UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

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October 12, 2006
8:30 a.m.

USDA South Building Cafeteria
1400 Independence Avenue, S.W.
Washington, D.C.

CHAIR: DR. BARBARA MASTERS
Administrator
Food Safety and Inspection Service

FACILITATOR: MR. ROBERT TYNAN
Deputy Assistant Administrator
Office of Public Affairs
Education and Outreach

COMMITTEE MEMBERS:

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DR. DAVID F. CARPENTER
DR. JAMES H. DENTON
MR. KEVIN M. ELFERING
MS. SANDRA B. ESKIN
MR. MIKE FINNEGAN
MR. MICHAEL W. GOVRO
DR. ANDREA L. GRONDAHL
DR. JOSEPH J. HARRIS
MR. MICHAEL E. KOWALCYK
DR. IRENE E. LEECH
MR. CHARLES M. LINK
MR. MARK P. SCHAD

ALSO PARTICIPATING:

DR. CHRISTOPHER BRATCHER
MR. PHILIP DERFLER
MR. JANELL R. KLAUSE
DR. KARLEASE KELLY
MR. ROBERT McKEE
MR. MARCELO OLASCOAGA
MR. STANLEY PAINTER
MR. BOBBY PALESANO
MR. VINCE PAYNE
MS. LISA PICARD
MS. GERRI RANSOM
DR. RICHARD RAYMOND
MS. JANET STEVENS

I-N-D-E-X

I-N-D-E-X

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

(9:38 a.m.)

MR. TYNAN: Good morning. It's about that time to begin our fall 2006 session of the National Advisory Committee for Meat and Poultry Inspection [NACMPI].

My name is Robert Tynan, and I think you all have had the opportunity to talk with me or meet me at one point or another over the last couple of years.

We're going to start our agenda pretty quickly. We have a pretty fully agenda I think for you today, and a couple of changes in the agenda that I will come back and talk with you about in a few moments.

But first and foremost, I'd like to introduce our Under Secretary, Dr. Richard Raymond, for some welcoming remarking.

DR. RAYMOND: Thank you, Bob, and welcome everybody to Washington, D.C. for those of you who had to travel to attend this meeting.

It was about a year ago, not quite a year ago, it was November of '05, which is the first time I

had met with NACMPI and the first time I had met many of you. I think we've grown to become friends and associates and colleagues since that time. But in November of '05, I shared with you with some fear and trepidation that I had been advised that the National Advisory Committee for Meat and Poultry Inspection had evolved over the years to more of a rubber stamp committee to approve things that the Agency was going to do, that were basically non-controversial, had no risk and had no hitches, and was a fairly easily Committee to sit on, deliberate and then say, yep, that's a good idea, and then we went about our business.

In November of last year, I told you we were going to task this Committee with a little bit more work perhaps than they had been used to doing, and we asked you to roll up your sleeves and give us your wise counsel and sage advice on issues that are a bit more controversial than some of the ones you had had before, especially risk-based inspection. And we asked you to help us with devising the risk-based inspection system that would make better use of our

resources, that was not to do about employee numbers, had nothing to do about budget savings, but had to do with putting the resources where they would do the most good, to further improve the safety of the food supply for America and for the countries that we export to. And I thank you for the work that you have done.

Many of you who are here on the Committee spent the last two days with us at George Mason University, in a very public meeting [Risk Based Inspection System Public Meeting], where we had employee representation, scientists, industry, consumer reps and, of course, FSIS there, to discuss the plan that's on the table so far. And so for those of you who are on the Committee who came in early and spent two days participating in that discussion and then are bringing the knowledge you gained from that discussion into this meeting, I commend you, and I thank you, and I think the majority of the Committee was able to be there for those two meetings.

And then there are some with us in the audience today representing the public part of this

meeting who were also at the two day meeting, and I thank them for their continuing interest in this risk-based inspection system for devoting almost four days of this week. Actually a short week with the holiday on Monday, you devoted the whole week many of you to working with us to help us devise a system that will get the most bang for the buck.

That said, today we're going to continue to ask you to help us with using risk for risk-based inspection in processing plants. We're also going to ask you for advise on using risk analysis for slaughter operations. We'll continue to make you work and earn your high pay that you get from being at this table.

And lastly, before I sit down and let Barbara give her remarks, I was going to thank the 13 of you who have done your third 2-year term, and acknowledge you. It would be easier to acknowledge the four that are still eligible to come back for another two years. So rather than reading off the 13 names, it's unfortunate we have such a big turnover coming up in this Committee. But that's the way the

ball bounced I guess.

For those of you who are eligible for another two years, I would ask you, encourage you, beg you to make sure that we are aware of your interest. I ask you to stay interested in this Committee. We've got a lot of work to do, and we will need your expertise in years to come, particularly with the new members that will be coming on next spring.

So I'll publicly thank the 13 of you, without reading off the list of names, because that would take too long. We've got things to do but thank you again for your time.

With that, Dr. Masters has some comments to make, and I thank you all for your contributions.

DR. MASTERS: Thank you, Dr. Raymond. On behalf of FSIS, I, too, want to welcome everyone and to thank the Committee for your service that you do provide.

I want to say that you provide service not only this week, and as Dr. Raymond mentioned, many of you were here for the full week, but I also want to acknowledge the work that you did throughout the

course of the year, particularly the Subcommittee that's been working with us, particularly through conference calls to ensure that we kept the ball rolling so to speak, in trying to work with us to review documents, to help get an agenda together for the workshop that we had this week. And, many of you were willing to step forward to do that. And we really do appreciate the work that you did in making that happen. So I want to publicly acknowledge you and thank you for the work that you did in making that happen.

We appreciate that time, and as we often say, we know you have a real job outside of these efforts, and so thank you very, very much for working with us to make that happen.

It was your recommendation to have the third party facilitator, and so based on that recommendation, we are pleased to be working with RESOLVE to help gain solid and solicit input. And I believe RESOLVE is with us today as well on the second half of this session, to listen to the input that goes on at this meeting. So it's been kind of an iterative

process throughout. So I think they're looking forward to hearing what comes out of this meeting as well, and so we appreciate their work. And I think they're probably sitting in the less comfortable chairs perhaps. They got accused for getting the comfortable ones at the last meeting, and I'm sure they're going to enjoy the dialogue that happens in this couple of days. So I want to thank you very, very much.

At the meeting that we had, the public workshop, we were able to discuss risk-based inspection in processing plants and off-line slaughter operations. We primarily focused on the two measures of risk, the product inherent risk and the establishment risk control. These two measures we believe to be used to determine how to allocate in-plant resources.

We also went on and had a third presentation on our initial thoughts on how we might implement inspection based on these two measures of risk. That was a presentation titled using risk to direct in-plant processing and off-line slaughter activities.

That presentation, given by Mr. Bobby Palesano, is going to be represented here at this NACMPI meeting but he's redone that presentation based on feedback that he received at the RESOLVE workshop. He is then going to ask one of our Subcommittees at this meeting some additional questions that he came up with, with our management team, based on feedback that we heard at the RESOLVE workshop.

So when we say an iterative process, we really are going to take what we're hearing and take it to the next level. So that material was presented. We heard some very good comments, and we're trying to take those comments right back to you as a Subcommittee to get some additional input from you as we move forward.

We also heard some other good comments for those of you that were not with us on the two papers that were presented. For example, I just want to mention some highlights and Dr. Raymond and I both committed that the RESOLVE final reports that is due to the Agency in December, will be available on our website. We also encouraged everyone to continue to

give the Agency comments through our risk-based inspection websites.

But, some of the common themes that just came very clear, just in listening, were that our expert elicitation generated a lot of comments, and we are interested at looking at those and reexamining the process and the rationale behind that. So we're going to be looking at those comments very carefully.

There were certainly a lot of interest in volume and where volume appropriately fits. The Agency tied it to the inherent risk factor and several of the small groups when they broke out suggested maybe different ways to factor in volume, either as a standalone, making it rather than a two dimensional figure, a three dimensional figure. So we're going to be looking at those comments very carefully since they seem to be very common across all of the small groups that broke out.

When we asked about components of risk control, it was interesting that all of the groups that considered that, both in Washington, D.C. as well as the remote Netcast sites, seemed to come to the

same place, that food defense was not as important as things like food safety design or food safety implementation and pathogen control. So that's something the Agency will be looking at very carefully.

And we also heard from pretty much all of the group that we should be including industry data when possible.

We heard a lot of good data over the course of two days and in particular we've heard about the importance of attribution data, and how we should be incorporating attribution data when we look at risk control. And Dr. David Goldman, from our Office of Public Health Science, shared that the Agency will be co-leading a meeting in December focusing on attribution data. So we need to look at how we can incorporate that in our risk control model. So there was a lot of information on that.

The second topic that we're going to be discussing here today was not covered at our RESOLVE workshop. We felt it was time to also move a little bit beyond those topics and begin to consider other

topics as well, so we can continue working on one realm and move forward in another realm.

That topic will be presented by Mr. Phil Derfler, and that is using risk in slaughter operations. As an Agency, we believe that we can apply many facets of our food safety program and look at how we can apply our risk based approach to those many areas of our food safety program. So we're very excited about hearing your ideas and recommendations, as we look at moving forward to enhance our risk-based inspection system ideas to another facet of our program. So we'll have a Subcommittee looking at that as well.

We believe you all are an excellent group to work with us and provide recommendations to our efforts to continue to improve our mission because we believe it is appropriate that we continue to move forward to protect consumers and to provide public health in every way that we can.

We think that it's important that we openly communicate and do that often with our food safety stakeholders to get your input and ideas.

Additionally throughout the day, we'll be reviewing previous reports that we've talked about at the last meeting, as well as some updates from the last meeting including some of the requested reports that you asked for on NRs, that you asked for some data on analysis that you asked us to do. So you'll see that on the agenda. So that's something we'll be talking about today.

And finally, before I close, I want to acknowledge that at the last meeting, we introduced you to some of our employee organization representatives. We felt that they were a very part of our meeting, and that they were able to give you some real life examples. They were particularly helpful were helpful in sitting in in the Subcommittees I think, where they were able to answer some questions from on the ground and give you some insights into those subcommittee meetings. So again, we've invited the association to select a representative to represent the organizations. So at this meeting again, we'd like to welcome them. We have Stanley Painter from the National Joint Council.

We have Bob McKee from the Association of Technical and Supervisory Professionals, and we have Chris Bratcher from the National Association of Federal Veterinarians.

And we welcome all of you and appreciate the time that you've given to attend those RESOLVE workshops as well as joining us at the NACMPI. We think that this is a constructive way to provide input from an employee association perspective. So thank you very much for joining us today.

So again, we'd like to thank all of the Committee members for working and your commitment to our mutual goal of protecting the food supply. Again, we know you've given a lot of time, not only this week, but throughout the year on working on these issues, and we have benefited greatly from your insight and dedication. So thank you very much. I again look forward to a product meeting.

MR. TYNAN: Thank you, Dr. Masters. Before we get into our rules of order and talking about the agenda, for the benefit of our folks, our employees organization people that are sitting with us, perhaps

it would be a good idea for us to go around the table and introduce ourselves so that there's a name to go with the faces. Maybe you could start with us, Kevin, and just sort of identify yourself and your organization.

MR. ELFERING: Kevin Elfering. I'm the Director of the Dairy and Food Inspection Program for the Minnesota Department of Agriculture.

MR. SCHAD: I'm Mark Schad. I own and operate Schad Meats in Cincinnati, Ohio.

MR. LINK: Charles Link. I'm Corporate Manager for Technical Services for Cargill Incorporated in Wichita, Kansas.

MR. KOWALCYK: Michael Kowalcyk. I'm a member of Safe Tables Our Priority. In my professional life, I work for a consultancy firm that works in database marketing and marketing research.

DR. LEECH: I'm Irene Leech. I represent the Virginia Citizens Consumer Council, and in my work life, I teach consumer affairs at Virginia Tech.

DR. HARRIS: I'm Joe Harris. I'm the Executive Director of Southwest Meat Association.

DR. GRONDAHL: I'm Andrea Grondahl, Director of the North Dakota Meat Inspection Program for the North Dakota Department of Agriculture.

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

MR. FINNEGAN: Mike Finnegan, Training Officer for the Montana State Meat Inspection and also a USDA grader.

MS. ESKIN: I'm Sandra Eskin. I'm a consultant -- a number of non-profits in the food safety area, and I have a really bad case of laryngitis. Sorry.

DR. DENTON: That's going to be difficult. I'm James Denton with the University of Arkansas, formerly the Director of the Poultry Center there, and now work half-time at the University.

DR. CARPENTER: David Carpenter. I'm with Southern Illinois University School of Medicine in the Department of Medical Microbiology, Immunology and -- Biology.

DR. BAYSE: Gladys Bayse, Professor of

Chemistry, Spelman College in Atlanta.

MR. PAINTER: I'm Stan Painter. I'm the Chairman for the National Joint Council of Food Inspection Locals.

MR. BRATCHER: Chris Bratcher, National Association of Federal Veterinarians.

MR. McKEE: Good morning. I'm Bob McKee, with ATSP and in my real life, I'm a front line supervisor in San Diego, California.

MR. PALESANO: I'm Bobby Palesano with the Office of Policy.

MR. TYNAN: I think we know the two at the end of the table. And again, I'm Robert Tynan, and I'm with the Office of Public Affairs, Education and Outreach at FSIS.

I wanted to mention also in follow up to some of Dr. Masters' remarks, that today is the closing date for applications for the next committee. This is last meeting of this Committee. We will be rechartered probably the first of next year, and we'll have a new committee figured at that time, but if those of you who -- all of the members of the

Committee as you know, have to reapply to for the next session. Some of you have worked out through your three terms, that you're allowed to have without taking a break, and so we thank you for the efforts that you've put in. The remainder that can come back, should reapply if you're interested in participating again for the next session.

And again, I want to add my thanks to Dr. Masters and Dr. Raymond for the hard work that you've all put in. I know it's very difficult for some of you, for all of you, in fact, to take time out of your busy schedules to come here and help us with some of these issues. So again, for my part, I appreciate all the help that you've provided, the good insight and advice.

I wanted to stop for a moment and go to our Rules of Order which in your notebook are in Tab 3. And we might just take a minute to go through the rules of order and how we're going to conduct the meeting and some of the issues that we have.

As you know in the Rules of Order, we've gone through these before. So I don't think there's

anything new or exciting that you haven't seen or heard probably a couple of times before.

In the rules of order, the Chair is the FSIS Administrator. She conducts the meeting. The Chair opens the meeting, recognizes those that want to speak, imposes limits on the time and the number of speakers and adjourns the meeting. And essentially I think Dr. Masters delegates that to me to actually run the meeting so she can concentrate a little bit more on the conversation that's going on among the members.

All questions and requests to speak will be addressed to the Chair. People much be recognized by the Chair before speaking. And I think as we found out, you have to hit the button on your microphone in order to engage it. So when you see the red light there, that means it's on. But if I could also impose on your to -- if you have a question, a comment, something that you want to bring up as part of the discussion, if you would take your tent card, sort of stand it on its end, that's the practice I think we've used in the past and we'll try and find some orderly way to acknowledge the people that have questions and

comments.

Presentations of Issue and Briefing Papers are going to be followed by short question and answer periods. As everybody knows, we've changed the format just a little bit. Instead of doing presentations on the papers, we simply provide those to you, and if you have questions about that, we'll have people in the room that can respond to those for you.

The questions and the comments should be limited in length, and to those who are speaking for clarification, perhaps on the paper, and the Chair will exercise discretion on the time that is to be allotted.

Speeches or statements of opinion by the audience or even by the Committee for that matter, should be made during subcommittee discussions or during the time that's set aside on the agenda for that purpose. We have a lot to go through. So if everybody took 10 minutes to do a speech, we'd be here probably 4 or 5 days. So if you could, if you could confine your, you know, be clear and concise on the questions and comments you want to make, if there's

longer statement you want to make, if you could hold them for the public portion.

Committee members and members of the public will be recognized by the Chair during the public comment period. Request to speak may be presented to the Chair in advance, and in that regard, if anyone at this particular point knows that they have a comment that they want to provide during the public portion of the session, I think we have a sign up book at the registration table. I would ask that you put your name in there so that we can sort of get a sense of timing and how much time we can allot for the different speakers. So if you have a presentation that you want to make, if you could, or a comment or a long comment that you need to make, if you could sign up outside for us, that would be great.

The Chair approves, in advance, material to be distributed by the Agency, by Committee members, and by the public at large. So if anybody has any materials that they want to pass out or leave on the table for distribution, you need to check in with us before you put that out there for the audience in

general.

The Committee members are expected to append the plenary sessions. So when we have this session here, you need to be here for this, and for the subcommittee meetings to which you're assigned. So we have subcommittee things, and we'll talk about that in just a moment, but you have to participate in those subcommittee sessions. Committee members who don't attend the presentation of the issue for their particular subcommittee meeting, are restricted actually in participating the following morning in the final plenary session considering that issue. So essentially what we're saying there is, if you don't participate in the Committee session, you decide you want to go to the other, in the morning, you can't be investing too much effort in the original session you were supposed to be in. If you wanted to do that, you should have been there. So enough said on that.

The Subcommittee Chair is designated by the Chair and controls the subcommittee sessions. So we have two individuals, I think Dr. Carpenter is going to take care of one, and Dr. Denton is going to take

care of the other. They will have discretion in the subcommittee sessions to determine how those sessions run. Members of the public may attend these sessions and at the discretion of the Subcommittee Chair, they may ask questions or provide comments as part of the overall presentation.

And the Rules of Order are subject to review at each Advisory Committee meeting at the discretion of the Chair. So if anybody has any issues with that, we need to add, modify, delete, please let myself or Dr. Masters know sometime at the break.

Any questions on the Rules of Order?

(No response.)

MR. TYNAN: Okay. Now let me just take a minute and -- oh, I'm sorry. Yes, Mr. Painter.

MR. PAINTER: Robert, I don't have a notebook. Can I get a notebook that has the Rules of Order listed?

MR. TYNAN: Absolutely. We'll do that for you right now.

MR. PAINTER: Thank you.

MR. TYNAN: I'm sorry. I thought you had

one. And the other thing I might ask in terms of the session -- the other thing I might ask you do to when you start to make a comment, in addition to putting your tent card up, if you could identify yourself for purposes of our transcript, so we know who's saying what.

If I could impose on you to go to the Agenda which should be in the front pocket of your notebook, and we'll walk briefly through the Agenda so that we all are on the same page and understand where we're going for the next day and a half.

We've already -- obviously, we've done our Welcome and Opening Remarks and the Charge of the Committee is now finished.

So in a few minutes, we're going to begin looking at some of the issues from previous meetings and briefing papers from either previous meetings or new issues that have come up that we want to provide information to the Committee. There's a number of those, and we've added an additional discussion that we will try and get in before the break, if time permits, and if not, perhaps right after the break,

which has to do with Analysis of NRs, and that was something I think the Committee asked for at a previous meeting. So we're going to have a little bit of discussion about that on or before the break.

We're also going to -- we'll have a break at 9:45 and I know that that's something that everybody looks forward to. I always do.

At 10:15, we're going to -- on your Agenda, it should Using Risk to Direct In-Plant Processing and Off-Line Slaughter Inspection Activities. We're going to take maybe 15 minutes out of that, in response to a couple of comments I received from members yesterday, to have sort of a brief discussion and overview of what happened on Tuesday and Wednesday, sort of digest some of the information and comments that came out of our public meeting the last two days. So I thought that would be beneficial before we began the actual subcommittee or the presentations that will lead to the subcommittees. So that will be maybe about 15 minutes, if that's agreeable to everybody. So we'll fit that in at about 10:15 after the break.

We'll then have Mr. Palesano do his

discussion again, review what he talked about yesterday at the public meeting, and talk a little bit about some of the revisions he's made in his presentation and the questions he has for you. So it will be Using Risk to Direct In-Plant Slaughter -- I beg your pardon -- In-Plant Processing and Off-Line Slaughter Inspection Activities.

We'll have lunch hopefully as close to 11:30 as we can, and after lunch, on page 2 of your Agenda, we'll be reconvening, and we'll begin the issue of Using Risk in Slaughter Operations, and Mr. Phil Derfler will be here to discuss that.

At 2:00, we'll have public comments, and again, if I can remind everybody, anybody that wants to make a comment or a presentation, at that point if they could register outside. We'll have that from 2:00 to perhaps as late as 2:45, depending on the questions or comments that need to be made.

And then at 2:45, we'll start our subcommittee deliberations, and we have, as I mentioned, two subcommittee. And the rooms there are not accurate. We had a problem with a couple of our

conference rooms. So we'll be using the back of the cafeteria for one and we have another conference room that's a little bit further away. So we'll get you to, group 2 to that conference room successfully after lunch. So we'll do subcommittee deliberations in the afternoon, and that will take us through whatever time you need. The cafeteria here closes at 6:00, but I'm sure you will all be done probably by that time.

On Friday morning, we'll reconvene. Dr. Masters will do a bit of a recap on the discussions for today, and we'll have our reports out for Subcommittee 1 and Subcommittee 2. We'll get the plenary session to concur in both of those Subcommittee reports, and then we'll have another commentary, another public commentary as part of the wrap up, and then we will adjourn probably, it says 11:15. Hopefully, we'll be able to be that early. I would think probably closer to noontime.

But at any rate, that's sort of the Agenda as we have it. So there are a couple of little adjustments we made. Are there any questions or comments?

(No response.)

MR. TYNAN: Okay. With that, let me ask you turn to table 2, and we'll do the last logistical thing before we get into the substance of the meeting.

I think the other day in your notebook, we had Subcommittees set out. We assigned the members that we knew were going to be here to the various Subcommittees, and we made a few changes to that. And so I wanted to let you know now so that you can get thinking about it, and if there's any additional changes we need to make, we can do that sometime during the course of the morning.

The first issue, Using Risk to Direct In-Plant Inspection Activities, as I mentioned earlier, will be chaired by Dr. Carpenter, and the members of that group will be Dr. Bayse, Mr. Govro, Mr. Kowalcyk and Mr. Schad.

And then under Using Risk in Slaughter Operations, as I mentioned earlier, Dr. Denton will be the Chair of that, and it will be Ms. Eskin, Mr. Finnegan, we'll have Mr. Elfering, Dr. Harris, Dr. Leech and Mr. Link. So we made a few minor

changes to the Subcommittee structure. I hope that's agreeable to everybody. As I say, if not, please check in with me during the morning, and we'll make appropriate adjustments.

And with that, I think we've taken all the logistical issues. Are there any comments or questions at this point?

(No response.)

MR. TYNAN: Okay. Then why don't we -- I'll begin the substance in talking about updates and issues, and what I propose to do is I'll take the issues almost in the order you see them on the page. I'm going to change one because somebody has a conflict. So they need to be leaving.

So what I would like to start with is the update that's under Tab 5 which is the Working Together to Protect Health: The Public Health Communications Infrastructure. Were there any questions on that? I have Ms. Janet Stevens and is Marcelo here?

UNIDENTIFIED SPEAKER: He's outside.

MR. TYNAN: He's outside is he. Okay. He's

on his way in. Were there any questions on that particular paper? I'm sorry. Michael or Mr. Kowalcyk, I apologize. Marcelo, why don't you come on up and you can sit at my empty seat there.

Mr. Kowalcyk, you had a question. Go for it.

MR. KOWALCYK: This is Michael Kowalcyk. The past couple of days there's been quite a bit of discussion about data using appropriate data into whatever risk-based ranking the Agency would use as a way to allocate resources and, you know, I would commend the Agency on their work to sync up their systems. You manage a lot of information from a variety of sources, and it's actually a very challenging task I would imagine working in the data management field myself.

Could you provide any specific information on where you see the infrastructure today and where the Agency feels it needs to be to manage to manage some type of risk-based system and what type of timelines, resource needs that the Agency's spec'ed out that you feel based on your expert analysis of

your current systems and where you think the systems need to be?

Is there any specific information you can share with the committee about timelines, key milestones, project management tasks that are currently underway?

I know that's a broad question. There's a lot to that but it's just we're asking very specific questions about how we would use certain data elements in coming up with a really robust system, and at least for me personally, if I had a better grounding into what you can do today and where you feel you need to be to do that, that would help me in helping make my recommendations. Thank you.

MR. OLASCOAGA: Well, FSIS is just like any other Government agency -- agencies and we have a lot of stovepipe systems. And that's something that we've been working to consolidate in the past year.

So, for example, key milestones. I think sometime in the beginning of February, like February 15th, we will be able to consolidate five separate or five different reporting systems which will have a

single log in to get to all these different types of screens, and I do call them screens because we'll have everything on a web platform. So at a minimum, we'll be able to consolidate the five reporting systems, which now you would have to log in separately to each one of them to try to get reports.

This will also allow us to utilize the data warehouse that we have already built and obviously that's going to evolve on a daily basis as we consolidate the systems. So all of the data will be in one place with basically 12 or 24-hour turnaround each time we refresh the data on a nightly basis or whether we do it more than that, it just depends on the requirements. But either way, we'll have the data in one database that we can do all of our reporting from. So at that point, we can start using the data in many different ways. So whether it's risk based or whatever we need to report on, we can do that.

So that would be definitely a key milestone and an activity that we're undertaking right now of great importance. And by doing so, after studying and conducting an analysis of the separate databases that

we have or system if you will, we'll be able to standardize the data so that we can move forward with risk-based inspection and collect the data in a format that's necessary to conduct any algorithm against it.

MR. KOWALCYK: I guess a follow up to that, as mentioned, across agencies. When you say that, is it across areas of USDA, like ERS, FSIS or is it outside of USDA to maybe FDA, CDC? Is the work going on to sync up those systems in any way?

MR. OLASCOAGA: Well, I mentioned FSIS being, you know, an agency like any other Government agency having different stovepipe systems. It just -- we're just like any other agency. We have numerous stovepipe systems, and what we are doing and we're having success at is consolidating it. So we're no different than other Government agencies but, yes, within a short timeframe, we're able to consolidate the systems. That's a very key milestone for us. And that's all I meant.

MR. KOWALCYK: Yeah, and that make sense within FSIS but my question was is the Agency looking towards ways to integrate information from FDA for

example, CDC? I mean is that part of the scope of your project now?

MR. OLASCOAGA: Yes. Well, we do have various initiatives, one of them called -- Surveillance and we also have another one for import and exportation information that we need to take in as well. With that, we can use an XML technology which you're probably aware of and we'll be able to exchange information between all of the agencies, and we can just wrap the data within a set and just send it out.

MR. KOWALCYK: Okay. And is that along the same timeline as that? Is that all part of the same project or is that after you get your internal systems where you feel they should be, and then that's the next step?

MR. OLASCOAGA: Well, I would say it's part of the big picture, the whole initiative itself but, yeah, we are taking it in steps. So in February, we'll consolidate the reporting systems.

MR. KOWALCYK: Okay. Thank you.

MR. OLASCOAGA: You're welcome.

MR. TYNAN: Thank you, Michael. Are there

other questions on the infrastructure?

I might take just a minute, Janet, if you had a moment, did you want to come up? I think some of you, when we did our presentation for you at our May meeting, I think some of you submitted questions and I think Janet was kind enough to put together sort of a few bullets regarding those comments and how we've used them. So I want you to be aware that we have been following up. So, Janet, if you could identify yourself maybe and then --

MS. STEVENS: Thanks, Robert. My name is Janet Stevens. I'm the Director of the Management Controls Technologies staff, the new staff here, and I just wanted to, first of all, thank everyone for the comments we've received so far. I wanted to first update you on one point from the last meeting, about we had mentioned one tool assurance net that we had scheduled to launch in June. It did launch in June. It currently monitors over 50 inspection based performance measures, and we're additional measures with an additional measure to launch in March of 2007.

The major comments we received were --

ranged from minor to I think pretty specific. One was to really clarify the terminology that we're using. There's a lot of terminology that was in there. They thought that public health data and communications should be clarified, that they should be differentiated from such terms as industry or plant data, consumer data, education data and other Government agency data.

We also received comments that the components of industry plant data needs to be analyzed and validated to determine, if possible if there are any correlations or statistical relationships that exist, and that contributor was actually kind enough to give us a table listing some potential data and -- some potential data input and some questions to be answered regarding validity and usefulness related to public health.

We had positive feedback on the use of business intelligence technologies, to show that FSIS and industry are meeting their public health commitments. We had comments that were generally around consumer complaints, to insure that that data

is counted but also that it is not counted twice, possibly skewing your data.

Other comments were that the data needs -- should include *Salmonella*, LM, *E. coli*, chemical/pesticide residue analysis, and also Food Net data. There was a preference made for using the e-mail alerts to push data and analysis information out to the public and to stakeholders.

We had some comments stressing the importance of assuring the security of data that is stored and transmitted.

There was also some needs on the understand AI [Avian Influenza] implications especially for the elderly and parents, and we had an ideal outcome submitted, that they wanted to insure that FSIS can be in a position whenever possible to notify the public of a problem before it is actually over, so there can be the greatest possible window to protect public health.

So we wanted to assure folks that we did receive your comments. We'll be including this information as we planned. Especially as Marcelo, the

future systems, the stages that we have and gather requirements for them, and I did want to say that we welcome your feedback in this area.

MR. TYNAN: Any follow up questions? Mr. Kowalcyk?

MR. KOWALCYK: I'm very interested in learning more about your data and processes. I know you could probably bury us in paper if you wanted to. Is there any HTML site that is available to share with the public or Committee members as to, you know, how far back does your data go in your legacy systems? What data are you, you know, what's your look-back window, things like that, just so that we can get some more information back because I think a lot of questions we have from the data side might be answered just by being able to look at what you've done or what you're planning on doing.

MS. STEVENS: So in addition to what we are planning, you'd like to know historically what do we have --

MR. KOWALCYK: Yes.

MS. STEVENS: -- right now to work with.

MR. KOWALCYK: Yeah.

MS. STEVENS: We can certainly talk about that, and let the Committee know if that information is available and how to get there.

MR. KOWALCYK: Okay. Great.

MR. TYNAN: Other questions on the infrastructure?

(No response.)

MR. TYNAN: Janet, thank you very much. Marcelo, thank you very much.

MS. STEVENS: Thank you.

MR. TYNAN: Okay. Let's go back to the beginning, so that we get everything covered. I think the first update was going to be on the Strategic Implementation Plan for Enhancing Outreach to Small and Very Small Plants. Were there any questions or issues in relationship to that? Mr. Govro. We have Dr. Kelly coming up and Mr. Palesano, both very knowledge in this particular area. Please ask your question, Michael.

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. In the first bullet here, you mention

that you established a call in, toll free call in line and I'm just curious about when that was put in effect and how much it's been used.

MR. PALESANO: I will start with that, Michael. This is Bobby Palesano. We did put in a new phone system at the TSC. We do have a group of OPPED staff officers out there that have been assigned the responsibility for responding to the needs of the small and very small plants as well as the inspectors that are assigned in those establishments.

Right after the number was established, there was a rather significant increase in the number of calls that were coming in. So after that, we've made some changes as to the type of calls that were coming into the Tech Center, and we took some of the labeling calls from the Tech Center and had them come to the labeling staff here in D.C. So right now it's a little bit difficult to get a good read on the data coming in, for those particular reasons.

MR. TYNAN: Mr. Schad, you had a question?

MR. SCHAD: Yeah. First of all, I just wanted to commend the Agency for the work they've done

on this, in this area. It was needed, and you've been doing a good job so far. I've been seeing the effects of it, positive effects.

I just need a clarification on the last bullet on the second page. Now by trade publications, I assume you mean like meat trade association magazines. Is that correct?

DR. KELLY: Yes, that's correct.

MR. SCHAD: Okay. Is there a timeline on that? Maybe it's just me. I haven't seen anything like that. Has that started or --

DR. KELLY: This is Karlease Kelly, and that was a recommendation of the committee back in December. We have begun the process, and we have at least one article in clearance, and I understand that our strategic partnerships initiative outreach staff is putting together a calendar of different articles that we're planning to issue in the upcoming year. So it's taking just a little bit of time to get started, but I think you're going to see a steady stream coming out soon.

MR. TYNAN: Dr. Harris?

DR. HARRIS: Just one quick question concerning your collection of feedback from users of the Technical Service Center. As Mark mentioned, as someone who uses that number fairly regularly, I have definitely noticed a change for the better there. But a question, do you have any other means of soliciting user feedback, maybe a little less formal than a Federal Register notice because honestly I didn't even see that Federal Register notice, but is there any other means?

DR. KELLY: This is Karlease, and I'll answer some of that and Bobby may want to add onto that. At the regulatory education sessions that we're conducting, we distribute questionnaire, essentially evaluation forms asking all the participants to give us feedback, not just on the regulatory education session, but any other kinds of outreach activities that we're providing, and we're paying attention to the input. We also are -- our Office of Food Defense did an informal users group type of feedback on some materials, food defense materials, that works very well this summer and we're looking at doing more of

that, getting people together, providing them copies of information that we distribute and asking them for what works well and what can be improved. I know Bobby and I are always open to hearing from anybody, you know, what you think is working well and what can be improved.

Bobby, do you want to add anything to that? No. Okay.

I would invite you, if you have other mechanisms that you think would be effective, we're certainly open to that. The feedback and input is very important to us.

MR. TYNAN: Mr. Finnegan.

MR. FINNEGAN: Yeah, Mike Finnegan. In regards to the third bullet here, discussing the outreach sessions, I'd like to commend the Agency on these sessions. I did attend the one in Billings, Montana, the outreach session, with Bobby Palesano and Karlease Kelly, and it was very well needed.

I was just wondering if there's any plans to go a little bit deeper into advanced HACCP [Hazard Analysis and Critical Control Points], sort of a HACCP

training, even preparing for EAIO [Enforcement Analysis and Investigations Officer] review or FSA review [Food Safety Assessment].

MR. PALESANO: I'll start with that. Mike, we've -- this is Bobby Palesano. We are looking at some different types of training options. We have not worked through those completely. So we're not ready to actually start those trainings yet, but they would be more in line with what you are saying, where we would have some type of joint training session to try and attempt to get industry and FSIS personnel on the same page.

In addition to that, you know, we are doing and exploring any ideas that become available to us, so that we can insure that the needs are met by the small and very small plants.

DR. KELLY: And I --

MR. FINNEGAN: Mike Finnegan again. One of the things that we particularly liked was you invited industry and regulation to sit down at the same table. I thought that was just -- it was excellent. It really was.

DR. KELLY: Thank you. I'll just add to what Bobby said, and that is for these regulatory education sessions, one of the things that we do have planned and you're going to see in the future, we not just going to do the same sessions over and over because in some cases, we are going back to the same areas. We're going to be adding some additional topics.

Our initial sessions covered HACCP, SSOP [Sanitation Standard Operating Procedures] and Rules of Practice. In the near future, we're going to add sessions on sanitation performance standards and food defense and I think over time, we'll just continue to get more targeted. That doesn't address the question that you raised about more advanced topics, but it is additional regulatory review, basic regulatory review.

MR. TYNAN: Do we have other questions on the small and very small plants?

DR. KELLY: I just want to add a thank you on behalf of Bobby and myself to the Committee for the review and the feedback that you gave to our Strategic Implementation Plan, to the support that many of you

have provided. We have seen some of you attending some of these sessions, not just the Committee but also some people in the audience. We know that you have made members and other people aware that people have been attending some of the sessions.

People have been utilizing the services that we're providing, and we also the value the feedback that you sent to us, especially feedback on things that you feel like could be improved. It's always nice to know about things that are working well. We appreciate that encouragement but the things that still need to be improved, we value that feedback as well.

And you may notice at the very end of the paper, we did make substantive progress on the action items that we had planned. Such substantive progress that we have gone back to look at what our plans are for '07, and so if you have ideas and input for us on that, we'll be here and we welcome that input.

MR. TYNAN: Thank you, Dr. Kelly. Thank you, Bobby.

I would refer you to Tab 6, that has to do

with an update on State Reviews. We have Mr. Vince Payne from our OPEER Office that can answer any questions.

Mr. Elfering, you had a question?

MR. ELFERING: Yes, Kevin Elfering. There was recently an OIG Report I believe that just came out, and I see that USDA is going to be preparing a report, a summary report in January of 2007. What, if any, effect is this OIG Report going to have on your final report?

MR. PAYNE: My name is Vincent Payne. I'm the Director of the Internal Control Staff.

The OIG Report, we're currently preparing comments to address those recommendations. Those recommendations will be addressed as we go to our next round of reviews in the coming fiscal year. The current report that will be issued in January of this year, excuse me, in November of this year, will basically pull together all the data we've gathered so far.

MR. ELFERING: This is Kevin again. A follow up, when are you going to be starting the next

fiscal year reviews?

MR. PAYNE: The -- well, the next fiscal year's review will start in January.

MR. TYNAN: Are there other questions on the State Reviews?

(No response.)

MR. TYNAN: Thank you, Mr. Payne. That was easy.

I refer you to Tab Number 7, the Update on the Harvard Risk Assessment of BSE. Are there any questions in relation to that? Mr. Elfering. Is Janell here? Mr. Elfering.

MR. ELFERING: Kevin Elfering. I don't know if you're going to answer this or Dr. Masters.

In 2004 I believe, there was the Interim Final Rule on specified risk materials, and as part of that, there was a concern and a requirement that non-ambulatory livestock would not be able to be slaughtered, and there was some questions on whether or not animals that are slaughtered under the custom exemption would meet that definition and that they would also not be able to be slaughtered even though

that animal would not be entered into commerce but would only go back for the consumption of the owner of the animal, their immediate family, non-paying guests and employees. There has been a lot of concern that there are a lot of non-ambulatory cattle that are being slaughtered clandestinely and many times in very unsanitary conditions but those carcasses could still be brought into a custom exempt processing plant after they have been slaughtered.

From the standpoint of public health and risk, since we're looking at risks associated with the consumption of meat and poultry products, I would be more concerned of these animals being slaughtered in these types of conditions rather than the risk of Bovine Spongiform Encephalopathy. I think that the Harvard Risk Assessment clearly shows that if specified risk materials are removed from the carcass, that the risk of these consumption of meat products is next to nothing.

Is there any possibility that there would be some method of allowing foreign non-ambulatory livestock to be slaughtered in custom exempt plants

under conditions that they would be received in the plant perhaps under a veterinarian certificate, that there's a broken appendage. We have cattle, people have called me up, that have had a 14 month old steer that broke a leg that they have to destroy and they're not real happy about it, and they are usually the ones that are going to be gripping to me. And I'm just wondering if there's a way that some of these things could be changed to really reflect what the Harvard Risk Assessment says and the true risks to the public health.

DR. MASTERS: This is Barb Masters, and I would comment three ways. The Interim Final Rules are still in place. The Final Rules are still under consideration in the Department. The Final Rules took into consideration three things. One was the Harvard Risk Assessment. In addition to that, the Final Rules take into consideration the surveillance program by APHIS as well as by the over 20,000 comments that the Agency received. So the Final Rules are still under consideration at the Department taking into account all three pieces of data.

As to your comments about animals being slaughtered clandestinely at custom exempt operations, I would remind you that those animals, it would be illegal to slaughter those animals at a custom exempt slaughter plant, recognizing that the burden would be to prove that that had happened, and I recognize that's much more difficult, but I would remind everyone that it's illegal to slaughter those animals currently in a custom exempt slaughter facility.

MR. ELFERING: Just as a follow up. This is Kevin Elfering again. Now these are animals are not being slaughtered in custom example plants. They're being slaughtered on farms. They're being slaughtered on farms and they're probably being hoisted up using a front-end loader that was just previously used to clean out the barn. We actually had a food-borne illness outbreak, a pretty significant one, with the -- it was actually through a church, dinner, custom exempt farm slaughtered animals, and to me the risk from that is much greater, and I really think that -- I don't know if the Agency really has the authority to tell people what they can and cannot eat,

and I think custom exemption was put in place back in 1967 for the purpose of the owner of the animal should be able to know and determine the health of the animal, and I just -- I don't really agree that the Agency has the authority to say that those animals cannot be slaughtered.

MR. TYNAN: Thank you, Kevin. Other questions on the Harvard Risk Assessment?

(No response.)

MR. TYNAN: Okay. With that, Janell, thank you very much. You got off real easy on that one.

I think the next topic has to do with Avian Influenza under Tab 8. We have an update on that one. Are there any questions in relation to that? Dr. Carpenter, let me see if somebody's here. Perfecto or Dr. Evans. I'm sorry. I apologize.

DR. CARPENTER: Okay. Thank you. On the second page, the third paragraph, you talk about tabletop exercise where you exercise -- focus on the role of the state, federal and local government agencies and consumer groups, was any representatives from the state and consumer groups at that tabletop

exercise? And if not, were their expected roles conveyed to them after?

DR. RAYMOND: In the absence of Perfecto being here, Bob, I'll take that one. This is Dr. Raymond.

MR. TYNAN: Thank you, Dr. Raymond.

DR. RAYMOND: Yes. We had representations there. Caroline Smith-Dewaal from the Center for Science and Public Interest was there representing consumers as was Barbara Kowalcyk from the Safe Tables Our Priority. We had also invited the Consumer Federation of America, but they were unable to attend. We had four states represented. Kevin was there for the tabletop, Virginia, Minnesota, Ohio and North Carolina.

We had people from state ag, people from state health, people from city and county health departments, chief veterinary medical officers for some of the states. You know, multiple states were invited, and they send who they could.

MR. TYNAN: Mr. Elfering, you had a question?

MR. ELFERING: Kevin Elfering. As we all know, avian influenza, especially high path avian influenza is a rapidly progressing disease, and for the poultry industry, in Minnesota, we've been doing surveillance for avian influenza for the last 30 years. And turkeys, all turkeys that have gone to slaughter, are tested in the plant, serologically tested, and whether or not they have been exposed to any avian influenza.

The industry, the poultry industry now is going to a system of pre-harvest where they will be doing PCR pre-harvest testing to see if there is any active virus, and I'm just curious why FSIS would start looking at doing testing in a plant where I would think that the testing is going to be much more appropriate pre-harvest and I don't know if you even want to bring in high-path avian influenza into a processing plant, when the industry is already testing them pre-harvest.

DR. RAYMOND: Dr. Raymond again. The industry is not testing 100 percent pre-harvest within that 24-hour window. The chicken industry tests those

birds a week or two or three weeks before harvest. They're doing it as far as surveillance which is important but if you test a bird at 4 weeks and slaughter the bird at 6 weeks, with the mortality, morbidity of high-path avian influenza, you know, within 24 hours those birds are sick, within 48 hours they are dead. So testing two weeks before slaughter, other than surveillance for avian influenza of all types really doesn't help me tell the American public that your meat is free from the virus.

Now I don't disagree with you, Kevin, that pre-slaughter testing, if done within that 24 hour window, would be better than holding and testing after slaughter. The best thing I have right now available to me is if we would have a grow out facility show up with 5 or 10 or 20,000 birds dead this morning and another 20, 30, 40,000 sick, and APHIS would say this looks so much like high-path avian influenza, we are immediately quarantining that 10 kilometer zone. What I have in plan now, with the cooperation of industry, to the great part, is to hold any product that's been slaughtered within 24 hours within that 10 kilometer

zone and test it for avian influenza. We have been able to take our tests that were available and modify them so we can test for virus in muscle in four hours. We could not have done that a year ago. We can now do that. So the industry has been willing to hold and test. That's if it happens today.

If something happens in the next month and industry is able to institute immediately pre-slaughter testing for antigens, that obviously would be much more desirable, but we're not just there yet.

You heard at the tabletop, the consumers that make is mandatory. I don't think we have that authority to make it mandatory. And so I don't think we have the -- I don't think we can say 100 percent the birds will be tested within 24 hours prior to slaughter. We did meet with cargo reps already -- I mean this morning. We continue to meet with industry. We met this morning to find out where their, you know, minds are at on this issue. Most of industry will tell us there has to be a trigger first before they'll start doing this testing 24 hours pre-slaughter. There has to be a trigger. There's a difference of

what the trigger is and how extensive the pre-testing will be but those are things we continue to work on.

MR. ELFERING: One other question is on the egg pasteurization. It says that the virus is eliminated by most egg product pasteurization. Has there been any sort of -- I mean one of the things is there is a process called hot room pasteurization for spray dried eggs, and really I don't even think that there has ever been a true risk assessment whether or not that particular process is effective against *Salmonella*. And is that one that probably has not been looked at as maybe having the efficacy in eliminating the virus?

DR. RAYMOND: Barb says she thinks you're correct. I don't know for sure. But I think we'll all admit that high-path avian influenza and how it affects humans from consuming poultry and/or egg products is something that has not been extensively researched. Our research shows us what it takes to kill the virus in poultry meat. But I don't know that that's ever been tested, you know, in the field. If we had 10,000 birds with virus in the meat, how safe

is it to eat? I don't think we know that because it's not -- the capacity has just not been there, the incidence has not been there to do that type of testing. I think eggs is even less tested.

That's why I agree with you, pre-slaughter testing is the best thing to do to keep the virus out of the plants.

MR. ELFERING: And one final question is, it's been obvious all the years, including during the exercise, when it comes to eggs, it's very confusing about who has ultimate jurisdiction over eggs including egg products. For example, a tanker load of eggs that have been pasteurized, that are driving down the highway is under the jurisdiction of USDA FSIS. A tanker load of eggs that are non-pasteurized driving down the highway are under the jurisdiction of the Food and Drug Administration. Have you been working with the FDA and perhaps it would even be better to put together kind of a cooperative agreement with state programs who really have a clear jurisdiction over eggs and egg products in movement, to really make sure that who had responsibility at what part of the

process?

DR. RAYMOND: Dr. Raymond again, and at some point in that process, USDA AMS actually has some authority and jurisdiction also. Yes, we work with FDA [Food and Drug Administration] to make sure that this is seamless. We both have to follow the statutes as they are written. I met with Bob Brackett from CFSAN [Center for Food Safety and Nutrition] and talked about eggs and egg products and shell eggs. We continue to make sure that that process is as smooth and efficient and effective as it can be.

MR. TYNAN: Dr. Harris, did you have a question? Are you withdrawing it?

DR. HARRIS: He answered my question.

MR. TYNAN: Okay. Cool. We're way ahead of you. Dr. Bratcher, you had a question?

DR. BRATCHER: Just a comment. For a lot of people here, they probably don't realize that just within the last week, FSIS has disseminated a training program for avian influenza to all the veterinarians in the field, and I would encourage that the people that are in the state programs, because of the way

that we're going to try to organize these people, that the states should be contacting some of these veterinarians and there should be some plan in place for the state working with the veterinarians that are in the field, because oftentimes in these remote locations where slaughter plants are located, the veterinarian there may be the only medical trained professional in the entire city or town, and I think that we need to coordinate those -- I guess the activities that could result if we did have an outbreak of avian influenza in some of those small communities.

DR. RAYMOND: Also we would need -- Dr. Raymond. Not just activities but also the communication because the media will go to the person that has the most science background education, and you're exactly right, Chris. It very well could be the veterinarian that will have that information for the media, and we all need to have the same message when this hits.

MR. TYNAN: Other questions related to avian influenza?

(No response.)

MR. TYNAN: Okay. Let's take a look at Tab 9 for the update on the National Advisory Committee on Microbiological Criteria for Foods. That's our sister committee. I don't know why it's not a brother committee. Do you know what that is, Gerri?

MS. RANSOM: No.

MR. TYNAN: No. It's a sister committee. Okay. Are there any questions on the update on the NACMCF Committee?

(No response.)

MR. TYNAN: There appear to be none. I'd like to move on then to the Legislative Update. You received that this morning. We always hold that one until the end. I know you would argue that we hold a lot of them until the end, but we held that one to the end simply because it's always something occurring in that field. So it's always changing at the last minute.

We have Ms. Lisa Picard here, and she's Director of our Congressional and Public Affairs staff and can answer any questions you might have on the

Legislative Update.

MS. PICARD: Let me just say that I'm aware you just received this recently. So if you haven't had a chance to look at it, I will be around, if you want to review and go through. I'll be happy to answer questions if you don't have anything right now.

(No response.)

MR. TYNAN: Could I suggest this. We're getting close to our 9:45 time. Why don't we take a quick break and that will give some of you a chance to perhaps look at that or sometime during the morning, if you have some issues and questions, Lisa will be around, we can have her come back and respond to some questions at that point. So if everybody's agreeable to that, that's the way we'll proceed.

(No response.)

MR. TYNAN: Thank you, Lisa. This is the time you've all waited for. This is break time. We have 15 minutes on the Agenda, until 10:00, and since we've added a couple of things to the Agenda, I would appreciate it if you could come on back promptly at

10:00.

(Off the record.)

(On the record.)

MR. TYNAN: We have Mr. Don Anderson from our OPEER Office who has an analysis of NRs that he wants to share with you. And he's allowed me to be the guide to move his PowerPoint. So he's living dangerously today.

DR. LEECH: Robert, do we get to ask questions about the Legislative Update?

DR. RAYMOND: Thank you. Dr. Leech, you had a question about the Legislative Update.

DR. LEECH: Yes, I do please.

MR. TYNAN: Well, let me see if Lisa is back? Lisa, are you here? No. Could, could I impose on you? Could we hold the Legislative Update questions until we have Lisa back? Thank you. I apologize. I didn't realize that we were going to just jump right into that, but are there a number of questions on that?

Okay. All right. We will come back to that. In the meantime, we're going to let

Mr. Anderson talk a little bit about NRs.

(Pause.)

MR. ANDERSON: You warned us, Robert.

MR. TYNAN: Yes.

MR. ANDERSON: Okay. That should work. Thank you.

UNIDENTIFIED SPEAKER: You're welcome.

MR. ANDERSON: I am Don Anderson with the Program Evaluation, Enforcement and Review Program. Robert, let's move to the next slide.

For some context -- we should just be able to hit the down arrow and it should work. Just click the -- there we go. Very good.

Okay. At the May National Advisory Committee Meeting, remember, we talked to the group about our initial thoughts on how we might measure establishment risk control for risk-based inspections, and one of the things we talked about was NRs. And one of the questions we asked the Committee was whether some NRs are more important than others and how they should be used in the measure of establishment risk control.

And the Committee reported back to us, really the Subcommittee reported back to us, and recommended that the Agency undertake a review of the NR system and that are a result of the review, recommended that we consider only those NRs that relate to food safety and public health when we develop our measure of establishment risk control. Next slide please.

So what this group set out to do or what a team of us has set out to do is assess the support of the hypothesis that some types of NRs are more predictive of adverse events or loss of process control in establishments than other types of NRs. Next please.

So since May, we've been working with the OCIO, which is our Chief Information Office, information office, with members from the technical -- the TSC staff in Omaha, to collect data and begin analyses to test for associations between different types of NRs and the presence or absence of what we call adverse events in establishments.

What we're trying to determine here really

is to find out if certain types of adverse events are preceded by certain types of NRs, and we're trying to do that through analyses.

So let's talk for a minute about what it is we're trying to predict. Well, what we're really trying to find is we're trying to identify establishments in advance, or predict the establishments that are losing or are in danger of losing effective controls of their food safety processes. As a proxy for that, or an indicator for that, we talk about establishments that have adverse events. And by adverse events here, what we've been working with so far is we've identified establishments with certain types of laboratory failures in their testing programs or establishments that have experienced recalls or establishments that have had NOIEs, Notifications of Intended Enforcement.

And when we go through data for a six month window, and I'll explain why we use this particular window in a moment, but when we look at six months of data beginning in December of '05, and ending in June, we find these numbers. We find 77 adverse lab events,

17 recalls, 105 NOIEs, all in 178 federally inspected establishments. The 178 you see is lower than some of the others because some establishments experience more than one adverse event. We'll go to the next slide for a minute.

This is just a -- just to give you some idea, these are random numbers that I've attached to establishments, but these are actual -- this is just to show the actual data that we can identify for each establishment that we inspect whether there has been a lab failure, whether there has been a recall, or whether there has been a NOIE [Notice of Intended Enforcement]. This is just a sample of 12 establishments out of a population of roughly 5600 that we're talking about here. Next slide please.

So what we've talked about so far is, okay, what is it that we're trying to predict, and that is adverse outcomes as an indicator or proxy for process control loss.

Now how are we trying to predict that? What are we trying to do?

Well, we're trying to identify certain types

of NRs, and we've got two basic approaches that we think we can use to do that. One is to look at specific regulatory citations when NRs are written, and the other is to look for certain types of key words. So let's discuss that a little more. Next please.

To do this, we've created a NR search engine, which is still in a developmental phase. It's actually in a testing phase, but it's working quite well. This is just a screen shot of a search engine. Without going into a lot of details, it let's us specify a period of time that we're interested in, the reg cites, the specific regulatory citations that may have been indicated when NRs were written or we can look for certain key terms in the narrative of NRs. So it's basically a search engine tool. Next page please.

The reg cite search feature is particularly important. This is just seven or eight very specific regulatory citations that inspection personnel can select when they write NRs. So since December of 2005, when inspection personnel write NRs, they check

one or more specific regulatory citations to indicate what is the nature of the non-compliance. This makes it possible since December of 2005, makes it possible for us to electronically search NRs for regulatory citations. Next please.

This again is just illustrative data. Actually it's real data in the sense that the data on the right side is real, the random number on the left is just that. It's a random number to indicate an actual establishment, but what we can do here now you see, the key point is that for each establishment, we can see the establishment size and type which is demographic type information but most importantly, under the adverse event column, a 1 under the adverse event column indicates that that establishment has had some sort of a process control loss or what we call an adverse event, like a positive sample test, you know, a NOIE or a recall.

The three columns on the right are what we call -- most of us are going to be familiar with NR rates, which is the percentage of procedures that are performed that result in non-compliances. The columns

on the right are very, are very special or very specific type of NR rate. It is the NR rate for specific regulatory citations. So, for example, and I know it's hard to read, but we've put up -- in this analysis, we've got three different regulatory citations that we're looking at.

The first one, which I've coded net weight rate, is a violation of 317.19 in the regs which says that the establishment is not complying with net weight requirements in their product.

The second which I've labeled sanitation CA rate is 416.15(a). That's the reg cite which means that the NR was written because the establishment is not putting in place an appropriate corrective action following a sanitation problem. It's a sanitation corrective action citation.

And the third one that you see there which I call CCPCA rate is the analogous reg cite 417.3(a)(2) which says that the critical control point corrective action or the really the critical control point has not been corrected or the problem has not been corrected once identified in a HACCP procedure.

So the first citation on net weight is what we generally think of as a non-food safety or other consumer protection type of a violation whereas the other two are food safety. If we could go to the next slide please.

What this table shows is this table -- what this table shows is the NR rate or the specific NR rate for the three types of regulatory citations, net weight and the two corrective act. It shows the NR rate in establishments with and without adverse events.

So you notice for example that, and again I apologize I know it's a little hard to read, but it shows for example that the, that the next weight NR weight in establishments with adverse events or process control problems is a little higher than that in establishments without adverse events but not much. But notice, for example, the sanitation corrective NR rate and the 178 establishments with adverse events, the specific NR rate, these are in percents, so that's actually .085 percent is the NR rate. Whereas in establishments without adverse events, the NR rate for

that same citation is only about half as high.

So what we see here is that especially for the corrective action citations, the NR rates for corrective action problems in establishments with adverse events are significant or appear to be higher than in establishments without adverse events. Next please.

Without going into a lot of detail, this is -- these are the results of what is called an independent means test, and basically what this shows is that the difference between establishments with and without adverse events, that for the net weight NRs, they're not different. They're not statistically different from one another. For the sanitation corrective action rate and the CCP correct action rate, those NR rates are significantly different from one another. So this is evidence, this is some evidence from a preliminary analysis that there's reason to believe, following the hypothesis of what we're trying to find here, are predictors, NRs that are predictors of adverse events. This shows that for at least several types of regulatory citations that

we've looked at, corrective action NRs are significantly higher or occur at a significantly higher rate in establishments that do experience adverse events than in establishments without. Next please and the last.

I just want to sum up by identifying some other activities that we're going to be engaging in. One, of course, is we need to go through a systematic analysis like this for a lot of specific types of regulatory citations. There are hundreds of regulatory requirements that should be analyzed in this way so we can identify those that are most predictive of establishments that suffer process control problems.

Secondly, we want to consider and possibly revise our definition of adverse events. Again, we've looked at *Salmonella* set failures, RTE failures, O157:H7 positive tests, recalls and NOIEs. There may be other types of adverse events that we should look at as kind of indicative variables of process loss or process control loss.

Third, there have been suggestions made to

us by others in the Agency, that we should be -- that we should consider doing this type of analysis not just all plants lumped together, but doing it by plant type. Maybe certain types of NRs are predictive in some kinds of plants and not in other kinds of plants or for some types of events and not other ones. In other words, certain types of events NRs may predict RTE failures whereas other types of NR events might predict O157:H7 or *Salmonella* set problems.

We want to analyze further the look-back period. Now the analysis that I just put up here, we looked at six months of data from December 5th through June, and we selected that window because December 5, 2005, was when the new version of PBIS [Performance Based Inspection System] was put in place that allowed us to machine count, if you will, regulatory citation. So that's a new feature. So we want to analyze the look-back period. There's been a lot of discussion over the last couple of days, should we look at one year of data, should we look at six years of data, more data, less data. Hopefully we can use the data itself to help us make that determination to figure

out which period of time is most predictive.

And finally, we may want to consider combinations of regulatory citations. It may be that this type of regulatory non-compliance in combination with another type of regulatory compliance may be of a more powerful indicator of a loss of process control than any one type of regulatory non-compliance, you know, by itself.

So that's just to give you some idea of the types of analysis that we're doing, the direction we're going to be moving in and if there are -- I'll leave it to the Chair here, if there are any questions, I'll be glad to answer them.

MR. TYNAN: Do you have questions? Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk. With regards to the system issues at the beginning, that's not an Agency issue. That's a Microsoft issue. So --

I'm curious as to the types of citations that were used in this analysis. In that time period, what percentage of overall NRs during that time period do they represent? Is that a super majority of the

NRs that were written during that timeframe or --

MR. ANDERSON: Yes, let me, let me give you a little idea on that. If you look, of course, NR rates vary a lot by type of plant and how well the plant controls their processes, et cetera, et cetera. I think if we look at a long period of time, and you look at all NRs without regard to being cited, I think that NR rates in the one to two percent range are pretty typical of what I might call a gross NR rate. What we're doing with this type of analysis by definition, you're going to get slower NR rates because we're looking at the rate of a specific type of NR. So we're going to be looking at NR rates here that are generally going to be under, you know, one percent. They're going to be fractions of a percent, but as I say, there are hundreds of different regulatory citations. Does that help?

MR. KOWALCYK: Yeah, that does help, and I know in a lot of conversations we've had the past couple of days, that I've had with others about NRs and how they should be looked at. In your work on this, has the Agency identified aspects of the NRs?

As they currently are structured, has the Agency identified any areas on the actual physical form in the data that you collect electronically now that you would want to look at as a way of standardizing it? I know key word searches, I commend the Agency for tackling a complex issue like that, but I mean you're going to get spelling errors all the time. So it's difficult to muck through that data. Is there any discussion about revisiting the NR form and how that would be -- how you would be able to capture more of that information so you can classify it for a system like this?

MR. ANDERSON: I know I mentioned towards the beginning that the search engine that we're developing will allow us to do not only regulatory citation counts which is a relatively straightforward process but also key word searches which are text string searches. It's got that capability as well. That's a feature that we are continuing to work on because as you said, it's an inherently complicated process, but the idea would be that if we found -- presumably if we found that certain types of key words

in NRs were especially predictive of process control loss, then I would like to think that the Agency would consider further changes to the PBIS system to allow us to do that more efficiently.

MR. KOWALCYK: Okay. Thank you.

MR. ANDERSON: Sure.

MR. TYNAN: Dr. Harris.

DR. HARRIS: Joe Harris. First of all, I want to say that I think that that is very much a step in the right direction in terms of what a lot of us had in mind in being able to analyze these NRs. In going forward, and I understand that you say there's still a lot of work that can be done to really start to sharpen the point on this and narrow it down even further, my question is could you envision a point in the future where based on some of these predictive indicators that you've identified there, maybe begin to -- from the perspective of NRs, categorize, you know, low, medium or high likelihood of an adverse event as you've termed it? Is that -- because what I'm trying to do is link this back to our two days worth of discussion on risk-based inspection and how

that might could fit into that.

MR. ANDERSON: Yes, I think that as you point out, clearly what we are trying to do is we are trying to make a first cut at categorizing NRs meaning we're in some sense categorizing some NRs as being of greater public health significance than other NRs of less public health significance. Whether or not further categorizations of that would be appropriate or feasible, it's premature for me to even speculate on that.

MR. TYNAN: Mr. Finnegan.

MR. FINNEGAN: Mike Finnegan. I was just curious, you were using the words key words. Are you talking in the narrative part of a NR, like key words you would pick up there and what would be a couple examples --

MR. ANDERSON: Sure.

MR. FINNEGAN: -- of a key word that would red flag a certain NR.

MR. ANDERSON: Sure, I'll be glad to. The answer to the first part of your question is exactly yes. As many of you know, when a NR is written, some

of the information that is put in the PBIS is kind of put in, in a certain kind of restricted field format, like the date, but other, other parts and a significant part of the NR is a NR narrative. Don't misunderstand that the inspectors are not completing paper forms, but they are going into a PBIS system and entering information in a narrative form. So, yes, we are talking about searching through that narrative format.

The types of key words that we've already started to look at and most of these will make, you know, a certain amount of sense to you are product contact surface or non-product contact surface, critical limit, deviation, adulteration. Those are a number of key words and, and as Mr. Kowalcyk has already pointed out, doing text string analysis and anyone who has ever done it, knows that it's intrinsically difficult to do. It's one of those things that the human eye can do better than the computer, except the human eye has thousands and thousands and thousands and thousands of NRs to read and none of us want to raise our hand to read all

those NRs. So we need to program as much as we can into kind of a machine-readable format. But those are some of the key words that we've been exploring.

MR. TYNAN: We're going to take the questions that are up and then we're going to try and move onto the issues. This was intended to be sort of a quick update, and the conversation is getting pretty long. I know there's a lot of interest in it, but if there's time later, we can come back to it.

Mr. Painter, you had a question or a comment?

MR. PAINTER: Yes, Stan Painter with NJAC. My question is regarding what I guess I would consider the true number of NRs, and when we were under the PDR system, an inspector, for instance, under operational sanitation would write a deficiency for each, for each deficiency found and it was assigned a number. And under the NR system, we started doing that, and is, is there any look at going back to writing a NR, assigning a number for every deficiency rather than having multiple deficiencies under one number?

MR. ANDERSON: I'm not sure I fully

understand. I would like to explain that, and we are using all of these fields. When an inspector writes a NR, and they select the regulatory citation that is non-compliant, they actually can select one, two, three, four, or more fields. So they can, they can select multiple regulatory citations in a NR that they think are non-compliant. But maybe -- I'm not sure I'm --

MR. PAINTER: That's not what I'm referring to, selecting multiple fields. I'm saying that if I find an operational sanitation deficiency under Code O1 CO2 for instance, I find product on the floor and the plant's not taking care of it. Thirty minutes later, I come back and I find the same thing, you know. I'm going to instead of having two NRs I would have one NR with an attachment, and I'm asking is the Agency looking at going back to a system that would reflect the true number of deficiencies found rather than having multiple deficiencies categorized under one number?

MR. ANDERSON: I'm going to have to defer to somebody else to answer that question. I'm not

familiar with the issue.

MR. TYNAN: Dr. Raymond, and I think Dr. Masters wants to respond to that, too, Stanley.

Some of the conversation we have had would be like you take an O1 CO2 and there's variations of severity in a O1 CO2 and we just do the number search, a plant got an O1 CO2. Was the public's health seriously threatened or was it kind of a, you know, a little piece of something on the floor or was it stuff all over the floor? And we've been talking about consideration of an O1 CO2-A or -B, like is it a really bad one or it was there but it wasn't a really bad one, or an A. Maybe it didn't get cleaned up for three hours. We're trying to figure out ways. We would like help on that. We're trying to figure out -- I don't want to have to have people spend a lot of time reading the NRs to figure out how bad it really was because that takes a lot of time. I'd rather have some way electronically we find out the As and the Bs and the Cs within the number.

MR. TYNAN: Dr. Leech, you had a question?

DR. LEECH: I guess it's more of a comment.

As you're looking at the look back, I would encourage you not to at what you want to put in the algorithm but I would think that it would be useful to invest various look backs, and it would be useful in other parts of making decisions because I would assume that that algorithm helps us for one purpose, you still may have use to look at it longer. So I wouldn't lock into just one look back.

MR. ANDERSON: That's a good comment. Thank you.

MR. TYNAN: Thank you. Ms. Eskin.

MS. ESKIN: I have a comment and a question. The comment is I think it would be really important to have a lot of input from inspectors as you go through this since they're the ones who fill these forms out. That will give you an important piece of this, and the question is obviously this is the first take on this issue. Do you have any sense how long it will take until this data, the NR related data is useable to the point where you can plug it into whatever ultimate formula is developed to determine frequency of inspection under a risk-based system? Do you have any

ballpark sense of how long this will take?

MR. ANDERSON: Well, on the -- I'll address the second point -- but your first comment on the involving inspection personnel and that, I think that's a good comment. But in terms of the -- how long it might take in some sense to do this, of course, you know, we're going to have to meet as an Agency to process a lot of the good comments, of course, that we've received over the last couple of days. One thing I would say though is that the regulatory site data, this drop down data that I've been talking about, has been in the PBIS since December of 2005. So come December of 2006, which is just a few days, a few months I should say down the road here, we will have 12 months of regulatory site data that we would be able to use, analyze, use, however way we decided to use it. How long this is going to take, I really can't answer. It will depend partly on what we find in the early stages.

MR. TYNAN: Okay. Dr. Bratcher.

DR. BRATCHER: Within my circuit, I have a demonstration team that's a team of veterinarians that

are looking at this very thing right now. In my entire circuit, they're looking at NRs. They're looking at data, and they're trying to make some sense of that, and I would encourage you to share this information with one or more of these teams because they're in the field, in the plants, know exactly the problems that are involved with writing the NRs, and then going back and looking at that and trying to mine the information from those. So could you share this system with them and let them take a look at it and give you some recommendations?

MR. ANDERSON: I see nodding at the table. That makes sense to me. It's certainly consistent with what Ms. Eskin just said a few moments ago, to get some real in field experience to bear on this as well to make this analysis as good as we can. I certainly agree with that.

MR. TYNAN: I'm going to let Dr. Bratcher have the last word and perhaps we should close up the discussion on this. Don, are you going to be around?

MR. ANDERSON: Yes.

MR. TYNAN: Okay.

MR. ANDERSON: I'll be around today and tomorrow.

MR. TYNAN: Maybe after Mr. Palesano's presentation, if you have additional questions, Don will be here and he can answer those sort of individually.

With that, we're going to close out that discussion, and I'm going to introduce again Mr. Bobby Palesano, and he's going to do his presentation again regarding Using Risk to Direct In-Plant Processing and Off-Line Slaughter Inspection activities, and he just whispered to me a moment ago, that he preferred to have another person work the slides. I don't know why that could be but perhaps my performance in the earlier presentation may have caused that.

(Laughter.)

MR. PALESANO: Thanks, Robert. It had nothing to do with your performance or lack thereof.

For those of you that had to suffer through my presentation yesterday, that was the revised version. The version we're going to present today is the new and revised version. It's on the desktop I

think, Lee. We have added some slides, taken some slides away based on the comments that we received yesterday, and again I would like to commend all of you that were at the group for the comments that you gave us. And we certainly took a lot of those into consideration. Obviously we will be using those comments as we move forward with this initiative but we have taken some of the comments and incorporated them into the questions that we will be using for our Subcommittee members later today.

That's not it. Good job, Lee.

As we spoke yesterday, this presentation deals with using risk to direct in-plant and off-line slaughter inspection activities, keeping in mind that this does not affect the on-line slaughter inspection activities. Next slide.

It was suggested that we review this particular slide briefly from yesterday. I'm not going to attempt to do as good as Dr. Masters did on this slide. In case there are people here that did not attend yesterday's session and have exposure to this, this have been fondly referred to I believe as

the data wheel. Just to give you an idea that the bullets around the wheel are actually the factors or components that Don referred to in an establishment's ability to control the risk in their establishment, and so as you can see, we have system implementation as one of those factors or components. Don just talked to you about the NRs. That information we do have in our data warehouse presently.

As you can see, there are other components, system design. We have the *Listeria monocytogenes* alternatives. We do have FSA reports that are electronic. However, they are not in the warehouse at this time.

Pathogen control is the next bullet or component. As you can see, we have a lot of pathogen testing data in our data warehouse. The one item that's listed up there that we do not have in our warehouse is AMS testing results. We do have those test results.

Moving on around the circle, is in commerce. Hit the other arrow.

MR. TYNAN: Lee, do you need some help?

(Laughter.)

MR. PALESANO: In commerce, we have consumer complaints and recalls. We have that information presently in our data warehouse. We do not have product control actions that are taken in commerce in the warehouse at this time. Enforcement actions, as you can see, we have NOIEs, injunction actions and consent decrees, and we have none of that information in our data warehouse at this time.

Obviously under the food defense bullet or component, all of the information that we have listed there, we do have in the data warehouse.

Again, I want to be sure that everyone understands that the statutes require all processing establishments to have daily inspection. That will continue under risk-based inspection. The risk-based inspection that we're talking about today again focuses on processing and off-slaughter inspection activities and does not cover carcass by carcass inspection.

As we talked about yesterday, this will be a multiphased process. We had a lot of discussion about

that and we felt like it's important because it will allow time for inspection personnel to familiarize themselves with the new system. We also heard a lot of concerns yesterday about when and when we would start and what we would start with, et cetera, and as we mentioned yesterday, and I would like to reiterate that today, it will depend a lot on what we heard yesterday in the recommendation of the committee that we hard farther into this meeting as to what those phases will consist of and how we will be implementing them.

This multiphase process will also allow training to be provided to our inspection program personnel as we move forward. And it allows time for programming of our computerized risk-based inspection system and for the development and delivery of training.

As you know, we talked about yesterday under risk-based inspection, the inspection level for each establishment will be based on a combination of the plant's ability to control the risk and the inherent risk of the product, and as you know from the previous

discussion, we talked about non-compliance will still be documented for regulatory non-compliance, but not all NRs would be treated equally when determining the plant's ability to control the risks.

One thing that we did talk about was during the period of implementation or maybe the first phase that we might implement is turning the PBIS scheduler off. This would allow the inspection program personnel to familiarize themselves with how they could write or recognize predictive indicators as a basis for concern, and we gave some examples of what predictive indicators might look like. Those predictive indicators and the term predictive indicators came from a previous NACMPI meeting.

Inherent risk and risk control are combined to calculate the inspection level for each establishment. We talked a lot about that during the past few days.

And we have the chart to kind of depict how this might look. We have -- on this particular charge, we have five levels, using risk control on the X axis and inherent product risk on the Y axis.

We have some questions for the group that we would like some assistance with based on -- most of these questions came from comments that we received during our public meeting.

The first question is, what information should we use to support the optimum level of inspection?

The second question is, what are the essential inspection activities for level 1 inspection?

And the third question is, what other inspection activities do you consider appropriate to perform an RBI above level one.

And with that, I have two comments. One is that we will have for you after lunch and certainly before you break for the Subcommittee sessions, the questions and the updated PowerPoints. We're trying to do this as a result of the meeting yesterday. So we couldn't get everything quite Xeroxed in time. So I apologize for that, but we will have it before you do your breakout sessions this afternoon.

And the second part would be to entertain

questions. So are there any questions from the committee? And let me start perhaps with Mr. Painter, and then we'll go around from there.

MR. PAINTER: My question refers to a bullet that was or a point that was referred to close to the beginning of the slide session, and it referred to carcass by carcass, and I think the way the law reads, it refers to bird by bird and carcass by carcass. Are we saying that carcass by carcass will not be affected and bird by bird will?

MR. PALESANO: No, this is Bobby. No, we are not saying that at all. In this particular one, carcass by carcass and bird by bird would be synonymous.

MR. PAINTER: Thank you.

MR. TYNAN: Ms. Eskin?

MS. ESKIN: Two points or questions. The first is again those predictive indicators, maybe we talked about them in a different context. I don't recollect us talking about them, and I've actually went back and checked the transcript. So if it's relevant to this discussion, could you just refresh my

recollection. As far as predictive indicators in this context, again what would that predictive indicator trigger? It triggers -- again you've said what we've all talked about yesterday, a more enhanced look. I mean what, what happens if a predictive indicator is in play, and just one other technical question.

Yesterday there were two different charts, that nine box graph, one had numbers 1 through 5, and now yesterday's notes had I think it's 1 through 3. Are we not -- was that a different example or different way of the numbers? So there's a question on the predictive indicators and then a minor one about the charts.

MR. PALESANO: Okay. First of all, I will attempt to make sure that I understand your question. I think one of your questions was did the predictive indicators have anything to do with the presentation you had in your folder that had two different charts in it.

MS. ESKIN: Actually, they're two separate questions.

MR. PALESANO: Okay.

MS. ESKIN: Let me just ask the chart first.

MR. PALESANO: Okay.

MS. ESKIN: We removed one of the charts because it wasn't --

MR. PALESANO: Okay. There were two charts in there, and the purpose of the two charts that were in the original presentation was just to give you an example or two examples of how inherent risk and risk control could come up with numbers, or levels of inspection, Sandra.

MS. ESKIN: Uh-huh.

MR. PALESANO: Okay. And then we decided that that might be confusing, and so we eliminated one of those, I believe the morning of my presentation.

MS. ESKIN: Okay. So the 1 to 3 is probably not -- it wouldn't necessarily be three levels of inspection. I notice that one of the questions you're asking but again looking at it, at least a model of it, says five levels at this point, just as a starting point.

MR. PALESANO: The question that we're trying to get is regardless of what the levels of

inspection came out to be, whether it was 3 or 23, what kind of information would we use to support those.

MS. ESKIN: Okay. And again, that's the predictive indicators. Again, assuming one is triggered, what that I know would be also an issue, what does that mean for practical purposes?

MR. PALESANO: I believe her next question deals with predictive indicators, and when the indicator is observed or recorded, what will that trigger?

MS. ESKIN: Right.

MR. PALESANO: Obviously it might trigger inspection personnel to view a particular activity or an event or a location within an establishment to see if that indicator is actually having a concern or bringing about something that will result in increasing or decreasing the risk.

DR. RAYMOND: This is Dr. Raymond. I'm going to jump in here for just a second, Sandra, to take Bobby off the hook on the matrix with the five levels of inspection. He's being diplomatic, but the

reason he didn't have two on the PowerPoint yesterday was because I asked OPAEO to take the other one off, just before he presented it.

I did not think, to be honest with you, that I could defend the first one that had three levels. If you look at the X axis on there, from the plant's ability to control the risk, a plant that was two thirds of the way over to the right would get the same level of inspection as the very best plant clear on the left. I can't defend that.

Now is 5 the right number? I don't know. Maybe it should be 9. Maybe we should have 4 squares across and 16 levels. We're open to that. So Bobby didn't want to say, well, Raymond made me do it and, you know, (laughter) but I could not defend three levels. I think I can defend five, and if someone wants to narrow that down to 16 or whatever, we're open to that. It was for examples, but the first one I could not defend.

MS. ESKIN: Okay. Thank you.

DR. MASTERS: This is Barb Masters. On predictive indicators, I wanted to clarify, the

discussion on predictive indicators by this group. Actually it came out, Dan Englejohn presented a paper to you all and it's been like three meetings ago, I believe where he talked about ready-to-eat products and he had a Subcommittee that helped bring forth predictive indicators that the Agency could look at, and controlling risks and coming up with a risk-based program when we were trying to look at risk-based pathogen controls and that's where you provided to us predictive indicators, and it was more in context of a risk-based pathogen control.

And so we felt because we were looking at risk-based pathogen control, they were still relevant and looking at risk-based control within an environment or they could be still relevant and looking at risk-based control within an environment, and that's why we felt it was so worthy of looking at did they still apply directly at the plant's ability to control risk at the in-plant environment and how would they or could they still be relevant. So we asked the group looking at risk-based control to take the list that was provided from that working group,

the Subcommittee of the NACMPI, to take those and look at them and see if there was an applicability at the in-plant level controlling risk. So that's where they came from, Sandra.

MR. TYNAN: I'm not sure who was next but I'm going to work my way around from Sandra and ask Mr. Finnegan if he would pose a question or make a comment.

MR. FINNEGAN: Yes. Mike Finnegan, and I would like to make a comment. On your chart with all the different spokes of the wheel there, one of the general consensus I believe, voices a low priority of food defense, and especially for the very small plants, to penalize the very small plant because they do not have food defense, where you're looking at 10 to 20 people, as compared to a bigger plant that has 2,000, 3,000 employees, it would be very unfair to penalize a small plant because they did not have a food defense program in place which bring me to -- my question is I notice on the Legislative Update here, they allocated $15.8 million for food defense. Is the Agency heading towards a mandatory food defense

program?

DR. RAYMOND: Not at this time we're not, Mike. We believe in voluntary. We do believe in our, you know, ability to review the food defense plans of the plants. It's not mandatory they share them with us, but most of them do. We've made over 2500 recommendations to plants on how to improve their food defense plans. We take it very seriously.

We had it in there as one of our six spokes feeling that if the plant is vulnerable to contamination, it's vulnerable to, you know, putting a bad product out there, and we also hoped it would encourage -- we certainly heard yesterday that most of the people at the meeting did not even think that should be factored in and if it was factored in, it would be at a very teeny, tiny level. So, you know, we certainly heard that, and I think Dr. Masters addressed that in her closing remarks yesterday, too, that we -- all four committees pretty much said that to us.

MR. FINNEGAN: And so far, the Agency is satisfied with the voluntary program for food defense?

DR. MASTERS: The Agency has conducted surveys and we're not finding the number of plants that need to have food defense plans have them. We will say that up front. But we are at this point willing to engage through regulatory education programs, such as what was done on food safety, to provide that information, trying to insure that we are providing tools that are tailored to the industry and the sectors as appropriate. So we're learning through the surveys for example, in the large plants, what are their vulnerable points so we can provide that information to that segment of the industry. And the smaller size plants, what is the vulnerable notes that they have, so they can have specific and pertinent information to their plant. And in the small and very small plants, what is the type of information that you provide them because we do recognize that it's not a one size fits all, and we want to make sure that we give very tailored information to the audience. And so we're going to work with the trade associations to see if they can assist us in getting some of this information out to the regulated industry of all

sizes. And we want to see if we can move that mark forward, to make sure that we work with the associations to try and further that mark.

We do find food defense to be very serious and it's something we do think plants need to take seriously. Our inspection program personnel do have inspection procedures and they are following up on those procedures and we think they do a good job of that. And we think they will continue to do that. So we don't want to walk away with anybody thinking it's not a very important component that we do as an Agency.

As Dr. Raymond indicated, at this point we're not looking at doing it in a mandatory fashion, but we believe there's a lot more work we can do in the area of education and outreach to provide tailored, specific information if we know a vulnerable node in a particular size operation, how can we give you the information you need to insure that that node is, in fact, covered. So that's the kind of efforts that we're putting in place.

DR. RAYMOND: Dr. Leach, you had a question

or a comment?

DR. LEECH: Yes, Irene Leech. As we've talked about this, it sounded to me as though we're looking at trying to come up with a number that comes out of an algorithm to specify where a plant is, and it sounded like it's something that's going to be set for a period of time, maybe as long as a year or whatever. I would encourage that we think about having this underlying database that then the dynamic and I would envision that down the road, if you're really looking at putting resources even on a daily or weekly basis, that what's going on and what's changed could affect things, and so it would seem to me that the most useful thing would be if it could be dynamic, and so that it wasn't something that lasted for a huge period of time and I think people would approach it a little differently than -- if they know that when the next change comes, their score immediately goes up or, you know, versus something that they've got to live with for a long, long time.

And the other point that I might make is that it may come to be that we need more than one

algorithm for different kinds of purposes, and I think that's something that maybe ought to be considered as well. So it's not just a thing but again as we're looking at different kinds of things, the weighting and things that are coming out, and maybe in some cases, what you're trying to select, maybe that food defense, for example, wouldn't be in some of the things but it might be, and I use that as an example, but it seems to me that ultimately you may be moving towards not just one thing but multiple, and if it can be dynamic, and with technology going to the computer as you're describing things, that seems very realistic to me. And then just be sure, you know, that the data's good that goes into it.

MR. TYNAN: Thank you. Mr. Kowalcyk.

MR. KOWALCYK: One question and a couple of comments. The first question I have is the data elements you have here in the various nodes around the warehouse in the model, how far back does this data go historically? Are we looking at the NR analysis that goes back to December of last year? Is that consistent across all these data sources or is there

some data that only goes back as far as three months ago or how consistent is the data from a time perspective?

MR. PALESANO: I can't answer that. Is there someone here that knows how far back the data goes back? Don.

MR. ANDERSON: Okay. Don Anderson. The time period over which data is archived and is machine readable is actually fairly extensive. It depends on what type of data and sometimes even what variable of the data. For example, laboratory data, we can go back -- I'm just going to be generic here. We can go back a year and retrieve laboratory data in machine form, whether it's O157, *Salmonella*, RTE, what have you.

For NR data which is, of course, a important component, what I meant to say, and I think I said it but it may not have been clear, is that the regulatory citation data is machine readable since December of 2005, but we have years and years of NR data, parts of which are machine readable that go back, you know, much, much farther. Food safety assessments, of

course, have been -- food safety assessment data has been archived since the beginning, and they go back several years now. Enforcement actions. I would say that most of the data that you see on those which we're calling the nodes now, the spokes of that wheel, we can go back not a month, but years and retrieve that data, and again it's sort of depends on what aspect or what particular data elements you're talking about.

MR. KOWALCYK: So is it safe to assume that the Agency is trying to determine what the most appropriate window is, how far back you would want to go back because obviously processes seven years ago aren't as relevant.

MR. ANDERSON: Absolutely.

MR. KOWALCYK: Okay.

MR. ANDERSON: Absolutely.

MR. KOWALCYK: And I guess my comment is about the implementation, I've had some discussions with some folks yesterday about changing -- using this as a management tool and changing the way inspectors do their daily work. Has the Agency entertained the

idea of a type of pilot program where they would randomly select plants within the district let's say and simulate what the order of work would be under a risk-based system in an early implementation phase and compare that against what the current system is to look for, and then to see where there the gains in efficiency are occurring, where things might not have been caught under the current system would be cause with the risk-based system. Has the Agency discussed any strategy as far as piloting this process? Now this is away head of this discussion, but I just wanted to get that issue out there.

MR. PALESANO: Yes, we heard that comment yesterday, Mike, and I thought it was a very good comment, and certainly I made a note of it as I'm sure others did. So we do think that that is an excellent idea to take into consideration.

DR. RAYMOND: Mr. Govro?

MR. GOVRO: Mike Govro. At yesterday's meeting, there was some discussion and I believe some confusion around what exactly is a predictive indicator, and I'm wondering if you could give us

again a brief description of that, and perhaps a couple of examples.

MR. PALESANO: Yeah, I will do my best. Typically when we refer to a predictive indicator, we are talking about something that may cause a concern about the process control without rising to the level of regulatory non-compliance. One example that we gave on the slide was a major construction activity that was occurring in a RTE plant. The construction itself is not regulatory non-compliance but it should or could rise to the level of non-compliance if the establishment is not maintaining the controls that they should be to insure that their products are not being adulterated with LM. Does that help?

MR. GOVRO: Yes.

MR. TYNAN: Mr. Elfering.

MR. ELFERING: Yes, Kevin Elfering. There was one -- actually there are a couple of comments. I don't know if I ever did hear an answer. There are people yesterday who thinking turning the scheduler off was meaning the elimination of PBIS. Is that what's going to happen? Is PBIS going to be

eliminated?

MR. PALESANO: No. The intent is to turn PBIS scheduling off, just the scheduler itself, Kevin, not that PBIS would be eliminated.

MR. ELFERING: Then as kind of a follow up to that, when this system is put in place, are state inspection programs expected to follow the same system, in order to maintain equal to status?

MR. PALESANO: I don't know that we would have to say they would have to follow the same system. I do believe that as our present requirement is, we would expect the state programs to have something that is considered equal to, at least equal to.

DR. RAYMOND: Other questions or comments? I'm sorry. If you were closer I could have seen you.

(Laughter.)

DR. RAYMOND: Mr. McKee.

MR. McKEE: Bob McKee. I realize I'm a late comer in this process, and maybe I don't completely appreciate the value of the time that we've spent on these predictive indicators. In reality, our people deal with predictive indicators every day. They go

into plants. They recognize that construction has begun in the departments, that there's a problem with condensation and many of these things that I think we're talking about as predictive indicators are short term in nature or seasonal. And I think as we get further into RBI and have the ability to deploy our resources more effectively, we're going to have the ability to address those situations a lot easier and more effectively.

So I'm starting to wonder really about the value of trying to file predictive indicators into the algorithm. I just am not sure, and I hope this wasn't Dr. Raymond's idea to do this.

(Laughter.)

MR. McKEE: I think we need to think about it.

MR. PALESANO: I did want to follow up a little bit on that, just to be sure everyone understands that at least the initial thought was not to include the predictive indicator into Don's calculation for the measure of risk control.

MR. TYNAN: Dr. Bratcher.

DR. BRATCHER: I just want to follow up on what Bob said. Many of the things that you see as spokes on that wheel that are in place today are being used on an every day basis by management at all levels, from the district office all the way down to the front line supervisors. So we're using those tools to predict trends, to look for problems, to look for things that are -- that we feel need to be examined or looked at or evaluated in each one of those plants, in each one of the day shifts, night shifts, whatever the case may be, because there's so many variables that you have to take into consideration, just with the personnel and the situations that vary from plant to plant, from shift to shift, and we use those tools constantly, and we're bringing more and more of those on and those are a tremendous asset for us to management our people and to manage the facilities, to look and see what needs to be done, and as well as whether the plant is doing what they need to be doing.

So I encourage you guys to take a look at some of these things at some point if you get a

chance. It's just a better method of doing what we've been doing for years, and doing it in more of a scientific approach really. So I think it's a great asset to what we're doing now.

MR. TYNAN: Dr. Leech.

DR. LEECH: One more thing. From the discussion that I was involved with the other afternoon, there was some talk that we maybe need to go to a classification system for things and put back in that middle grounds, so that it's not non-compliance or compliance but maybe there's an in between kind of a thing that you think about as well. And as you're trying to get the data appropriately collected, that may be something that needs to be considered.

MR. TYNAN: Dr. Bratcher?

DR. BRATCHER: We had the decision tree at one time, and I think Bobby and some of the other people can attest to the fact that that was -- it was a tool but it was labor intense in trying to get everybody to use that tool in the right mechanism, in the right way.

I really think that there's probably a place to do something like that again. I think we need to take a better look at it though and comments from the field and from industry both I think would be very appropriate. I think we do need a method, and I've heard some people recommend having a place on the NR for critical or non-critical or major, minor critical. You know, we've had all those comments before but if we're going to do that, we need to have it very clear and concise, so that everybody knows exactly what those mean, and then we have a method to sort those out. And I would suggest a drop down box or something like that so we can do some data analysis on that, and that we're consistent on how we do it.

MR. TYNAN: Thank you. Do we have any other questions or comments on this particular portion of the Agenda? We're getting pretty close to the 11:30 timeframe. And maybe rather than introduce another topic at this point, we might take our break for lunch and come back for the second issue of the date. Is everybody in agreement with doing that?

(No response.)

MR. TYNAN: Okay. Then I think if we could all be back at 12:30, and we'll start our session for later on this afternoon.

(Whereupon, at 11:25 a.m., a luncheon recess was taken.)

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

(12:35 p.m.)

MR. TYNAN: Before I introduce our speaker for the afternoon, I wanted to mention that we had an Agenda item earlier to talk a little bit about with the Committee as a whole on sort of recapping what happened on Tuesday and Wednesday. I think there was some interest by members of the Committee to have a little bit of a discussion, not necessarily a lengthy one, but a little bit of a discussion on that issue.

Because of the way everyone's schedules are working out, Dr. Raymond needs to be here for this, wants to be here for part of that discussion, has speeches that he has to do. So if it isn't an imposition on you, perhaps in the interest of time

tomorrow, instead of starting at 8:30 as we had originally planned, with the report out, sort of a recap and then the report outs, if we could start perhaps 15 minutes earlier, maybe starting at 8:15, so we could have that discussion at that particular point, and that won't push us off on the other end where I know you all may have airplane arrangements and travel arrangements that you have to deal with.

So if you don't object, we'll start tomorrow at 8:15. The topic of the day will sort of be -- or the topic at that particular point in time will be sort of a recap and discussion of the Tuesday and Wednesday meeting, and then we'll go into the Subcommittee report out. Is that okay with everybody?

(No response.)

MR. TYNAN: Okay. Cool. All right. And with that, I'm going to introduce to you, Mr. Phil Derfler, who is our Assistant Administrator in our Office of Policy, and he is going to be speaking on Using Risk in Slaughter Operations. And he is risking it again. I'm going to be the PowerPoint guy.

(Laughter.)

MR. DERFLER: Okay. Go to the next slide. Thanks.

(Laughter.)

MR. DERFLER: I'm having Robert do this so that he'll pay attention to me.

(Laughter.)

MR. DERFLER: Beginning about a year and a half ago, with the meeting of this Committee that Dr. Masters referred to this morning, and then in a couple of meetings after that, this Committee and the Agency quite frankly, has been talking a lot about risk based inspection particularly at processing.

Now what we'd like to do is start a discussion of using risk in slaughter inspection, specifically in poultry slaughter inspection. I want to emphasize that we're at the beginning of a discussion.

It's clear from the discussions that we've had so far about risk-based inspection though, that FSIS believes that using risk has already improved how we do our jobs and that enhancing risks -- our use of risks, will make our inspections more effective and

more efficient, but what does it mean to use risk in a slaughter context, where our inspection personnel have traditionally been deployed online, making judgments carcass by carcass. That is what we want to begin to explore with you at this meeting.

Why are we starting our exploration with poultry? The reason we're looking at poultry as the first type of product in which to use an enhanced risk-based approach to slaughter, is because the rate of disease in the vast majority of poultry that comes to slaughter, that is young chickens and young turkeys, is extremely low. Next slide please.

This chart shows you that of the 8.8 billion young chickens that were slaughtered between October 3, 2005 and October 3, 2006, only .16 percent, .16, 0.16 percent were condemned because of toxemia or septicemia. And only .32 percent of young turkeys were slaughtered for septicemia or toxemia. That's a very low percentage. Next slide please.

And even if you carry it out to some of the other diseases that could cause condemnation, like airsaculitis, inflammatory process, contamination,

cadaver, even for young chickens, if you add up all those percentages, it's still leaves it at approximately 0.3 percent which is very low. Next slide.

And if you look at young turkeys, and you add it, it would still be less than .5 percent of the birds that are offered for slaughter.

Now this low level of disease among these birds is the reason that we're willing to consider the use of risk at slaughter. Given this low level of disease, sorting of carcasses, potentially becomes a low risk activity. It was this perception of risk that led FSIS to experiment as it did with the HACCP based inspection model project or HIMP. Next slide please.

HIMP was designed to provide us with a means to assist whether plants could successfully perform sorting of carcasses for food safety and other defects. It was also designed to help FSIS to assess whether the agency personnel could be as effective at slaughter operations as they are at processing operations in verifying that the success of the

establishment's operation. And HIMP, we believe, has provided evidence that the answer to both of these questions is yes. Next slide.

Now some evidence of this is provided by this data which is the total number of birds slaughtered in traditional plants, that's young chicken and young turkey plants, minus the HIMP plants as opposed to the HIMP plants, and then the percent positive. These are accumulated across all the plants and not on a plant-by-plant basis. If you look at that data and there is a slight correction from in your slides that you have in your book, for 2005, the traditional -- it actually got transposed. It should be 16.3 under traditional and 15.9 for total, but as you can see, HIMP plants have consistently had a lower percent positive rate in our testing for *Salmonella*.

Moreover, while HIMP plants followed a general upward trend in *Salmonella* positives with traditional plants, up until about 2003, in 2004, the rate of positive in HIMP plants actually stabilized while in traditional plants it continued upward. And in 2005, the percent positive rate in traditional

plants continue upward to 16.5 percent or 16.3 percent as I said, but actually the rate in HIMP plants showed a small decline. And through June of 2006, HIMP plants continued that decline down to about 9.5 percent. While traditional plants have shown a dramatic decline up until June of 2006, they are still over the 10 percent target that we've established.

So based on our experience with HIMP, we think there is a basis to explore how to use risk and how we design our inspection at slaughter in that it is time that we begin to consider how we do so.

But I want to make very clear, that we do not think that risk based inspection at slaughter means broad adoption of the methodology that we use in HIMP. HIMP can provide the basis for some significant advances in slaughter inspection and we think that there is much that we can learn from our experience with HIMP, but we think that we need to make improvements on it.

Thus, as I stated in the briefing paper, I want to review at a high level the basic aspects of the inspection of the slaughter of poultry to provide

a basis for us to begin to talk about new ways in which we can factor in risks to help us do a better job of inspecting poultry at slaughter.

Again, this is initial thinking and we are just starting the process.

And one additional point, I'd like to make preliminarily, and that is I'm going to focus on risk and food safety. I will not be talking about food quality. Now I do not mean to imply in any way that food quality is not important. What I am saying though is that in a risk-based system, food safety is the driving factor in that while we need to address quality issues, we would do so in a system primarily designed to insure safety. Next slide please.

Okay. So what I want to sort of do is, I don't know if you remember my talk from November of 2005, but I sort of laid out some big items, purpose, you'll see, purpose, deployment, what we do. What I've tried to do is pare that list down and talk about four things that are particularly relevant I think on how we do poultry slaughter inspection.

Now first I want to talk about the purpose

of inspection at slaughter. By statute, at slaughter, no matter who sorts the carcass, and in traditional plants and FSIS inspection personnel who sort the carcass, and in HIMP plants, it's been plant personnel who sort the carcass, no matter who sorts the carcass, FSIS is required to have its inspection personnel perform a critical appraisal of each carcass that is to receive the mark of inspection. The Agency does so by having inspection personnel check each carcass for any visible defects that would render them injurious to consumers or that would cause consumers to reject them. Next slide.

But online inspection can only provide a visual appraisal, and while a visual appraisal of each carcass is important, there is more than needs to go into inspection at slaughter if the risks are to be dealt with effectively.

First of all, pathogens are not visible but they're obviously important. If not controlled, they can turn the carcass into a vector for the spread of disease. Through sampling, inspection personnel can verify that that a plant prevents or minimizes the

occurrence of pathogens on carcasses, and that the plant acts to reduce their presence to the extent possible.

Pathogen control will surely be significant -- a significant focus of any risk-based poultry slaughter inspection program that the Agency puts in place. For example, in the initiative that FSIS instituted in February of this year, to address the rising *Salmonella* levels on chicken carcasses, and to assess poultry carcasses, they include -- we included a number of risk-based elements. We would expect that this type of approach would be part of any risk-based slaughter inspection program that the Agency institutes. Along with *Salmonella*, the program would also likely address *Campylobacter* and other pathogens of concern.

Inspection also needs to involve Agency personnel in verifying that an establishment's process is under control. The slaughter process is not static. Conditions change during the course of a day. Birds vary from flock to flock and within a flock. Equipment may malfunction or need adjustment. Debris

can pile up and other unsanitary conditions can be created. Things can go wrong.

Thus, if an establishment is to produce safe and wholesome products, it must insure that its process is under control, and FSIS needs to verify that this control is maintained. Next slide.

This leads me to the first question that we want to put to you or the first set of questions, and they are, are the things -- are there things other than examining carcasses and verifying pathogen and process control, that the Agency should be accomplishing in a risk-based approach to inspection at slaughter? How can risk be factored into the accomplishments of these other necessary purposes of inspection?

Now in considering these questions and the other questions that I will be presenting, it is important that you keep in mind that we're not asking you to be experts about the poultry slaughter process. We asking you, give your perspective as a consumer, state official, academician, or industry representative, what are your expectations for the

slaughter process and what should FSIS be accomplishing? Next slide please.

The second topic I want to address is Agency deployment of its resources. That means inspection personnel at slaughter. Given the purposes of inspection at slaughter, as identified, and any additional ones that you may identify, what's the best way for the Agency to deploy its personnel to accomplish these purposes? How does taking a risk-based approach bear on how the Agency assigns its resources?

Now in the current -- next slide. I'm sorry.

In the current system, FSIS has on-line personnel who examine each carcass. We also have off-line personnel who verify that carcasses meet the zero tolerance for fecal material and that the critical control points that the plants have designated, in their HACCP plans, are under control. These critical points have tended to focus on meeting the chilling time and temperature requirements and the use of anti-microbials. Next slide please.

As I've said, we will need to continue to have on-line inspection personnel making critical appraisals of the carcasses. Given the range of potential hazards at slaughter, however, FSIS has become concerned that it may be necessary to deploy at least some of its inspection personnel in a way that leaves them free to verify some frequency that the establishment's process is, in fact, under control, rather than focusing so heavily on the conditions of each carcass.

Now in this respect, let me acknowledge that there's some overlap between what I'm presenting and what Mr. Palesano presented this morning. After all, he talked about off-line personnel, but just to make clear, I am focusing particularly on the slaughter process where Mr. Palesano's presentation was a much broader presentation, and there are questions that we'll need to see how much of what Mr. Palesano presented actually will be applicable in the slaughter context, but let me continue.

As with processing inspection, FSIS will likely need to find a way at slaughter to factor into

the design of its inspection the hazards posed by the type of species slaughtered, in the process used in slaughtering that species, the significance of the hazards that are presented if they're realized, and how well the plant actually controls the hazards in its process.

In the slaughter of young chickens, for example, these factors would suggest that we would identify the potential hazards associated with each step in the slaughter process like picking, eviscerating and chilling, assess the significance of those hazards -- that those hazards could have if the risk of their occurrence is not controlled and determine whether and how well the establishment is actually controlling the hazards.

In order to do this, we would consider bring our off-line inspection personnel, that is our inspectors not assigned to making carcass-by-carcass appraisals, so that they would be able to move up and down the line from step to step to verify that control is being maintained and that the expected hazards and the unexpected hazards are not emerging. They would

still focus on CCPs [Critical Control Points] but perform additional verification activities periodically. Next slide.

So the question I would like to pose to you in this regard is, what comments do you have on the use of this type of approach to guide how FSIS deploys its resources at slaughter? For example, do you have any suggestions as to information that we could consult in developing our ideas on how to deploy our inspection personnel? Do you have any other suggestions? Next slide.

Next I want to talk about the tasks performed by inspection personnel. Having asked you to consider how risk bears on what we're trying to accomplish in our inspections and slaughter, and how we deploy inspection personnel, we ask you to consider what effect risk should have on what we ask our inspection personnel to actually do. Next slide.

FSIS' traditional model in young chicken operations and young turkey operations, as I've said, has been to have its inspection personnel perform tasks related to the condition of the carcasses. They

look for a range of defects, some food related, some not. Next slide.

The Agency has come more and more to believe, however, that if slaughter inspection is to be risk based, Agency personnel need to spend at least as much time verifying that the plant's process is under control, as they do looking at carcasses. Under this view, inspection personnel would need to understand what should be occurring at each step of the plant's process. They would verify that what is occurring is what should be occurring, and moreover, they would review the plant's records to verify that the plant is maintaining control and they would also sample product at various points in the process to assess whether the plant is maintaining control.

By considering all of the resulting dating and information, Agency personnel should be able to determine when and if the establishment is in danger of losing control of its process or if any part of its process is out of control and to take steps to address the situation. Next slide please.

So the question we ask is, what comments do

you have on the Agency having its inspection personnel performing these types of tasks in poultry slaughter operations? Again, if you have any suggestions, ideas or other comments, about the concepts that I've presented, and how to improve on them. Next slide.

Finally I want to talk a little about FSIS personnel should respond to findings suggesting a loss of control. As I said, under FSIS' current poultry slaughter inspection system, inspection personnel primarily see problems on a carcass-by-carcass basis and they respond on a carcass-by-carcass basis. They have carcasses trimmed or condemn the carcass and if the situation is bad enough, where problems with the process are manifested on the carcasses, they will stop the line.

If FSIS were to move to a system that put greater emphasis on process control, inspection personnel would presumably be able to identify emerging problems with the process itself. FSIS personnel should be able to respond in more flexible ways if they're not focused only on carcasses. For example, in the compliance guide for *Salmonella*, that

FSIS recently issued, the Agency discussed interventions that could be employed at each step of the slaughter process to insure that levels of this pathogen, levels of *Salmonella*, are controlled in a way that avoids recontamination during the process and actually progressively reduces the level of *Salmonella*, any *Salmonella* that may be on the carcass as they move through the process.

At picking for example, the Agency pointed to the need to avoid feather build up on the equipment. If FSIS personnel observed that a feather build up was occurring, creating the potential for an unsanitary condition, they could take a range of actions based on the evidence of loss of control, from talking to plant management to tagging the equipment, to stopping the line.

Now I'm not suggesting that FSIS inspection personnel should provide quality control for the plant. I am suggesting that it is in the interest of public health for the Agency to verify process controls and to have its inspection personnel act if they can anticipate that a problem is developing or if

they find that one has developed. It would be up to the establishment, however, to decide how to correct the situation. We would want any system that we establish to provide as much flexibility as possible to our inspection personnel. Next slide.

So the last question, what comments do you have on including process control as a focus and emphasis of identifying and addressing emerging risks in indications of loss of control, as something that FSIS personnel should react to? And we would be interested in your ideas on how we can maximize the effectiveness of the response by our inspection personnel.

That's the end of my talk, and if you have any questions. I expect that other people will answer these questions just like they did for Bobby.

MR. TYNAN: I'm going to start to the left. I'm going to ask Charles Link to start us off.

MR. LINK: Charles Link. Phil, kind of what you just describe sounds a lot to me like what we've been doing for years. We've had NELS [New Line Speed Inspection System] systems in chicken plants and NTIS

[New Turkey Inspection System] programs in turkey plants that are all built on process control, identifying from live receiving through the chilling process, all the different steps, all the parameters around those steps. The off-line inspector has been involved in monitoring those process steps.

So I'm not sure what you're proposing that's really different, unless we're talking about freeing up the on-line inspectors to get off the line to do some of that work in addition. And so I'm not sure if I understand that. That's kind of -- I think that was kind of the direction of the HIMP program was to get the guys off the lines so they could do more work, but then you commented that that wasn't what you were going after right now. So maybe you can elaborate a little bit about what's different?

MR. DERFLER: The question about what's different has come up a number of times. I think what's the most important thing that we're trying to do is insure that we factor in by design, risk, so that we can produce the best system that we can, the most efficient and effective system. There are, you

know, I'm not sure exactly how the ultimate design is. It does seem to me though that there are, you know, sort of fundamental things that need to be included in a system. I don't know that we revisit the same thing is a terrible idea, but if we can improve on it, that's really what we're interested in, in getting comments on, how we can improve on it and make our system better. That's what we're really striving to achieve.

DR. MASTERS: This is Barb Masters. The one thing I would add to that and I think Phil alluded to it on one of his earlier slides, is that we laid out in our February *Salmonella* initiative, targets that we have as an Agency for all of the plants to achieve in controlling *Salmonella*. So certainly we would see that as something that would be part and parcel of any type program such as this.

In addition, Phil mentioned that we would be looking at other pathogens such as *Campylobacter* and other pathogens. So I think we would certainly have expectations for performance measures around pathogens, moving forward in this sort of a program.

And I think *Salmonella* in particular laid that out, that we had a target of being at less than the half the standard, the performance standard of *Salmonella*. So I think that's one way I would look at it.

MR. TYNAN: Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk. I have a couple of questions. One was related to the sampling table that I noticed in the presentation about sampling, and I was just curious as to the number of samples that are indicated through June of this year. If you can discuss a little bit about the sampling methodology for the 2006 calendar year. I'm assuming these are calendar year comparisons. Are they sampled equally throughout the year because then if they are, the Agency's on pace to take under 4800 traditional samples and compare the previous years. It's in my mind a significant reduction. Is that an accurate assessment or is it something with the sampling program that would lead us to see increased sampling in the back half of the year? You might not be able to answer that now but I'm just curious as to --

MR. DERFLER: The only thing I can tell you

is that we started changing how we did sampling, to try and make it more risk based, and so there might have been some reduction as a result of that. There also was some reduction in the number of samples that we took because of budgetary concerns.

MR. KOWALCYK: Okay. Because I guess if the Agency can provide some clarification to this Committee in the future because especially if the sampling methodology has changed, it's not necessarily comparable to prior years. I was just questioning that. That's all.

DR. RAYMOND: And I don't want to debate Phil in public, but you deserve an answer, and we'll get you one, but I have gone on record to Congress that we did not decrease sampling because of budgetary concerns. So one of us is wrong. So I want my statement or Phil's statement to show up in the media.

MR. DERFLER: I'm wrong.

DR. RAYMOND: And I don't mean that at all. I mean the Committee deserves an answer, and we'll get it. Loren, you know the answer. Get up there.

MR. LANGE: Loren Lange, OPHS FSIS. We

changed the sampling criteria in June. The reason we had the traditional way of scheduling sets, January through June, that we had a large number of the broiler plants that were sampled towards the end of last year, and under our old system, they just didn't come up for sampling in the first half of the year. I think when you see the third quarter results published later, it will be almost like 5,000 broiler samples in the third quarter this year, and probably over 130 of the largest 150 plants had some samples in that third quarter. So it's just a quirk of how we changed the system.

MR. DERFLER: So I'm right. I'm wrong.

(Laughter.)

MR. DERFLER: For the record, I'm wrong. I'll go on record as saying Dr. Raymond was correct. I don't want to say you were wrong.

DR. RAYMOND: Michael Kowalcyk was right to raise that question because when I looked at that number I thought, my gosh, what did happen. So thank you, Loren.

MR. KOWALCYK: Thank you. And my second

comment was about process control and the discussion in your presentation of moving off-line inspectors to different task, maybe away from what carcass inspection they do do currently. I'm not on the Subcommittee but I'm just wondering if members on the Subcommittee would be helped by some certain aspects of process control that the inspectors could impact. I don't know if things such as line speeds are certainly a variable that can be moved which would allow current inspection levels to increase their focus in area that they need to be, because it seems to me like you're asking inspectors to focus on what is deemed to be maybe a riskier part of the process, while still meeting their primary responsibilities and it seems to me that you would almost have to add inspectors at certain plants. So I'm just kind of struggling around how you would move folks around within that eight-hour shift. So if there are any examples that the Agency can provide for those on the Committee that they can discuss, that would be helpful.

MR. TYNAN: Thank you, Michael. Ms. Eskin.

MS. ESKIN: I have two questions really. My first is along the line of Charles' in that I'm having difficulty understanding conceptually even how this is different than what's done now under the HACCP system, and again there's one slide here that says we'll be moving I guess some inspector who are on-line off-line. I mean draw me a picture. How many inspectors are in the plants and let me understand what you're suggesting even at a conceptual level. That's my first question.

MR. DERFLER: Okay. I mean what I'm really suggesting is, I mean most of our verification activities are now off-line, are focused on HACCP and verifying HACCP, and I'm not -- and I'm saying that one of the ideas that we need to think about is how we look at the whole process. There may be steps in the process that are not considered to be critical control points, but maybe we need to look at those as well.

MS. ESKIN: Okay. And the second question I have is obviously there's a concern among many people listening to this, is that how this proposal would be reconciled with the legal requirements, carcass by

carcass, and as you're well aware, the HIMP program was challenged in Court and certainly in those decisions the Judge has said that it's got to be carcass by carcass. So again, can you give me some assurance that that's exactly what we're talking about here, that that will be preserved?

MR. DERFLER: Well, I think in my slides I talked about over and over, that the Agency's obligation, as we understand the AFGE is to provide a critical appraisal of each carcass. That doesn't necessarily mean that they would sort the carcasses, but it does mean that we've got to provide a critical appraisal.

MS. ESKIN: So again, in terms of the inspector doing the carcass inspection, that's not going to change under this program what you're talking about, if different things that the off-line inspectors are going to look at?

MR. DERFLER: Yeah, that's what I'm talking about so far. I mean that doesn't mean that --

MS. ESKIN: Conceptually.

MR. DERFLER: -- as the ideas for poultry

slaughter advance, there wouldn't be additional ideas but what I'm leaning on here is that.

MR. TYNAN: Mr. Painter.

MR. PAINTER: Stan Painter, with the NJC. My question was, I noticed we had some stats regarding *Salmonella*. Where are your stats regarding *E. coli*?

MR. DERFLER: I'm sorry.

MR. PAINTER: Where are our stats regarding *E. coli* in poultry?

MR. DERFLER: You mean generic *E. coli*? I mean I don't have them --

MR. PAINTER: Any type of *E. coli* that would cause someone to get sick or die regarding poultry?

MR. DERFLER: I mean the Agency I believe doesn't take generic *E. coli* samples in poultry plants. They're taken by the plants.

MR. TYNAN: Stan, could you rephrase your question? I guess I'm not tracking with it. I know I'm probably the least knowledgeable person here on this, but --

MR. PAINTER: Well, my point being is the fact that there's little to no testing for *E. coli* in

poultry and all we can talk about is what we test for is *Salmonella*. And I'm wondering why the Agency is not testing for *E. coli* in poultry?

MR. DERFLER: The only thing I can say, and I think I did say, that as part of any program, we want to make sure that the pathogens of concern are under control, and we would, we would -- to make sure of that, Loren, to my rescue again.

MR. LANGE: OPHS, you know, has no record of finding *E. coli* O157:H7 or other pathogenic *E. coli*, you know, in poultry. There was -- there's been a couple of reports of a foreign country claimed an isolated O157 from a frozen chicken wing at one time, but we have some questions about the methods. So I mean we monitor the literature on which animals O157 has been found in the research community and at this point in time, no one has found it in poultry that we're aware of.

MR. TYNAN: Dr. Bratcher?

DR. BRATCHER: Chris Bratcher, NAFV. As a result of the changes in *Salmonella*, most of the large poultry processing plants are now doing extensive bio-

mapping and what they're looking for is enteric organisms, total flight counts, *E. coli*. So they have a pretty good handle of what's there and what their loads are coming into the plant as well as interventions that they may have starting from the picking room all the way through the process.

As a result of the changes that we made trying to bring *Salmonella* under control, they've had a direct impact I think on *Campylobacter* which is also an area of concern, and we've had a direct correlation with the number in total flight counts and enteric bacteria as well. So I think maybe what Stanley is trying to get at is there are other bacteria concerned, but we're addressing that really to the *Salmonella* regs right now. The plants are doing a really good job I think in most situations in controlling and reducing the bacteria loads in the plant as they go through the process.

MR. DERFLER: The other thing I would add in response to what you said is, I mean we intend to do a new chicken baseline. We're moving closer towards that, and as part of that, we are going to look at a

range of organisms. So --

MR. TYNAN: Mr. Link.

MR. LINK: Charles Link. Just a question about HIMP. Sandra mentioned that they got challenged in Court around the carcass-by-carcass, bird-by-bird inspection. I assume that the results of that challenge were satisfactory because it's still alive and well. So we are meeting the requirements, statutory requirement under HIMP today.

MR. DERFLER: The answer is a qualified yes. I mean for purposes of full disclosure, I think the Court essentially upheld what we were doing in HIMP, but the Court also said that they thought it would likely -- that they would be given an opportunity to review it again if we decided to make some of the things that we were doing there permanent. So I would imagine there would be an opportunity to review it again, but the Court did uphold what we were doing, yes.

MR. LINK: You mentioned that this effort here, a risk-based inspection slaughter was not an effort to go to HIMP for lack of a better term? So

that mode of inspection, even though your data bears out it works and we think we're meeting the statutory requirements, certainly it frees up resources to do all these things --

MR. DERFLER: What I said was we want to have the best poultry inspection system that we could. HIMP got bogged down in a lot of OCP stuff, and what we're really interested in and insuring is that the product -- is food safety, and we want to have a system that insures that -- is primarily directed and judged on how well it's making products safe. If the other stuff comes along with it, then obviously it's going to have to and we need to figure out how, but assuming we go forward with this, the most important thing is or the key to the design that we're looking for is food safety and risk.

MR. TYNAN: Ms. Eskin.

MS. ESKIN: To follow up on the point Charles just made, and this may go more broadly to risk-based inspection and not just whatever happens in slaughter, again in that Court case, a model's project was at issue and the Court clearly said as you just

summarized, we may have a very different view on this type of approach, if, in fact, it becomes permanent through rulemaking. Is it FSIS' intention to, when it moves towards or creates a risk-based inspection system, whether for processing or for slaughter, that it will be done like HACCP was through rulemaking and not just directives?

MR. DERFLER: I think it's going to depend on the particular facts of what it is that we're looking at and what we think we need to do based, you know, what we're doing at the particular time. We'll do that in consultation with our lawyers. Probably some things we'll be able to do without rulemaking and some things will require rulemaking.

MR. TYNAN: Other questions on the presentation?

(No response.)

MR. TYNAN: Thank you, Phil. Okay. We've gained a little time in the Agenda, and according to the Agenda, we have a 2:00 public comment period. When I checked at lunch time, there was no one signed up for the public comment period, but I would invite

anybody that wants to come up and make a statement at this point to do so at this time. And again, I would ask that when you come up to the microphone, if you could please identify yourself and the organization that you represent.

MR. CORBO: Tony Corbo, Food and Water Watch. It knows I'm coming.

(Laughter.)

MR. CORBO: First of all, I want to commend the Agency for permitting the employee representatives to finally sit at the table after numerous requests to do that. Hopefully this will be a permanent fixture on the Committee. If it is, then it will remove one of the tasks that I'm going to ask the 110th Congress to take up. So I can cross one of those things off my list.

I wanted to ask a couple of questions. One on the use of risk in slaughter operations. In the FY 2008 budget request that the Agency submitted to Congress, it had a section dealing with the section dealing with the expansion of HIMP across all poultry, and it was intended to hold a series of public

meetings, plural, on the issue prior to rulemaking. Is it the intent of the Agency after this Committee issues its recommendations, answers your questions, to do that?

DR. MASTERS: Tony, I think I would say at this point, I think you've seen that with some of the other budget requests for '07, we've put forward our best projections when we write the budget two years in advance. I think it's very clear that Dr. Raymond and I are trying to be as transparent as we can moving forward with our more robust risk-based inspection. I can tell you that what we have done on moving forward with the slaughter component, as we talked yesterday and today, that we're going to be looking at different components and moving forward with our more robust risk-based inspection system, that we have already started talking to RESOLVE about working with us. Now that we've brought it to the National Advisory Committee. RESOLVE is aware that the next opportunity that they will have is to work with us on the slaughter component, and I would envision pieces of that would include public meetings, yes.

MR. CORBO: Okay. Another issue is the fact that our organization has a pending FOIA request. It's over a year old on the HIMP data, and we urge the Agency to respond to that request as quickly as possible.

The last question is a repeat of the question that I asked yesterday about the Office of Inspector General indicating that they were doing an audit of the Pathogen Reduction Enforcement Program sampling features, and I would like to know whether, in fact, the Agency has been contacted by the OIG regarding that audit report?

DR. MASTERS: We're not aware of being contacted by the OIG on that report, no.

MR. CORBO: Thank you.

MR. TYNAN: Are there other comments from the audience?

(No response.)

MR. TYNAN: Okay. If not, we're at the point in your Agenda, where we're going to break for our Subcommittee sessions -- yes, Dr. Leech.

DR. LEECH: When we started this morning, I

think you said that if any of us had anything that we wanted to say that didn't fit with the presentations that you wanted for us to do that now.

MR. TYNAN: You certainly can.

DR. LEECH: And I'd like to do that. This is my last meeting of my six years of service. I'm not going to be able to be here tomorrow although I have been here through the week to this point. And I feel that before I leave that it's really important for me to share that as I look back on the six years, I have to admit that I'm really frustrated. And I honestly discouraged one of my colleagues from applying for the Committee. I don't feel like what I've done made a difference at all in six years.

I do see that there are some positive things that are happening at this point. There certainly is a much better environment between the Committee and the Agency than there was when I first started six years ago. It's certainly a much more pleasant thing to do than it was when I started. But I continue to feel that the expertise is not adequately used particularly in the fact that the Agendas don't come

out early. We don't know what our comments are going to be. We really need it a month or -- we're all doing lots of things. We really need it a month or more before we get here, not after 7:00 on Friday night before we leave on a holiday weekend for people to be coming to town on a Tuesday. There's no way to do any homework, talk to the people at home. I would have gladly talked to folks, gone to visit people, tried to do homework so that I was more prepared. I've generally felt that I've come in and just talked off of common sense, and I think we really need more than that, and that's why I discouraged my colleague from applying. I told him I thought his expertise could be used in other ways that would make a difference in the world, and I haven't felt that what I've done has.

As I said, I see that there are some improvements in some things. You've got a break opportunity here with a lot of turnover in the Committee for things to possibly completely be changed. I mean we've got a better environment than we had six years ago, but I really encourage you, as

the new folks come in, to consider letting people know what the Agenda is going to be at least a month in advance, that when there are going to be public meetings, to advertise it well in advance. I was amazed how many people were here for the meeting given that the Federal Register notice came out what, 10 days before the meeting, and for people to get plane tickets and to afford to come and use money responsibly, usually you don't get the best plane ticket 10 days in advance, and I don't know about other people's schedules, but mine's so nuts that, you know, I had the date because I was involved in this, but convincing other people who weren't to come was difficult and when the information didn't come in until late, there were a number of folks that would have liked to have been involved who couldn't.

So just as we, you know, wrap this all up, we've said some of these things as a group several times in the process but I felt like I needed to say it one more time, that I don't think this Committee is used in the best way. I see some positive things and I encourage you to keep doing positive things but I

think either this Committee needs to be really effectively used and people need to be able to do what needs to be done or we really shouldn't do it.

MR. TYNAN: Ms. Eskin.

MS. ESKIN: I know you said that we would wait until tomorrow about some of our reactions to the public workshop, but assuming -- if Dr. Raymond is here for at least the next 20 minutes, I was going to pose that we do it now so we have enough time to perhaps talk about our concerns, that tomorrow we might not be able to. But, Dr. Raymond, if you're not going to be here for much longer, then I won't.

DR. RAYMOND: I'll be here until about 5:00.

MS. ESKIN: I would ask that we do it now, and if everybody else feels that way, to be able to talk about the public workshops and anything related, even along the lines of what Irene just said.

MR. TYNAN: We're amenable to doing that? We were going to do it tomorrow but if today works and you're all agreeable to doing that, then let's get started, and we'll use the time tomorrow.

MS. ESKIN: You --

MR. TYNAN: Well, you have to help me a little bit. What am I asking?

MS. ESKIN: Okay. I'm sorry. I don't --

MR. TYNAN: You just want to have a discussion --

MS. ESKIN: Well, I'll be happy to start. I mean a couple of thoughts. Many of us were there both days yesterday and I guess I wanted to make some specific comments and some more general ones.

The first one is that as far as the two papers go, and I think this was reflected in Dr. Masters' comments earlier, I think on the inherent risk piece, it is quite clear that there are lots of issues with the expert elicitation that need to be addressed.

On the establishment control, there are lots of gaps in data, and some concerns about the ability to use the data. What that translates into, in a very simple message, is that the Agency needs to slow down, it needs to take its time.

I do want to respond to Dr. Raymond's analogy as far as a doctor, and I'm not a doctor. I'm

a lawyer. So I'll make that clear. When using the analogy of treating patients, someone comes in, he diagnoses a problem, makes an initial decision as far as treatment goes, but awaits test results, to perhaps change that -- change the treatment, I would say that current system is like that initial diagnosis. We have been operating a certain way to address a certain problem. It is by no means perfect. But unless and until we get the functional equivalent of that test, to see if you have strep or some other infection, until we have the data that is reliable, I don't think there's a high level of confidence that what we're going to replace in lieu of the current system is going to be better. And I understand and applaud his desire to really focus on public health, and I think it's very important.

Let me use a different analogy to reflect my reaction to this process, as far as risk-based inspection goes, and I'll speak as the daughter of a builder. I'll use a house analogy.

Let's assume we're all going to be building a house together, and we've made a plan to meet for an

initial meeting to discuss designing, general ideas. You know, is it going to be a ranch? Is it going to be a two story? And we all as a committee show up and not only have the plans -- architectural plans been completed, okay, but the foundation has been poured and the frame has been going up and the materials used we're concerned may be substandard, may be defective.

Now again with the discussion, let's put that in the context that we have today about slaughter. Phil said a number of times, and I know I appreciate it, this is very preliminary. When I look back over the six years of Agendas that I also have been to the meetings, I thought yes, we might have talked about risk based in pathogen control but in terms of risk-based inspection systems, I saw one subcommittee in November 2005 that talked about using data in terms of risk control, and I raised the question about it yesterday if we had made any progress towards those specific things. But until that November 2005 meeting, we had never been approached with this more conceptual framework.

So again, I would agree with Irene, I think

that our committee could have been helpful in an earlier stage.

And I'll close by finishing with the expert elicitation. There's a perfect example. We were discussing at the last meeting some issues surrounding establishment control. We have never discussed inherent risk control. If you would come to us before you went out with the expert elicitation and said here's our thinking, we would have hopefully been able to and I think have contributed in the same way the group did before. Yesterday I meant to say, not only say if you're doing an expert elicitation, this is what you should do, and you need more than that.

So again, I think having an Advisory Committee is very important and I have learned a lot from my experience and hope I have contributed, but I think moving forward, I think you need to look at the experience with this risk-based process and hopefully improve the point at which the Advisory Committee comes into the loop.

MR. TYNAN: Any comments from the rest of the Committee at this point? Mr. Schad.

MR. SCHAD: Yeah, Mark Schad. I'm going to repeat maybe some comments from Tuesday and Wednesday by some of my industry colleagues, but somebody that works in this every day, deals with inspectors every day. I think we're maybe farther along -- because we do some of this risk-based stuff already.

And I'll just repeat some of the examples that were brought up. I don't want to take a lot time repeating examples but like *Listeria* and Dr. Bratcher brought up some things about indicators. I know exactly what you're talking about, dealing with the inspectors, inspectors deal with that already, indicators like construction, they have some questions. I see something different going on here. I see you've got a different supplier. So you're asking questions and looking into that.

So I don't see this as a -- we're jumping off a cliff or anything, starting something new, because it's like some of my industry colleagues said. We're doing some of this already.

And I wanted to speak also to that expert elicitation. I personally studied that very hard and

looked at all the raw data. I know it didn't identify -- it identified the list of people but I didn't know, you know, each person and their raw data. And I saw that the scores were all over the place, and when I first looked at it, I kind of questioned it myself when I see these large ranges of scores. But then I looked at some of the comments next to these scores and it was brought up like the 300 million and 400 million, and first I thought, you know, does this make any sense or not, but I looked at the guy's comments, and he was being very objective. He had very objective reasons for putting these scores down. And when it got down to the bottom line and on the ranking, I thought, well, I don't agree -- I agree with the top and the bottom. In the middle there, I didn't agree with every one of them. If I was one of those individuals, my ranking would not be exactly the same, but all in all, it would be tough to question that ranking, in my personal opinion. It's tough for me to question the final ranking that it ended up with. I don't see a problem with the finalization of that expert elicitation.

Is it statistically sound? I can't tell you that. I'm not in a position to tell you that but I believe the ranking is a good one.

MR. TYNAN: Mr. Govro.

MR. GOVRO: Mike Govro from Oregon. I appreciated Dr. Raymond's patient speech yesterday, about moving forward with this, and I appreciate your sense of urgency and your passion about this, and I think it's important that you have that in order for this to go forward quickly.

However, I operate a program, a very small program, but we undertook something similar to this a few years ago when we adopted the food code, and it was -- while we continue to do inspections and do them pretty much the same way, it did become of a risk-based system.

DR. MASTERS: -- medical emergency. I'm sorry.

MR. GOVRO: Well, I wanted him to hear this but I'll go ahead.

His passion for this is what gives me a little bit of nervousness because there's really two

ways that this could go. One is if it was designed poorly and one is if it was implemented poorly, a couple of terms I think have been bandied about here a lot lately, and I'm just -- I would urge the Agency rather than to go forward and what I heard Mr. Palesano talk about yesterday and moving forward with the first step, maybe turn off the scheduler, I assume that means for the entire Agency, perhaps to go forward with -- I don't want to use the word pilot because I'm afraid that when you get into a pilot phase, you might get bogged down and never get out of it, but I would say a dry run, trial run, where you take a dozen people, put them on the system, and run it side by side with the existing system and see what you learn, see how things get done differently, compare results, see if the system that you have gives you better results, and I think you also will learn a lot along the way about anything you haven't thought of. I mean there's a lot to implementing something, training and communication to your staff. There's training and communication to the industry. There's the computer considerations and on and on, and I would

be willing to bet that somewhere down the line you're going to find yourself going, gee, we didn't think of that. Because anybody that's gone through what we've done with the food code or made a major change in their program, generally finds that they go forward too quickly. So I would just say give it a trial run and have your own in-house lessons learned on a very small scale.

DR. MASTERS: I will pass this along.

MR. GOVRO: Okay. Thank you.

MR. TYNAN: Thank you, Michael. Other comments from the Committee? Mr. Elfering.

MR. ELFERING: This is Kevin Elfering. I wish Dr. Raymond would be here because I think hopefully you can relay all this.

Yeah, we've been doing risk-based inspection for years and, you know, the Agency that I manage, we probably inspect about 16,000 establishments, anywhere from small meat and poultry plants to dairy farms, dairy processing plants, retail stores, manufacturing plants. We assign a risk to each one of those types of operations.

It's a rather simplistic system though. It isn't real complicated and we rely so much on our field staff to be able to either increase inspection frequency based on the risk of the product that they're producing and also the establishment history, and I think you're doing all of that but I don't know if you realize what a monster you're going to have, that you've got out there with all the things that you want to try to put in place.

You know, I think that there's some good examples of a seasoned inspector is going to be able to identify a lot of these indicators but I think that you're almost trying to make it too complicated and I think you just need to have a more simplistic system.

Risk-based inspection is the most wonderful system that you could ever put in place, and it makes so much sense but I just think that you're trying to build so many things in here that I don't think that you're going to be able to accomplish all of those, and I think you just may need to make it a much more simplistic system.

MR. TYNAN: I apologize. Let me do the

Committee first, and then I'll come around to Mr. Painter and our employee organization representatives. Mr. Finnegan.

MR. FINNEGAN: Mike Finnegan. I agree that risk-based inspection, it's a good system, and we do it, and we have been doing it, and I think it's the best bang for our buck, I really do. But one thing that I believe we learn from HACCP was training. We have to instill a good training course and make sure all of our troops are on the same page, our inspectors really know what they're doing before we install our risk-based inspection. I think training is going to be a major piece here.

MR. TYNAN: Thank you, Michael. Mr. Kowalcyk.

MR. KOWALCYK: Thank you. I think my experience from the past couple of days reconfirm the fact that change is always difficult. Looking at what data issues the Agency faces and the value of that data if managed properly, could give the inspection force, as well as industry, a valuable tool to do their jobs more efficiently and to ultimately create a

safer product for the consumers. I think it's very clear that all stakeholders ultimately want that, that 14 people dying a day as a result of food-borne illness is unacceptable, and what can be done to improve that?

With that said, looking at a system that's data driven, there's always going to be challenges. To echo Mr. Govro's comments about a testing phase as part of implementation, I think would be very valuable and would provide the Agency with tremendous insight.

Another thing that is apparent from the two day meetings and my discussions with people from industry as well as other stakeholders, is let's not throw away the knowledge that's already there. There's a lot of people in the inspection force that are experienced. They know their plant and Mark is right. They do take a risk-based approach through their experience. And I would hope that rather than a replacement to risk-based inspection should be incremental to the current tools that are at their disposal, a way to guide their work and their intensity of work within statutory requirements and,

of course, that's a whole other issue but, you know, I would just hope that the Agency's approach is that this is in addition to what works well, and always looking to make things better. And I see the Agency is going in that direction, and I'd like to compliment the Agency on that.

MR. TYNAN: Thank you, Michael. Other comments from the Committee? Dr. Denton. You've been reasonably quiet today. This would be a good time.

DR. DENTON: Thank you. I'm trying to save my energy for this Subcommittee meeting.

Seriously, in thinking about everything that everyone has said, I can understand the issues that come about with change. Change is always hard. One of the things that those of us in the academic world have learned to deal with is change because nothing ever stays static in research or education.

As we look at this whole issue of risk-based inspection, and I try to look at this from every aspect, the consumer, the industry, the Agency, our inspectors, our state level people, and from my own personal perspective having spent more than a couple

of years doing this. It was a dramatic change when we went to the HACCP based system, much more intensely data driven than anything that we had experienced before. There was lots of pain associated with that early on, but as we begin to collect the information and started to see some of the outcome of moving to that type of a system, it began to make sense to a lot of us. I think if we look at the data that the Agency collects, if we look at the data that the industry collects, it's pretty difficult for anybody to look at that set of information if you have the opportunity to look at that information, and not see some of the opportunities that are sitting out there, just on the edge of where we are, that can really make a significant difference with regard to protecting the public health.

Now I know that there's always this concern that we're about to trade this for that. I don't think that we ever trade this for that. We slowly, methodically move, from where we are to the next generation or the next best system that we see, that we can utilize to really get at some of these things.

One simple little example is sitting here in our notebook with regard to this *Salmonella* incident table associated with traditional inspection in HIMP type plants, and I can understand that the folks that are sitting on this side of the table, looking at that information and saying, holy smoke, why aren't we capturing this and moving to something that's going to help us improve the food safety system. It doesn't mean we have to adopt HIMP. It doesn't mean that we do away with inspection. What it means is that we take this information that we have and we look where we need to go next, and really get focused on what caused this distinction between these two sets of plants. Because what we'd really like to do is take all those plants that are on the left-hand side of the page and slowly move them over to the right-hand side of the page with regard to the incidents of *Salmonella*, the incidents of *Campylobacter*, *Listeria*, it doesn't matter. You will in whatever the pathogen is that you're trying to focus on.

But the only way that we're going to make progress is when we see opportunity, we have to seize

the opportunity and try to work toward that.

I don't have that many years left to do this. Okay. I rotate off of this Committee tomorrow at noon or slightly before noon but I really do feel like that as difficult as the process is that we probably made some significant strides during the past six years. It hasn't always been easy but that's my two cents, and I'm sticking to it.

MR. TYNAN: Thank you, Jim, very much. Other members of the Committee?

(No response.)

MR. TYNAN: Okay. Then I'm going to ask Mr. Painter, you had a comment that you wanted to make?

MR. PAINTER: You know, I hardly know where to begin listening to the process over the last few days, and the Agency dealing with the Union and the fact of not sharing information that it apparently had and talking about going in a direction in which we didn't know where we were going, it seems as though today we have a clear vision. And the sharing of that information, you know, would surely have been helpful

and to give an understanding and there may be some cases that we disagree and that's okay. But in what I determine to be the deliberate hiding or withholding of information is what I determine to be unacceptable and not dealing in good faith, and I want to say that my confidence in some of the people in upper level Agency has really been tested lately, and I hope to be able to get back to a level that I don't feel as though it's quite so tested.

I'm really confused regarding the numbers with the *Salmonella* regarding traditional versus HIMP. I would have like to have saw the stats regarding traditional versus HIMP, in the use of anti-microbial agents, if that came to play in the numbers as well. Was it that HIMP plants use more anti-microbial agents? It could be. It could not be. We don't know.

I would like to conclude by saying this. If I'm a parent, I would expect to give more parental supervision to a child to make it turn out the way I wanted it to be versus less supervision.

MR. TYNAN: Dr. Bratcher.

DR. BRATCHER: I think it's extremely important from the standpoint of upper management that they consider not only the Union's perspective on all these things, but also ATSP and NAFE, and as many of you know, we've not had consultations with our organizations for several years now, and I think that it was extremely critical that we had some representation from management and supervisors which our organizations are particularly made up of field people, because I think we could have lent a lot of expertise to some of the process and the direction that the Agency is headed. I think it would be critical that we start some of these consultations back particularly as we move forward with some of these new initiatives, and I would hope that you would consider that.

MR. TYNAN: Thank you, Chris. I'm going to let -- Mr. McKee, did you have a comment?

MR. McKEE: I do. This is my first go around in an event like this, and it's been very enlightening to me. One of the things that really occurred to me as I sat and listened the last few days

is that there may be a disconnect between the consumer groups and possibly part of the Agency with regard to what we actually do in the plants, and I would just like to assure everyone here that we have a very well qualified, well trained inspection team to carry out the proposals that are before us now. It's extremely important to inquire about what's going on and come to a full understanding and proceed armed with full knowledge. I think that has been reiterated time and again. You've got a great group of people here, that work well together. There are some conflicting agendas by nature. It's to the Agency's credit that they have brought all players on board now. We have our labor force represented, our employee groups, and I think all stakeholders are now present at the table, and hopefully working together, we'll get this packaged up and be able to take it on the road.

MR. TYNAN: Thank you, Robert. Anyone else have a comment?

DR. RAYMOND: Yeah, I do. I will and then I'll run, and then we can re-engage at 8:15 if we would like, if there's a response to my comment, but I

do have to run, but while these things are fresh in my mind, I do want to make a couple of comments. Mike, I'm sorry I had to run out, and if you've got something that you want me to remember, you'll have to come and tell me. Barb maybe took good notes.

Some things a lot of people may not know but I think they're important to put out on the table as part of this discussion, it was a year ago, a year ago and 2 months ago, 14 months ago, when the Agency actually showed me their plan for more robust risk-based inspection. And at that point in time I said, you know, parts of this I just cannot sell, I cannot defend, I do not believe in, and I asked them. Go back. Take your committees and this is what I would like to see more of, and a lot of it was around the NR issues and other things, but I asked them to please go back and let's get something that's more solid, less human. I won't call it error. Differences between inspectors, the human element. Let's see how we can get some of the human out, you can't get human element gone but get it so that it isn't such a factor. You know, and they went back and they worked diligently,

and so a year ago, we didn't have the product because the product we had, I was not going to push. And so that's one reason we didn't have things out there real early.

Also I had asked, and I said who in the consumer groups had you discussed this with, who in industry have you discussed this with, how many of our employees have you discussed this with, and I did not see -- I was not convinced I should say, to at least the style that I want to display, I did not see that it had been vented enough in the public's eye. I wanted it more open. I wanted it more transparent.

Now we've been criticized for not being open and transparent, but we certainly made an effort in the last year to get more input. We've modified things as we've gone along. Barbara and I actually flew down to Alabama, probably about a year ago this month, to visit Mr. Painter personally, just to have a three person conversation to begin to discuss at that time, my goals for risk-based inspection. I wanted to hear Mr. Painter's concerns about what our goals at the time were, so we could start making adjustments

early on to take into effect those of our members that are out there in the workforce and are in the field and should have input. We've begun having town hall meetings with our employees. We've had four focus groups just on risk-based with all levels of employees just in the last few months. We tried to, you know, involve them in that way. We've met monthly with the consumers and probably 90 percent of the hour I spend with consumers every month is between budget and risk-based. I mean we have talked about it, and it was just two meetings ago, that it became apparent to me that the inherent risk of the product and the methodology that had been used to define that, which I did not have anything to do with, that doesn't make it good or bad, but the other one I said go back and change, inherent risk, I thought if we have 23 scientists that know a lot more than I do about food microbiology and food safety, I just did not think it would be controversial. I apologized to the consumer group when I met with the last time. I apologize to this group. That's my ignorance. I thought who would argue with the scientists and I did not realize how

volatile that part of ranking 23 food products in order and as someone said earlier, I think most of us agree on the safest and the riskiest, and those ones in between maybe we could have discussions about, but that doesn't really change the Y axis a lot. But hearing at the two meetings that I had with consumers and then hearing two days of the same concerns voiced yesterday, we do need to take a look at the data. I admit that. And I apologize for that. If that hadn't have been so contentious, maybe we'd be rolling something out before Christmas, but our database won't be ready, but we're going to have to go back and reframe some of those things. So I accept that. That's my fault. I did not look, I did not pay attention to it.

Comments have been made many times that we already do some risk-based inspection by our inspectors and I certainly agree with that, and that's good that they do that, and it's good that they have the knowledge to do that but, you know, once in a while, people like Mark Schad called me up and said, that inspector of yours is in my plant four hours and

the guy down the street is making the same stuff I make, and they're only giving him two hours. They don't like me because I had an appeal last year and I won it or whatever. There's the human element there that comes in, and then we have to answer that then. If we can say, you know, it's based on your track record, Mark, it's based on the product you make, therefore you fall into category 5 and you've got to move to the left to get out category 5. So I'm not saying inspectors do that out of spite, but sometimes the human element enters in and then we have to get into that fight. So we're just trying to help the inspectors out by giving them science base to support it.

And then lastly, and then I'm going to run, but, Mr. Painter, you said if you were a parent, you would give more parental attention to a child to make it turn out the way you want, I think that's kind of paraphrased what you said, and that's exactly what I want to do with the plant out there in zone 5. That plant needs some parental supervision because that plant owner is not showing that he or she can do it on

their own. They're still an adolescent. They need a little help, and we're going to try to give them that help. The child down in zone 1, you know, that's the Eagle Scout. That's the one that you let go out at night and say be home by midnight and you never question. So that's not a builder analogy, but it's the best I can do on the slide there, Sandra.

Okay. See you all tomorrow morning.

MR. TYNAN: If there's no other comments from the Committee or from our employee organization representatives, then I would suggest we take maybe a 15 minute break. Subcommittee 1, and again just for purposes so that everybody knows because we made the changes, but it's Dr. Carpenter is going to be the Chair, will be in this room. Dr. Bayse will be a participant, Mr. Govro will be here, Mr. Kowalcyk and Mr. Schad will participate in that one. Then we have another room called FM-7, don't ask me where, but we have somebody who will guide you Dr. Denton, so you will not be lost, but Dr. Denton is going to be the Chair of that, and he's going to be addressing the issue of Risk in Slaughter Operations, and in his

group will be Ms. Eskin, Mr. Finnegan. It'll be Mr. Elfering, Dr. Harris, Dr. Leech and Mr. Link.

Now I think at the end of the day, did we get everybody assigned properly? No. Okay.

DR. MASTERS: And just to be certain -- can I have your attention for one more minute.

MR. TYNAN: Just a minute.

DR. MASTERS: Our employee representatives should choose the Subcommittee that's most interesting to them because we do want them to participate in the Subcommittees and their input is very valuable.

MR. TYNAN: I was going to say that. Okay. With that, we're going to take a break, and then we'll convene back here --

(Whereupon, at 2:00 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:

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

Washington, D.C.

October 12, 2006

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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TIMOTHY BOND, Reporter

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