UNITED STATES DEPARTMENT OF AGRICULTURE

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PUBLIC HEALTH BASED

INSPECTION IN SLAUGHTER TO ADDRESS

CAMPYLOBACTER, SALMONELLA

and

OTHER PUBLIC HEALTH CONCERNS

+ + + + +

August 7, 2007
9:00 a.m.

George Mason University School
of Public Policy
3401 Fairfax Drive
Arlington, Virginia 22201

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I-N-D-E-X

I-N-D-E-X (cont.)

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

(9:10 a.m.)

MR. TYNAN: Welcome to our public meeting on Public Health Based Inspection in Slaughter to Address *Campylobacter, Salmonella* and Other Public Health Concerns. That's a long title for our meeting, but it's a very important one, and there's a lot of substance that we're going to address today.

I am Robert Tynan. I am the Deputy Assistant Administrator for the Office of Public Affairs, Education and Outreach, and I'll be moderating the session today.

I was going to say at this point, in addition to our audience here, that we have some folks on the phone. We do, as we have had in a couple of other occasions, we have a little bit of a technical glitch bringing in one line, but as soon as we do, we'll have them join our meeting. So I don't want to delay those of you who were kind enough to come and join us today to delay you any longer in your schedules.

Let me take you through the agenda very,

very quickly at this point before I introduce our speakers. You should all have a copy of that. If not, there's some at the registration table. Has everyone received a copy? Okay.

Essentially, we're going to begin with welcoming remarks from Mr. Almanza, and discussion by Dr. Raymond, a little bit about improving public health in poultry slaughter inspection. We have Dr. Carol Maczka from our Office of Food Defense and Emergency Response that's going to talk a little bit about the rationale and process for our public health initiative.

We're also going to have a discussion of what we've learned from our *Salmonella* meetings and our *Salmonella* Initiative, and that will be Dr. David Goldman, who is our Assistant Administrator, the Office of Public Health Science.

We'll have Mr. Loren Lange. He'll talk a little bit about the public health lessons from our HACCP-Based Inspection Models Project, the HIMP project.

Dr. Goldman's going to come back and talk a

little bit about the scientific foundations for future decision making. And we're going to finish up with Dr. Dan Engeljohn, who is our Deputy Assistant Administrator in the Office of Policy, Education and -- I've forgotten now, and I'm embarrassed, but nevertheless, he is our Deputy Assistant Administrator. He's someplace in FSIS. It seems easy to do what I'm doing, but it gets a little nerve-wracking here. So I apologize, but he is going to talk about next steps, and that will conclude our presentations.

You will notice on the agenda, that after each presentation we will allow about 10 minutes for comments on that particular presentation, and at the end of the session, we've allowed a greater period of time for longer comments, questions and a broader discussion. So the 10-minute blocks are to give you an opportunity to ask any clarifying questions you may have regarding each of those presentations.

Before I start, I should also mention that our risk-based inspection e-mail address is still available to you. So if there are some comments that

you would like to make and do not get an opportunity to make during the session today, you're welcome, you're invited, you are encouraged to send comments to that risk-based inspection e-mail box.

As you will also notice on the agenda, we did not build in any specific break time. That's our usual method of operation for these shorter public meetings that we have. We're going to leave it to each of you to decide when you need to take a stretch break or grab a cup of coffee. There is a little coffee shop downstairs in the bookstore that you can grab a cup of coffee if you need to.

And finally, a very important aspect for some of these meetings is our restroom facilities. They're out this doorway and around. You can follow it all the way around to the right. The ladies room will come up first, the men's room will come up a little bit further along on the right-hand side. So just to make sure we don't have any mistakes in that regard.

If there are no questions at this particular point, I'm going to begin the agenda, and

ask Dr. -- I beg your pardon, Mr. Almanza to come up and do some opening remarks. Did I promote you?

MR. ALMANZA: I just got my degree.

MR. TYNAN: Mr. Almanza and I go back a long way. We worked in labor relations together years ago. I'm very pleased to introduce him. He is our Administrator in the Food Safety and Inspection Service. Mr. Almanza.

MR. ALMANZA: Thank you, Robert. Well, good morning, everybody. I am Al Almanza, the new Administrator for FSIS. I've been with this Agency for almost 30 years, and held numerous positions. I started out on the slaughter line in Dalhart, Texas. Most people won't know where that is but if you go much more than 30 miles in either direction of it in the Texas Panhandle, you're in another state.

My dad actually was an inspector and kind of filled out this, when I got the offer for this job, he filled this thing out for me. He said I've taken care of you and so when I got this call from a personnel specialist and said, are you serious, you want to go to Dalhart, Texas, I said, sure, why not.

She said we've been trying to fill that job for three years and we can't get anybody to take it. So his response was if you can live in Dalhart for a year, you can live anywhere. I'm testing it now.

So my whole career was spent in the State of Texas where I held numerous positions in the slaughter line, processing position. I was a PQC inspector. I was a labor relations specialist, and my favorite job of all was being the Dallas District Manager. And I plan on this just being a bigger district and running this just like I did the Dallas District. So those of you who know me, you know that I'm not comfortable standing up here. I'd rather be moving around. I'd rather have clip on and talk to you from out there. This podium seems a little constricting, but I'll do the best I can.

I believe that my field experience will be useful in shaping policy, using the experience and knowledge that I gained at the basic levels of this Agency. What that means or should mean as the Administrator, I believe that there are some things that can be done that will be of benefit to everybody

in this room. Consumer groups, the union, the industry because in Dallas, I stayed in touch with pretty much every group that we dealt with. And I want to do the same thing here, and I think that this ought to be an opportunity not only for myself but for everybody that is in this room.

I also believe that through these meetings, where we exchange ideas and have discussion and dialog that this is where we will get to where we all want to be. Now we can't do it everybody's way all the time, and there are always going to have to be some give and some take. But in these meetings is where we will be able to succeed and where we need to be.

I also believe that this Agency has made great strides in being open and transparent. And I've seen that at the district level, and I think that the people that are in the key positions here at Headquarters are very attuned to that. I think they're open minded and very willing to do things that haven't been done before. I also believe that it is imperative that we take into consideration the

input of all of our stakeholders in the creation of a policy that is effective.

I'd also like to take this time to introduce our employee representatives, Dr. Dana Vetter from the National Association of Federal Veterinarians, Ms. Olga Morales, the Association of Technical Supervisory Personnel, Mr. Stanley Painter, and Dr. Pat Basu, the Asian Pacific American Network in Agriculture.

I want to share a few thoughts about public health based slaughter inspection and my personal experience with HACCP based inspection Models Project, HIMP. We have three plants in the Dallas district that were under HIMP, and I visited those plants, I wouldn't say routinely but I was there regularly, and in discussion with the inspectors that were assigned there, I believe that they were more focused on the big picture. They had more time to do offline food safety tests, verification activities. It also allowed the plant to enhance or revise their activities based on the data collected and their performance. I also felt that our supervisors were

much more gauged at the workforce because it wasn't as restrictive to our line inspectors as it is in the traditional type of inspection process.

I also believe that in my discussion with those inspectors, they felt as though they had a more meaningful role in public health. We also saw a reduction in the number of carpal tunnel type claims and they also felt like they were more a part of not only the district team but part of the big team. I also believe that the plants took their role more seriously and were more amicable to sharing information and records in all of those plants.

Those are just a couple of things. There are a number of other things but if I talk any longer, I'll make Dr. Raymond a little bit later, and I know that he's anxious to get up here and tell you about his experiences with this. So with that, I'd like to introduce my boss responsible for me being here, Dr. Richard Raymond.

(Applause.)

DR. RAYMOND: Thank you, Al. Good morning, everybody. Thank you all for coming out today. Some

of you commented about the heat and humidity. At least Mr. Painter's commented about how cool it is here compared to where he just came from. So we think it's hot here. It's all in perspective.

Just a couple of little announcements I'd like to make before I get going. One is we have a two day meeting starting tomorrow with the National Advisory Committee for Meat and Poultry Inspection. Many of the members of that committee are new, 11 of them, in fact, of 17. And many members of the NACMPI Committee are here today. I would just like a show of hands of how many NACMPI members are here today and keep your hands up so I can do a quick count. I see 15 hands on a quick count. Thank you.

I think that shows the commitment and dedication of that particular group of individuals. They're here for three days. They came a day early to hear what they could hear today about our proposals and that's why they are on the NACMPI Committee because it's an important committee and they take their role seriously. So thank you all for being here, and hopefully tomorrow we'll get to know

each other a little bit better and start putting some names to faces.

The second announcement, one of the things we did over a little over a year ago, actually it's been a two year project, but as a result of some listening sessions, in the State of Montana, the small and very small plants, and then listening sessions all across the country, began to get a picture that perhaps we weren't all in the same step with HACCP and we needed small and very small plants to have very robust HACCP programs if we're ever going to get to risk-based inspection where all plants would be equal.

And so we began an initiative called Small and Very Small Plant Outreach. We announced this in -- a little over a year ago and we had phone lines open to a lot of people who were listening and one of the associations that called in during that press conference said unless you have dedicated budget lines, unless you have a dedicated person running it, you'll never last. Your enthusiasm may be today but it will not last. So one thing I'd like to announce

today is we listened to that person and we are adjusting how we do things. We are trying to create a new program area that will be outreach, we'll be training. We'll combine all of our educational activities and if down that road we have opened a position up to consider all the applicants and I can now announce the new Senior Executive Level of Administrator who will be running our outreach and training program who is here with us today and most of you know Dr. Karlease Kelly, back in the back row. She'll soon assume front role positions I'm sure. So congratulations, Karlease, on that competitive slot and I think we'll all -- Mr. Painter asked me this morning a particular question about whose in charge of a particular part of outreach, and I said I don't really know for sure but once we get this done, if anybody has a question, about training or outreach, just call Karlease.

The last thing I wanted to announce is since the last meeting with most of you, I've joined a new national association. I think it's the best association I've ever been a member of. Now one

thing about this association, they do have a Hall of Fame that goes with it, and Mr. Painter is already applying for that Hall of Fame. He gave me some advice. He says to get into the Hall of Fame with this association, every time somebody mentions a grandchild, you have to show a picture. And if they don't mention a grandchild, you have to bring the subject up. So I've joined the National Grandfather's Association where we go and here's the picture.

(Laughter and applause.)

DR. RAYMOND: Now that I've got that little one to worry about, food safety comes a little bit nearer and dearer to my heart. It has always been near and dear but when you've got family members that are more at risk, you begin to have even more passion.

One thing that has always bothered me since two years ago since I took this job is the statistics CDC keeps putting out and people keep repeating, that 5,000 people will die from foodborne illnesses this year. That's a big number. It's hard to imagine.

If you put the math to it, that's 13 people a day. That's just inexcusable. We can do better. I know we'll do better. We have to do better. That number should not be repeated day after day after day.

What I want to talk about today is our goals and how to reduce those, how to bring increased food safety to the meat and poultry supply of America. We've been studying ways how to get this done. We've been looking how we conduct our federally mandated inspection activities at the poultry slaughter facilities throughout this country, using resources and science that are currently available to us. We looked at data from seven years of HIMP.

This meeting today is going to give us a chance to share with you our ongoing work. You are food safety partners and we need your buy in to take the next step. We can't do this alone. We need your help. We need your constructive comments, your frank criticisms but you need us helping us move forward. These are to be constructive meetings if they're to be successful at all. We want to discuss our

principles with you. They're central to making this an improved poultry slaughter system. We want you to listen to our proposals. We want you to comment on them constructively.

We're looking for a system to provide our employees with more time, more flexibility to conduct focused offline verification activities at poultry slaughter facilities. We'll show you graphs of why we think this is the way to go. These activities will be tailored to risk factors that are present at each establishment and at different points in the slaughter process where food safety hazards and associated risks are greatest.

We know that our dedicated employees can help protect the public health. But as leaders, it's paramount for us to give them the guidance and direction and the capabilities to use their abilities to improve activities in slaughter facilities and decrease foodborne pathogens that get into the food supply.

You know, industry can do their own quality control. The HIMP plants have shown that. No one

ever got sick from eating a bruised chicken breast or broken drumstick. And that's a lot of what we're doing right now. Quality control. We need to share many common goals with FSIS' other public health efforts. We need to combine these efforts in processing now with slaughter.

The paths involved to reach those important goals, however, are very different. I'm getting ahead of myself now. I'm digressing a little bit and talk about processing.

Today is about slaughter. Today is about how we get to the important public health outcome of reducing foodborne illnesses. It's about sharing the rationale of a science behind our approaches to public health based inspection with you, the public, industry, consumers and our own employees.

This is also a wonderful opportunity to present the data, the detailed analyses that have helped FSIS place into context its preferences and its experience with programs like the HACCP based inspection project referred to as HIMP.

I remain firmly dedicated to the idea that

our actions to improve public health should and will be conducted transparently as Mr. Almanza already mentioned. We'll continue to be open. We'll continue to be active participants with you all. But it is critical to provide you with the data and scientific foundations that have shaped how we're going to approach this issue, and that you consider that data and you consider those foundations and you take it at face value and you consider them when you form your opinions about what we're going to talk about today, tomorrow and Thursday.

This will help ensure us that the steps that we take to reduce the prevalence of foodborne illness will be better understood by all of us, and all of our partners who are not here today, and the public that the media will educate for us.

I'm going to boil this down to bare essentials to what we do. There's a manual from 2004. It's called "Multi-species Disposition Basics with a Public Health Focus." Dana, you know what I'm talking about here. It's a public health veterinarian training book, April 2004. If you go to

the first page, the index page, for Section 1, Diseases and Conditions of Public Health Significance, Category 2, Poultry, two bullets. These are diseases and conditions of public health significance in poultry, number one, septicemia. Number 2, contaminations (fecal). Two conditions that affect public health in poultry, sepsis, contamination. I think we've done a really good job of keeping septic young broilers out of the food supply, but we still see *Salmonella* served up on chicken parts and carcasses that's too high a number in this country. It's time that we direct our energy, our resources and our time on the second item in the training manual, and that's reducing the *Salmonella* numbers.

I'd like to close my remarks with a quote from our friend, Mike Taylor, who was in the Washington Post Saturday. There was an article comparing FDA inspection methods with USDA inspection methods, and Mike Taylor said, "You can visually examine chickens all day. You will still not see the *Salmonella.*" People have been saying this for 20

years, and it's high time we finally took action to find *Salmonella* and to get it out of the food supply, and that's what we're going to talk about for the next three days.

Once again, I want to thank everybody for coming. I look forward to your comments. We really truly appreciate your participation. If we didn't, we wouldn't be having these meetings. We want to work with all of you today and in the future to improve the safety of the U.S. meat and poultry products that we are responsible for regulating. And NACMPI members, new members, once again, welcome to the work that is laid out for you.

And with that, we'll turn it over to Carol Maczka, almost back on schedule.

(Applause.)

DR. MACZKA: Hello. My name is Carol Maczka, and I'm the Assistant Administrator for the Office of Food Defense and Emergency Response. I also lead the Data Analysis and Integration Group for FSIS.

The title of my talk is Rationale and

Process, and that's the rationale and process for an enhanced slaughter inspection system.

I'm going to start with a question in an attempt to define our goal with respect to slaughter inspection. And the question is, how can FSIS enhance slaughter inspection to achieve measurable improvements in the control of foodborne pathogens and improve public health?

And the approach to accomplish this goal is twofold. First, we want to apply a formal process for data collection and analysis, and I'll go into that in a few minutes. You'll also hear more about that tomorrow at the Meat and Poultry Advisory Committee meeting.

The second part of this is to define using a science-based approach, the factors and accompanying data that can be used to inform our inspection activities. And the second of these is really a cornerstone of the first.

In terms of the process, we are responding to stakeholder comments which suggested that we formalize an overall process for data collection and

analysis, and this process involves the development of a technical plan and a technical paper, and those two pieces will address the problem to be addressed, the data collection and analysis strategy, the results and the interpretation of data analyses. And the process also would incorporate stakeholder and peer review.

And for those of you who will be attending the Meat and Poultry Advisory Committee meeting tomorrow, we're going to ask the Meat and Poultry Advisory Committee to comment on the process and particularly when we should be opening up the process to stakeholder input and peer review.

The next slide I'm going to show you is an overview of the process. So the process starts with product definition, and that's pretty much the goal statement that I or question that I presented at the beginning of the talk.

The second step would be to develop a technical plan, and that plan will describe data collection and analysis strategies. It would address any statistical methods that we would use. The next

step would be to collect, perform analyses and develop a report, a draft report. The conclusions of that draft report would take into consideration any assumptions, sources of uncertainty and data limitations. Once the draft report is completed, we would use that to inform our decision-making.

And then eventually, we would do a program evaluation. We would ask the question, are the risk management actions we're taking, are they working? Are we achieving our goal? And our goal would most likely be a reduction in pathogen levels or it could be improving, you know, carrying that all the way out to improving public health.

On the right-hand side of this process, I've indicated where we are proposing that we seek stakeholder input or peer review. And so you'll see that stakeholder input comes into problem definition, the draft report and also in the technical plan, and we're also suggesting that we subject the technical plan as well as the draft report to peer review.

And so we're interested in your comments with respect to the process and we're also going to,

as I said before, ask the Meat and Poultry Advisory Committee to comment on the process.

The next step for enhancing slaughter inspection, involves determining what factors and data should be used in resource allocation, and what we'll be doing here is we're going to be doing analyses to determine what are the important factors, and then of those factors, we would like to analyze them to determine how they could be used to prioritize activities within establishments or to rank establishments.

As far as potential factors within an establishment, a risk assessment has been completed at FSIS which examines offline HACCP activities that would lead to greatest reductions in pathogens. And specifically here we're talking about *Salmonella* reductions. It incorporated PBIS data and *Salmonella* testing results, and David Goldman will be talking about the risk assessment in more detail later in the program where we talk about scientific foundations for decision making. The risk assessment will also be the subject of a later public technical meeting.

As far as looking at potential factors for ranking establishments, some of the factors that we're going to be considering are volume as an indicator for potential exposure, *Salmonella* and *Campylobacter* and generic *E. coli* as indicators of contamination and process control. And again David Goldman will be addressing those particular data, *Salmonella, Campylobacter* and *E. coli* when he gets to the scientific foundations for future decision making. And other potential factors could be non-compliance records, food safety audits, enforcement actions, consumer complaints and recalls. All these factors will undergo additional analyses to determine which of them should be included in an algorithm for slaughter inspection.

And that brings me to my last slide which is entitled Next Steps. Our next steps then is to seek your input into the process that I've presented as well as the information that you're going to hear in this meeting with respect to slaughter inspection. What we're interested in specifically is what factors should be included in an algorithm for slaughter

inspection. We're also going to continue to develop the technical plan and once that's completed, we will ask for your input and subject that to peer review. And then finally in the beginning part of this, we're going to ask the Meat and Poultry Advisory Committee to comment on the process on food data collection and analysis. That's it. Thank you.

(Applause.)

MR. TYNAN: Thank you, Carol, very much. I understand that we have our connection with the folks on the phone. So I think they heard the majority of the discussion to this point.

As I mentioned earlier, we have about a 10-minute block of time that we're allowing for comments and questions. We're a little bit early which is good. So I'm going to allow some questions from the audience, and then I'm going to ask the operator to take some questions from the folks on the phone.

We have microphones in both aisles. If you could come up to the microphone, please introduce yourself and your affiliation for purposes of the transcript, and we'll go from there. Felicia.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Can you explain the difference between this and RBI because the factors that you're looking at seem to be similar, if not identical, to the factors being considered in RBI in processing? And as far as I know, the Agency has made a distinction recently saying that this is not RBI in slaughter.

MR. TYNAN: Thank you. Dr. Raymond, did you want to address that?

DR. RAYMOND: Sure. You bet. This is risk-based inspection but to avoid the confusion that we seem to have created when we talk about risk-based inspection in processing and risk-based inspection in slaughter and having people seem to be unable to differentiate between the two, one which was a public gathering of information, conversation, thoughts and ideas, and rewriting the plan as we went along. The second, in slaughter, is gathering information, ideas and thoughts and then writing a proposed rule which would go to a public comment period once it is published, and then we will have a final rule eventually which will direct us for inspection and

slaughter. We decided to change the name to public health based inspection and slaughter because it really is based on public health data and that will hopefully help to clarify between the two when we have these discussions.

MR. TYNAN: Other questions from the audience here?

(No response.)

MR. TYNAN: Operator.

OPERATOR: If you would like to ask an audio question, please press star 1 on your touch tone phone. You will be prompted to report your name. To withdraw your question, press star 2. Once again, if you would like to ask an audio question, please press star 1.

(No response.)

MR. TYNAN: Operator, there are no questions?

OPERATOR: Not at this time.

MR. TYNAN: Okay. Thank you. I'm going to go back to our audience here.

MS. NESTOR: Felicia Nestor, one follow-up

question, Dr. Raymond. You said this one is public health based because it's based on public health data. Isn't RBI -- doesn't RBI in processing use similarly the microbiological data? What other public health data is being used in the RBI in slaughter that's not being used in the RBI in processing?

DR. RAYMOND: There are slight differences, but if we wanted to be a little sarcastic, we could say, well, it's public health based inspection in processing, and there's public health based inspection in slaughter, and then we once again have everybody confused. We're trying to separate processing from slaughter. There are very different regulations which direct our activities, daily continuous inspection versus daily inspection, rulemaking versus no rulemaking. It's all public health based. It's all to reduce the number of foodborne pathogens and other adulterants that the public is exposed to. It's all about putting our resources, our energy, our time, our dollars where they do the most good to reduce the risk of foodborne

illnesses. And you can call it whatever you want to call it. What we're talking about today is inspection in slaughter plants and how we propose to change it based on the data that we have to better protect the public's health.

MR. TYNAN: And I think some of your questions will be answered by some of the other speakers as well. Mr. Elfering?

MR. ELFERING: Yes. Kevin Elfering, I'm on the National Advisory Committee. Just for in preparation for tomorrow, one of the comments that you had was that offline HACCP leads to some of the largest pathogen reductions. If we could maybe have a discussion of which ones those are and have them available for our meeting tomorrow.

DR. MACZKA: David Goldman will be going into that in the presentation on the scientific foundations.

MR. TYNAN: Ms. Kowalcyk.

MS. KOWALCYK: Barbara Kowalcyk, CFI. I just wanted to comment that I am pleased to see that the Agency has kind of undertaken going through this

process. This is something that I think has been needed for a while and will help. I will caution the Agency, this is a monumental undertaking and I've seen the agenda for tomorrow's meeting, and I think a lot more time should be devoted to flushing this process out and making sure that you have it down right because the long term ramifications of it could be significant. And it's very important that you have data people and statisticians involved in this process from the very beginning and taking a very active leadership role in the process.

MR. TYNAN: Okay. Thank you. Are there other questions from the audience here?

(No response.)

MR. TYNAN: Operator, could I ask you to query the folks on the phone?

OPERATOR: We do have one question, sir.

MR. TYNAN: Okay. Thank you.

OPERATOR: Nancy Donley from STOP, your line is open.

MS. DONLEY: Good morning, everybody. It's hot and humid here, too, in Chicago. A question

regarding the small and very small plants outreach efforts, I guess my question is what has now necessitated the move to do this, low these I want to say it's 9 or 10 years HACCP was supposed to have been implemented in the plants? Has there been a new set of problems or just continuing problems so that the folks in RBI system is suggesting that the Agency needs to be more involved in getting more help?

DR. RAYMOND: Good morning, Nancy. This is Dr. Raymond. I'll try to answer that to the best of my ability. What precipitated this was actually we pulled inspection in a plant in Montana, I can't tell you whether it was a very small or small, but it was the small or the very small. Do you remember, Bryce? Bryce says it was a very small plant. We pulled an inspector because of sanitation issues. We got many calls from the Governor of Montana, Senators, et cetera, with many accusations about why does it happen. I asked Bill Smith who at that time was Assistant Administrator for Field Ops to go up to Montana and visit these folks, let them know why we had taken this action, and I asked Mr. Quick as the

Deputy Administrator to go with Bill. And they went up and had a listening session. Actually, they had three listening sessions in three different parts of Montana so that small and very small plants and their elected representatives could come and explain to us their views and Bryce and Bill came back and told me, we've got a real problem in Montana. They just don't get it, and we've got a problem up there. I said just make sure that if it's Montana, fine, but let's do some listening sessions in representative parts of the United States for small and very small plants and get their opinions.

And what we did is we conducted several of these listening sessions and we did find a lot of small and very small plants had not embraced HACCP perhaps as robustly as we would have liked them to. They didn't quite understand what we were trying to get. We hadn't done a real good job probably of working with them in the early phases of HACCP. When we worked with the large plants, they hired -- they had quality assurance folks. They hired HACCP folks to write the HACCP rules to make sure they stayed

within the HACCP regulations but as you get down to the very small plants, they didn't have that type of resource, those type of people, and they really needed some help. A lot of these plants really wanted to have more robust, more science-based HACCP programs but they didn't know where to go to get the help. And that's, that's the message that we got.

So we had a two day meeting with the International HACCP Alliance in Dallas in December of 2005 to discuss what we had heard in these listening sessions, and the International HACCP Alliance spent two days kicking around how we could do a better job of reaching out to these groups. They then went to work and Carrie Harris (ph.) wrote a very nice summary for us, which recommended next action steps which we discussed at FSIS and that all culminated in the public announcement or -- that we were going to put some energies, time and focus and finances into revisiting outreach to small and very small plants.

Many things came about from these listening sessions. One is answers to questions when the resource center, technical service center was called

in Omaha, often times were variable, depending whether you were plant management or whether you were the inspector. Sometimes they were variable depending on who you talked to. We urged our small plants and inspector workforce to call together so they got the same answer. We worked with the tech center to make sure our answers were more consistent. We developed a spot on the web where the most frequently asked questions could be published, so we could just go to the web and get the answer from there instead of dealing with human variabilities. We tried to make it more seamless. But we also began having combined outreach sessions. We combined plant management with our inspection workforce so they were hearing the same thing at the same time. These have been extremely well perceived across the country for the last year.

So I think, Nancy, it was basically a matter of us going out and listening, and once again taking what we heard and instead of being defensive and saying we're right, you're wrong, we said we need to go back and revisit this. We need to try to do a

better job. We need to get everybody more up to speed. We realize there's some risk when we do this. There will be some very small plants or small plants that may say this was good enough for my father and I'm not changing the way I do business. And the point is if we pull inspection from a plant like that, that did not participate in the outreach, I have a little easier time talking to that plant's Senator or Congressman or Congresswoman and saying we tried, they didn't come. The plants that have really wanted our help have come and they have changed and they have much more robust HACCP systems now and our inspector workforce has told us that. So it's been a very productive year.

And thanks, Nancy, for the question, for letting me expand on that.

MS. DONLEY: Could I ask a follow up?

DR. RAYMOND: Certainly.

MS. DONLEY: And that is as you know, in the Farm Bill there's provision where state inspected plants are looking to be able to conduct -- state commerce, and as you know, there is a large number of

small and very small plants are under the state inspection system. Will this outreach -- will these outreach efforts be available to state inspected facilities as well?

DR. RAYMOND: From looking around trying to get an answer, Nancy, I'm not -- I've got one yes and I get one.

DR. KELLY: They are now.

DR. RAYMOND: Oh, they are now. That's why Karlease's got that new position. She's in the back row but she can stand up and yell.

Small and very small plants that are under state inspection currently are invited to these sessions, Nancy.

MS. DONLEY: Okay. Thank you.

MR. TYNAN: Other questions from the group on the phone?

OPERATOR: No, sir, not at this time.

MR. TYNAN: Okay. Thank you. Do we have any others from those in the audience?

(No response.)

MR. TYNAN: Okay. With that, we'll make a

transition to the next group of speakers. We have Dr. Goldman, Mr. Lange and -- yeah, if you'd like to come up, that would be great. And while we're making the transition, I should also mention that we have one of our very public health partners on the phone with us today, Dr. Arthur Liang, who is the Director of Foodborne Disease. He's with the National Center for Zoonotic, Vector-Borne and Enteric Diseases, the Center for Disease Control. He was willing to join us today. So we're pleased that he's on the phone with us.

Dr. Raymond is taking the picture of his grandson and we'll be mailing our pictures out to everybody after the meeting.

At this time, I'd like to introduce Dr. David Goldman. He is our Assistant Administrator in the Office of Public Health Science.

DR. GOLDMAN: Good morning. While we're waiting to get the slides up, I know that everyone in the Agency is gratified to see the interest in this meeting. As was pointed out earlier, this is a monumental effort on our part and to take the

contributions of everyone here in the room and all of our partners who aren't joining us today, to make this successful.

I'll be with you two different times this morning initially to talk to you, remind you about the *Salmonella* initiatives that we have performed over the past year and a half and just to remind you, among other things, that despite the name of this meeting, this entire effort is largely driven by our *Salmonella* problem.

So I'm going to start with this slide. This is again to remind you that our efforts go back now a couple of years. And some of you in the room were at the meeting in Athens, Georgia, which would have been in August of 2005, just about two years ago now, in which we invited the public to come and discuss interventions that may be successful in the preharvest area at reducing *Salmonella* in poultry. Again, in that meeting and as today, focused primarily on *Salmonella* in broilers, but in that meeting we also discussed *Salmonella* in turkeys as well.

We're not going to focus on this. This is a single slide about that meeting, and we're not going to focus on that meeting, but again it serves as a reminder that we did start this effort sometime ago. Some of the takeaways from that meeting in Athens, two years ago, is that we have very good discussion both through industry and academic researchers who have been working on such efforts for sometime to -- and who laid out for us much of the research that has been done on various types of interventions, things like bacteriophages and bacteriocins and certain vaccines and probiotics, many of which show great promise at reducing *Salmonella* as well as other pathogens in breeder stock, in layers, and throughout the farm food chain, farm end of the food chain.

One of the takeaways for me, and I think was shared by most people, is that despite the promise of that research, there are quite a few regulatory obstacles in that some of those advances are regulated by other federal agencies, not FSIS, and specifically APHIS and FDA, and as of yet, many

of those promises have not been able to clear some of the regulatory hurdles in terms of getting approval for those interventions on the farm. But I thought it was a very productive discussion for us to engage in and to hear about the promise of research, and we'll always depend on research to help us solve the problems that confront us.

Another thing, a tangible outcome of that meeting was that we did produce compliance guidelines for preharvest efforts at reducing *Salmonella* and those are on our website.

The focus of the rest of this talk from me will be on our current *Salmonella* initiative which is most familiar to most of you here in the room. Of course, that effort was launched in February of 2006 with a meeting in Atlanta, Georgia, and I think many of you in the room and on the phone were at that meeting.

What I want to do is review for you in the next several slides the changes that are in place in terms of our program which was announced at that meeting, and each of the bullets that you see on the

next several slides correspond to some of the 11 action steps that were proposed and announced at that meeting.

So to begin, we already now have in place a system for categorizing all of the plants but began to focus mostly on the poultry production into three different categories based on their process control as measured by the results of their *Salmonella* sets. I know this is well familiar to most of you, so I won't belabor the details of it, but suffice it to say, we have established three levels of process control indicated by the *Salmonella* set results and basically the best control was defined as less than half of the current regulatory standard for whatever production class you're looking at. And so we've now had that fairly well established.

The initiative has been in place for a year, and so again we'll -- I'll show you some of the results of that, and I believe this is the first time we've publicly discussed the results of the first year of that initiative. However, I think we've also been very good about getting up results onto our

websites and many of you are familiar with looking on our website for the results of those, of the initiatives that we have going.

Another point is that we have now incorporated turkey carcass sampling into the program, another that we announced that we would do. That actually began in late -- in June of '06. So we now have a full year's worth of data for turkeys.

We said that we would post the results of serotype data for the *Salmonella* results that we got, and we have fairly recently posted the results of the latter two quarters of the calendar year of 2006 on our website. I think it actually went up in late June of this year and, of course, the interest for us as well as our partners is to be able to associate the levels of particular serotypes of human health concern with a reference to the CDC's website which lists the serotypes of greatest human health concern. And so we have now posted that data. I think we can expect one of the new postings in the near future will be the first two quarters of this calendar year. So by that time, we will have a full year's worth of

data of the serotype data in particular.

We also said that we would post the quarterly reports. We have been very successful at getting those quarterly reports up by product class. Hopefully again you have looked at our website and are familiar with those reports. In fact, we just this past Friday posted the second quarter report. So we are getting those reports up in a timely way and hopefully you'll find that they're beneficial in your review of them.

We also did produce a compliance guideline for broiler production, and that was issued first in August of 2006, and there is a second edition going through clearance right now. Part of the ongoing effort is to focus our food safety assessment. This was a very important part of this initiative, and we have decided that in addition to the historical focus of food safety assessments on plants that failed *Salmonella* sets, we are now increasing our food safety assessments in those plants with what we call variable process control, Category 2.

The Agency is also continuing to look at

its subtyping data and ensuring that we fully subtype all of the *Salmonella* isolates that we have available to us, and that we can look at that data and analyze that data in order to do two things. One is to associate with ongoing human illness but also hopefully in the future to be able to use the subtyping data in a predictive way by recognizing trends in certain subtypes and certain product classes and being able to intervene with the industry or other partners as appropriate to address those trends.

And just so you know, some of you probably do know this as well, we've asked our National Advisory Committee on Microbiological Criteria for Foods, to look at what I would call the next generation of subtyping methods. This is something that we've recognized for a couple of years now that we need to do. There are a variety of lab methodologies out there that will help us more precisely isolate the pathogens that we're concerned about, and be able to associate those pathogens across the spectrum from food specimens to human

isolates. So NACMCF is looking at that currently, and there's a subcommittee looking into that. In fact, this week they're looking at that.

Finally here, you do know that we have a young chicken baseline that's been ongoing. We will begin a turkey baseline late in this year. Once we get information from those baseline studies, we will obviously do some analysis of the results of that but in the second talk I'll present later today, I'll talk about how we'll incorporate that into one of the risk assessments that's been done to support this effort today.

We continue to look at our risk-based algorithm for conducting food safety assessments and scheduling sets for example. One of the ways we're looking at this, continue to look at this is to decide how to incorporate serotype information into making those decisions about which plants we should schedule for *Salmonella* sets or which plants might need a food safety assessment.

And, of course, the final couple slides here will talk about or will actually show you how we

have continued to monitor the changes between the categories, and I'll show those over the next couple of slides. I want to remind people that we set a target at the beginning of this initiative that we wanted 90 percent of broiler production facilities to be in Category 1 by the year 2010. And so just keep that in mind as you see the next table here.

I'm not going to go through all of the results here. You already have these slides and, of course, they'll be on our website as well. And again the focus is on broilers primarily with this initiative but I just show all of the product classes because it's important for you to know that we are tracking the progress or lack thereof of the other product classes as well. But I want to point out to you, if you'll look at the numbers in the upper left there for broilers, we began with 35 percent of the broiler establishments in Category 1. And as of the end of the second quarter of this year, the end of June this year, we now have 72 percent of those establishments in Category 1. So this is actually remarkable progress we think, and it exceeds our

expectations, and it'll show that on the next slide.

Just to point out for those who aren't familiar with looking at this data, the reason, of course, there's no data at the beginning of the initiative for turkeys is that we weren't conducting ongoing or regular testing of turkey carcasses at the beginning of the initiative.

Okay. This is a real busy slide, and it's a depiction again of the change in categorization of broiler establishments. So this slide is just focused strictly on broiler establishments. And what I want to point out is that this is actually just a different way of depicting what I just said a minute ago, but if you look at this bar here, this shows that 72 percent of the broiler establishments are in Category 1. And if you were to start here and draw a straight line, we've just established a linear measure of our progress, as we started the initiative, but you can see that we've already changed that line so that again, we've exceeded our expectations to date. Of course, the final results won't be in until 2010, and ultimately the final

results won't be in until we show that we can reduce human illness relating to *Salmonella*. So again, we appear to be on target, in fact, exceeding our target at this point in terms of moving broiler establishments into Category 1. And I think what this demonstrates and what I've just laid out to you demonstrates is that the various steps, the action steps that the Agency has implemented, and that the industry has responded to, have so far resulted in some meaningful reductions in the level of contamination of raw products, and in particular, broilers. And we again assume and hope that that will lead to reductions in human illness.

I will point out that the ongoing baseline in broilers as well as the baseline that will start at the end of the year in turkeys, will provide us important information on *Salmonella, Campylobacter,* and generic *E. coli,* and we will actually be quantitating each of those results. And that information will be very helpful to us as we continue to monitor our progress.

So with that, I will entertain any

questions you have about that rather quick review of our *Salmonella* initiative.

MS. KOWALCYK: Barbara Kowalcyk, CFI. I have a couple of comments that I'd like to make on the new *Salmonella* initiative. First of all, I do want to caution the Agency on their use of the *Salmonella* verification testing program data. It was designed to test whether or not a specific establishment was meeting the HACCP performance standard at a specific point in time. It was not designed to draw inferences about an entire population. I've raised this point before, and I just want to caution the Agency again, once again to watch that.

Earlier you said in describing the percent of establishments that were in Category 1, jumping from 35 percent at the beginning of 2006 to 72 percent in the second quarter of 2007. This is not exactly surprising. I would have anticipated, based on the way that the *Salmonella* initiative is structured, that this would have happened. The *Salmonella* results are fed back to the plants on an

ongoing basis. They have knowledge that they would be placed in Category 1 if they achieved less than 50 percent of the *Salmonella* performance standard and are aware when they are approaching that limit. Furthermore, they have an incentive to be in Category 1 because that means they are not inspected or tested for another two years. So one would anticipate that establishments would do whatever necessary to get the Category 1 establishment categorization. So they could -- in essence what I'm trying to say is that these results are not necessarily reflective of process control over the entire period of time. You have to really question whether or not this jump in category 1 is really in response to the fact that they have the incentive that they won't get tested for another two years. So there's that issue.

The next issue is based on your last slide, you're hoping by 2010 to have 90 percent of establishments in Category 1. The whole premise of HACCP to my understanding is statistical quality control and in statistical quality control, you're trying to reduce variation, and you do that by

setting performance standards or limits, bringing everyone into control and then further reducing it and bringing everyone into control. There's always variation of every process. So you'll never get to zero.

Okay. Now my question is if 72 percent or 90 percent of plants are in Category 1, isn't it time to reduce the performance standards? You can't just be looking -- by not reducing the performance standards, you're in essence maintaining status question rather than improving the system. We don't just want to increase the number of Category 1 plants. We want to improve statistical quality control and have less foodborne pathogens going out in those products.

DR. GOLDMAN: Okay. I heard your first two comments and the question there at the end. I think that you make a point that we have discussed in the Agency for sometime. Of course, when the HACCP was first introduced, there was always the intention of reexamining the performance standards and making some determination in the future that it may need to be

adjusted. I think that we still have that discussion here, and I think your point is well taken. Dan actually may address that toward the end of his comments when he wraps up and puts this altogether but, yes, we have discussed that, and I think we understand that that's an important consideration as we move forward. We don't want to just get to some level and just stay there, especially if we get to that level, and we haven't seen a reduction in human illness. Then obviously we need to do other things.

MS. KOWALCYK: Well, obviously the 2006 FoodNet data shows that some levels are currently at the 1996 levels. So that is a problem. I think that there should be no time that we should have 90 percent of establishments in Category 1 because that indicates that the performance standards are too high, and HACCP is based on statistical quality control. This whole thing was the performance standards were supposed to be reviewed and adjusted on a continual basis, and they have never been adjusted. It's at the levels of the 1990s. So the Agency just can't -- I know one of the things this

meeting is to consider and the NACMPI meeting is to consider are adjustments in the processing such as lines, meats and so forth. You can't allow adjustments in processing by reducing or increasing line speeds without also adjusting the performance standards down. That's my point.

DR. GOLDMAN: Okay. Thank you. And let me point out for everyone here that the Category 1 is actually half of the existing performance standard. So I'm not discounting your point at all. I just want to point out for everyone that the Category 1 that we're striving for at the moment is half of the existing performance standard. I'm taking over Robert's job.

MR. TYNAN: I was put out of work. I do want to mention that we are going to have a longer period for comments. So if there's questions and multiple follow up questions, we don't want to discourage you from asking those questions but we do, in fact, have a timeframe that we're trying to work against. So if you could just pose a couple of questions and clarify a presentation and then let's

move onto the next questioner. So, Mr. Corbo, it's your turn.

MR. CORBO: Tony Corbo from Food and Water Watch. I recall when the Agency announced its *Salmonella* initiative that at some point it was going to post on the Agency website those establishments that were not meeting the *Salmonella* performance standards. And as I recall, the date that was targeted was July 2007. Does the Agency still intend on posting those and when will those be listed?

DR. GOLDMAN: If you are here at the end of the meeting, you will hear about our plans to do that. So we will get to that. Thank you.

UNIDENTIFIED SPEAKER: Tony took my question. So I'll just reinforce Barb's point about the need to really adjust the performance standards. If 72 percent now of these plants are meeting half of the performance standard, that tells me that the performance standard is way too high. So I just advise the Agency to continue to focus on trying to bring those down. Thank you.

MR. ELFERING: Dr. Goldman, I apologize if

I didn't hear this. I just have a quick question. I'm Kevin Elfering of the National Advisory Committee. Are you going to be doing any molecular subtyping by PFGE of any *Salmonellas*, comparing that to public health data and what you know as to actual outbreak cases?

DR. GOLDMAN: Yes, yes. We do a little bit of that now. We're going to make it a fully robust program in the very near future.

MR. TYNAN: Are there any questions on the phone?

OPERATOR: Once again, if you would like to ask a question, please press star 1. One moment.

(No response.)

OPERATOR: We have no questions from the phone audience, sir.

MR. TYNAN: Felicia.

MS. NESTOR: Felicia Nestor from Food and Water Watch. As some of you know, I've gotten a database for the *Salmonella* testing statistics since 1998, and I've been looking at them, analyzing them periodically. And the one thing that I note is that

just because a plant achieves a terrific performance on the *Salmonella* standard, doesn't mean that it's going to maintain that. In fact, there are some really drastic fluctuations and I've got that on a chart if anybody wants it.

So I'm just wondering, how are you going to monitor that when you decrease the *Salmonella* testing of these plants. You promised them you're not going to test them again for two years. How do you know they're not going to all of a sudden lose control because they have no incentive? Would the Agency consider doing something such as doing *Salmonella* testing at the plants on an unofficial basis? In other words, there's no regulatory action if you fail the set, but we're just going to monitor and see whether exempting you from regulatory action gives you an incentive to loosen your controls.

DR. GOLDMAN: Thank you for that comment and that question. I think I'm going to defer answering. I think we will get to that, and if we don't, remind us at the end of the presentation but thank you for that question.

DR. VETTER: From an in-plant verification perspective, what my experience has been is that a lot of these plants that are attempting to achieve Class 1 goals, have either implemented CCPs or a multiple huddle approach, and they themselves are doing ongoing testing, that we monitor through our verification activities on a daily basis. And if they're outside of those controls or boundaries, then we would write that as a noncompliance.

MR. TYNAN: Thank you, Dr. Vetter.

MR. STROUT: Don Strout (ph.) from George's Chicken. I just want to clarify that, you know, our company does not totally rely on the USDA's sample set for their monitoring. We do multiple testing every day and it's continuous testing, and we share that information with our FSIS people at the plant. So it's not just a once every two year testing period. We test every single day.

MR. TYNAN: Thank you. Any other questions in the room or on the phone?

(No response.)

MR. TYNAN: We're actually a little bit

ahead of schedule, which is also good. What we're going to do is -- I know on your agenda it says break, and as I mentioned earlier, we're not going to take one, other than to -- if some of you gentleman as I look out, I know I'm a little bit warm up here myself. If you want to take your jackets off and relax and get comfortable at the meeting, we'll take a two-second break to do that.

With that, I'm going to introduce Mr. Loren Lange. He is also with the Office of Public Health Science, and he's going to talk a little bit about the public health lessons from our HACCP-Based Inspection Models Project.

MR. LANGE: Good morning. I'm glad to be here but I'm having more senior moments as recently accounted in the speech for Dr. Karen Hovac (ph.). I ran through the whole speech and the introductory slides. You -- keep me on track so I don't do that.

Anyway, good morning. The topic I'll be talking about is public health lessons from HACCP-Based Inspection Models Project. I think the title is an important distinction because if you look on

the FSIS website, you'll find volumes of material that cover the HIMP project or what's called the Models Project and most of it did pertain to what we in the Agency have always called other consumer protection responsibilities. So a lot of HIMP was focused on trying to control the defects that had been mentioned of bruises and feathers and pinfeathers. So this talk is entirely about HIMP and *Salmonella.*

I'm going to cover three topics. I've divided it into three sections. I'll begin with an overview of the current young chicken HIMP establishments, sort of who are they, what are they. Then I'll move to a summary of data that was collected before and after HIMP implementation and specific plants and finally, I'll end with comparing data from the HIMP establishments, the data for traditional establishments.

As I said, this will just be an overview of the current HIMP establishments. There are currently 20 young chicken HIMP establishments. If you go into our HACCP designation, it says that 18 of these are

large and two are small. Sort of just ignore that because that's based on 500 employees, and I think if you look at the -- well, since we have the slaughter volume data, it's more about whether the plant has an intensive number of employees for cut up and packaging. These are all really large slaughter operations and HIMP is about what occurs on the slaughter side of an operation. So I tend to think of these as they all fall into large slaughter operations irrespective of the HACCP designation.

In calendar year 2006, there were actually 224 different federal establishments slaughtered young chickens under federal inspection. 177 of these account for greater than 99.9 percent and that is sort of how I define the population of young chicken slaughter establishments. Once you get beyond this 177, you're into plants that feed I guess what an economist would call a niche market, free range chickens, organic chickens, and also there's a fair number of plants that operate under religious exemptions. There are a surprising number of plants that have Confucius and Buddhist exempt operations

where the birds are actually, you know, shipped out with the feet and heads still attached, and I think there's one or two plants in the country that still do a little bit of unviscerated Kosher type slaughter.

So the 177 really is the population that we're talking about. So HIMP is 11.3 percent, 20 of that 177. In calendar year '06, those 20 HIMP establishments account for over 16.5 percent of the young chicken production. So one could conclude right now 1 out of every 6 birds is now produced under HIMP.

I thought it would be good just to sort of review when the existing 20 joined the HIMP plant. The first two started in 1999. The biggest chunk was added in the first half of 2000. There were 8 plants started from January to June of 2000, and then nothing for half a year and the last 10 came on from January 2001 through 2003. In 2003, there was a plant that actually closed and there was a plant added to take the number back up to 20. So it was added just because of a plant that had closed.

I will say, before we leave that slide, that in the early years if you followed the dialogue on HIMP, there were a lot of issues. It was a volunteer project. Five plants, you know, dropped out very early and plants were in and out of it. So there wasn't a constant. This 20 that exist today I think have about 11 of the plants that originally started in the project.

And to conclude this section, I just remind people that HIMP was designed to free up inspection resources for additional higher priority public health tasks or higher priority public inspection procedures. It was not specifically designed to be the goal of reducing the incidence of *Salmonella.* But more recent data indicate that HIMP, in conjunction with the types of inspection procedures performed, is having a positive effect overall on public health because it is producing chickens with overall lower levels of *Salmonella.*

Topic number 2, in this section, I want to summarize some of the data that was collected before and HIMP implementation. This will be dealing with

data that covers the same establishments but different time periods, before they joined HIMP and after they joined HIMP.

As the establishments were joining HIMP and we had a contract with RTI that had a subcontract with a laboratory that collected and analyzed samples from 300 carcasses before and 300 carcasses after HIMP implementation. This process was actually applied to both before and after to 11 different establishments. There were some plants that got the before and dropped out. There were others that came on later and didn't get the before but we got the after. But there were 11 plants that actually had data from both before and after.

These samples were collected, 10 samples per day for 30 days, for about a six-week period. The sets of 300 that were collected were referred to as baseline versus Models data.

There is also the first eight that were completed, were published in the Journal of Food Protection in 2001. The reference is on here. As you can see in the small table, the cumulate results

from the baseline for those 8 plants, that was before HIMP, was 5.7 and after the Models Project was 5.9.

The conclusion was published in the Journal that although *Salmonella* prevalence rates for the two phases were not significantly different, there was a minor increase numerically in a lot of the states. This may be a reflection of the more sensitive *Salmonella* detection method used in the Models phase for two of the plants. I wasn't even aware of that until I put this talk together. But one thing I do want to point out, is we had those eight plants, when you look at the HIMP data, they all look very unique. There were three that actually went up significantly. There were three that went down significantly. And there were two that weren't changed.

And before I move on, I do want to mention this. Since I mentioned there were 11 plants that had this data, this is the published data I could find on this was in the Journal of Food Protection, there is a reference in what I'll talk a little bit later about what was called the third party review, a

team selected by the HACCP Alliance. There is a reference in there to when they looked at all 11, that there was a larger difference in the before and after. In fact, in that paper it talks about going from 4.6 to 9.2. I didn't put a slide in on that because I don't like to have a slide when I don't have the data, and I can't get the data, and my understanding is that FSIS does not have the data by specific plant that was collected, you know, under contract. But again, just why I'm a little suspicious of it, the HACCP Alliance Team sort of said, well, they found that but it seemed to be inconsistent with other data, and I looked at -- you can sort of back into it. What would those plants have had to have to sort of change it that much, and those 3, if they 300 before and 300 after, they would have had to have gone from 1.78 percent before to essentially 21 percent after. It's totally inconsistent with what we were seeing in HACCP verification results during that timeframe, but in the interest of wanting to be all inclusive, for people who search the website, that's on there, and

it's sort of on there and it's sort of on there a little bit unexplained data, but I did want to cover it. Next.

As we mentioned, this data was collected in 30-day windows. There were a lot of questions raised at that time about how the 30-day window could have been affected by seasonality because there was no control over when the baseline samples reflected versus when the Models sample was collected. Not quite yet. I want to show a slide from the February 2006 public meeting that really shows that seasonality was in early years a big issue. I also presented data down there that shows that it's totally -- it may not have disappeared, but it's been totally masked by other considerations. I mean if the seasonality is still a real factor, if you can hold everything else constant, it would probably still show up but other changes have just totally obliterated seeing any visible seasonality in the data. So this is the data that was presented last year, and it covered from 1998 to 2004, and I think -- that was always one of my favorite slides because

I loved trigonometry and you never find real world data that follows such a single, solo type curve as this over seven years of data. But it really doesn't exist anymore.

Okay. From one other internal FSIS analysis of before and after HIMP implementation, this was sort of a little bit of an extension I think of some data that was presented at the June 5, 2002 Advisory Committee, but this is through the end of 2002. The staff had looked at 20 plants at that time. Nineteen of them are the same that we have. The only change has been the one that closed and the one replacement, and they looked at the data, the HACCP verification data from the period in 1998 when HACCP sampling started through the actual date of when each plant converted to HIMP and then after, and they found that 1998 through HIMP implementation, those plants averaged 8 percent and from HIMP implementation through December 1, 2000, 7.9 percent.

Now a familiar pattern from what I said before. There's 20 plants here, 11 went up, 8 went down and 1 remained the same. That's 20. Good. So

that is sort of a similar pattern, and we don't see consistent patterns in what happens when we look at this data.

The conclusion from this second section of the talk is that the majority certainly have the data to support the conclusion that the implementation of HACCP in young chicken establishments from 1999 to 2001 does not appear to have had any short-term effect on the overall *Salmonella* rates on an average across the HIMP establishments. You see differences from establishment to establishment, but on the average, we don't see a significant change there.

The last section, third topic, this is now going to be comparing the data between HIMP and traditional establishments. So we're talking the data they compared over the same time period but different establishments as opposed to where we had the same establishments, different times periods.

And first back to what was called the third party review. That was conducted in September-October of 2002. FSIS had asked the HACCP Alliance to select the team that conducted this review. They

reviewed the literature on HIMP that they had at that time. There was a GAO report. They have the RTI Journal of Food Protection article I mentioned and the Agency gave them other data because they did look at FSIS data for 21 establishments that were operating under traditional versus 21 that were under HIMP.

Now I assume, but I couldn't find an exact record because I don't have what we gave the third party alliance, but I assume the 21 traditional were kept somewhere on a matching pair, either by size or by state to try to form a similar group of establishments under traditional inspection at that time and compare them with this. I know that the data is prior to September 30, 2002. I couldn't find the exact timeframe. In this analysis, they report in their paper that they found 8 percent from traditional establishments, not significantly different from 8.2 percent under the HIMP system. The review team stated that they thought that since this data was from sets over 51 days, over approximately 3 months of -- time, they should have

reduced the potential for the seasonal bias that might have existed in the earlier data, and plus the 51 sets across the 20 establishments were being scheduled at different times of the year. So I certainly wouldn't quibble with their inclusion there. Their review conclusion is these data suggested implementation of the HACCP system did not affect some -- recovery frequency.

Now the slides that I'm going to show pretty soon here will compare the *Salmonella* results from HACCP verification sampling, again, this is our regulatory sampling of the 51 sets but it's the HACCP verification sampling for HACCP versus traditional covering the complete timeframe from 2001 to 2007. I'm aware that earlier presentations of data trying to make this type of comparison have asked the question, do HIMP establishments have lower levels today, will they continue to have lower levels because of the group of volunteer plants favor the plants that have the best control system and continue to have the best control system.

My conclusion is that it's kind of hard to

answer, and it's really next on that. I did generate this table where I looked at our 1998 data when we started sampling. We had 17 out of the 20 current plants were tested as large establishments in 1998. Interesting, one of the ones currently a small was actually large in 1998 and was tested in the first year. Those plants that were eventually going to become HIMP plants had 10.7 percent and all large establishments, of course, this was 1998s, so only large establishments were being tested, across the board they were 10.8. Now I would say they're essentially the same. We didn't see any difference.

In 1999, we do start to see some difference, some evidence that the HIMP plants were doing better but as I sort of drilled down into the data a little bit, I did find the observation that four of the plants that were in 1998, that had the highest results and were over 15 percent, they were barely represented in the 1999 data. Don't know why. Those four plants I think had about -- combined about one set of data in 1999. So that could have had an influence. And I did make the comparison here with

large. The 9.8 was essentially the large recognizing that, you know, the 19 plants have a couple which were small, but as I tried to explain earlier, they're really large plants, and when you get down into small, you start getting into plants like I mentioned earlier that do have the, you know, religious exemption, and we were fighting over 70 percent, *Salmonella* in those plants, and we don't test them anymore because they weren't part of the original baseline, but with the heads and feet remaining on the birds, they do have a unique control problem.

My last bullet here is were the better plants starting. I'm thinking of Felicia's comment here. You just see a high level of variation. I mean they weren't all plants that started out well. We had a plant that had three sets. One of these plants had three sets under traditional, almost 22 percent and while they've been under HIMP, they're down to 8.4 percent. We've had other plants that have gotten worse. The one thing I do see when I look at them, I didn't get a chance -- I got the data

run finally yesterday showing each HIMP plant over time so I can actually graph it out over time. What you do find is there's a lot of these plants, not every one, they'll have a spike. They'll have one year, they'll have one time period where we did a set. There's a plant that has 11 sets. Ten of them are down there in 2003. It just had a spike.

We had another plant that had a spike -- actually a plant that failed the set after we announced our initiative last year. Over time, the plants have good records and then another one spiked in 2005. So 2003, 2005, 2007, you see these sort of anomalies and the data.

And now the graphs. This is a graph that shows HIMP versus non-HIMP plants, 2001 to 2007, all FSIS sampled. So they would include what we used to call A, B, C and D. So both follow. It's all the samples that we've collected in the mandatory program. We do see that as a group, these 20 plants that are now in HIMP, have consistently had lower levels of *Salmonella*. At times, I think the biggest differential here is that in 2005, the non-HIMP

plants, the rest of the industry hit 16.9 percent. The HIMP plants were down to 10.5 percent. The other thing I observed on this one is that we see when the rapid increase is going on and overall from 2003 to 2005, the HIMP plants actually did decrease those from 2003 to 2004 and 2005. And, of course, the data for the first half of this year, 5.4 percent. That's a level we haven't seen before. That's a pretty impressive I think level of *Salmonella* control. There are 650 samples already in 2007. So, you know, if we've got 20 plants, if they all had a complete set, we'd have 10,020 samples in a year. We've got about 64 percent of that already. So we've got a set where we've gotten data from essentially, you know, almost two thirds now of getting -- year. The 2006 data that was 8.9, we had essentially a set from every plant in 2006. So at this time, none of the HIMP plants have been devoid of samples for any period of time.

Since we think of the HIMP plants and I described them as essentially large plants, this graph, it's the second of three on these where we

compare the HIMP plants versus the large non-HIMP plants. The difference that you see here is that where the non-HIMP plants went up, in that 2003-2004 period, large plants really didn't. They actually went down in 2004 and then spiked up in 2005. The plants were a little bit closer together on the average when we compared the large versus non-HIMP but again, as a group, collectively every year they have had lower levels of *Salmonella.*

And for completeness, we have one more comparing large non-HIMP versus just the large HIMP even though dropping out the two small ones really doesn't drop out the small slaughter operations. I didn't really see any noticeable change here except you don't have that three year slight reduction in HIMP plants, and it actually increased a little bit in 2004. But again, collectively a lower level of *Salmonella.*

The conclusion from the third part of the talk before I wrap up is over the years, the HIMP plants have continued to control *Salmonella* below the industry average, and overall industry rates were

increasing during the 2003 to 2005 time period. The 20 HIMP plants actually shows a slight decrease.

Before I end, I just want to talk a little bit about tying in what we know about characteristics of these plants and what we're doing, and the next slide will point out that what are the major differences that we're aware of. HIMP plants have a far larger number of offline inspection tasks, that is HACCP verification tasks, and we know that the establishments and these plants are assuming different responsibility for sorting carcasses along the line. And the final bullet here is what both Carol Maczka and David Goldman have already referred to is we have this risk assessment now that will be the subject of a public meeting. This risk assessment will integrate the details from issues like numbers of inspection tasks, the types of specific inspection tasks, the results, the number of NRs and *Salmonella* results and do a risk assessment covering all, not just the HIMP plants, all young chicken establishments.

And I think I'm right on this, but this

model in my mind, it's dynamic as opposed to -- It won't look at averages. There will be a time consideration of different types of NRs occur and relating that to the *Salmonella* positive/negative rates in relationship to NRs. So I think this will be a tool that will provide a lot of input to the Agency and will help us justify potential changes in the future and changes to what controls, whether we call them guidelines or we have standards, and it will just be a very valuable, you know, instrument, tool, method for the Agency to have.

I wanted to make a couple of specific things, this risk assessment will incorporate specific NR findings such as has been found in recent internal study and that was of the HIMP young chicken plants are receiving approximately three times as many HACCP, O3J procedures, as their non-HIMP counterparts, and they're achieving a higher level of compliance with the statistical significant difference of at least 95 percent confidence level. Also the HIMP young chicken plants are receiving nearly the same level of sanitation inspection as the

non-HIMP counterparts at this time. They are achieving a slightly lower level of compliance but it isn't statistically significant at either the 90 or 95 percent level.

And finally to wrap up a summary of conclusions of this presentation is the implementation of HIMP in young chicken establishments during the 1999 to 2001 period did not appear to have an effect on *Salmonella* rates before and after. But over the years, the HIMP plants have continued to control *Salmonella* below the industry average and the overall industry rates were increasing. The 20 HIMP plants actually were showing a slight decrease and that we now have a risk assessment that's going to add to our understanding of the relationship between the -- procedures and pathogen levels across all young chicken slaughter establishments. Thank you.

(Applause.)

MR. TYNAN: We're going to let Mr. Lange sit down but before Felicia comes up, I'm going to change the routine a little bit and allow the folks

that are on the telephone to maybe pose the first questions. Operator, can I ask you to query the people on the phone please? Operator?

OPERATOR: Once again, if you would like to ask a question, please press star 1.

(No response.)

OPERATOR: At this time, there are no questions.

MR. TYNAN: Okay. Thank you, Operator. Now we'll turn it over to the people here in the room for any questions they may have.

Thank you, Felicia. I'm sorry to have gotten you halfway up before I changed it.

MS. NESTOR: That's okay. Unfortunately, I'm not near --

MR. TYNAN: You're going to have to speak into a microphone.

MS. NESTOR: I was saying unfortunately I haven't been near an outlet, and so my computer is going to shut down on me any second. So I'm going to do this by memory.

MR. TYNAN: Please, would you identify

yourself.

MS. NESTOR: Sure. Felicia Nestor, Food and Water Watch. Loren, you were talking about the drastic difference between the two data sets. Was that between FSIS and RTI?

MR. TYNAN: I gave Loren a chance to sit and relax and --

MR. LANGE: Okay. I wanted to bring -- I wanted to make sure I mentioned it because if you're familiar with the third party review that's on the website, they did point out that when they looked at all 11 of these, they saw a significant increase. They saw this 4.6 to 9.2 from the baseline of the Models. So then what I did is I said, well, there's three plants that weren't in that RTI general food protection plants, and I said, what would those plants have had to be before and after to sort of change the data that I showed in the table to get to what was mentioned here, and I said they would have had to go from 1.7 to 2.7 and then what I did after that is I said, okay, I went and looked at those three plants. We had essentially six sets from

before HACCP implementation. These are plants that had very low levels then. They did have 3.4 people in 293 samples. After HACCP implementation through the end of 2002, they had gone up to 31 out of 306, essentially 6 states under the Models with about 10 percent which is a lot different than 22 percent. So I don't have the data from those three plants. I don't know if it was given correct to the third party review. I just didn't put it in the presentation because it just doesn't seem to comport with --

MS. NESTOR: Well, what were the dates they were collected and who collected that data? Did RTI collect the data?

MR. LANGE: RTI collected the data, yeah.

MS. NESTOR: So, in other words, the FSIS inspectors did not collect that data?

MR. LANGE: No, well --

MS. NESTOR: They did not collect the samples.

MR. LANGE: You're asking the wrong person on that one. I'm not familiar with that, but that was the 300 before and after and RTI collected those

samples.

MS. NESTOR: Okay. And was that around maybe 2000, before 2000? Around 2000?

MR. LANGE: The start date for those three plants for one of them was January 16, 2000. The start date for another one was June 26, 2000, and the other one was January 22, 2000.

MS. NESTOR: Okay. We can probably discuss this more in the public meeting, but I have just some evidence of why you may have had the great difference. In 2000, I called the tech center, and asked the tech center, the person responsible for slaughter inspection and *Salmonella* inspection, test collection, if an inspector chooses a random sample for the *Salmonella* test and it's a fecally contaminated carcass, should the inspector sample that for *Salmonella*, and I was told no because we already know it's contaminated and therefore the inspector should work with the plant to get the process back under control and then take a random sample. And I said, wait a minute. That doesn't really sound like random sampling. Aren't you

supposed to sample whatever comes up, and he said, no, because we already know that it's fecally contaminated. So I wrote a confirmatory memo. I said please write back to me if I'm wrong. Didn't get anything back. Then I wrote to him many months later, and said I just want to make sure again that we're on the same page here, and I got the same answer again. So it appears that I don't know how many inspectors were calling the tech center answer line on how you take a *Salmonella* broiler sample, but if they were calling, perhaps they were throwing away the fecally contaminated samples and RTI wasn't throwing away the fecally contaminated samples. Maybe that's the source, I don't know. You have sample sets for all of the HIMP plants. Do you have sample sets for 165S?

MR. LANGE: Yes.

MS. NESTOR: You do. Okay. You know, as I said FOIA, I've gotten all the *Salmonella* results at least four times, and I've never gotten any results for 165S. So perhaps the Agency can share those with me.

MR. LANGE: I'll share them with you.

MS. NESTOR: Okay. To your remark about, you know, anomalies, unfortunately I only have data up through 2005, and I think you said that it would be -- the standard on HIMP was about 10 percent. The HIMP plants had about a 10 percent *Salmonella* rate.

MR. LANGE: In that period 2005, yes.

MS. NESTOR: Yeah. Well, some of the -- there are 20 plants, and I have results for five of the plants that are at least over that. One had nine positives. I don't know what that is, but that's -- I guess that's close to 20. One had 11. One had 19. And then a set that's not recorded and then 5 positives, another had 7 and another had 10. So, you know, I think that the variation in the HIMP plants also needs to be considered because, you know, it doesn't matter to a consumer whether the chicken that they're eating, there are several other plants that are doing so well that it offsets the condition of the chicken they're eating. So I think that's something that the Agency needs to look at also.

MR. LANGE: As I mentioned, I do, and I

just yesterday got a chance to look at the detail for each of the HIMP plants and, you know, I'm open to discuss it with you anytime. I know you can get it under FOIA but since you spend more time looking at this data than I do, I'd rather have you look at it and --

(Laughter.)

MR. TYNAN: Mr. Painter, if you could identify yourself and your organization please.

MR. PAINTER: Stan Painter with the National Joint Council. I'm wondering if we have any statistical data regarding the HIMP plants versus a regular plant as far as microbial. I'm wondering if the HIMP plants are using more of an anti-microbial rinse versus the rest of the plants because the Agency over the years can never give me any explanation as to why the numbers are lower.

DR. ENGELJOHN: This is Engeljohn with the Policy Office. Stanley, we don't collect that information at this time but as we move forward in our process for better understanding what's happening in the systems we regulate, that information will be

part of what we collect, so that we would have some knowledge as to what's in use at the time the samples are collected and whether or not there are changes in the use of those treatments after the point in which the sample set is done and another set is taken. So that's the kind of information we'll have in the future. We don't have that now.

MR. PAINTER: I have two further questions. When is the Agency going to or is the Agency going to look at the leukosis regulation that states 1/32 lesion or greater when identifiable lesion and when is that going to be given the weight it deserves and when is the Agency going to stop sending product out the door and HIMP plants with the mark of inspection that has never been inspected?

MR. LANGE: If I could, Stanley, the leukosis issue we'll deal with the rulemaking process, and I'm not familiar with the issue you're raising there, but I am curious to get more information about product not being inspected, if you could give us a little more context.

MR. PAINTER: Well, the Agency allows it to

go on every day in your giblets, your livers, your hearts, your necks, and gizzards go out every single day that never pass by an inspector. There's two tests that are done of 10 pieces of product each two times a day, and yet it goes out with the mark of inspection just like the chickens that are supposed to go by every inspector. So how does the Agency allow that to happen with the mark of inspection when it's never been inspected?

MR. LANGE: We'll deal with that issue as we go forward with the rulemaking.

MR. PAINTER: But can you give an explanation for the reason -- how has it gone on, in other words, you're saying that you're going to deal with that during rule making, but how can you justify since October of 1999?

DR. ENGELJOHN: Stanley, this is Engeljohn again. The only explanation I would have at this time, and I certainly will have to get clarification on this, if I'm wrong on this, but if the issue is that the -- this would be part of the 10 bird viewings that are done in terms of verification by

FSIS, which I'm assuming that's what you're referring to, the 10 bird or 10 sample verification, and they're listed as OCP activity, other consumer protection as opposed to food safety.

MR. PAINTER: No.

DR. ENGELJOHN: If that's not the case, then I'll get more information and we'll get back to you on that.

MR. PAINTER: See, that's totally not the case. I mean to infer -- it has nothing to do with the bird. It's the liver, the heart, the internal organs that go out with the mark of inspection daily as we speak.

MR. TYNAN: Stanley, if I could, I don't think Dr. Engeljohn quite understands the circumstances and we're taking up the whole time trying to communicate that. If we could, if we could maybe do that either at the end of the comment period, perhaps you could meat with Dr. Engeljohn offline and sort of talk about the context and you can perhaps explain it because I'm not quite clear on it at this point.

MR. PAINTER: I'll step down and yield the microphone, but this is a concern. I've heard three people come to the microphone and you all say we have that information but we'll share it with you later, and if we don't share that information, will you get back with us and, you know, I don't like the comment to go on the record, you know, so in being totally transparent, I think that we need to do so. We need to put our money where our mouth is.

MR. TYNAN: Thank you, Stan. Ms. Kowalcyk.

MS. KOWALCYK: Barbara Kowalcyk, CFI. Loren, I had a couple of questions for you, just trying to get at the question you were trying to address in your presentation about are the HIMP establishments just overall better than the non-HIMP establishments, and what are the criteria for being put into the HIMP program?

MR. LANGE: They were volunteer plants.

MS. KOWALCYK: Well, obviously then if they're volunteer plants, then there is a self-selection bias for HIMP plants over all plants, and that may explain the difference. I think the

important thing to note here is that there really is no significant difference based on a post baseline in the HIMP plants and one would then not expect that the HIMP program would reduce *Salmonella* contamination but really should be viewed as a management tool and not really be expected to have a public health benefit.

MR. LANGE: Well, I think that that question will be something better addressed when we get into the deals of risk assessment because the risk assessment is starting to show that with HIMP in conjunction with the increase of offline inspection tasks, they are seeing relationships between, you know, compliant verification tasks and *Salmonella.* We'll learn more about that. I agree at this point.

MR. TYNAN: Okay, Ms. Kowalcyk. Hold your thought until -- we're right at 11:00. I'm going to take this gentleman's question and then we'll go to the phones.

MR. KLOPP: My name is Buzz Klopp. I'm a veterinarian with Townsend, Incorporated, Georgetown, Delaware, and I just -- we have been a pilot plant in

the HIMP program almost since day one, and I think the important something that Mr. Lange did not mention in his presentation, or I didn't hear it, was the extensive time and resources devoted to the training and monitoring of the company employees that we station throughout our plants to evaluate for analeptic disease, and the question and concern that raised about leukosis carcasses that can go out the back door being unchecked, and I think this is available for the public record. If you look at the carcass rate of condemnation for leukosis in young broiler plants in the United States, HIMP or non-HIMP, you find an infinitesimally small fraction and to further state the amount of vigilance that's put into the evaluation of these carcasses, FSIS conducts its own inspection of lots when they begin.

And I also thank the two speakers who mentioned earlier about the extensive amount of work that companies do in microbiological evaluation of carcasses. And these data are available to FSIS inspectors every hour of every day in all these plants. So I'm not asking a question as I am kind of

speaking to defend my own industry here that we don't want bad product going out the door, and when you start looking at an issue as complex as *Salmonella* and try to explain it based on a HIMP or non-HIMP or chicken or whatever, you're not going to do it. It's a very complex subject.

And my last plea, and then I'm going to sit down, it's been mentioned already about serotyping and subtyping of *Salmonella,* and I hope that FSIS will move into the new millennium and evaluate the different species of *Salmonella* that are being recovered in plants because I keep hearing about human illness and correlation to plants. The most prevalent *Salmonella* recovered in broiler plants today is *Salmonella* Kentucky. And I ask you to find that on the list of human borne illnesses associated with *Salmonella* and you will not find it in the top 20. And I don't know all the reasons for that but there's a -- of good molecular science that helps explain that. Thank you.

MR. TYNAN: Thank you for your comments. I'm going to take one question from the phone.

Participants, Operator, can you forward the phone group please?

OPERATOR: Nancy Donley with STOP, your line is now open.

MS. DONLEY: Thank you. I want to start by saying that I was on the National Advisory Committee for Meat and Poultry Inspection when the HIMP Project was proposed and rolled out, and a couple of things that the consumer groups -- very, very strongly for were the following: one, that the plants must only slaughter and process young healthy birds, that there cannot be mixed types of animals in the facilities.

Secondly, the point that my organization made is that HIMP would only be viewed a success if it consistently did better than the traditional plants, the plants with traditional inspection. And then also that wanted to be updated on a regular basis as far as how HIMP plants were performing. I think the Agency has been woefully lax in the last point as far as keeping the Advisory Committee -- my understanding of what information they're being

given.

The last thing is that we were promised that this was not going to be an effort to cut inspection and inspectors in the plants, that the inspectors were to be redeployed to the other more important food safety tasks.

So I guess my question for the Agency today is have you kept your word on all of these issues. Are in the HIMP plants, are the same number of inspectors there today when they started? And are there still only slaughtering and processing one classification of bird?

And then lastly I'd also like -- this is a whole separate question, is why do the plants drop out, the plants that did drop out, why did they?

MR. TYNAN: I'm just looking at the panel.

MR. LANGE: I can answer one.

MR. TYNAN: Mr. Lange is going to answer one of the questions.

MR. LANGE: Looking at our EAAVRS (ph.), yes, these are young chicken plants that where it's called light fowl and heavy fowl are slaughtered in

separate establishments in the larger ones. They're unique.

MS. DONLEY: What about the number of inspectors in the plants?

MR. TYNAN: We don't have an answer for that, Ms. Donley, but we will get that for you and get back with you.

MS. DONLEY: Thank you.

MR. TYNAN: Okay. Thank you.

MR. LANGE: Just to clarify the question though because there was talk about using freed up resources for higher priority public health tasks, you're asking if in the same inspection establishment or using them, you know, within the inspection program?

MS. DONLEY: It was supposed to be within the establishment, that that was one of the things, that it was going to maintain the same level -- the number of inspectors, but they would be doing more important food safety activities in the plant itself. And hence my question. Has that number of inspectors remained in the HIMP plants or have they been

redeployed elsewhere or let go?

MR. TYNAN: We will have to check on that, Ms. Donley. But thank you for your comment.

MS. DONLEY: And I guess my one last question was why did plants drop out, that started and then they left the program?

MR. TYNAN: Okay. I'm sorry. I was distracted. Was there another question or can we deal with --

MR. LANGE: It was a business decision.

MR. TYNAN: Evidently it was a business decision but we would have to check on the rationale for the plants that left the program, and I apologize for not paying attention to your question, Ms. Donley.

MS. DONLEY: That's okay. And if I may, how will you be following up with these questions?

MR. TYNAN: Well, we'll have those and perhaps publish them as part of our website, respond to the questions that way.

MS. DONLEY: Okay. Thank you.

MR. TYNAN: Would that be satisfactory and

then everyone will have an opportunity to see the responses to the questions?

MS. DONLEY: That's fine.

MR. TYNAN: Okay. Thank you. And with that, I'm going to close out the discussion of Mr. Lange's presentation, and I'm going to turn it back over to Dr. Goldman to talk a little bit about the scientific foundation for decision making.

DR. GOLDMAN: All right. Good morning again.

In 20 minutes I hope I'm going to present to you a rather high level overview of two very important studies that this Agency has done over the past couple of years that I think will go a long way toward perhaps answering some of the questions that have arisen already but as well, informing the Agency as we determine what a new poultry inspection system should look like.

Before I move on, I want to say I have the unenviable task of presenting someone else's work twice in 20 minutes, and for those of you who have been in that position, it's a little bit daunting to

do that. So I want to make sure I hit the high points. This is not a technical meeting. There will be other opportunities and other venues for discussing the results of these studies in detail, and has been mentioned a couple of times already, we will have a technical public meeting on the risk assessment that was conducted to support the rulemaking that will be discussed a little bit later. Typically and historically we have such meetings before a meeting like this. We just weren't able to get it scheduled but it will be held in the very near future. As you know, the Agency is committed for sometime to presenting its risk assessments kind of in their full glory, usually about a half a day meeting, and we will be announcing that sometime soon.

So the first of the two studies I want to review with you is one in which FSIS collaborated with ARS to look at what I would call process control in broiler establishments. And in this study that was conducted over the calendar year of 2005, there were 20 randomly selected large broiler

establishments that were evaluated as part of the study. Each of the establishments was sampled over four seasons to try to get at some of this question of seasonality that's been discussed earlier.

There were some important features of this study that I want to highlight with this first -- I want to make sure I'm on the right slide, with this first slide here. This study looked at levels of generic *E. coli* which, of course, plants are already doing as part of their HACCP programs, and correlated with levels of *Campylobacter.* This is something that we did a *Campy* baseline many years ago.

There have been some issues and questions about the methodology used to quantify *Campylobacter* which we feel were resolved with a NACMCF report of a couple of years ago. So we correlated the *E. coli* levels with *Campylobacter* levels. We also correlated *E. coli* levels with *Salmonella* occurrence on product. We did not quantify the *Salmonella* on these samples. So we'll come back to that a little bit later.

Another important feature is we took samples from two different points of processing. One

we called for these slides rehang which is essentially after picking in the plant and the other is the more traditional site for sampling which is after the chill tank. So we termed those early processing and late processing points of sampling. Another important feature is that although the same birds weren't sampled obviously, the samples were from the same flock. So all of the conditions that would have existed in the grow out facilities would have been captured in this sampling scheme.

This next slide is just to show you that it is focused on *E. coli* levels across all of the observations in this study. And what it's designed to show with this rather complicated looking graph which is on a log scale, is that there is a fairly symmetric distribution of results, again on a log scale, and that this 1.1 log 10 of *E. coli* per millimeter of rinse provided us what's termed here demarcation level or a way to separate what we would consider good process control from less than good process control.

I want to point out here as well that in

this study, it was discovered that 13 plants had *E. coli* levels less than 1.0 on that log scale, and 7 had mean *E. coli* levels on both or equal to 1.2. And as will be shown in some of the following slides, there are relationships between the *E. coli* levels and the incidence of *Salmonella* as well as *Campylobacter* levels.

Bear with me here. For those who are not familiar with the scatter plot, I'll walk you through this in a minute or two. Each point on these two scatter plots depict both a *Campylobacter* level as well as an *E. coli* level for a single sample. And then enforce thereon the X and Y axis as well, and we depict those results for both the rehang which again is that early processing point as well as at post chill, which again is the traditional point for sampling. And what this slide depicts here is that there is a relationship, it may be a little difficult to see on the scatter plot, but there is a relationship and you can see that what's typically done with the scatter plot, is the computer program will draw a line that is meant to depict the

relationship between the X and Y axis. And again for those who may not be familiar, the 45 degree line would be a perfect correlation and you can see from these two scatter plots, that there's a little bit of a difference and just so you know, the one on the left, the correlation between *E. coli* levels and *Campylobacter* levels at rehang, which again is early in the processing, was statistically significant. So that is -- this line here is a statistically significant line.

The conclusion of this slide is that *E. coli* levels samples as was done in this study may provide us presumptive information about what we would expect of the *Campylobacter* levels which, of course, is one of the pathogens we're quite concerned about.

This next slide is a different way of depicting the relationship between generic *E. coli* and *Salmonella* incidence. Again, remember that we did not quantify the *Salmonella* levels but rather just looked for an absence or presence of *Salmonella* in this particular study. You can also see on this

table, there is -- that the data is presented by season, and I won't go into any detail. In fact, there is -- I should have pointed out in the beginning, there is a manuscript that has been written. It is undergoing clearance and will be submitted to a peer review journal with an analysis of these results, cut the conclusions about seasonality were minimal in this paper I can tell you because it's only a one year study. So it's hard to draw conclusions, a meaningful conclusion about seasonality.

But again, this shows the relationship between *E. coli* levels and *Salmonella* incidence in the plants that we're studying, and you can see at the bottom line here, is that for those plants that have *E. coli* levels less than 1.1, their *Salmonella* instance was 17 percent and for those that had the higher levels of *E. coli,* their *Salmonella* incidence was 27 percent.

Now the next slide is a statistical treatment of both *Salmonella* instance as well as *Campylobacter* levels against the *E. coli* levels. So

this table shows you on the left, the combination, what's called pathogen status, again combines both *Salmonella* incidence as well as *Campylobacter* level. You can see the parameters that were used for categorizing the pathogen status as either low or high, and you can also see that for those who read papers of this sort, that there's a statistical test that was applied to this table and that the relationships between pathogen status are correlated with *E. coli* levels at the various points in which they were taken in the plants.

Now you will see, if you're familiar with this, that .06 is just a little less than statistically significant by the customary measure. It's usually .05 but it's pretty close. So I wanted to show you these results as well.

So in less than 10 minutes, I've summarized a year's worth of work that was quite complicated and hopefully have done it justice, but I wanted to just highlight some of the conclusions that the authors and the researchers concluded in this work, and that is as I've said before, there is a correlation

between *E. coli* levels and *Campylobacter* levels as well as a correlation between *E. coli* levels and *Salmonella* incidence. That third bullet talks about the distribution of *E. coli* levels on a log rhythmic scale that I pointed out earlier, and then the final point is that the purpose of the study was to determine whether or not generic *E. coli* could be used as an indicator of process control, and at least the preliminary analysis of these results suggests that we can indeed use *E. coli* results and *E. coli* levels particularly at the post-chill sampling cycle which again is the usual place for sampling broiler carcasses as a measure of process control and again the hope, as I mentioned earlier, in the first talk, the hope is that by monitoring the process control and determining that there is good process control in the plant, we'll see a consequent reduction in both *Salmonella* and *Campylobacter* as this study points out, and ultimately reductions in human illness resulting from broilers from those two pathogens.

So I'm going to move on now to the second of the two studies. This study is actually the risk

assessment. Again I want to point out that we will have a technical meeting, and we'll spend literally hours going through the full details of the risk assessment but I think I want to highlight some of the findings as has already been alluded to by previous speakers, so that you can get an idea of what the risk assessment looked at and what the conclusions were and perhaps some ways that the risk assessment needs to be improved as we move it forward.

So FSIS risk assessment division conducted a risk assessment specifically to help us determine how this new slaughter inspection system should look, and the second bullet is really the key here. The risk assessment model that was initially constructed and that exists now correlates observed inspector activities in the slaughter establishments with the *Salmonella* prevalence or incidence that occurs on young poultry carcasses, and I'll go through in a minute the data sources. But again, looked at the inspector activities as reflected in PBIS with the *Salmonella* prevalence as reflected in our HACCP

verification testing.

And finally we used the results of *Salmonella,* in this slide, it's called dependent variable. That's, of course, the variable interest. We wanted to see what effect changing the inspector allocation within a plant would have on *Salmonella* levels, and that's the purpose of the risk assessment.

As with all risk assessments, we began, we being the Office of Public Health Science, began with a discussion with our risk managers, and initially at least with the Office of Policy as well as with other leadership in the Agency, to determine what the specific interest of the risk managers are in conducting the risk assessment. So I'm just -- without too much discussion, I'm just going to go through the list. There were four questions in this case that the risk assessment was asked to try to answer.

First was whether FSIS could reallocate its inspectors within a plant without significant negative impact on *Salmonella*. The other is whether

or not the relocation of inspectors from, for example, online to offline duties, either within or outside of the plant, what effect that might have on human illness. The third question was where within the plant can the inspection personnel be relocated that would have the most impact on reducing microbial prevalence, and then what was the uncertainty around these estimates? As all risk assessments do, they try to measure the uncertainty of the conclusions that are drawn from the model.

So this risk assessment used -- the next couple of slides will tell you about the data sources. There were 2,395 total observations composed of various data types. The data as mentioned for the *Salmonella* results were pulled from this case, the calendar year 2003 through 2005. They were aggregated as it says by month and year so that we could potentially draw some conclusions about seasonal changes. There were various types of inspection activities represented or inspection programs rather represented in this particular risk assessment. You can see that there were some

implants included as well as some variations on traditional inspection which have been improved under our regulations.

The risk assessors talk about two different kinds of variables in this risk assessment. One is called a decision-tracking variable. In essence, it's the procedures, the online and offline inspection procedures as well as scheduled and unscheduled procedures. You can see the list of procedures for those who are familiar with our PBIS. You'll be familiar with those codes, as well as the number of inspectors on and offline. Those were what we call our decision-tracking variables.

The next category is called performance efficiency variables. These are the PBIS non-compliant and not performed procedures. That should be non-compliant, not non-complaint there. So those are the variables that were in the model.

Now I'm just over the next couple of slides going to walk you through some of the results from the model output. First is that an increase in the number of offline inspectors is associated in this

model with the reduced *Salmonella* prevalence. A decrease in the number of unperformed sampling sanitation and HACCP procedures were also associated with reduced *Salmonella* prevalence. To the first point, just to drill down a little bit more, establishments with 25 percent more offline inspectors that compared to a baseline group, saw their *Salmonella* prevalence go from -- it was 13.9 or excuse me, it was 12.7 percent compared to the baseline of 13.9 percent. Again, our interest here is in making changes that affect pathogen contamination rates but ultimately affect human illness.

An increase in the number of scheduled sampling, random facility sanitation and some wholesomeness procedures, are associated also with reducing *Salmonella* prevalence in those plants. And finally, the increase in the number of plant scheduled sampling and sanitation procedures, which are often done because of conditions that exist in the plant on a given day, are also associated with reduced *Salmonella* prevalence.

I'm going to end up by talking about what the next steps are. As has been mentioned before, our risk assessment models are dynamic models. They are meant to be able to have new data incorporated as well as new data fields for example, new variables, so that we can model those changes that we like to see models so that we can examine the output and see whether the changes that have been modeled result in the expected changes, in this case, in pathogen prevalence.

We need to continue the evolution of this model. We will again further refine our look at the optimal deployment of our resources and the consequent public health impact of the reallocation of those resources. And we will also want to look at the correlation between the reallocation of those resources and the process control. So back to the first talk in this session, the evidence of process control that was depicted in an earlier talk, we want to incorporate into the model as well.

Finally, as with all risk assessment models, there's always a need for data. We would

rather rely on data rather than assumptions although risk assessment models need to rely on both because in some cases, there's not data.

The first data here is probably one of the most important. We did not have quantification data of the *Salmonella* and, of course, this model looked at only the absence or presence of Salmonella without knowing what the levels were which makes it hard to conclude that or to draw a strong conclusion about whether or not *Salmonella* is related to changes we make in the deployment of inspection resources, that is meaningful in terms of affecting human health.

So we will, as we pointed out earlier, you have this ongoing baseline study for broilers. We'll have one for turkeys as well. But for the broiler model, I'm just talking about now, we will be able to incorporate this baseline sampling data which will include enumeration data, and we can improve the model that way.

As also was mentioned earlier, we would like to incorporate some more specific data about both *Salmonella* serotypes and subtypes. The point

was made earlier that not all serotypes are the same. We do realize that, and we need to incorporate actual serotyping into the model as well.

And then finally, we want to look at what's called process control evaluation, and we'll look at modeling, for example, changes in line speed, offline reprocessing and the relationships that were discussed in the earlier talk about the relationships between rehang and post-chill pathogen levels.

So those are some of the kind of next steps in terms of this particular model. We will have this public meeting coming up soon. So this is a preview of that public meeting, and I hope that you will develop some questions and comments and bring to the public meeting in which we will discuss this risk assessment model so that we can make the model meaningful to our purposes here.

I think I've covered everything I need to. I will try to entertain any questions about either of the two talks that I just gave.

DR. BERNARD: Thank you, Dr. Goldman. Dane Bernard from Keystone Foods. My sympathies for

having to give somebody else's material, and please forgive me for asking an in depth question.

Regarding the correlation between *E. coli, Campy, Salmonella* paper, was there any attempt to remove infective process in airsaculitis birds from the data set? In-plant experience would indicate that if you have those conditions, which do occasionally come in, those will skew your data. So I'm curious as to whether those were accounted for in the database?

DR. GOLDMAN: If you'll forgive me for not answering your in depth question. I will ask if there's anybody in the room who is more intimate with the study who could answer that, and if not, then we will get you an answer to that.

DR. BERNARD: Okay. Thanks. One more question.

UNIDENTIFIED SPEAKER: The answer is no.

UNIDENTIFIED SPEAKER: The answer is no, we did not --

MR. TYNAN: Okay. So for those of you who couldn't hear, the answer was that those conditions

were not excluded from the study.

DR. ENGELJOHN: This is Engeljohn with the Policy Office. If I could just interject that it raises an interesting issue, one from the National Advisory Committee for Microbiological Criteria for Foods identified, that is an issue with regard to generic *E. coli* and I do know that we'll look at that issue, but it wasn't accounted for in the data that was presented.

DR. BERNARD: Okay. Well, we don't know whether we had any birds with those conditions included in the data set or not.

DR. ENGELJOHN: Well, get that issue resolved and we'll make a statement on it.

DR. BERNARD: Thanks, Dan. One other question if I may. Your risk assessment model, of course, we had several correlations there, and we all recognize the correlation is not necessarily causation. How may we get to that next step? Thanks.

DR. GOLDMAN: This is David Goldman. That's a big question. It's not an in-depth

question, but it's an important question. I don't know how necessarily in this model we'll get at causation. I think to the extent as I showed on the last slide, if we can get more precise data in there, we may be able to draw some conclusions but I think it's going to be perfect in terms of drawing conclusions that because we've redeployed inspection resources in a plant, it has resulted in this. What we've done with this initial output is just simply show the association of those two sets of data.

DR. BERNARD: Thank you.

MR. TYNAN: Ms. Kowalcyk.

MS. KOWALCYK: Barbara Kowalcyk with CFI. Just before I forget, I just wanted to follow up on something that Dane said. It's very important that the Agency truly understand that correlation does not necessarily mean causation and the industry does not attempt to make the leap from correlation to causation in drawing inferences.

Okay. With that said, I have a couple of questions, and Dr. Goldman, I'm not necessarily expecting you to be able to answer these. I was

interested in the 2005 national survey, if the Agency could provide information on what the actual correlation, you had your scatter plot diagrams, and what the actual correlation coefficients were in those scatter plots. I don't need them right now.

The other question in your summary on the two 2005 national survey on poultry operations, your last bullet says that supports process control based on post-chill *E. coli* and I would agree that just initially looking at these results, it's probably true but the samples are small, and as you noted, you only looked at one year of data. Does the Agency have intentions to continue looking at this or is this done or are you going to continually look at this, whether or not post-chill *E. coli* supports process control?

DR. GOLDMAN: Again, I think Dan will probably get to that a little bit. I will tell you that the study that was done in 2005 has not been continued as such. It was an initial attempt to look at those correlations but I think we will probably get to the answer to your question when Dan comes up.

MS. KOWALCYK: Well, I would hope that --

DR. GOLDMAN: Unless he wants to address it now.

DR. ENGELJOHN: What was the question?

DR. GOLDMAN: Okay. The question is whether we will continue to look at the correlation between *E. coli* levels at post-chill versus the pathogen levels?

DR. ENGELJOHN: This is Engeljohn. If I could just address that the current baseline for young chickens and for any turkey that we would have in the future, both have or had, both rehang and post-chill, and will continue to definitively and specifically look for associations related to indicator organisms whether that be a pathogen or a non-pathogen. So the answer would be, yes, we definitively will and our intention to the baseline will be to establish what the likely average or some other marker should be such that we could use those for performance measures. So they will be incorporated in future criteria that we would set.

MS. KOWALCYK: One last question. In the

model -- in the risk assessment model results, one of the results on the first bullet was that there was an increase in the number of offline inspectors associated with reduced *Salmonella* prevalence, and if I recall correctly, HIMP plants were included in this risk assessment. Did FSIS look at whether or not that association is coming directly from HIMP plants which may be of a different population than traditional plants?

DR. GOLDMAN: That's a good question. As far as I know, that sub-analysis that you refer to was not done or has not been done yet. It may be that the observations for HIMP plants were so small in number that they can't do that, but I think that's a good suggestion. If it hasn't been done, we will look at that.

MS. KOWALCYK: I would strongly recommend that you do that before you assume that that's -- that applies to all plants. Thank you.

DR. ENGELJOHN: And this is Engeljohn. Just to address it, because we anticipated the question, and for the presentation that Dr. Goldman

gave, it did not include those results, but when we have that technical meeting, there is going to be a very specific breakout of the data along the lines that you're suggesting.

MS. KOWALCYK: Okay. Thank you.

MR. TYNAN: Okay. I'm not sure who came up first. I didn't see Mrs. Foreman but I'll ask her to start, and then I'll come over to Felicia, and then we'll take questions from the phone and move onto our next topic.

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation. Am I the only person who wasn't -- who has never seen this risk assessment, you know, I thought I had downloaded all of the relevant papers for this meeting but I don't have that paper. I've never seen it.

MR. TYNAN: We don't have the risk assessment at this time, and I think we're going to make that the subject of a public meeting, so there will be a more in-depth discussion.

MS. TUCKER-FOREMAN: I understand that but I just find it extraordinary that you would have two

presentations on a paper with slides that none of us has seen. You have made it part of the basis for this meeting, and yet none of us has been able to see this, or at least I haven't, to be able to see what the parameters were for your risk assessment and what you chose to exclude in the risk assessment. We have no idea whether this -- it has been put together in a manner that we would not want to challenge certain basic assumptions because goodness knows, we have often challenged the basic assumptions in FSIS risk assessments. I just find it extraordinary that you come and make this part of the record of this meeting without providing us with the basic information. And frankly, I just don't think that's appropriate and that it should not be part of the basis for this meeting. And if I were a Judge, I would say to the jury, you will please disregard this information because it's not properly before this body.

MR. TYNAN: Well, I certainly understand your concern, Mrs. Foreman, and as I said, we are going to have a specific public meeting to address the details of that.

MS. TUCKER-FOREMAN: But for any reporters who are here today, it's really not appropriate to come and make a presentation and make these assertions without providing people with the information on which they're based. You shouldn't have raised it at this meeting.

MR. TYNAN: Okay. I understand your concern, but the questions regarding the risk assessment will be addressed at a public meeting.

Ms. Nestor.

MS. NESTOR: Felicia Nester, Food and Water Watch. I actually was going to say similar to what Carol was saying except, you know, rather than saying that we've often challenged the basic assumptions, I point out that the OIG and GAO have criticized FSIS' scientific design of any experiments that you do repeated. And so my suggestion is that prior to the meeting on the risk assessment and the discussion of how you're going to be doing this experiment, that you post for the public all of your plans so that we, for instance, when we hear you're going to be looking at line speeds and how they correlate with this or

that, that we know exactly, that you present us first with what your instructions to the field are going to be, because I've been doing this since 1995 and repeatedly I hear the Agency say, this is what we're going to be testing and then you start the test and then I talk to inspectors in the field and, you know, the design of the sampling doesn't pass the laugh test for elementary school scientific design.

You know, it's not proper to do -- to waste all that money on an experiment. Give us the opportunity first to see how you're going to be collecting this data. And if anybody thinks that, you know, I'm picking here, the Agency has been -- one of its foundational programs has been *E. coli* O157:H7 since 1998. They've been collecting data on that since 1998.

Recently the consumer groups asked in that data set, do you include the results from ground beef lots that have been pretested by industry or if the industry finds out that that lot is contaminated with *E. coli*, do you throw that sample out? And we approached the Agency with this in early April. We

got one answer and then we got another. We got one answer, we got another answer. Back and forth, back and forth, and we finally got the answer four months later. Now that's not appropriate, and if that kind of performance is the same kind of scientific design that's going to be used as the basis for doing these correlations, it's going to be a waste of money and a waste of time and a threat to public health.

So contrary to what's happened here, and my guess is probably what happened with the NACMPI meeting, we need the information before we come to this meeting. I know that we can submit public comments, but this is supposed to be a public meeting. This is supposed to be a meeting where members of the public can communicate with other members of the public and provide them information that they worked out based on what the Agency was putting forward. So I know it's FSIS' typical pattern to provide the information the night before, perhaps after the meeting on the subject, but we need it before. Otherwise, it's just a farce.

MR. TYNAN: Before you go on, Dr. Raymond,

I --

DR. RAYMOND: Well, several things I'd like to respond to here. We've got about an hour and 15 minutes left. The reason we had this meeting this week is to present what we have and what we're going to base public health based inspection slaughter on. We'd like to see the comments, and I think we strayed from the purpose of the meeting. I've done a couple of public meetings, asked people to stay on task here a little bit. Talking about ground beef is a long ways away from poultry slaughter I would venture to say.

Also, we've had a lot of public meetings in the last year. We do this to have an exchange. I'd like to keep the exchange at a level that are constructive and have constructive dialogue. Saying something we do wouldn't pass an elementary laugh test doesn't really stimulate me to go on and try to improve beyond what we're doing or even to conduct more public meetings. I don't know how many we've had in the last year but probably this is number seven or number eight, and they tend to kind of get

down like this one's getting right now.

And with the limit of time we have left, I think we should get back to task. I've never said we were perfect. I think in the two years we've probably had more public meetings we had six years before that. There is the danger of our receiving criticism when we do public meetings. We didn't have to have this meeting today. This is to help everybody understand where we're at, where we're going and to get your comments. And again, we're doing this in the spirit of communication openness, transparency. To go back to something we did wrong, 8, 9, 10 years ago, isn't going to help us get better in the next year.

I know we can get better. I know we're not perfect, and we won't be perfect for a long, long time, but if we're going to let perfect get in the way of better, you all have to remember the 14.4 people per 100,000 will get Salmonellosis this year, the same number as last year, the same number as the year before. We must do something different, and that we have shown. We've seen the examples. We did

not cherry pick the HIMP plants. They're voluntary. Loren's data showed you the first HIMP plants had almost exactly the same *Salmonella* ratings as the large plants that are doing non-HIMP at that time.

I know if we had two countries, one to export chicken to America, and one of them had *Salmonella* rates of 10 percent, and one of them had *Salmonella* rates of 5 percent, and FSIS said we'll take the chickens from the country with 10 percent, you would all call for my head. I'm saying we've got plants that are at 10 percent. We've got plants that are at 5 percent. I want to eat chicken from the green line plants, not the red line plants. Help me get more plants into the green line.

MR. TYNAN: Ms. Nestor, I'll let you have a short follow up. Short.

MS. NESTOR: I just wanted to say that the example I gave was not about ground beef. It was about the most recent example of FSIS not knowing what the heck they were doing with the scientific critical part of their public health program. And I'm sorry my comments do not -- would not stipulate

Dr. Raymond to improve because we really need the Agency to improve above that level.

MR. TYNAN: And I think we're trying to do that. I think the point that Dr. Raymond made is that it's -- your comments are going in a wrong direction. They aren't helpful when you talk in terms of laugh tests, and that's just not the way we want to conduct the public meeting. Mrs. Foreman.

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation. Dr. Raymond, I'm really troubled by your comments here. I just don't expect to have a public official call a public meeting and then stand up and chastise members of the public for making their views known. I don't think it's appropriate. There were parts of your comment that might have even been taken as a threat if you keep doing this, we won't hold public meetings. I don't think that's appropriate. I think you're obligated to hear from the public and certainly this Administration has said it wants the kind of transparency that is in public meetings and you have as well. I think those comments were really contrary

to the way you have acted and certainly are contrary to what we would hope you would do.

The problem that I have raised is that you have brought to this group and asked for public comment on a paper you haven't made available. How can I possibly responsibly comment on this meeting and your proposal when I haven't seen a basic risk assessment document that you say is part of your decision-making process. That makes this meeting I think maybe it wasn't worth having it.

MR. TYNAN: I think what Dr. Raymond pointed out is that we have tried very hard to be open and transparent in all the things we're doing. This is probably at least the seventh public meeting that I personally have been involved with, and I'm not at all certain that there haven't been others as well. I admit perhaps in this particular case, we would have been better served by doing the risk assessment first perhaps, but I think what we're trying to provide is an overview, and we're giving you also the assurance that we are going to have a public meeting related to risk assessment.

MS. TUCKER-FOREMAN: But you are asking for public comments now.

MR. TYNAN: On the --

MS. TUCKER-FOREMAN: How can the public, and I'm not talking about the industry, which I am sure has seen the description of your risk assessment. How can we give you any kind of meaningful comments on a project where the basic document, the risk assessment document, is not a public document?

MR. TYNAN: I'm going to take one question from the phones, and then we're going to go on and begin our next topic.

Operator, can you query the phone participants please?

OPERATOR: Our first question comes from Ms. Pat Buck.

MS. BUCK: Hello. Am I on?

MR. TYNAN: Yes, Ms. Buck.

MS. BUCK: Yes. This is most certainly interesting. I mean I think there's a very good point to be made to the fact that consumer groups

like the industry can only evaluate things when we have total information. And in the future, you know, I would recommend that you provide us the documents with the information, as quickly as possible.

The question I basically have though, I keep coming back to the fact that *Salmonella* has returned to the 1996 level according to the most recent -- data. And I would take issue with the gentleman who spoke about the fact that Kentucky will see, you know, *Salmonella* that they were finding the most of. Perhaps that is true. I don't have access to my computer right this minute but I remember reading in the 2006 *Salmonella* report, that of the top 10, something like the top 7 strains of *Salmonella,* I think enteritidis and Newport and Java, accounted for something like 70 to 80 percent of all the human illnesses. And I think that is a problem that we need to keep focused on, that we do not have the type of control for *Salmonella* that is preventing human illness. And whatever we need to do, whether we need to increase the sampling sizes or the frequency that we take samples, which none of the

presentations presented today, gave me any indication of how often or what size samples would be taken.

Until we start doing that, you know, on a scientific basis, I'm a little nervous about moving forward with other innovations to increase like the line speed in, you know, poultry processing or in poultry slaughter, and I hope some of the more detailed information pieces will be provided in the future presentations by FSIS. Thank you.

MR. TYNAN: Okay. Thank you, Ms. Buck. Do we have another question from the phone callers?

OPERATOR: Not at this time.

MR. TYNAN: Okay. Thank you, Operator.

With that, I'm going to change topics, and I'm going to invite Dr. Dan Engeljohn to come on up and talk about next steps.

DR. ENGELJOHN: Thank you. I'm going to talk about the next step with regards to our public health-based slaughter inspection activities, and the plans that we have in terms of moving forward.

First, the Agency is, in fact, going to be pursuing rulemaking with regards to our activities on

slaughter for poultry. The activities would include both broilers and turkeys. Rulemaking will address both ultimately but unless processing, we need to do rulemaking because we actually have regulatory barriers in place that prevent us from being able to make the types of inspection changes that we believe will have an impact on public health, a desired impact on public health while, in fact, refocusing some of those activities to allow the industry to, in fact, sort birds and do other actions that may, in fact, not be directly related to public health outcomes.

Some of those existing regulations are specific to the types of inspection systems that we have. We have a streamline inspection system. We have a new line speed inspection system, all of which have criteria built into them that are directly related to other consumer protections but not necessarily items that deal specifically with public health.

We also asked for as part of our *Salmonella* initiative last February, petitions from industry or

suggestions as to how industry could, in fact, make modifications to their programs while still addressing desired public health outcomes, one of which was we had suggested because we knew industry had an interest in increasing line speeds over and above those that are in the current regulatory requirements. In addition, we have time/temperature requirements for broilers that were based on prior prescriptive type regulations, not necessarily on a scientific basis for which birds have to get to 40 degrees within a very specific time period based on the weight of the bird, but the objective of ensuring that there's no growth of pathogens was not formulated as part of that rulemaking.

In the advent of HACCP being put in place, there are other means by which birds can, in fact, be controlled as far as pathogen growth goes during the processing intervention for which that particular regulation does pose an impediment. And so this was one of the petitions that was included along with the industry recommendations.

And then thirdly, the Agency has some very

specific regulatory requirements for fecally contaminated birds in which by regulation the birds are required to be taken offline and handled and reconditioned. We actually have data that shows that the handling of the birds makes the condition worse than for those birds that are not handled online, and so the Agency's intention, as we've already published a proposed rule on reprocessing is to incorporate this into the rulemaking and add a performance major for industry to meet. This would be the considerations that we would have.

And then as part of the rulemaking that went in place with the pathogen reduction HACCP regulations, the Agency put a requirement on industry to test for generic *E. coli,* a certain number of birds out of the production over a period of time, but there were no regulatory consequences of not meeting those criteria. And so the Agency has, in fact, looked at its performance matrix that it has in place and is considering a means by which we can make that a more effective program whereby there is a necessity to address the data with regards to process

control for this indicator organism.

For current thinking then, under rulemaking, and whats received through two petitions from the Agency, would be to consider issues related to HIMP. Information was presented this morning in that there are lessons learned from HIMP. HIMP, as designed in its current protocol, is not precisely what the Agency would view as being the optimal design for an inspection system, but there were important features to it that we believe should be considered, one of which is industry's capability to sort birds before they're presented to FSIS' inspection. Another would be for us to principally focus on food safety hazards, for example, the septicemic or toxemic carcasses and fecal material, and as well animal diseases. And then to put in place considerations for online reprocessing that can be built into the overall control program. But the continuous improvement with regards to pathogen control so that throughout the processing and dressing of the birds, there isn't a rise in the level of contamination.

And then as we've done through our baseline designs in more recent times, as well as through the ARS FSIS research study project that was conducted, we know that there is a need to look at both pre-chill and post-chill and to ensure that there's continuous improvement. We believe that there is some relatedness with indicator organisms and pathogens and think this is a first step of looking at rehang and post-chill. We need to be looking at the parts and I'll discuss that a bit later.

We also know that there is a benefit from looking at enhanced offline verification activity that's specifically related to sanitation and food safety, for which our employees could be deployed when they're not on the line conducting carcass-by-carcass inspection. And then we would, in fact, ensure that whatever we propose would have some predicted public health gains to the design of the inspection system. All these would be through a new means by which the Agency is starting to do its business whereby we would, in act, publish a technical plan in advance of this rule publishing

that would identify the type of data that we'll be using, how we intend to use the data and more importantly, the scientific basis for decisions as we move forward. So that would be a component that we would want to put in place prior to this rulemaking publishing which at this point in time, considering that we do already know based on preliminary work of just addressing these issues that I'm identifying here, that this would be an economically significant rulemaking. It's been designated or will likely be designated by OMB as an economically significant rule having an effect on the economy of $100 million or more. This would be a criteria that OMB would use. And so for that reason, there would need to be some very specific options identified as considerations that we would have made, and then the cost and benefit associated with each of those options.

A second issue in terms of our next steps would be stakeholder input on the draft risk assessment. Our intention is that as quickly as we can arrange to have a full venting of the assumptions made in our risk assessment, that was information

that was presented earlier, to give you the perspective that the Agency has in terms of how we looked at the data, the assumptions that we used, and then why we would, in fact, draw the conclusions that we did with regards to an impact on public health. This really would be the first time that we've looked at a risk assessment that's tied directly to the inspection procedures that are performed in the establishment. And so this would, in fact, give us an opportunity to present to you a unique way of looking at a risk assessment to make predictions on public health.

I would expect that as we have done in the past, we've had at least a full-day meeting on risk assessment. I'm not sure how long we would schedule for this one, but we know the importance and sensitivity of it, and we would, in fact, want to make that available prior to its discussion that we would have asked for input on it. Clearly peer review is part of that process, and this would be one of the foundation documents that would go into the rulemaking that we're developing and expecting to

publish later in spring of '08, would be the earliest that we could publish an economically significant rule. So there is ample opportunity between now and then for there to be public input to inform and influence our decision making as we go forward. We would want to have this risk assessment public meeting sometime early this fall.

In terms of our activity related to our *Salmonella* initiative, we did receive two petitions as I suggested. We've had some considerations of those petitions as well as what was asked for. Line speeds was, in fact, a focus of the petitions because they dealt in part with broilers but they also did deal with turkey establishments and so the considerations that the Agency has at the moment is that we're interested in looking at the initiative proposal that we had put out in terms of tying any changes to our inspection activity to predicted public health outcomes.

With that in mind, the Agency is interested in looking at a potential initiative project that would not change our inspection activity in the

plant. At this time, our current thinking would be to keep the inspection activity as it is in the plant, that's not operating under HIMP, but put in place some criteria for which there would be a direct performance element related to control for *Salmonella,* generic *E. coli* and *Campylobacter* clearly at rehang and at post-chill, as well as any online reprocessing that would occur.

In this particular scenario, the Agency would look at the feasibility of adding inspection personnel to the line. We've at first assessed whether or not that's feasible in the plants that could qualify for this, and we would ask for volunteer plants at this time. Our consideration would be to establish criteria that would give the plant some perspective as who could likely qualify. And then we would make an assessment as to whether or not inspection personnel could be added to the line in order for ultimately the plant could perhaps increase line speed but there would be some consequences related to its pathogen performance criteria and meeting that.

In order to deal with this particular issue in which these would be plants that we would like expect to have exceptional performance, and so you know, we do have a number of broiler plants and turkey plants that would qualify at having in essence less than 2 percent positives on any *Salmonella* set that the Agency has conducted, and likely under the industry data, showing that or even better performance. So the Agency would set a very restrictive performance criteria to qualify to be in this particular volunteer program, and then require that there be performance met throughout the program.

In any case, the Agency has heard the comments that have come forward. We have had some concern about the issue of our *Salmonella* sets being once every two years in these exceptional performing operations, and the Agency does intend to construct a means by which we would make unannounced sampling of carcasses and send that information in to compare our results with those of the plants. So this would not be a full *Salmonella* set but it would be one in which we would take samples, send them to the laboratory as

a means to have some check against the industry's data for which our intention would be the industry would share their data with the Agency as is one of the approaches that we have in our algorithms, considerations that we have for our inspection system activities in the future. Industry data would, in fact, serve the same purpose as if it were FSIS data. For that reason, the data would be made available to FSIS, and we would, in fact, make decisions based on it. In order to do that, we have to have some additional assurance for verification for which we would take unannounced tests.

In addition, the Agency is focusing on the public health gains that we would consider in terms of rulemaking that we would have for our *Salmonella* initiative. And in this case, we would be looking as the Agency will be doing, putting all of our *Salmonella* positives isolate PFG patterns and other multidrug resistant information into databases that can, in fact, be used to close what we consider to be a need with regards to an attribution gap. This would, we believe, if we were to focus on trying to

associate subtyping with public health that, in fact, we would have a better means to be able to identify whether or not changes in the present positive rate in the products that we regulate as raw products will then have a positive impact on public health if, in fact, that rate is reduced. This information would go both into FoodNet and PulseNet and we would want to put the industry's data into those databases as well.

We would set performance criteria for maintaining a status in the initiative. For those of you that are familiar with the current HIMP program, there is no disqualification criteria in essence within that program, but this would have some very specific criteria that would, in fact, be put in place to stay in the initiate or to operate in existence of a variation from current regulation.

And as well, because our employees would be in these plants, any activity that we would pursue here, we would need to ensure that all of our bargaining obligations are met before we would actually implement that.

Considering where we are and how we would want to go forward, we would like to initiate this by putting out a list of the criteria that we would consider to go forward with, publish that on our web page, ask for volunteers, and then pursue the obligations that we have with bargaining in terms of making known what our intentions are.

I would also say that the Agency's intention, as a question was asked earlier whether or not we intend to pursue publishing the percent positive rate for performance of plants, the Agency has. It has not yet published in the Federal Register, but at this point in time, it is our current thinking and our intention to make known that we will post the results of the establishments with regards to the FSIS verification testing program.

As well, if the Agency were to rely upon industry data, and this will be a topic at the public meetings tomorrow, in terms of our National Advisory Committee, that the industry data may as well be used and made available on that website and identified as being industry data verified by FSIS. In any place,

the Agency's intention is to publish a prototype of the type of page that we propose that would have the information there, when the last set was, in fact, collected and various information about that set and categorization. That we intend to do yet early this fall.

In terms of our fourth next step, the Agency intends to pursue microbiological enhancements within the HIMP plants. This is a little more complicated in that there is more activity the Agency needs to consider here, but we do have in place current HIMP plants that are operating. They're performing as they have for, as Loren Lange's slides presented, in some cases for nearly a decade or more almost, in terms of how long they've been in the program. The Agency would intend to put in place some criteria, that's some performance criteria related to pathogens and indicator organisms would need to be met in order to maintain status in that HIMP program. The Agency would identify these criteria much like what we intend to pursue with regards to the *Salmonella* initiative project where we

would keep the inspection system the same. In the HIMP, we would conduct the same type of activity we're doing today except that we would look for ongoing pathogen testing, *Salmonella, Campylobacter* and generic *E. coli,* for that information to be submitted and performance criteria to be met in order to stay in that program.

Again, here this would be an issue where *Salmonella* positive isolates from the industry, we would expect the industry to share with us and to put into PulseNet and FoodNet. Our goal here is to protect public health and demonstrate that our inspection system enhancements will have the desired impact on public health. In order to do that, we need to have better information about whether or not the types of *Salmonella* and pathogens in the products we regulate are, in fact, having an effect on public health. In order to do that, we believe it's the subtyping information and the multidrug resistant factors and so forth that, in fact, could help close to a great extent the attribution gap that we believe is present. And again, there because we have an MOU

with our bargaining unit, it would require us to make known what our intentions are and how we would like to go forward. This we don't think we could actually get underway until later this year, winter of '07, but in any case it is something that we would want to move forward with and certainly would seek input on.

Our fifth next step then looks at assessing new points for microbiological sampling. The Agency knows that there is an attribution gap with regards to the products we regulate, particularly the raw products that go into distribution and that are handled by the consumer for which lethality is applied to them, and so the attribution becomes far more complicated. We know through our own *Salmonella* rinse test, that today we only select one *Salmonella* colony from the rinse that is plated out onto a plate. There may, in fact, be more types of *Salmonella* present on that plate. The Agency intends to pursue that issue with its research partners and agricultural research service as well as any information that the industry may have. But we also believe and strongly believe, as a matter of fact,

that as the carcass is dismantled and handled, the individual parts, that the likelihood of contamination and further contamination occurs and that the Agency must establish performance criteria for the individual parts. These are sold to the individual consumers at the retail level, and we need to focus there. Our current baseline studies don't address those particular components, but we believe that we must address them in order to again have better information about attribution. This would require some redesign of the baseline studies, but it would also require us to begin focusing on the carcasses as they're dismantled.

As you know, with the ground products performance criteria, we have some of the worst performance particular in the broiler industry with regards to ground product, ground poultry or ground chicken in particular as compared to ground turkey. But in any case, the issue is the Agency doesn't really know or understand why in many cases the ground product *Salmonella* level is considerably different than that on carcasses for which the

carcass data would show it to be very good. In any case, this would be an area the Agency will focus as we go forward. It's the parts and the ground product for which we will consider developing baselines to get at the issue of what actually is happening with those products.

And then, sixth, our next step would be continue to have open and transparent dialogue in order to ensure that we're addressing the issues of concern that are raised by stakeholders, that we are, in fact, moving forward with changes in our inspection system, that will have the desired and intended public health impact as we make those change.

Again, we'll have a technical plan that will be accompanied with what we intend to do. We'll make that known to you and available in plenty of time for you to be able to comment before we actually propose the rule. There will not be a rule until sometime next spring, and there's plenty of time between now and then to seek input from the public.

That's all the slides that I have. There

were a couple of questions raised earlier that I'll address now, and then if I don't catch them, then please signal me in some fashion, and I'll try to get to your answers. If not, we'll make a point to post written answers as part of the transcript and follow up on the web page.

A question was asked about continuous improvement and whether or not the Agency is intending to change current performance standards or guidelines that we have presently published in the regs, and in some cases, we don't have performance criteria published in the regulations.

The answer is that we do, in fact, have the broiler baseline study that's underway, the turkey baseline as well, will, in fact, establish over the course over a full year of analysis at least, what the current performance is. The Agency will take that information and much like establishing the prior performance standards, the 20 percent positive rate that we have for broilers at this time. That would be the new performance standard or guidelines that we would put in place and from which we would establish

a new Category 1, Category 2, Category 3. So I hope that answered that question. The baselines are the intended route to establish what the current true national prevalence and enumerative level is of various pathogens and indicator organisms, and those data will be used to establish a new standard from which we will then ratchet down.

So as you know presently, Category 1 is half the current standard. And so a new criteria would be established as a consequence of the outcome of the baseline. We recently conducted a ground beef or trim study which will establish a similar type of standard for that product.

The question about whether or not the Agency intends to publish plant performance. You should expect the Agency will publish all plants performance for all completed *Salmonella* sets. For those low volume operations, I think Loren mentioned religious exempt and then we have some plants presently that are not sampled because they either produce intermittently or the Agency has failed to get them incorporated into a sampling set. The

Agency intends to come up with alternative means to gather information about *Salmonella* and other pathogens in those plants on some recurring basis such that we could establish some guidance for similar types of operations that don't fit into the current construct that we have for full *Salmonella* sets. In any case, we intend to make that information published and available. We will present some means by which we will update the information. Clearly we would like to incorporate industry data into the current plant's ongoing performance. And I would just say, because I may not have made it clear in the slide that I had about the *Salmonella* initiative and the HIMP plant project, part of the petition that we received was that the industry as they identified earlier today by industry members, their intention is to sample every day their operations on an ongoing basis.

And so that will be part of the criteria. There will be ongoing industry sampling that will supplement and be ongoing whether or not the Agency tests at any given period of time. So that will be

part of the criteria that we would put in place. It would be part of what we would continuously verify, and if we were to use that data and it were to influence inspection activity in that plant, that data would be considered the same as FSIS data. It would be available in term of to the public. It would, in fact, be posted on our web page in terms of identifying whether or not it's industry data or FSIS data, the point being that it's an opportunity to find ways to use industry data to supplement that of FSIS in a way which is verifiable and that we can have assurance that there's ongoing enhancements and improvements to the inspection systems.

I have an answer to the question, Stanley, that you raised, and if I don't completely answer it, we will get a written response fully articulated but your question related to why in HIMP plants we don't inspect the viscera organs, the liver and giblets. Part of that answer is that we do have an online inspector stationed at the end of the line and the viscera is gone at that time, as you well know. The Agency had made a decision that leukosis is the issue

for which we're concerned about in these birds, in terms of that's what we're actually looking for when we're looking at those organs. We do have some criteria, decision criteria that we use for a 300 bird set if, in fact, we believe leukosis is an issue. I'm not fully aware and understanding of those decision criteria. Clearly, if that's an issue you have concern with, we need to talk further about that, but that is one of the decisions that we make. If it is a flock for which we believe there is concern about leukosis, then we do do a 300 bird check, and then if, in fact, it passes, or we don't have further concerns, then we go back to the type of sampling that you mentioned earlier. But I certainly can clarify this further if that's something that you desire. In any case, we will post a more thorough answer on the web page.

Why plants drop out? I don't have an answer to that. We'll certainly get that but I would say that in any case, I can't imagine why it would be anything other than a decision that was made by the plant, not by FSIS. In the future, we clearly would

have performance criteria in place.

We intend to collect the interventions each time we collect the samples so that we know what is being done in terms of better informing us about the, the integrity of that sample and what it represents in terms of production process. That is an activity for which we're designing the methodology now to collect.

I think those are the questions that I was asked to answer. If I've missed something, I do have a list of the information and we will make a point to put written answers on the web page as a consequence of this meeting.

And with that, Robert, if there are any questions, I'll be happy to try to entertain them.

MR. TYNAN: Thank you, Dan, very much. I'll open it up to -- I have somebody here. I was going to open it up to the phone, but we'll ask Dr. Vetter, and if you could identify yourself and your organization, please.

DR. VETTER: Dr. Vetter with NAFV. I just have a question for clarification. The new

rulemaking process, is that going to consider just young poultry and exclude breeders as it has with the HIMP project? And also, when you're going to pursue microbial testing enhancements, with the HIMP plants in particular, will you also look at it in the turkey establishments that are operating under HIMP?

DR. ENGELJOHN: If I understood the question correctly, you asked whether rulemaking will look at only young versus older, perhaps not as healthy birds?

DR. VETTER: Breeders.

DR. ENGELJOHN: Breeders. Okay. I think -- at the moment, I don't know if we have the data on the breeders, and I'm looking for my staff to tell me whether or not we're incorporating it into this initial rulemaking. It doesn't include in this initial design but our intention ultimately will be to effect all the slaughter operations, whether they be breeders or old fowl, whatever. Ultimately when we have the data to inform how we go forward, we will incorporate that into the construct of rulemaking. So the initial one will be young. Turkeys will

ultimately be a part of that as well.

MR. TYNAN: Thank you, Dr. Vetter. Mr. Painter.

MR. PAINTER: Stan Painter of the National Joint Council. I wanted to address what was mentioned earlier regarding the MOU from Dr. Engeljohn. Does the Agency envision the MOU that it holds between the Agency and the Union to be in place until the rulemaking is complete?

DR. ENGELJOHN: Unless I get signals from somebody else, this is Engeljohn, and the answer would be, yes, to my understanding it would remain until we get rulemaking published. I think this is the criteria that we are set to operate under.

MR. PAINTER: Okay.

MR. TYNAN: Thank you, Stan. Ms. Nestor, and then I'm going to take a call from the phone.

MS. NESTOR: Do you want to do that first?

MR. TYNAN: No, no, go ahead please.

MS. NESTOR: Felicia Nestor, Food and Water Watch. A couple of comments. Food and Water Watch submitted a FOIA request on the NRs from HIMP plants.

I think we submitted it in early 2006. So far I've gotten the results I think it's from three plants, possibly four. So I'm just hoping that before the public meeting in early fall of 2007, we could have the records from the rest of those plants. This is 2005 data we're asking for.

Second, on the issue of using industry data, what safeguards will there be to prevent industry employees from cherry picking the chickens that they're using for *Salmonella* testing? I mean if FSIS was following a protocol of discarding the fecally contaminated carcasses because we already know they're contaminated, what's to prevent the industry from doing that if FSIS is going to be relying on that data? And that I think is it.

DR. ENGELJOHN: This is Engeljohn. To answer the FOIA, I don't have an answer for you. We clearly will look into that. The public meeting that we would intend to have on the risk assessment on the HIMP plants does deal with the performance, the NRs from them. So clearly I believe we would have something more thorough and more recent data as well.

You're asking about 2005 I think but I'm sure you would not object if we make more recent data available as well. I'll follow up on that.

On the issue that you have about industry data, I think you raised some extraordinarily important questions that do need answers and for which tomorrow's public meeting by the National Advisory Committee on Meat and Poultry Inspection is intended specifically to address, how to use industry data. And so I would just ask that if you don't bring it up, clearly the staff that's dealing with that issue at the public meeting will, in fact, make sure that it gets covered. But I think you raise important issues for which criteria is very important to have articulated and should be a part of that as well.

MR. TYNAN: Ms. Kowalcyk, do you have a question?

MS. KOWALCYK: You can go to the phone line first.

MR. TYNAN: Okay. I just didn't want you standing up there.

Mr. Bernard, do you have a question as well?

I'm going to do the phone if that's all right but is that -- okay.

Operator, do you have anyone on the phone who has a question please?

OPERATOR: Yes. And once again, if you would like to ask a question please press star 1. Our first question comes from Jeff Frank (ph.) of Oldham's Industries (ph.).

MR. FRANK: What are the next steps for the swine, the butcher and sow kill operations?

DR. ENGELJOHN: This is Engeljohn with the Policy Office. Swine, there is some swine slaughter HIMP activity that occurs and that will remain for now. We do have some interest in terms of *Salmonella* performance of swine plants, and there are differences with regards to HACCP plant size with regard to *Salmonella* performance. The Agency's intention will be to, as we did with broilers and turkeys, in terms of focusing on poultry and *Salmonella,* we will, in fact, be looking at what more

we need to do with the hog slaughter operations in order to address what we see as highly variable performance within that operation.

In terms of rulemaking and where we're going with swine slaughter, that would be something at this point in time that isn't being anticipated in the short term. I'm not aware of regulatory issues that need to be dealt with there but clearly would welcome any input that you have that we should be considering. At this time, rulemaking isn't a consideration that I'm aware of with regards to hog slaughter.

MR. FRANK: Thank you.

MR. TYNAN: Operator, other questions from the callers?

OPERATOR: Another question comes from Pat Buck.

MS. BUCK: My question is, in listening to your very detailed proposal of what the next steps will be, I didn't hear any mention of including the CDC in part of your development plans in the next steps. I would like to see a stronger effort made on

the part of FSIS to reach out to CDC and include them in their plans so that we can, you know, better reduce foodborne illness.

DR. ENGELJOHN: Thank you. This is Engeljohn, and I would just respond by saying that you should expect shortly information related to how the Agency specifically is, in fact, going to be working with CDC and ARS in terms of partnering and using the *Salmonella* isolates in a more defined and constructive way to address public health as well as animal health, and this would specifically tie into this line that I had on the use of *Salmonella* subtype information and serotype information to close the attribution gap. And the Agency, FSIS does have some very specific activities that are occurring right now with CDC. We will have a pilot project that we're intending and have actually begun constructing in terms of how we're going to use the *Salmonella* isolate PFGE patterns and look for associations in public health and that will begin, if it hasn't already, it will begin before the end of this month. And so there is some very specified and detailed

activity that we will make known to the public as to how we're better working with the CDC data to close the attribution gap.

MS. BUCK: I appreciate that very, very much and I would also represent to FSIS that they actively pursue the very science-based agenda that they've set for themselves, that they look at their hired to make sure that they have adequate resources in science personnel. Thank you.

MR. TYNAN: Thank you, Ms. Buck. Operator, one last question.

OPERATOR: There are no questions at this time, sir.

MR. TYNAN: Okay. Thank you very much. Ms. Kowalcyk.

MS. KOWALCYK: Barbara Kowalcyk, CFI. I had a couple of quick comments. First of all, I would like to just say that on the surface, this sounds very good, you know, the random sampling, serotyping and increased contributions to PulseNet. But, of course, it's always the details that really matter, and I'll be looking forward to seeing those.

Just a couple of comments though as you flush out those details in the next couple of days, I've seen the NACMPI agenda and I've reviewed -- I've read all the issue papers, and I think that's a very ambitious agenda for a day and a half meeting, and I hope that the Agency in response to its sense of urgency, to deal with *Salmonella* and improve public health, doesn't unintentionally do more harm than good by rushing the process. So I hope that, you know, anyone of those issue papers that have been presented to the NACMPI committee could easily be the focus of a week-long meeting, and I just encourage the Agency not to rush in developing them and really consider all the aspects.

One thing on industry data that know, I am not entirely against the use of industry data as FSIS has proposed, except for the fact that the current system and a passive system, needs to be proactive in that the data is available for the Agency to go seek. With the lack of human resources, particularly in sections or resource that the Agency has, I wonder how often inspection personnel will be able to go

actively seek that data. It needs to be a proactive system where industry is required to proactively provide the information to the Agency and it needs to be mandatory, not voluntary for reasons that Felicia brought up earlier.

Then the one last thing that I wanted to comment on was again, I feel like a broken record, the Agency really needs to be careful about using data from one population to draw inferences about an entirely different population, and this gets to something Dr. Raymond said earlier. In terms of HIMP, the HIMP plants voluntarily select themselves to be in the program. While the Agency didn't cherry pick those plants, they in essence cherry picked themselves. It's well known among statisticians and data analysts that self-selection bias is a real concern. You have in essence, I mean I heard several people here today say, well, our plant is doing all this to improve public health, and I truly believe this, but this room is not necessarily representative of the entire population. The people that are here self-selected themselves because they believe that

this is a very important issue, and they are committed enough to spend time and money to come here. So the problem is, that you just need to be very careful. I guess my point is to be very careful and do not take the data that you get from one sub-population and try and draw inferences about the entire population. This is a point I've raised many times before, and I just feel the real need to raise it again.

DR. ENGELJOHN: Thank you. This is Engeljohn. There are two issues I just want to address. One is, and again it's to be discussed in the Advisory Committee meeting over the course of the next day and how we use industry data. But in terms of the *Salmonella* initiative project that I identified as well as the modification to the HIMP plant, those will be conditions of performance. They have to actually provide them, and we will be looking at e-electronic, e-authorization and other ways by which the data automatically comes, if not from the plant itself, from the laboratory if that's a possibility.

So we're looking at ways to -- if we're gong to make decisions about changing inspection activity, we do have issues about how we need to verify and ensure that on an ongoing basis, and industry collects far more data that, in fact, could be used in a better manner by the Agency, and that won't be a passive one. It will be some means by which it's either required or it's conditioned.

And the rulemaking processing is not going to be one in the future where they're volunteers. We're moving towards rulemaking for which many of these criteria will become regulatory. So it's a function of how we intend to go forward with the rulemaking process.

MS. KOWALCYK: Dan, just to follow up on that. This is Barbara Kowalcyk, CFI, and this is something that I have said to you in the past but to go on public record, I would like to repeat it. I need to make sure that the Agency understands that by using industry data, you will not necessarily save resources. You will need a different type of resource. It will require being able to go out and

audit the plants and make sure that they are actually providing all the information that they can and also the Agency needs to be able to take some sort of action if it is found that an establishment is withholding or cherry picking their data that they are providing to the Agency. And that is a crucial part of making this work.

MR. TYNAN: Tomorrow, I hope you'll join us for the Advisory Committee meeting because I think some of those issues that you're raising will probably be good in the breakout sessions that we'll have that are associated with that.

MS. KOWALCYK: Unfortunately I will not. I have to be at home. My husband will be here instead.

MR. TYNAN: Ah-hah. Okay. We'll make sure that Mike passes the word along. Dane.

DR. BERNARD: Dane Bernard. I did leave my cherry picker back in Pennsylvania. So no worries. I was curious as to whether the Agency or Felicia had come up with a way that we can actually select birds with *Salmonella* versus not. I thought that's what we were here for but I do have a serious question.

The Agency has been collecting serological data on isolates now for sometime, and I understand, Dan, from your remarks, that the Agency intends to continue to do that and to use that to try to fill in some gaps on attribution and I think that's a wonderful use for the data. But does the data that you have so far index any other way that you may want to use that data?

DR. ENGELJOHN: To answer the question, this is Engeljohn, in terms of the data that we have and how we use it, I would say the serological data that we have now, and we've begun the process of posting serotype information on a regular basis, but we've never published anything related to subtype nor have we had an ongoing routine means by which we have used our isolate data to look at associations with public health, except in an as need to know basis. If CDC identified a human illness and is looking for whether or not we have information that may be associated, then we go look for that. So it was one for which we reacted as opposed to actually using that subtype information in a constructive way to

actually be looking for human illness. So we've never used the data in the manner for which we're intending to use it in the short term, beginning later this month.

DR. BERNARD: Thanks.

MR. TYNAN: Before you ask a question, I think we just have a few minutes to clarify things for Dane, and I think we've gotten into probably the general comment period at this particular point.

DR. YANCY: This is actually a specific question for Dr. Engeljohn.

MR. TYNAN: I should have known. That's why I stepped into the --

DR. YANCY: Especially when it's me.

MR. TYNAN: That's why I stepped into the ibis at the wrong time. Please.

DR. YANCY: Al Yancy. I'm a veterinarian with U.S. Poultry and Egg Association.

Dr. Engeljohn, on the third slide of your presentation, you mentioned enhanced offline verification activity. Not to assume but to ask for some further clarity, should we expect that to mean

that we may see in the proposed rulemaking in spring of '08 a performance standard for offline reprocess.

DR. ENGELJOHN: You should expect in the rulemaking that we're developing for which we already have one, one docket out there on line reprocessing -- your question was on line reprocessing.

DR. YANCY: Offline.

DR. ENGELJOHN: Okay. I'm sorry. The verification activity in terms of enhancements there would be focused in great part much like we do now with the offline verification activity and what activities do we know may have some impact on public health in terms of the *Salmonella* or *Campylobacter* performance in that plant. So our goal would be to be able to identify those tasks and procedures performed and how they're performed as to whether or not they have any predictive value in terms of performance by that plant. And then criteria would be established for that. It's much in the line of what we presented on RBI for processing where one level of plant may get reduced level of verification activity whereas another one may get increased focus

on verification activity. This would be this same construct but it would be based on actual data that demonstrated there was some relatedness. And so that would be the point, and there would be an opportunity to comment on that. Much of all that information will be made available as part of the risk assessment public meeting we intend to have shortly.

DR. YANCY: But as a follow up to that, I guess to be even more specific, are we -- I know we're not speaking specifically or entirely -- let me back up and say entirely about microbial data but that is not ruled out in this arena. In fact, microbial data may very well be part of that decision-making as far as verification. Correct or not correct?

DR. ENGELJOHN: Perhaps could you give me some context, microbial data?

DR. YANCY: *E. coli*, such as CFUs, you know, product sample wash for *E. coli.*

DR. ENGELJOHN: Absolutely. The microbial data in addition to verification observations of procedures performed as well as records reviewed but,

yes, microbial data would be a component of that.

DR. YANCY: And if you would indulge me for one second, just one final question, and this is either for Dr. Raymond, Dr. Goldman or Dr. Engeljohn. At the meeting in February of '06, my recollection was that held out as either a carrot or a stick, depending on how long you wanted to view it, the posting of Category 1, 2 and 3 data would be a reality with which our industry would be faced, unless our industry made significant improvements in the performance as we approached meeting or not meeting the performance standard, and that was, if my recollection serves ballpark roughly 90 percent of the establishments would be in Category 1 by July of this year.

Now I remember in several of the public meetings in April, all four of which I attended, it was mentioned on more than one occasion that that number would still be roughly 90 percent of the plants in Category 1, but it would now move to 2010.

So with that thought process in mind, and not detracting from the need for adequate *Salmonella*

control, which I absolutely agree we must have as an industry, taking in mind the significant financial effect that post-data numbers such as a Category 1, 2 or 3 on a website could have, simply based on Dr. Raymond's statement a few moments ago, that we would much rather take product into this country or imported into this country product from a country that had 5 percent *Salmonella* versus 10.

My question is what is the Agency's current thought process as why this is now necessary especially in light of the fact that the industry is performing so much better a year and a half later?

DR. ENGELJOHN: I would just answer shortly, just to make a response. The Agency will publish this all through Federal Register documents, the rationale and all should be there. I'm just giving you an indication right now of where our current thinking is. But the issue really becomes one of just how serious we at the Agency are considering where we are now with human health and relatedness to the products we regulate. Quite frankly, the issues with regard to *Salmonella* are a

very great disappointment to the Agency with regards to, even though we've had changes in the performance within the industry, whether or not there are public health changes or not, that's another issue, and part of this is how we do attribution.

But in terms of maintaining an assurance that performance goes forward, my simple answer is we see this as the alternative that we have right now to make things work and to keep them working. Our 2010 goal with regards to *Salmonella* performance is one for which the Agency has established its public health goals for *Salmonella, E. coli* and *Listeria*, *Listeria* 1 being set for 2005, which we did not meet, but O157 in *Salmonella* being for 2001, and the effectiveness of the Agency's programs are based on the 2010 health people goals. We've identified that in order to meet the healthy people 2010 goals, we have to make dramatic changes industrywide for all the species we regulate now in order to even get there, and we're not willing to wait until the last minute to do so. So we have stepped up where we're pushing the industry as a matter of public health

need to make changes in terms of protections, particularly for *Salmonella,* but *Campylobacter* is close to being one for which we care about as well.

DR. YANCY: Thank you.

MR. TYNAN: Felicia?

MS. NESTOR: Felicia Nestor, Food and Water Watch. I just want to point out that I'm glad we're seeing some HIMP analysis finally. As far as I know, there have been no Agency reports since possibly 2000 except for at NACMPI meetings, and at the March 20, 2000, the transcript says that the Agency will continue to provide HIMP data as it becomes available because it was an experimental program and consumers were eating the product.

Regarding the hog slaughter protocol, one thing that -- I was going to put this out later, but since people are interested, it should be pointed out that my understanding from talking to people in these plants and also from reading the protocol, is that the hog carcasses are marked at the beginning of the line. The carcasses that the Agency will use for its sampling, are marked at the beginning of the line.

So as the carcass goes down the line, all the employees that are working on the carcasses know which ones are going to be looked at by FSIS. So I would think you may want to look at that because if that doesn't change when we do start talking about hog slaughter, obviously we'll point out that that's not really a random sample.

Let's see. With respect to -- I really hope that you will again provide us with the data in advance of this meeting. We really need to know what you're looking at and what we're getting. My guess is that you're probably going to be giving us the categories Food Safety 1 and 2, and also the OCP categories. I think there's important information that consumers won't get through that. As I said, we're waiting for our HIMP FOIA to be returned to us, but I haven't gotten three plants and the plant for which I do not have the *Salmonella* data for some reason, I found the NRs extremely interesting. I mean I've been looking at NRs for many, many years, and I can't remember really how many DOA, you know, cadaver NRs I've seen but from this HIMP plant, we

only have the data for a half a year, but there were quite a few DOAs going down the line that the carcass inspector was able to see, and I don't even know what the line speeds are there, but they're higher than the traditional plant obviously. So this plant had DOAs. Dr. Raymond was saying that we've seen that HIMP shows that the industry can do its own quality control and there's an industry representative saying that, you know, the extensive training that the sorters are getting. Well, I don't know what the problem is, but there were DOAs in this plant on June 3rd, 15th, 16th, 17th, 20th and 24th. Then on July 6th, 8th, 9th, 12th and 13th, and the corrective action that was given in each case was that the plant instructed employees in the live hang area to properly identify and remove DOAs from the line and place in appropriate containers. What consumers were told at the beginning of HIMP was that plants that couldn't meet the standards would be kicked out of the program. Under HACCP, if you have repetitive deficiencies, if the corrective action is not effective, FSIS will step in and take regulatory

action to make sure that the corrective action is effective. So I just recounted the DOAs from June 3rd to July 13th. On July 14th, there was another DOA. Actually there were three of them, and the plant came up with a new corrective action which said that it instructed employees involved in the process to sort out potential birds that could be in this category in live hang and other points in the process to help reduce and eliminate future occurrences.

MR. TYNAN: Excuse me. Can I interrupt a second? Can you sort of summarize and wrap it up because we have --

MS. NESTOR: Sure.

MR. TYNAN: -- other people that --

MS. NESTOR: Sure. To my reading of these two different corrective actions, it's not really a change in corrective action. I thought what FSIS was going to do is ascertain whether the new corrective action that the plant is going to be proposing is effective.

All right. To summarize, let me just say that in the 6-month period, we have 47 days on which

DOAs were found and on many days, there were multiple DOAs found at different times during that period.

So my last point is this. During this six month period, there are also periods of time where there's very little NR activity. When you present us with the data from these HIMP plants, I think you should tell us when it looks like the NRs or any other indication suggests that the inspectors do not have the time to write NRs because they're short staffed in the HIMP plants. And the people that are supposed to be writing the NRs are actually being pulled to the line. Thank you.

MR. TYNAN: Okay. Thank you, Felicia.

Dr. Henry.

DR. HENRY: Thank you. Craig Henry with Grocery Manufacturers/Food Products Association.

First I would like to bring attention back to the number one objective that I think FSIS has so appropriately focused this meeting on, as well as prior meetings, and that is for the improvement and enhancement of food safety as focused on foodborne illness. The meeting today I think was an excellent

preview at least for the NACMPI and certainly for those of us who understand the science and are trying to capture that.

Certainly the first part of the meeting, reviewing HIMP, gives us a very good background to see what HIMP has accomplished and possibly what it hasn't accomplished. I think that the HIMP program is an excellent example of what FSIS, and more specifically, industry needs to move forward with relative to testing of a program. It was a test put forward. I've been in the industry now 28 years, and more than 3/4 of that have been dealt with direct industry operation and plant operation. There's a lot of programs that have come and gone in that period of time. And certainly I would say today, we have seen a huge improvement in the overall quality and microbial load at the slaughter level as well as improved products coming out from the process as well.

I think that what Barbara and Felicia bring to bear on an ongoing basis exemplifies the fact that the testing of programs need be real world. I think

that the continued criticism of any program, any data collection system that we have will continue, will remain because no program is flawless. And certainly looking as we go forward with either this enhancement of rulemaking to the slaughter program or with risk-based inspection, as would be applied to processing, both of those need to focus on one of the issues that Dan and David Goldman have brought up which is the attribution data.

We're going to look at collecting a lot of data. We can collect birds. We can collect samples. We can do everything we want to do but we need to make sure we understand what those results are telling us and whether they do or do not correlate with the end result which is certainly the outcome of foodborne illness as exemplified by CDC.

I think that the opportunity now results to or will require some allocation of resources at the state level, which we haven't brought to bear here yet today. It was brought up at a meeting earlier this year about the deficit of staffing that exists at the state level in order to bring attribution data

more online and more frequent. So I'm not sure if any of the members of the panel right now would like to speak to that, but I would certainly be interested to hear what we're going to do in conjunction with CDC and with the state affiliates, to try to capture the appropriate data for attribution. Thank you.

DR. ENGELJOHN: If I could just address the one issue that was just brought up with regards to state. We recognize that the public health particularly in the United States can't be fully addressed with regard to attribution if we're not looking at state inspector product. It's an important aspect. We do have roughly 28 states or so that have their own inspection systems that do do some level of testing, if they slaughter operations, in particular broiler operations. The Agency is further refining how we go forward with judging equal to status for those states. And I would just -- because it's new information, it's one for which we, the Agency are committed to, is that for the -- as we are in the federal system now going to be taking those *Salmonella* positive isolates or any other

pathogen that we have in terms of isolates, and looking for relatedness in the CDC database. We are going to take the state's isolates now and ensure that we have PFGE patterns, multidrug resistant patterns and other virulence markers and upload those and look at them in the CDC database as well, so that we do, in fact, have a more united system which we've never done before, but we have just as recently as last week, made the decision that that is something we think will dramatically also help to close this attribution gap, one way we need to focus on that. We have the resources to help, and we will do that. So I think that we have means by which we can work with the states and their programs as well. And that's in the states that have the programs and the states that don't, then other activities we'll be pursuing in terms of what we need to be looking at in states that aren't even in FoodNet or otherwise connected with some means for which we have real good data.

MR. LANGE: It was last week that David states that we would take any other isolates,

that we would run a PFGE analysis in our labs, we would see that those isolates are serotyped and we would see that they got entered into the database. If there's anyone from a FSIS lab listening, I apologize. I haven't told our people about that decision. I will soon.

MR. TYNAN: So we should keep it a secret?

UNIDENTIFIED SPEAKER: It's a secret.

MR. TYNAN: All right. Thank you. Mr. Corbo.

MR. CORBO: Tony Corbo with Food and Water Watch. First before I get to my point, Felicia has asked me to volunteer to any of the NACMPI members, if they want access to the *Salmonella* data she has, she's willing to share that information with them.

The point I wanted to make is that I'd like to share some polling data that my organization contracted to get, the public's perception of government inspection. In March 2007, we contracted with Lake Research, a nationally known public opinion research firm, to poll 1,000 consumers to ask them a series of questions on food safety, food policy, but

we had two questions in particular on food inspection. We asked consumers whether they wanted the Government to retain full control over meat and poultry inspection or whether since processing had gotten so sophisticated, that more of the inspection activities be turned over to industry with the Government playing a role of verifying that data. Eighty-one percent of the consumers who responded said they wanted the Government to retain full control over inspection.

We also asked consumers the question what emphasis should be placed on food safety versus wholesomeness issues in meat and poultry inspection. Sixty-four percent of the consumers who responded said that food safety and wholesomeness issues should be treated equally. Twenty-two percent said that food safety should take a dominant role of inspection activities with wholesomeness issues taking a secondary role.

So in the context of the work that you're doing now, I think you have to keep that in mind because that's what you're going to be up against.

MR. TYNAN: Okay. Thank you, Tony. Ms. Kowalcyk, could I impose on you just to hold for one second. Let me see if I can take a couple of questions from the callers. We have maybe another 5, 10 minutes for the meeting, and then I'm going to have Mr. Almanza come back up for some closing remarks.

Operator, do you have any comments from the people on the phone?

OPERATOR: No, sir, not at this time.

MR. TYNAN: Okay. Thank you.

Ms. Kowalcyk.

MS. KOWALCYK: Barbara Kowalcyk, CFI. I just wanted to follow up on something that was said earlier. As a statistician, I'm well aware that no data is ever perfect, but FSIS has repeatedly said that they would like to move to a science-based and data driven system, and part of the reason that I come to these meetings and make the kinds of comments that I do, is that I truly want FSIS to become science-based and data driven, and I think that the way that the Agency collects the data and analyzes in

the past has not been as good as it can be. And my hope is to push the Agency in that direction.

I also wanted to clarify that in terms of reducing line speeds and modifications that industry has petitioned the Agency to do, I think you need to really -- it comes back to me for one big point. HACCP is based on statistical quality control, and once the industry achieves consistent process control, the performance standards must be readjusted to reflect the new norm, not just once every 10 years but on a continual basis, and I am happy that the new baselines are being undertaken but it has been at least 10 years since that happened.

If the industry can then demonstrate that process changes, such as increasing line speeds, will not impact their ability to maintain process control and meet the adjust performance standard, then it is appropriate -- it may be appropriate to consider such changes. I'm not against letting industry do this. I just think you need to understand that you need to keep going with the performance standards, readjusting them on a continual basis, and that

simultaneously industry must use scientific studies to demonstrate that these proposed changes, they are petitioning the Agency to implement, will not affect their ability to meet those adjusted standards. Thank you.

MR. TYNAN: Thank you, Ms. Kowalcyk. I'm sorry you won't be able to attend tomorrow because I think Dr. Maczka and her staff are starting to move in the direction that you're hoping we would go. So I think we're all on the same page in that regard.

Yes, sir. If you'd introduce yourself and your affiliation.

MR. COBERLY: Yes, Craig Coberly (ph.) with George's. I just have two comments.

One on the comment about the rush, for the Agency rushing. From our perspective, since we've been in HIMP for nine years, I don't think that's rushed, and I think the Agency has taken a very cautious approach to this. And it's been from industry's perspective, I think we also have to remember that consumer advocates -- our customers are consumers, and we have a common goal here, to reduce

pathogens and to make food safe. So that's all I wanted to say, and thank you.

MR. TYNAN: Okay. Thank you, sir. Any other questions from the audience?

DR. ENGELJOHN: Robert, this is Engeljohn. I -- just by the last comment that was made and the earlier one, I recognize I didn't answer a question that was raised earlier that I could. I think Nancy Donley on the phone asked a question about our HIMP in the original design being one for which it would at least be no worse than the other traditional systems of inspection.

And I would say that we are not going forward with anything, particularly related in the poultry slaughter rulemaking that we have, that doesn't show some significant enhancement over the current systems. We'll have to define what that means, but there will be improvements over. That will be one of the criteria that we will be reviewing. Moving forward, I think clearly we will need to define how we will measure that, but it's not going to be no worse than it's going to have to

demonstrate that it's better than the current system.

MR. TYNAN: Operator, if you have anyone on the phone that has a last question, we're going to allow you to have the last word.

OPERATOR: If anyone has a question, please press star 1.

(No response.)

OPERATOR: There are no questions at this time.

MR. TYNAN: Okay. Thank you, Operator.

I'm going to close out the question portion of the meeting, and I'm going to invite Mr. Almanza to come back up for a couple of closing remarks. And you notice the presenters are getting off the stage as quickly as they can.

(Laughter.)

OPERATOR: I do have one question. Would you like to take it?

MR. TYNAN: We're going to ask Mr. Almanza to come up anyway and, yes, we will take that question.

OPERATOR: Okay. Nancy Donley, your line

is now open.

MS. DONLEY: Hi. Again, I just wanted to clarify something that you had said. I didn't say that it couldn't be any worse than. I said the only way that HIMP would be deemed a success in our viewpoint would be if it was significantly better than the traditional inspection.

MR. TYNAN: Okay. Thank you, Ms. Donley. Dr. Raymond is pointing out that we do agree with that comment. And with that again, I'm going to turn it over to Mr. Almanza.

MR. ALMANZA: Well, this was certainly interesting for my first public meeting. I want to thank Dr. Raymond for his comments, Dr. Maczka as well, Dr. Goldman for his comments and pitch hitting and doing a great job at that, and Loren, and also Dr. Engeljohn, you all did a great job.

My closing comment, yes, I know we're not perfect. I know that we can always strive to do better. Could we have done things differently? Certainly. Will we do things differently? We're going to try. And I think that this is what this

meeting is supposed to be about. Everybody states their opinions and we use the information that we have and move forward. I think that this is the process, and so I certainly didn't come in here thinking everybody was going to agree with everything that was presented, nor do I think that everybody is going to agree at the end of the day, but that's the process.

All the comments will be evaluated and the resources that will be available again will be the FSIS website and the constituent's update.

And with that, I appreciate everybody's comments and certainly welcome some more over the next couple of days. Thank you.

MR. TYNAN: Before everybody goes, could I mention that tomorrow's Advisory Committee meeting will be in this building. It'll be in Room 329, upstairs, in a larger room. So we'll see you tomorrow.

(Whereupon, at 1:00 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

PUBLIC HEALTH BASED

INSPECTION IN SLAUGHTER TO ADDRESS

CAMPYLOBACTER, SALMONELLA

AND

OTHER PUBLIC HEALTH CONCERNS

Arlington, Virginia

August 7, 2007

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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