisory committee meeting for the 16 plants.

The other request that had been made by the advisory committee at its last meeting is that the data for the 11 plants that were in from the beginning be profiled plant -- on the positions on the chart, Plant A to Plant A, Plant B to Plant B, rather than in the format at which it was presented at the last meeting, which is best scores to worst scores for all plants within a group.

So I wanted to let you know that the other handout that has the individual establishment data in fact compares the data, Plant A before, Plant A after. And the positions shown on the chart run continuously for each of those plants.

For clarity purposes, there is also a handout that identifies each of the plants that are in the group of 11, in the group of 16, in the group of 21, so that there would be no question about which plants are

referenced in which categories. Even in the group of 11, there is no identification to plant name or number. Again, RTI had shared all its raw data for the 11 plants with the National Alliance for Food Safety for purposes of their conducting their work.

We asked that RTI prepare the summaries, as you see them, in the same fashion in which they were prepared for the last meeting so that you would have a complete and comparable display of data from all data sets. Again, they prepared it. I cannot tell you who Plant A is. And that was in -- done intentionally. The data remains blinded to the Agency.

From the Agency's perspective, we believe that the review from the National Alliance for Food Safety, the conclusions of the review, indicate that adoption of the HIMP models system has shown clearly improved important scores related to the most important organoleptic parameters described as FS-1, septemia -- septicemia and toxemia, and FS-2, fecal contamination, and also notes markedly reduced contamination of carcasses with generic E. coli, which is a generally acceptable parameter -- or generally accepted parameter related to plant hygiene and process control.

Further, there were improvements noted in OCP parameters 1, 2, and 3, and with respect to animal

diseases, miscellaneous conditions, and ingesta contamination.

There were increases with respect to OCP-4 and -5 noted after the introduction of the HIMP models process in the volunteer plants. And again, we do have the data with respect to salmonella, that the salmonella numbers were increased, particularly in the data set for the 11 plants, also in the data set for the 16 plants, although less noticeably.

Again, the National Alliance for Food Safety noted the issue with respect to the compressed time frame on the data collection and the issue of seasonal variation and the issue of the antemortem salmonella infection rate of flocks being brought in to slaughter, which may be contributing factors. They did not find a basis to say that the HIMP inspection process either contributed to reductions or increases with respect to the salmonella.

I think it's important to note -- the Agency noted in its review -- and I'll be brief because we've only had the report a few days -- that all of the plants that are operating under the HIMP project have been meeting food safety and OCP performance standards that were set for this project that are -- that are tighter than the standards that are presently in place

for non-HIMP plants.

And even for the OCPs that showed some increase in defect scores from the baseline to the models phase of the project, still operated within regulatory requirements for non-HIMP plants. That does not mean we are satisfied with the direction of the numbers, and we need to know more about that direction. This is particularly true for the fact of the increased recovery rates of salmonella on carcasses for all of the data sets.

(Pause)

MS. AXTELL: What are the things that the Agency is doing in part and considering doing in part to address the issues that have been identified and where there are still some questions about the data. Dr. Santiago, at the beginning of this presentation, mentioned that the Agency is looking at revising the current instructions for young chicken plants which are known as Draft 6 and moving to Draft 7.

In part, one of the issues that we will be looking at in that Draft 7 is the use of statistical process control, which is also a recommendation that the GAO had provided to the Agency nearly a year ago now, with respect to having parameters for the Other Consumer Protection performance standards, the OCPs, in

order that we can clearly identify regulatory actions that can and should be taken when there is -- are repetitive non-conformances in those OCPs.

We think that that is an appropriate response for the Agency to make with respect to making further modifications in the instructions and guidelines for the project such that we can determine if there are appropriate means by which we can establish regulatory control over those activities where the data is moving in a direction still within existing regulatory requirements but in a direction we would prefer it not have gone in.

I would also like to say that with respect to salmonella we are looking at some options. The National Alliance for Food Safety, both in their written report and in the video presentation, made note of the fact that the Agency needs to look at controls, perhaps looking at the data from the 21 plants that have been involved in the HIMP project, looking at a certain number of other control plants, and examining salmonella data over time with respect to providing a greater degree of assurance that the HIMP project itself is not contributing to the increased recovery of salmonella. That would permit a focus on the issue of seasonal variation so that we can look at that issue

more closely.

Again, the Agency remains committed -- I should say for the record that the Agency did not request that the National Alliance for Food Safety provide a critique of the GAO report. But the GAO report is a public document and was one of the documents provided to the Alliance for purposes of its work.

Most -- of most concern to the committee has been the issue of the -- of the -- or to the Agency in this regard had been the question of study design. Was the study design, conducted as it was in a real-world setting, a appropriate means by which to make a comparison between the traditional inspection system and the HIMP inspection system. We believe that it was, and we were pleased that the Alliance found that as well.

The Agency remains committed to following through on the recommendations presented by GAO which specifically are that we have appropriate criteria for plants entering the project; that we focus on the use of statistical process controls for quality defects; that we look at mandatory -- mandating some aspect of formalized training for plant personnel; that we look at ways to increase communication with participants in

the project with our own workforce and with stakeholders involved and interested in the project; and that we do in fact have a basis for the use of this study design as a means of being able to move forward with the project.

Again, in summary, we are -- the data are what they are. We recognize that there are some very favorable data that have come forward from this project. We have approached this project from the standpoint of saying it is a comparison between systems, which means that we are looking at the overall -- assuring that we do not diminish the accomplishments overall of the traditional system. And that means that we want to be able to have a system that has data or data from the system that demonstrates improvements at least equal to but preferably improvements in food safety and public health concerns.

There are improvements that are here. We do not wish to turn our back on those improvements because we believe that they are in the best interests of food safety and public health for the consumers of poultry products in this country.

We know that we need to do more with respect to engaging our supervisors and managers in the project. We need to -- need to do more with respect to

statistical process control where appropriate, to ensuring that we have effective tools for accountability for plants participating in the project and for ourselves.

It has been about assuring that both inspection personnel and plant personnel understand our expectations for the conduct of the pilot, and those are principally the reasons we are looking at revisions of the existing Draft 6 and moving to Draft 7.

At this point, I'd like to open this up for questions from the committee. And I believe Dr. Johnson had the first question.

Questions and Answers on HIMP Presentation - Panel

DR. JOHNSON: Alice Johnson, National Turkey Federation. I know that there are -- are several industry folks here that are involved in HIMP. And I think that everybody will admit there's no perfect system. But I just wonder when we -- when we have our question-and-answer panel if it would be appropriate to pull some of the folks that are -- that are in HIMP facilities into part of the discussion as well?

MS. AXTELL: Is that acceptable? Yes. Yes. I think we are at the question-and-answer.

DR. JOHNSON: Oh, oh.

MS. FOREMAN: Are these public people who are

sitting out in the audience like those who only got three minutes to speak yesterday?

DR. McKEE: I think what we can do is to hear from the panel with questions from the -- from the advisory council. And we're running a little ahead of schedule, so we could have some questions from the audience that might want to address some of those issues for a short period of time as well.

MS. FOREMAN: Could that be open to all the members of the audience?

DR. McKEE: Well, we can just address the -- the members of the audience, regardless of --

MS. FOREMAN: Thank you.

DR. McKEE: -- of where they're from.

MS. FOREMAN: Good, good.

DR. McKEE: But this -- I will limit the time on this.

MS. AXTELL: Mr. Govro?

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. My experience with HACCP is in a regulatory environment where there is no continuous inspection. Might refer to that as a self-directed HACCP environment. And I think it's fair to say that HACCP has been more successfully implemented in firms where there is a high level of commitment to excellence

on the part of management and there is good management.

And I'm wondering about the farms that were involved in the study and if there was any screening of those firms or any method by which USDA evaluated the -- the level of competence of the firms that participated in the study? And I -- and I ask this because if we're looking at HIMP as a possible model for use in the entire industry, I think there may be varying degrees of success based on the companies that -- that participate.

MS. AXTELL: Thank you, Mr. Govro. I'd like to direct this specific question to Dr. Ken Peterson and with respect to the criteria for plants entering the project. And then I would also like to ask Dr. Calloway to comment with respect to situations where there have been -- there has been a need to take enforcement action in a HIMP plant.

DR. PETERSON: What we did for -- when we requested volunteers -- this really goes back to '97 and '98. And it was open to any plant that was interested in participating. They came forward with their name.

And then what we did was look at the -- several things related to that plant. We looked at their -- at the time, their salmonella compliance

history under our Pathogen Reduction initiative. Were they in compliance. And if not, then we didn't consider them eligible at that time.

We looked at their recent enforcement history. Had there been any suspension or other enforcement type actions taken related to their HACCP plant or their SSOP plant. And again, if -- if -- if that was the case, we didn't consider them to participate.

When we looked at them, the ones who volunteered knew that criteria. So I don't think we had any volunteers that were -- that were under those particular levels of scrutiny.

So, bottom line, we looked at those things. We made sure they were within compliance. They were. And then they stepped forward and -- and we took them in.

MS. AXTELL: Dr. Calloway?

DR. CALLOWAY: Again, I can speak only for my circuit, but all the applicable rules of HACCP are applied to the plants within the circuit equitably. Because it is a HIMP plant, it's not -- it's not given any special privilege.

And so there was a time in this facility that we felt that they were exceeding the FS-2 fecal

contamination levels and certainly were exceeding them above what the -- the norm within the circuit was. This resulted in me issuing a 30-day letter to this facility. And had they not taken appropriate steps to bring the facility back into compliance, to an acceptable level, we would have progressed on with regulatory action as applicable under the rules of practice. They did respond favorably and, as a result of that, did go to installing an antimicrobial rinse on the lines and to bringing in an expert -- outside expert to do an in-depth audit on their plan, their HACCP plan, the implementation of the plan, and to train their supervisors.

So merely being a HIMP plant didn't give them any special privilege, and -- and they are treated the same even though they do respond to a higher level of regulatory standard in that plant.

MS. AXTELL: Thank you. Dr. Jan?

DR. JAN: Lee Jan, Texas Department of Health. My question is more on a technical nature. And it goes back, and maybe I should have known this several years ago but I need to ask it again anyway.

Regarding the RTI's results and looking at the end of the line, I'm -- I'm satisfied that the results at the end of the line are better and -- and

the review gives me confidence in -- in the overall results. But I -- I'm a little concerned and maybe need some clarification from a technical standpoint on the process for Food Safety 1. When you move the inspectors to the end of the line -- and I don't have poultry slaughter establishments in my area so I'm not -- there may be a technique that I'm not aware of.

But it seems to me that when you move the inspector to the end of the line and you take away the opportunity for the inspector see those organs that may indicate septicemia or toxemia and then they may not be able to pick up on it at the end of the line, looking at only a carcass.

Now, I know in red meat and in the livestock portion, the internal organs are important to identify that disease condition. Is that the same in poultry? Or how -- how is that -- is one assured that it's not being missed in this process?

MS. AXTELL: Dr. James?

DR. JAMES: That question was one that was discussed extensively at the beginning of the project amongst subject matter experts within the Agency and outside the Agency.

We had quite a concern that -- that carcasses when they're looked at at the end of the line and don't

have the viscera associated with them, that we had quite a strong level of assurance that our experts, our inspectors, would be able to determine whether those birds indeed were septicemic and -- or toxemic.

And the subject matter experts that were consulted were virtually unanimous in that in young chickens, a septicemic, toxemic bird could be identified at the end of the line without the associated viscera. So that is -- that is a question that received great attention before the project was begun at these plants.

MS. AXTELL: Thank you. Ms. Donley?

MS. DONLEY: Thank you. Nancy Donley from STOP. I actually have two questions, and they're two totally unrelated questions.

One is, I believe, Jeanne, I heard you say that -- that 70 -- that because of HIMP that it allowed 70 inspectors to be redeployed to do other food safety inspection functions within a HIMP plant or to fill vacancies in a -- in other slaughter plants. Do you not have the breakdown of numbers there of what went to what?

MS. AXTELL: No, I do not. I'm just relating to data from the initial group of 15 -- 15 plants that participated in the project.

Again, whether the inspector was -- was doing other work within the plant, certainly the work within the plant was redefined by the HIMP project so that the focus of -- inspectors' time within the HIMP plant is more -- there is more attention devoted to food safety issues.

Additionally, by being able to redeploy inspection personnel from the plants, we were able to fill critical slaughter vacancies that were occurring within the local commuting areas of a number of the HIMP plants. The poultry industry over the early years of this project has continued to grow at a fairly steady rate each year.

MS. DONLEY: Okay. I think that's -- it's a critically important issue because at the onset of this project the only reason that, you know, my organization was -- were all receptive to the idea of HIMP was with the understanding that it would -- it would free up inspectors to do additional food safety activities within the plant and not to fill vacancies as they occurred nor would it in any way serve as the tool to decrease the size of the inspection force.

I -- this is -- it's an editorial comment with this project, and -- this is kind of my last hurrah on this since this is my last term. But our

members of Congress see this -- see this project as an opportunity to cut back on inspection staff, to cut the numbers, and this will defeat the purpose of the HIMP project, which was to improve food safety by increasing food safety inspection functions.

I am very concerned that that's the direction that this project is headed.

Also, having served on this committee from the inception of HIMP, I find it very difficulty today even to determine what successes that -- let's just say for the moment that -- that the numbers at the -- that have come out of these studies show a clear improvement for food safety.

I have a hard time justifying and rectifying what we heard from Dr. Aman today and Dr. Calloway that these plants -- and my own personal visits to HIMP plants where I have seen incredible plant innovations, technological innovations. Dr. Calloway, you mentioned that the plant did -- did a renovation. And Dr. Aman, you said too that they did -- that the plant did additional improvements within it.

How do we justify these improvements to a change in the way and the positions the inspectors are on the line? I don't see how you can clearly separate the success of this project from the way inspection is

being done to the way that the plant is being allowed to perhaps do some improvements of their own.

And I have said -- and I have talked to other plant -- plant -- plant managers and -- and companies that may not even participate in HIMP right now that just want the opportunity to do some of these innovations and technologies that we've heard about today. And under the traditional system, would we still see these improvements?

I'm also concerned if we open the door to let anyone and everyone who is into HIMP who wants to be and who don't implement these technologies. And a good majority of these plants, to my understanding, have implemented some really state-of-the-art innovations. But what it's going to do is just change the inspection and it's going to water down these successes until, frankly, we are going to be in a worse state than we are under a complete traditional inspection system.

I hope not. I would love to see -- I -- I -- I support innovation. My organizations support innovations, both technologically, both from FSIS to -- to constantly reassess what it is you're doing and how can you do it better. But I cannot, over these -- these years that I've been here and over what I've seen today, be able to say -- and I -- I challenge FSIS to

say, we can arbitrate all these changes because we've moved inspectors from this point to that point and that all of these new technologies that these companies have implemented have nothing to do with it.

MS. AXTELL: Just one comment before we move on. We have maintained the level -- the employment level of inspection resources throughout the duration of this project. So that -- there has not been a decrease in the number of inspection personnel, and that in fact for the inspection activities in the HIMP plants, many of the food safety tasks are actually done at an increased frequency level in these plants than we are able to perform them in a non-HIMP plant. And that is, we believe, an appropriate redirection of their resources.

Ms. Foreman?

MS. FOREMAN: I'm Carol Tucker Foreman with Consumer Federation. I have three issues I'd like to raise.

The first one, I'm sorry that Dr. Murano and Dr. Pierson had to leave because the first one is really not to this issue specifically but more generally.

We didn't get -- as I complained earlier, this is a very important and very complicated issue.

And we got no advance paper. We got to peel the plastic off of it. I can think of a lot of reasons why that should happen. There's always a reason why papers don't get delivered on time. But I don't know how you can expect the committee to deal with an issue this important and this substantive when you give us the papers within the five minutes before presentation begins, do not have the author of the paper present to give -- to talk and defend the paper, and is clearly the primary author.

I found that that's entirely consistent with a change in attitude toward the committee. That's why I'm sorry that your two principals are not here. You've moved it over to Public Relations. The papers have become increasingly last-minute sort of thing. And only when pressed do we get the papers that will make a subject be covered adequately.

I -- it seems that the Department does not value the work of the committee as it has in the past.

The second point that I'd like to make is -- is also more general. We hear a lot about FSIS wants to be science-based. We're going to have a science-based system. And as you know, I think that's terrific.

This morning I've been hearing a new word --

a new term called "real-world." I don't find that those two mesh very well. I may see the world in a very different light than you see the world. "Real-world" is subjective. It's not science-based.

I frequently see that victims of foodborne illness are dismissed because they -- their comments are anecdotal. But you bring us two inspectors who give us anecdotal information.

So you're either science-based or you're real-world-based, and in my view, real-world is usually subjective. I see it differently than you do.

Third, since this is my last time I want to offer you some friendly advice. Nancy and I and some other consumer people have been supportive of HIMP -- of HACCP and of HIMP at no small expense to ourselves. In my organization, we vote on our policy positions, and I have had to defend HACCP and HIMP in our annual meetings. And it hasn't always been an easy thing to do.

I would like to have a risk-based system so I would really like to be able to reallocate these resources based on risk. But I can't do it, and my organization won't do it. And I think I speak for a lot of other consumer organizations. When you try to make such a basic change based on material that isn't

just without question good data. You can't back into this with data that are challengeable. You can't -- back into it with a kind of apologetic, "well, you know, maybe we wouldn't have done it exactly this way ourselves" sort of review that you've got from these people. It won't fly.

Now, you may think that because of the current political situation you can push this through the Congress. But I'm going to tell you that the Agency's credibility with the public is pretty damn low after the last three months. I think you're spitting in your own soup if you try to push this forward without going back. It would take so much less time and it would cost so much less money to go back and get it done the right way before you move forward because the way things are right now, the next time the inspectors union goes to court and sues on this issue, Consumer Federation of America will be with them. And I would hate for that to be the case.

I think those are probably my final words to you.

MS. AXTELL: Thank you, Ms. Foreman. Mr. Link?

MR. LINK: Sorry. I dropped my card. I forgot.

Maybe this isn't the right time to ask this question, but I'm thinking about moving forward. Can you talk about where you are? You've got 21 chicken plants in the program right now. Are there more waiting in the wings? What's happening in turkey and pork and beef? Are you familiar with the status on that?

MS. AXTELL: Very briefly, we -- we do have a couple of plants that are swine plants that are participating in the project. And in fact, earlier this week we met with representatives -- several of us met with representatives from those plants and from additional plants that are interested in coming into the project. We are proceeding on -- on that side as well.

There also are two -- two turkey plants -- correct me if I'm wrong on the numbers here -- that are also participating in addition to the 20 young chicken plants that are in. There were 21 over the total course of the project, but one has dropped out. So there are only 20 in the project.

We are hopeful at some point of being able to have five swine plants engaged in the swine portion of this project and five turkey plants. We believe that we need, given the size of those two industries, we

will need data from five plants -- five market hog plants and five young turkey plants in order to proceed with making determinations on those two species.

Ms. Kaster?

MS. KASTER: Two questions. My first question is for Dr. Aman and Dr. Calloway. What was the mindset of your inspectors, excuse me, before you started into HIMP? Were they apprehensive, as we've heard that many inspectors are, and then they've become more positive about it, as you guys described? Or were they always pretty open to it?

DR. AMAN: Any time there's a change, you know there was some apprehension. They knew the duties were going to change. But I think they were enthusiastic about what they could see. I actually spoke to or saw several people that came to the plant, initially told them what their new roles would be, and they became very excited about it. And of course, that just was a competitive type situation. Had to vie for promotion to get these positions. So it's gone over very well.

MS. KASTER: My second question is, the group from GAO that reviewed the -- that -- in the report that was referenced, what do you know about the -- the technical background or makeup or familiarity? You

talked a little bit in the -- in the response. I'm wondering about the familiarity with the group from GAO. Do we know, are they statisticians? Do they have some familiarity with how this was set up? Just -- maybe I'm the only person in this room that doesn't understand how that goes, but if somebody could just walk us through that a minute, that would help.

MS. AXTELL: I actually -- I do not know the academic background of the individuals who participated in that particular project. I know yesterday two representatives from GAO were present in the room. I do not see them here today. So I really cannot comment on the -- the background of the individuals who conducted the study.

Dr. Lafontaine?

DR. LAFONTAINE: Yes. Just a brief comment. And I'm tacking onto Nancy Donley's comment.

In any species in any strata, there is a whole range of performers when it comes to plants. And I speak from personal experience in my -- my state. Those who -- remember when -- is to do it right the first time. Food safety unquestioned.

The other is that usually it's less than five percent, maybe -- whatever your situation is, that you, unfortunately, have to use command control. It just

doesn't go away. I don't care what system you have.

So my advice to the Agency is, and back to Dr. Petersen's comment, the change based on the GAO report, Dr. Murano publicly stated that it was no longer a mandatory across-the-board but rather voluntary on the basis of the plants, to carry that one step further. Use oral type criteria in making decisions on who -- who can eventually enter this program if it continues to progress because I -- I strongly feel that there is a subset that are going to need strong government presence and enforcement action in any species that you're involved with.

So put that -- my suggestion is, mark that down, as we say, as a must-do as you progress.

MS. AXTELL: Thank you, Dr. Lafontaine. Dr. Johnson?

DR. JOHNSON: I just want to throw something out to the committee. I think that the comment that it would be good to have had an opportunity to read the report and absorb it and -- and be able to talk to Dr. Hargis is valid, although I do recognize the Agency -- the whole review process was a part of the recommendations that were made from this committee in June, that we slow down and look at the data one more time. And so I -- without being too critical of that.

I wonder if the committee would want to try to find when Dr. Hargis may be coming back into the country. And maybe we could have time to read the report and have a conference call or something and be able to -- to have time to absorb the report a little bit and talk to Dr. Hargis directly, if that was something that we would want to recommend as a part of this project.

DR. McKEE: I certainly think that is a doable if the committee would choose to request that. Okay. I see a lot of nods, so we'll -- we'll plan on that. We can have a conference call and have time to absorb the material.

MS. AXTELL: Dr. Leech?

DR. LEECH: Irene Leech. My question is about the companies that dropped out of the project. You know, often in the research that I do, we try to show that the folks who are particularly in an experimental design where people are volunteered, to show that the folks who aren't in it are not different from those that are and that kind of a thing.

Why did folks drop out of the project? And were those companies different from the ones that stayed in?

MS. AXTELL: Dr. Petersen?

DR. PETERSON: Well, briefly, I can tell you what I know about the one plant in particular that dropped out, which isn't much.

They volunteer for reasons of their own. And we don't -- we don't investigate what those reasons are. And so if they drop out, they are for, presumably, business reasons of their own.

I can say the plant that dropped out was not in any particular jeopardy in what they were doing within the project. So for whatever reason, it was not related to that.

DR. McKEE: We -- we have -- we were ahead a while ago but are kind of behind on schedule at this point. What I'd like to do, I think, is we'll expand the time at the end for public comment and include any comments that those in the audience might have to make on this subject as well. There will be a sign-up sheet out front. I think that's the fairest way to do that.

And at this point, we will break for lunch. We're scheduled to come back at -- at 1:30. That'll give us about 50 minutes. So if we can, let's try to maintain our schedule and be back here at 1:30.

(Whereupon, at 12:40 p.m., the proceedings were adjourned for lunch, to reconvene at 1:30 p.m., the same day.)

A F T E R N O O N S E S S I O N

1:41 p.m.

DR. McKEE: Okay. Are we ready to get started, folks?

(Pause)

DR. McKEE: Yeah. Dr. Lafontaine, if you could point out to the full committee what changes you have made in the document from Subcommittee 1 so that we could get a final consensus from the full committee?

DR. LAFONTAINE: You bet.

DR. McKEE: And then we can move on to the next issue. Thank you.

(Slide)

DR. LAFONTAINE: We are showing Question 2 because there was no adjustments to Question 1 except one small typo. So let's concentrate on Question Number 2.

If you start with the -- the bullets, the first bullet, you know, "Training must result in learning." There is a new entry, "Training should also include an empowerment message for field personnel. The goal is to assure employees at all levels recognize they are key players in protecting the public health of consumers."

So that was -- I guess Ms. Donley's not here,

but that was her -- her recommendation on making sure that all levels understand they are empowered to protect public health.

Let me get my thoughts together here.

In the -- the next one was unchanged.

Then we get into the additions to joint training. The first sentence stays the same. And then I've added two sentences. "Example topics." We're talking about job training now. "Example topics would be technical issues such as food safety interventions and foodborne pathogens. Joint training is not appropriate for FSIS enforcement training." So that was the -- how I modified that.

Going to the -- the next item, a new entry that was a suggestion. And that is, "also encourage continued sharing of FSIS training materials with industry." So regardless of what is being put out, even though in some cases it's not appropriate for joint training, to share that with industry so they can be aware of what is being taught to the FSIS employees.

And then, the final change -- let me make sure I got my thoughts together. Yeah.

The final change is where we talk about considering alternative technologies. In addition to the use of land-grant college, we also put in "and

public health agency training infrastructures should be investigated."

And then also, another sentence. "Also input from consumer groups should be considered as you look at the training that you're going to extract from the land-grant colleges and the public health agencies."

So those are the -- the changes. Are there any comments? Yeah, Lee?

DR. JAN: Dan, I have no comment regarding Question Number 2. But when we talked about Question Number 1 earlier, we brought up a -- what we felt was a need to increase the education level of the inspectors entry-level. And I think it would be appropriate to include in this document.

DR. LAFONTAINE: Yeah, I -- Lee, you're right, and I apologize. In fact, my admin assistant reminded me but it still didn't get in there. So we will add a sentence to that effect in Question 1. A recommendation that we -- that FSIS work towards increasing the qualifications -- educational qualifications of their entry-level personnel.

Mr. Chairman, I think that's -- are you going to put it in there? Okay.

(Pause)

DR. LAFONTAINE: Is that succinct enough?

Okay. Good.

Are there any other comments or questions?

(No response)

DR. LAFONTAINE: Okay. I see no comments, suggestions. So let's consider it the full committee's consensus.

Mr. Chairman, do you have any -- Mr. Chairman, do you have any closing comments on this topic?

(Pause)

DR. LAFONTAINE: Dr. McKee, do you have any closing comments before we move on?

DR. McKEE: We'll make this a final, if that's okay with the -- committee.

DR. LAFONTAINE: Okay. Thank you.

DR. McKEE: Okay. Thanks.

DR. LAFONTAINE: Thank you for the opportunity.

(Pause)

DR. McKEE: Okay. I think we're ready to discuss Standing Subcommittee Number 2, Escherichia coli 0157:H7 Developments. The lead on that committee is Mr. -- Mamminga. Excuse me. I'll get it right by the time you leave.

MR. MAMMINGA: Okay. Well, Doctor, you are

not alone in not being able to pronounce my last name. So no offense taken at all.

Briefing - Standing Subcommittee Number 2

Escherichia coli 0157:H7 Developments

MR. MAMMINGA: First, I -- I would be remiss if I did not thank the FSIS support staff that assisted us in our committee. I'm telling you, these people are essential and they just do a really a good job. And they stay until it's over with. And there's -- I'm leaving this committee. I want to make sure that those thanks are handed out.

Dr. -- leaving as far as the issue, but for those who do flip charts and write on computers and stuff, without them we would still be in that room. So my thanks to you on their behalf.

When we first received our agenda and seen that we were going to be discussing E. coli 015:H7 developments, that's kind of a long and broad subject. And when we looked at the issue paper, however, we found that FSIS was asking us for a couple of very specific things and that the in-depth verification review of hazard -- control point systems at slaughter and fabrication plants that supply grinding operations with raw beef materials that have been found to contain E. coli 0157:H7. We were informed that FSIS has not

established a structured process for systematically assessing the HACCP system that these operations that supply raw beef material. And of course, we all know that the industry is being asked to reassess their HACCP system.

So with that in mind, the Agency asked us first, should FSIS target IDV review resources at slaughter and fabrication establishments. And then the next question was, if yes, explain; if it's no, explain.

So the first thing we did was address that first question. And we felt that, yes -- and this starts at the top of our report here -- that FSIS should target IDV review resources at slaughter and fabrication establishments.

We suggested that -- we know that IDV reviews can be done for cause. But looking at this issue, we thought that it would also -- IDV should become two programs to address this question. Automatically, when there is a positive sample for E. coli 157:H7 or human illness occurs, both of which we acknowledge are reactive. However, a random system addressing these questions might be more preventative or proactive. So we said -- and a random system which we thought would be preventative.

It was kind of necessary for us to go through all of our thoughts and processes about E. coli and then keep coming back to this issue. And even though we weren't asked about the next two things, we decided in good conscience we were going to say them anyway.

And that is, a trace-back system is important to help identify suppliers of grinders. Moshi's already taken that typo out of the report. This is difficult logistically because grinder use -- grinders use multiple suppliers to create grinding materials, as in coarse drying bull meat -- trimming.

We went on to say on farm interventions at the producer level should be done as well as interventions at every step along the farm-to-table continuum. FSIS and APHIS need a regulatory structure that can address pathogens that may not affect animal health, in the case of E. coli 157:H7, but do have a human health impact.

And then the committee members went through trying to give you some specific circumstances that might trigger an IDV review. And you can take them individually or collectively or -- or however because all of these things will play a part. And here we have to compliment committee members for really thinking and talking it out and putting their heads together.

But among these things, proactive IDV review triggers, assess more during the high-risk summer months. We're already finding a lot of data out there that there are certain months of the year where there's a much higher incidence than others. Obviously, look at HACCP plan deficiencies and NRs. Prioritize testing at larger volume plants or those that supply multiple grinders. Cross reference the suppliers and positive E. coli testing in a database. Multiple exposures to the database would trigger an IDV.

To have a district manager or consumer safety officer process to help determine IDV appropriateness. The consumer safety officer could review records and -- and trigger an IDV review team, another option.

Random plants selected for IDV based on information by -- gathered by FSIS. In other words, all the information that you gather. Again, to focus on the public health risks. We had a very specific proposal about a standardized testing program and using statistical processes to monitor the prevalence of E. coli 0157:H7 or other indicator organisms. Tests on trim or ground products. Develop a program based on plant size or production volume or based on lot size to determine if a positive test result is -- is a natural variation or out of control.

Sample size selection should be based on organism prevalence, sensitivity testing, and targeted -- levels. Obviously, that might be an option that not all plants would buy into, but it would be an option for them.

Again, going to the other end of the spectrum, target plants that -- that are without preventative measures. Have scientific data available to indicate if an IDV is needed.

And on the next point here, might have been the point -- really, one of the biggest points that maybe we didn't hit it between the eyes well enough. But the statements is, let the industry know FSIS expectations. And since then I have been approached to add, public and inspectors and almost everybody in the process. And that might be one of the more profound statements that came to me. And I'll leave it up to you folks. If you would like to add public, inspectors, along with industry and all those other constituents that you have to let them know the expectations.

And this was brought to us very clearly by a representative of a small and very small and medium-size meat process association, who, I think very correctly, observed that when we started, FSIS had a

perspective or expectation. Industry perhaps had a perspective. Inspectors may have had a perspective. States may have had a perspective. And they have not meshed together as well as they could have if we would have done a better job of clearly stating the expectation.

That ties into what Dr. Lafontaine's group brought up this morning about training and the appropriateness of training people together in the expectations. Then it's not a secret.

But that little -- that one right there probably should be expounded upon a little bit by at least indicating the constituents that we all have in this -- in this process.

And again, the last individual comment, random IDVs could be used to build benchmarks.

Now, all of these things that we have supplied, keep in mind that any one or two or three of them together could be what triggers this -- this IDV review.

But the last statement on here, the Agency should come back to this committee with the proposed criteria for withdrawing inspections if timely preventative measures are not put in place -- into place. Again, those of us that deal with rules of

practice on a daily basis and take actions based under law and regulation, sometimes for our -- all of our constituents, they wonder when does it ever end. When is the last straw. And so it was put in there not to write your program for you but to tell you that I think we'd like some -- some information from you about when is the time to withdraw inspections.

Now, Marty Holmes had some ideas, maybe, for finetuning it. And we'll see if we can get them out slow enough that Mr. Dreyfus can -- can work them in as we go.

I like that, Mr. Dreyfus. I think that's the first time I ever called you that. Oh, well. Be polite.

Marty, would you like to offer your suggestions up?

MR. HOLMES: I'd be happy to. First of all, I want to -- to again with -- thank the staff that helped us last night. We were the last group to finish, and at the very end we were scrambling around to get something on paper. So as I read through this again today, I -- I see the -- there's a lot of red herrings that don't necessarily all tie together here.

So I would like to at least make some recommendations here. And we can kind of shoot them

down as we go.

Obviously, you caught the grinder mistake.

The third -- the fourth paragraph, where it begins, "On farm." What -- I've just drafted some -- some potential language here. Let me just read it.

"Intervention -- intervention research and implementation should occur every step along the farm-to-table continuum." So not only intervention research but the implementation of -- of positive outcomes should be applied, whether it be at the producer level all the way through the farm-to-table continuum. I think that kind of makes it a little more concise and a little more -- we're talking about producers here, but then maybe saying that the -- and other places along the chain.

So I think I would -- I would make that one recommendation to -- to the committee to change that sentence to read, "Intervention research and implementation should occur every step along the farm-to-table continuum." And obviously, just because it's research doesn't necessarily mean we're going to implement it if it's not effective. But that would be one suggestion there.

The next sentence, I've drafted something here. It says, "FSIS and APHIS need better

communication and structure that can help address pathogens that may not affect animal health but do have human health impact." I think that's a little more what we were trying to achieve last night in our -- in explaining that better.

Anybody have any concerns about changing that to read that way? Would that make better sense?

(No response)

MR. HOLMES: Okay. I'll give you that -- motion.

In the -- the proactive IDV review triggers, I think these are more trigger considerations more than they are triggers. Because as you read through those, those wouldn't all necessarily be classified as a trigger or fit into that category. So I think that just considerations for FSIS to look at in making an IDV consideration to send a team in, I would change that to, "review trigger considerations" or even "proactive IDV considerations." I don't know exactly how you want to term that.

We had some -- quite a bit of discussion on bullet points three, four, five, and six. And I'd like to at least let the rest of the committee know where we were going with that.

We had -- some of us had concerns about

testing large plants just because they're large. Others felt large plants made sense because they're producing a larger volume of product, means just a multiple -- multiple customers, that if there was a problem going on there, it could have a larger impact on public health than -- than another plant that might not be as large or producing as much product or have as many customers.

And so we basically said, well, if you do that, you need to -- before you spend all this money -- we were talking about resources yesterday and how expensive it was to do an IDV and those kind of things. And before you go to spend -- spend a significant amount of time and resources and -- and money sending somebody to do an IDV, the CSO or the district manager, somebody at the district level would probably have some indication based on NR information or, you know, actual in-plant experience at that individual plant to know whether an IDV would be appropriate. You know, they have a good pulse on the -- on the plant to know whether or not they're -- they're a good operator and -- or whether there -- there's a legitimate concern there.

So that's basically what those four bullet points were trying to say. If you do -- and it also

comes down to, based on public health risk. The -- the -- the bullet point says, focus on public health risk. That is talking about large plants, but realize, just because they're large doesn't mean -- necessarily mean they're a public health risk. There may be plenty of information to -- before you go to that expense in resources of sending an IDV team out that you may -- may say, no, it doesn't make sense to do that in this instance.

So I'm not sure we've really captured -- captured that the way it was intended last night. So I don't want to give the -- at least the subcommittee's impression last night was not that -- just because it was a large plant, that would trigger an IDV, although that would be a public health risk to consider because of the volume and the potential for multiple customers.

But I want to make sure that the Agency is getting the right understanding from at least the subcommittee's perspective last night.

We also went on to -- to say that if all plants -- so that you didn't have a large-small plant confusion here, maybe all plants that are slaughter operations or fabricators producing trim that are going to be sold to customers, that all of them test -- test for 0157:H7 on their trim to develop some kind of

national baseline, for lack of a better term, of what -- what is actually occurring. And that just because a positive is reached by one -- say, one of my customers, if -- if I've got -- if I'm creating data that shows I'm within -- within whatever is -- is normally found, it doesn't necessarily mean that I need an IDV. There may be a large plant that's way outside the -- the national average or there may be small plants that are way outside the national average.

But maybe actually testing for 0157:H7 on trim at -- at both the packing house and maybe the fabricator level to see what -- what's going on there. So I don't know if I'm making that clear.

And then, this question about target a plant without preventive measures. I'm not sure why we even have that -- that in there because if there's no preventive measures they wouldn't be operating because we have a new 0157:H7 policy that says they do have to have a preventive measure in place. I'm not sure why that bullet point was actually in there.

And then, the -- I had made the same comment here. Let the industry and all -- actually, let all stakeholders know FSIS expectations, which was what Mike was just referring to earlier.

So anyway, those are some draft

considerations that I'd like for anybody on the committee or subcommittee to comment on. And you know, we could have a subsequent motion to give a revision.

Yes, sir?

MS. DONLEY: Nancy Donley from STOP. And I had to leave, as you were all scrambling to get the last few things on paper.

But I just want to go to the -- because I don't want to count all of them -- big -- the large -- on the SPC. We had talked about that as being something that would be an industry-generated process. And -- and that the companies would be -- be doing their own statistical process control. And -- and this is a big "and" or a big "but" or a big "we'll see" -- that they share this information, make this information available to FSIS, and that FSIS would have access to this information to monitor and -- and -- and see it.

The plants that choose not to do this type of process would then be targeted for an IDV. But if -- if -- if plants are willing to share their information and shows that things are all right, they would not be the ones that would get targeted.

So if we could put in there somewhere that it -- it's the plants doing this and sharing the information with -- or making information available to

FSIS.

DR. LAFONTAINE: I have a -- I don't know if you'd call it an editorial or administrative change. Not change but comment and change.

In the fourth paragraph, we talk about "FSIS and APHIS need a regulatory structure," et cetera. That is -- that goes against the current law. By law, in the mid '90s, APHIS was restricted from being involved in -- being considered or being involved in food -- food safety issues. And in fact, a certain group of people from APHIS came to FSIS at that time because of that congressional action. The folks who have -- currently have on-farm regulatory authority is the Food and Drug Administration.

So you -- I just wanted to point out to the full committee that that statement goes against current congressional law.

And personally, I think APHIS should have that authority, but that's -- that's just a personal opinion.

So you need to -- if you keep it as you -- as it is, recognize it's not a -- it's a no-go from a -- a law viewpoint now. Or statutory viewpoint.

MR. HOLMES: If I could interject there, that's -- obviously, it's not up there yet, but that

was one of the recommendations that I kind of read a second ago ,realizing exactly your point. And I think I -- I said FSIS and APHIS need better communication and structure -- whether you want to take out the word "structure" -- but we're moving the word "regulatory" there. FSIS and APHIS need better communication and structure that can help address pathogens that may not affect animal health but do have a health -- human health impact.

DR. LAFONTAINE: Marty, no matter how you cut it, you're still putting APHIS in a food safety role. And I'll just -- I'll drop it at there. It's -- it's a no-go in the current statutes.

MR. HOLMES: Well, it's really not -- I mean, currently FSIS and APHIS talk regularly on -- on these types of things. BSE is one specific instance I can think of, affects both animal health and human health. And -- and I agree with you, there's not -- there's not a -- I think asking for them to communicate better between each other about these pathogens that may not be affecting -- affecting live animals but they do affect -- have a human health impact, it'd be beneficial, even if we're not talking about changing a regulatory authority by any means. That's the only reason they would have done that.

MS. TUCKER-FOREMAN: Yeah. Dan -- Dan's right about that. And I think since we're a USDA committee that maybe the best way to do it is to limit it to communication and so we're not talking about structures. They're not prohibited from talking to each other. Would that be okay with you, Dan?

DR. LAFONTAINE: Yes, ma'am. That -- that would be consistent with what the current statutory language is.

DR. McKEE: Okay. Do we have anybody else that has an amendment they'd like -- Dr. Jan?

DR. JAN: Lee Jan, Texas Department of Health. I just notice or -- or you talked a lot about testing and your first trigger -- I think you've changed the heading now. But the first one says, "Test more during hot summer months." I don't see how that's a trigger unless you -- you're testing to identify positives and then those positives -- I'm assuming that may be what you're -- what you're testing for, to -- to --

MR. MAMMINGA: I think the object was that if you test more when the prevalence is highest, then you may find that the interventions, whatever they are, aren't successful. And that could then --

DR. JAN: And that would trigger an IDV.

Okay.

MR. MAMMINGA: That would be a consideration when -- when you're thinking about doing an IDV.

DR. JAN: Okay. And that -- I thought that's where you're going, but I didn't really read it that way.

MR. MAMMINGA: I understand.

DR. JAN: But the other thing, and Marty, you talked about testing trim and establishing a national level of acceptance or a national occurrence in trim and some of these other products going to -- that will be destined for grinding. I think FSIS Directive 44 dash 02 established a standard, and that's either less than detectable or no detectable organisms. So I don't know that you can recommend that you establish an acceptable level when they've established that zero is the acceptable or is the norm.

So I think that -- that with 44-02, that directive -- that notice requiring those type establishments to address that hazard and -- and -- and it almost states -- and I don't think that these words are verbatim. But basically, it says that it is a hazard reasonably likely to occur unless you can prove otherwise, I think. So if they're going to have to address that as a hazard really likely to occur and

then control that hazard, then that -- the only acceptable control is below detectable levels.

So I'm not sure that coming out and saying we want to establish a national acceptance level is appropriate from this committee.

MR. MAMMINGA: The only other thing was -- other indicator organisms -- or indicator organisms.

MR. GIOGLIO: This is -- I would just follow up on that. I think the discussion also was more centered on how confident the sampling program was to be able to find the organism. It was -- it's not per se what the positive rate is but how well you've designed that protocol to find it if it were there.

So I think that was more the intent that we had as well.

DR. McKEE: One of the -- go ahead.

MR. LINK: I was just going to -- this is Charles Link. I think part of the -- the intent of that bullet point wasn't to establish an acceptable level for E. coli but more a statistical what's happening in the real world when you're out there looking at these samples. If you've got a sampling program and one out of every hundred times you find it, and that's what typically happens in your facility, then that's -- becomes your norm.

Now, if all of a sudden you start finding it 10 out of every 100 times, something happened. And that might be the trigger mechanism to say, something's up, let me go take a look.

And you may find that one out of every 100 times, everybody finds it except for Plant A over here, who finds it more.

So it wasn't necessary to set some tolerance but more just a measure of what's going on out there and if it does tweak up, we see that and we can address that. If that makes sense.

DR. JAN: Just -- I know what you're talking about and I see where you're coming from. But -- but if you're talking about one out of 100 or one out of 1000 or one out of X, finding 0157:H7, it -- the plant still is going to have to take corrective action under 417.3, or whatever number that is. So -- so then -- then that would already be documented.

I mean, you're already going to have records. But that -- then you could use that information. So -- okay.

MR. MAMMINGA: The -- the challenge that this committee had you have now experienced because we were asked to -- to give FSIS some advice on what conditions, plural. And obviously, with the

intelligence of those folks who are in attendance, either as participants or in the audience, you can get about as many opinions on very specific items. Very good opinions. Expert opinions. Excellent opinions.

But we're -- we're -- we're kind of charged with painting with a broad brush to give FSIS some direction on some conditions, perhaps not all conditions or the only conditions. Better ones may come up.

So we in haste, after a lot of discussion, made this list. It is not perfect nor all-inclusive nor a mandate to you, obviously, that this is what you have to do. I think we've had some very excellent suggestions on fixing a few of the -- of the sentences to clearly give the direction that we wanted to give. But it was not our intent to give you a mandate ready to be put into a directive or a regulation, obviously.

So could we -- could we do a little finetuning? And I think Marty's doing that now. He's really a good wordsmith. And I would have him at my side at all times because -- yeah, he's triaging the computer as we speak.

And I -- I love these things because they're really -- when you get really smart people together, they -- they come up with great ideas. And sometimes

it's hard to get them on one piece of paper. But we did the best we could.

And Marty will work with Moshi and fix it. But I -- give him a few minutes to do that. Maybe you want to move on and then come back to the finished document, and then we can submit it to the committee.

And again, thank you all for your considerations in these matters.

DR. McKEE: Okay. I will move on to the Standing Subcommittee Number 3. I would remind, as we approach the -- toward the end of the agenda, if you have public comment, to sign up out front. We will continue to hear the discussion on procedures for evaluating state meat and poultry inspection programs.

Dr. Jan?

Briefing - Standing Subcommittee Number 3

Procedures for Evaluating State Meat and Poultry Inspection Programs

DR. JAN: Okay. Thank you, Mr. Chairman. I will report on this committee.

The issue, as you mentioned, that we were charged with was to evaluate the -- to review the procedures for evaluating state meat and poultry inspection programs. And we began our deliberation. And -- and we had part -- some of the members of the

subcommittee were not dissatisfied necessarily with the document but felt that it -- maybe it did not go far enough in that the document addressed the review in the system, the state inspection system, and not necessarily the outcome when you talk about the outcome being the product from state inspection establishments. The outcomes addressed in the document talk about expected outcomes to meet the requirements of the law, do you have a program that's equal to.

So after much deliberation, we felt as a subcommittee that to address that issue as well as outcomes related to the administrative management program that -- that part of the federal oversight -- or as part of the federal oversight, FSIS should take samples of product produced at state-inspected establishments.

And we considered several options. One of them would be that the states would just send the product -- the sample -- the products to be sampled to federal labs. And it'd be that way. It'd be the one lab -- the same lab that's doing all these testings. The other option would be that states continue to use the labs that they're using but quarterly or on some statistically sound plan FSIS would collect the samples and -- and have them tested. And then that would be

used to -- to then compare the product standards for food safety to the standards that are established in federal inspection establishments.

So we -- we kind of left that open then without any specifics on how to do that. But we left that at -- with the Agency then to look at how can the data that is acceptable to all parties concerned -- to give them the confidence that that product is safe. And so we feel that FSIS can revise that sampling procedure.

Some of the other issues that we thought that might make this a little better document would be when -- when the establish -- when the state program is required to submit a state performance plan, the document talked about documentation that is expected.

And the question -- or the issue that we felt needed to be addressed would -- would be that there be a little more delineation of which of the documents would need to be submitted to Washington as part of a plan and which of the documents would need to just be available for when there's an on-site review. And obviously, there -- some of those are pretty clear which ones need to go to Washington.

But there are some that may be some confusion. And to have it consistent from state to

state, we felt that it would be better that it -- that documentation was -- was broken down to part of STP and part -- and then the other part would be just records to be available for review.

We felt that in the section that talks about training, it -- it specified that state plants -- inspectors from state programs needed to be trained. And it listed certain training. It talked about basic slaughter, basic processing, but it omitted some of the important training that we feel states need to be able to receive if they're going to be expected to be equal to. And that -- and so we want those -- or suggest that those be put in the document. That would be consumer safety officer training and the EVMS or the humane slaughter training that are new training. And as other new trainings come up, that they be included in -- in that process.

And then the state annual report, that -- that they wanted to clarify that the state annual report, when they do the self-assessment, that that report would include a report from the states on each of the elements that are defined in the document and include outcomes of the -- of the evaluation for each of those outcomes.

One area that we actually failed to talk

about in the committee meeting I'd like to just bring up here and that way we can discuss that. The document also talks about in -- on the page three, it says, "On occasion, FSIS entered into a separate agreement with state -- programs to conduct federal inspection -- federal inspection activity on behalf of FSIS." These -- these are outside the scope of this document.

I want to point out that the document recognizes that but is not addressing that here.

And then there's a footnote that says that, "These agreements are governed by FSIS Directive 5721, cooperative agreements for federal activity to be conducted by state employees." And then there's a note to that footnote that says, "To be drafted based on Parts 3 and 4 of Directive 5720.2, Revision 2," which is the document that is currently being used -- that state programs use to assess themselves in FSIS -- state programs.

And I just wanted to go on record as stating that this drafted -- this proposed drafting of this, how to -- how to oversee this first part, be moved forward as quickly as possible because that -- those are important issues as well. And we need to move on with that and not forget that.

I mean, this -- this document makes that

reference, but when we're finished with this document, I think we need to move on to that as quickly as possible. And then that would take care of all the oversight of state programs.

And I open it to the staff to comment and the subcommittee members or committee members. But before I do that, I would like to -- our subcommittee thanks to the FSIS staffers for being there, helping us out -- again, without them taking the notes, preparing it as we go, it takes forever to do it. And also, Mr. -- and Dr. Leech for providing FSIS perspective on some of the thoughts that helped us out -- subcommittee members.

MR. GIOGLIO: Dr. Jan, on -- on behalf of all the folks that -- that were here and -- and have been throughout the meeting, we appreciate your kind words and the kind words that were offered by everybody else. We're trying to make this process as quick and -- and easy as we can and get through on these important issues.

So thank you. And we appreciate your time very much here, too.

DR. JAN: Okay. There -- are there any additional comments or questions addressing these issues that --

(No response)

DR. JAN: Okay. Either I can -- oh, you've got one.

MS. DONLEY: Nancy Donley from STOP. Just a quick question. Under three, training for states to be equivalent to federal standards CSO, NDV, and, training should be available? Are you just saying it should be available or do you -- are you saying that they should take the training?

DR. JAN: What we're saying here is that -- that those training -- those courses ought to be among those listed in the document that -- and the document basically states in here, "Training requirements on the same basis as FSIS inspectors, VMOs, state inspectors. They must satisfactorily complete FSIS -- FSIS-sanctioned instruction appropriate to job held." And then it lists, but it fails to list --

MS. DONLEY: Oh.

DR. JAN: -- CSO --

MS. DONLEY: Okay.

DR. JAN: And so we felt that if it's in here, then --

MS. DONLEY: Right.

DR. JAN: -- then they would be more apt to allow us to attend, which state programs have not been able to attend these before.

Any other questions? Comments?

(No response)

DR. JAN: I guess I either did a good job of explaining that or confused everybody or something, or it's getting late in the day. But I'll turn it back over to the chairman.

Thank you, Dr. McKee.

DR. McKEE: Okay. Thank you. Do we need to revisit any of the wordsmithing that we're doing now or would it better to take a short break and then -- okay.

Let's take about a 10-minute break. Or let's take a 15-minute break -- and we'll come back and they'll have the wordsmithing done, I think. So, 15 minutes would be about 20 till three we'll -- we'll convene again.

(Brief recess)

DR. McKEE: Okay. I think we're ready to -- to proceed. We've got the wordsmithing done. So if we could find our seats and get started here.

(Pause)

DR. McKEE: Mr. Mamminga, do you want to discuss the -- the changes in -- on the -- the report, subcommittee report?

(Pause)

(Slide)

MR. HOLMES: All right. I want to call your attention here, intervention research, at the bottom. Might pull that up a little bit.

"Intervention research and implementation should occur at every step along the farm-to-table continuum." We added here, "FSIS, comma, FDA, and APHIS need better communication and cooperation that can help address pathogens that may not affect animal health but do have human health impacts."

That's just basically a blanket statement. It's not -- certainly not having regulatory impact.

As you move down, I think -- let's just go through these.

To test more during high-risk summer months. So if you're targeting your resources at one -- at one place versus another, high-risk months would make sense.

Look at HACCP plan deficiencies and NRs, to take that into consideration. It potentially could trigger or -- for the plants potentially in a -- a consideration to think about in targeting individual plants.

Random plants. Select a variety of these based on information gathered by FSIS. That's similar to -- to the second bullet point, I believe.

Focus testing on public health risks. That's similar to the next point -- in terms of -- prioritized testing at larger volume plants or those that supply multiple grinders.

I would also make a point there that many times it's the larger plants that have the greater -- expertise and/or the money to put interventions in place to prevent them to begin with. So I'm not sure that's -- in and of itself is a -- is certainly not a reason. But we talked about public health risk and large -- large customer base. That's -- I'm not going to debate that issue. There are differing opinions on that.

Cross reference the supplier in positive E. coli testing database. Multiple exposures to the database might trigger an IDV. The district manager of the CSO process can help determine whether an IDV is appropriate or potentially inappropriate. If they had been targeted based on this database, the VM or the CSO could basically say -- could look at the information they have on hand to maybe either trigger or prevent a -- a -- an IDV from -- from occurring at that plant for whatever the appropriate reason or reason not to do it would be.

The next paragraph is, I guess, where we made

the most change. So let's -- let's look at it.

The absence of a standardized testing program conducted by the plant that meets statistical process control to monitor the prevalence of indicator organisms on trim or ground products would be a factor or consideration that might trigger an IDV. Develop a program based on plant size or production volume or based on lot size to determine if test results are a natural variation or actually out of control. Sample size selection should be based on organism prevalence, sensitivity of testing, and targeted confidence levels. These test results should be made available to the Agency to confirm that the process is in control.

If the plant does not have the data available or, obviously, the testing program to begin with, to confirm that the process is in control, the plant would be targeted for an IDV.

And then we drop down. Those other measures make sense if they were actually considerations or factors so we added those -- additional comments included. But all stakeholders know FSIS expectations -- could be used to build benchmarks. And the Agency should come back to this committee with a proposed -- for withholding inspection if timely preventive measures are not put in place.

So does that help?

MR. MAMMINGA: Marty, you're a prince.

MR. HOLMES: Thank Moshi. He's the one who helped me.

MR. MAMMINGA: Well, so it be. Can we --

MR. HOLMES: Did we triage that properly?

MR. MAMMINGA: Yeah. We triaged that. Salary increases for all. Someone will sign off on it.

Do we -- do we have any other comments before we submit this report that we can't do without?

(No response)

MR. MAMMINGA: I see none, Mr. Chairman, so we'll submit this report.

DR. McKEE: Okay. Thank you very much. Good job.

Let's look at the Subcommittee Number 3. Was there any changes on Subcommittee Number 3? No? Okay.

DR. JAN: We did -- we did add the -- the one comment regarding addressing or urging the Agency to proceed with drafting the document for oversight of state programs when they have agreement to provide inspection services in a federal establishment. That's -- we added that in the fifth bullet. And I can't read it from here.

DR. McKEE: Okay. I think that says what you

want. I think that says what you intended.

DR. JAN: In fact, I think I can read it. I'll just read it to you.

"Recommend drafting the document for oversight of cooperative agreements for federal activities to be conducted by state employees without delay." And if anybody has any other comments regarding that? And if not, we'll submit that as our report.

DR. McKEE: Okay. Good. Well, that's certainly -- job in getting those prepared. And that's very helpful to the Agency.

I'd like to move on with the agenda. The remaining issues and plans for next meeting.

Remaining Issues and Plans for Next Meeting

DR. McKEE: If you have comments, we'll entertain those at this time.

Dr. Bayse?

DR. BAYSE: We will, I hope, continue to be updated on the food supply in terms of bioterrorism considerations?

DR. McKEE: Okay. I'd like to move on to -- oh, sorry.

MS. KASTER: I think I might have asked for this before, and I should have pressed for it. But I'd

like to hear an update on dioxin screening because I think that's costly for you guys and it's costly in some ways for the plants as well. So I'd like to hear a little bit of feedback about whatever information's being collected. And then, possibly along those same lines, some discussion about the -- of course, it'll probably be a done deal by then -- but the directive on AMR hand-testing and those types of materials and where you're going on other CPs and that type of thing.

DR. McKEE: Okay. I'll just go down the row there. Dr. Jan?

DR. JAN: I -- I'd be interested in including in a future meeting some information about using irradiation as a control point or as a -- a critical -- as a critical control point and the various options and where we are with that.

DR. McKEE: Dr. Bayse, did you have an additional comment? Mr. Link?

MR. LINK: I guess this is the time to ask the question. Is there a formal feedback mechanism, I guess, for committee members to come back to -- to you guys on thoughts, concerns, issues with the meeting, administration of the meeting, or whatever, for future reference?

MR. GIOGLIO: Let me address that, Charles.

I don't think -- we don't have a formal mechanism. Certainly, we're open -- my office is open to hear from -- from the committee members.

And I would point out that we are, you know, beginning the process of -- of rechartering the committee. And it was obvious from today, we're going to have to replace some of the members of the committee. So we'll be looking at that.

I would say, certainly, let's keep the channels of communication open between members of the committee and our office. And if -- if need be, we can, you know, have a special conference call or something like that to discuss any issues that might come up.

DR. McKEE: Are you talking about administrative process issues or how we run the meeting?

MR. LINK: Yes, how you run the meeting. And I think to Carol's point earlier on some of the paperwork that came in late. Some of it we didn't get till we got here. I mean, just -- just some things that I think we could do better.

DR. McKEE: If you want to send us -- send those items that you've identified, we'd be glad to include those -- certainly, we want to make this

meeting as productive and easy as possible for all the volunteers. And we don't want to add any extra stress that's induced. So we certainly would appreciate those comments.

Dr. Johnson?

DR. JOHNSON: We -- we'd talked earlier yesterday about what the committee had recommended before on certain issues. I was wondering if it would be possible to include in our -- our initial information that we get just kind of -- the recommendations that were put forth this time and any type of steps the Agency had -- had done as far as following up on the recommendations. I think that'd be helpful to have kind of just a reminder of what we did last meeting.

DR. McKEE: Okay. Mr. Holmes?

MR. HOLMES: And that kind of answers one of my -- the point I wanted to make -- follow up on. This committee had suggested doing away with the retail exemption. I'm just kind of curious what -- maybe an update next time as to where that is and what -- the Agency --

MR. GIOGLIO: I think I'll make sure that that gets on -- on the agenda next time to at least give an update on -- on where we are within the Office

of Policy.

DR. McKEE: Mr. Govro?

MR. GOVRO: Other than this suggestion period that we're having right now, how does the Agency decide which items will make the agenda for the meeting? Is it open to suggestions from the public or committee members? Or how do you go about that?

MR. GIOGLIO: The way we go about that is that within our office and throughout the Agency, we solicit issues from the other deputy areas and assistant administrator areas to get to the agenda. We draft up, in fact, an agenda to try to, you know, get everything on within the framework that we've established for this meeting. And ultimately, they go up to the administrator's office and -- and it's decided on which issues will be forth as an issue.

We have certain standing briefings that we've committed to, let's say like the food security and so forth, that we want to continue to do for the foreseeable future.

And that's basically the process that we follow internally.

DR. McKEE: As we identify priorities within the Agency that we would like to have additional input, especially new initiatives and so forth, then, clearly,

that would be on the agenda for the committee to look at as well.

Ms. Eskin?

MS. ESKIN: Yeah. I wanted to make a general suggestion but first wanted to comment on a number of suggestions made here.

When you say "contact your office by email," should we email you directly, should we email Sonya? What's the most --

MR. GIOGLIO: I think probably the -- the constant in that equation is going to be Sonya West. As -- as --

MS. ESKIN: So if we -- we have no --

MR. GIOGLIO: -- the committee contact --

MS. ESKIN: Okay.

MR. GIOGLIO: -- she is, you know, and going to remain as the advisory committee specialist.

MS. ESKIN: Okay.

MR. GIOGLIO: And so forth. And then, certainly, we'll let you know of any other updates, if there's an easier way --

MS. ESKIN: Okay.

MR. GIOGLIO: -- than or a better way to get that done.

MS. ESKIN: So we send her and she can follow

up with whoever the appropriate --

MR. GIOGLIO: Sonya can collect that information and get it to the folks that need to evaluate it and respond back to it.

MS. ESKIN: I agree with Dr. Johnson. I think it's a great idea that we have just some follow-up on the specific recommendations made by the subcommittee in the -- prior meeting and what's been done to implement those or just to respond to those.

I also think it would be helpful earlier in the process to -- contact by email, whatever, the members of the -- members of the committee and let us know what your thoughts are as far as the agenda. And we too can then weigh in because I know it takes a while to -- to put these things into play, but I think it's really important that there's back and forth.

On the -- the agenda, I know we didn't have time to discuss listeria and I know that we'll have a summit in two weeks to discuss it. I would definitely like us to have sort of an update on what the Agency has done in response to developments in this area next time.

DR. McKEE: Mr. Holmes?

MR. HOLMES: One last -- I assume Moshi is making copies of the final two revisions?

MR. GIOGLIO: Yes. He's going to try to have them available out at the -- you know, on the back table there as soon as he can get those copies made.

DR. McKEE: Okay. Thank you.

Public Comment

DR. McKEE: I'd like to go on to public comment. We have four individuals that have requested time. And since we do have -- we are ahead of schedule, I will allot up to 10 minutes per person for the -- instead of 30 minutes.

I'd like to make a comment that the comments from the public should be in regard to the agenda items that we've discussed over the last two days. The purpose of the advisory committee is to assist the Agency in recommendations and problem-solving, so we want to keep it focused on the agenda the last two days.

So the first one that I have on the list, I'll have Charles -- but you can have up to 10 minutes -- you can have up to 10 minutes. And it doesn't even have to take that long. Whatever you want to do within that time is fine.

The first one is Charlotte Christian. If you would give your association or connection?

AUDIENCE MEMBER: Sure. Thank you.

Thank you for the opportunity to speak. My name is Charlotte Christian. I'm a senior food safety attorney at the Center for Science in the Public Interest. And I have a couple of issues that I'd just like to ask questions about and comment on.

A question I would have with regard to HIMP. Can you tell us how many plants currently have antimicrobial intervention in -- among the HIMP plants? Do we have a figure on how many plants are using antimicrobial interventions?

MS. AXTELL: I don't off the top of my head. We're checking to see if we have the data with us.

(Pause)

AUDIENCE MEMBER: While they're looking, one of the comments I have is that in the discussion of the HIMP report and the data generally, there seemed to be some broad conclusions reached about the ability of the HIMP system to improve food safety. I think the Department needs to be very careful about making those broad generalizations.

Yes, the data do show some improvements in FS-1 and FS-2. But the fact is that there are also data which show that there is no improvement or in fact may be an increase in salmonella recovery in HIMP plants.

Now, I understand that there is a question about seasonality. However, we are talking about young chickens. We are talking about plants that are supposed to have tight controls. And at least according to the report that we saw today, one of the responses to the GAO's criticism with regard to antimicrobial intervention is that in fact many HIMP plants are using antimicrobial intervention.

I think it's too pat of an answer to just try to explain this away by saying, oh, it's just seasonality. I urge the Agency to, number one, look deeper into the issue for why there may in fact be increases in salmonella prevalence, and number two, to again be careful in how you portray food safety measures under this plan because we don't know about salmonella yet. And I think it's wrong to say that just because FS-1 and FS-2 have been improved that we therefore have a plan that's going to improve food safety.

The second comment, and this relates to the agenda and -- and Ms. Eskin's question about listeria. Just in general, I think that it's important for the Agency to get the input of this committee when you're thinking about important issues that are on the front page of the newspaper every day. We've got a huge

recall. We've got two plants being investigated, possibly four plants being investigated.

And I think it's very important when you've got this august body together to at least give them an opportunity to give you their insights in how FSIS might best approach this problem and better protect consumers. Thank you.

DR. McKEE: Okay. Thank you.

The next presenter will be Dr. Dale Boil.

AUDIENCE MEMBER: Thank you. I'm Dr. Dale Boil. I'm executive vice president of the National Association of Federal Veterinarians. We're -- we're an association of supervisors and managers. Most of my bosses and most of my customers are veterinarians that are in plants throughout the United States. So at least in the first part of these statements I'm going to be speaking on their behalf.

Rarely do we have a win-win-win-win opportunity. I have listened carefully. Our organization has been extremely critical. And we have also been very much a part of the solution of trying to make the whole process of getting HIMP to work part of what we are about.

We started out as a group who were against. The ones that were in the plant were the first to see

the light. The people throughout the United States, veterinarians throughout the United States now are all clamoring to go to the HIMP plants.

What am I talking about a "win-win-win"? Well, I think it's fairly obvious to anyone who's really taken a look at it without trying to slant it for this or for that that this -- that this is clearly a superior system.

I say that consumers win by getting a safer product. I say that industry wins by having process controls in their hand. I say that employees win by having better jobs and a more significant ability to contribute to public health. I say that taxpayers win by having to pay fewer employee compensation checks.

So on behalf of our organizations, we encourage the rapid adoption of HIMP and moving it out.

I think we need to be careful. I think we need to continue to improve. But this is clearly a better system than the current one that's in place now.

Since I've got 10 minutes, we'll talk about another win. Let's talk about microbiological controls.

Microbiological controls are another way we can see a win-win-win. I say let's have salmonella performance standards and let's make that a part of

what we commit to. I think listeria species offer real opportunities for validating how good our sanitation programs are working. I say that a fecal indicator of some sort be a regular part of our microbiological controls and that be put into the system.

We've already talked about another one. But this is a win that is an investment in your future. The win-win of investing in people. The long-term investing in education and training for FSIS is the only way that you're going to get to that place where you want to be as an employer of choice and an agency recognized for its excellence.

DR. McKEE: Okay. Thank you.

Okay. Our next speaker will be Paul Johnson.

AUDIENCE MEMBER: I -- I just have a couple comments, and I'm not going to take 10 minutes.

But my first comment is that I believe that this group would benefit by having a representative of the -- the inspectors union present at these meetings so that you can get a -- I heard the word "real-world evaluation" about what's going on. I think it would benefit you to know what's going on out there in the field and what inspectors are actually tasked with.

We'd be -- we'd be glad to come. And we -- earlier this year, as you know or some of you may not

know, I'm the new chairman for the NJC. And I sent a letter to the secretary telling her that this new union theme is extending the olive branch. I kid Dr. McKee about it, that I brought my olive branch to Washington last time we came.

And so we would like to work with the -- with you folks and -- and try to make the best system that -- that can be provided out there. So that was my first comment.

One of the -- a small -- a short comment on HIMP.

Dr. Aman, your stationed at Carthage, Mississippi, right? I think one of the things that -- I heard the comment that the product from the HIMP plants seemed to be a less quality or a less desirable product to get. I know that just in the recent few months, an entire load of product came from the Carthage plant to a plant in North Arkansas that was grossly contaminated with feed. They may have that under control now. I don't know.

But it's not been long that -- that a load -- this entire load was rejected and sent back to Carthage because that -- it was grossly contaminated. And when the lids were popped, it had an off condition odor.

Those things now in the HIMP plant are not

considered food safety. Things like airsacculitis, glucosis, tumors, things that, in my experience with the -- the public have been grossly appalled that that kind of stuff would be allowed to be fed to the -- the American public.

I think that -- and also wanted to make -- make a point that when we find product that exceeds those tolerances for the OCP, we don't have the right to retain that product. We tell the company that it -- that they're out of tolerance on it but we don't retain it. We -- we -- if they want to, they can. We think that that would be an improvement.

I know Dr. Santiago talked about making some improvements to -- to the HIMP system. I know Jeanne talks about some. I think that that would add to your -- to your system, is to take a look at some enforcement on those -- on those type issues. I think those are the things that are, you know, turning people off against the product that comes out of those plants.

And this may be an avenue that inspectors that are in the plant could do those additional tasks, like -- I forget the lady's name. But Donna. I'm sorry, Donna. I apologize.

Donna talks about the inspectors doing additional tasks in the plant. That could be some of

the things that they're doing, is checking that cart before it goes out the door, those type things. There's additional duties that could be -- could be performed by the inspectors that are not on the line.

We'd be glad and open to sit down and -- and take a look with the -- with you on those things on -- on HIMP. And let's see if we can come to some kind of a closer agreement of -- of what would work.

I know we filed an -- we filed a lawsuit against the Agency because of the HIMP project. Maybe there's some way that we could sit down with you guys and find -- find a way that we weren't so ready to do that the next time.

The next thing is on training. I heard some of you guys talk about CSOs and -- and the duties that they're performing. And somehow I get the impression that -- that you're giving them more credit than -- than -- than they have got or more responsibility than they're actually supposed to be doing. Because it's our understanding that the CSO is basically focused in on the design of the HACCP plant.

The only difference in a CSO and many of the inspectors that we have out in the plant is four weeks of training. We -- we feel like that there's much more benefit in training all -- you know, and I think the

Agency has made a commitment to train all the veterinarians in the CSO training.

Why not train the inspectors also that are working in these processing plants, the IICs that are bargaining unit folks? You have somebody -- then you have somebody there full-time, not their supervisor, that may check it. You know, he may be there on the site but may not be checking that on a regular basis. You have an inspector, though, that would be there full-time and could check that plan 365 days a year.

When a CSO comes in that plant, he checks it that day or that week when they're there, and they're gone. That plant could change 364 times until they get back. It could change, you know, a numerous amount of times. But if you -- if those folks were trained on design, any time the plant made a change in their plan, they could evaluate it like the CSO does.

DR. McKEE: Thank you.

I think we do have the answer to the HIMP question.

DR. SANTIAGO: On the question of the number of plants using antimicrobial, we have 15 plants out of the 20 using antimicrobial. All of them have passed the salmonella cert except seven, seven are ongoing. All the others have passed the salmonella. Seven are

still ongoing.

DR. McKEE: Okay. Our next speaker will be Tony Corbell.

AUDIENCE MEMBER: Tony Corbell from Public Citizen.

Public Citizen at the outset was a critic of HIMP. And I've attended now four meetings on this issue, and -- and nothing has -- has been presented today that -- that is going to modify our organization's position in opposition to HIMP.

I want to give Dr. Santiago fair warning. We -- we are -- we ride the Metro together quite a bit back to God's country in Greenbelt, Maryland. If you see me on the platform, and since you're a new face at HIMP, believe me, I'm going to have questions for you. So your day is not going to end when you -- when you -- when you leave the building. So --

(Comment off mike.)

AUDIENCE MEMBER: Does he?

(Laughter)

AUDIENCE MEMBER: So that's -- I'm just -- I'm just going to, you know, just end it there, that we still have great concerns over the program.

And -- and now, you know -- the other thing I wanted to -- to point out, since -- since the GAO's

study has been -- has been attacked, I think you're going to have to come to some meeting of the minds with the -- the folks -- the so-called experts, the -- the group you've empaneled to look at the data along with the GAO folks. Because now the -- the muddy -- the water -- the water has been muddied even further.

The other thing I -- I wanted to address is to essentially follow on what Mr. Johnson just -- just spoke to. I think you're going to have to include your -- your inspection force in some way in these meetings.

Dr. McKee, you -- you addressed the issue of being a quarterback of a team, and -- and this is the major portion of your team, your inspectors.

I sat in the -- the training subcommittee last night. Dr. Lafontaine did a tremendous job in terms of including everybody in -- in that meeting, including Mr. Johnson, who -- who addressed some -- some real concerns in terms of the -- the lack of training that are currently provided to inspectors. He provided invaluable -- he was an invaluable resource in terms of what was actually going on out there.

So I would encourage you, if you cannot include him as part of the -- the committee itself, I think there should be a standing invitation for the employee representative to be here and to participate

in these meetings. Thank you very much.

DR. McKEE: Okay. Thank you.

Wrap Up and Adjourn

DR. McKEE: Are there any other comments that the committee would like to -- to make before we adjourn the meeting? Mr. Magmini?

(Laughter)

MR. MAMMINGA: All right. One time for the record. "Mamminga."

DR. McKEE: "Mamminga."

MR. MAMMINGA: -- and since I'm leaving, I'd just like your indulgence to thank Sonya West. I've been on the committee for four years. She has coordinated my getting here and going home and my expenses and my questions. And while she, like us, live in an imperfect world, she certainly has my gratitude and I'm certain on behalf of the members of the committee.

So, Sonya, thanks a million.

(Applause)

MR. GIOGLIO: Well, see, she's probably out there making copies or running around and -- or something.

MR. MAMMINGA: It'd be nice if we could bring her in here and just say "thanks." It's quite a job,

I'm sure.

(Pause)

(Applause)

DR. McKEE: Okay. Thank you.

Hearing no other comments, we stand adjourned until the next meeting. Again, thanks those -- to those that are going off the committee for the yeoman's work that you've done over the last several years. Thank you.

(Whereupon, at 3:25 p.m., the proceedings were concluded.)