UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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RISK-BASED INSPECTION (RBI) PUBLIC WORKSHOP

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October 10, 2006
9:30 a.m.

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

FACILITATOR: MS. ABBY DILLEY, RESOLVE
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PARTICIPANTS:

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DR. BARBARA MASTERS
MR. MATTHEW MICHAEL
MR. DON ANDERSON

I-N-D-E-X

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

(9:30 a.m.)

MS. DILLEY: Good morning. My name is Abby Dilley, and I'm a Senior Mediator with RESOLVE, and RESOLVE is a nonprofit organization based in Washington, D.C. We also have an office in Portland, Oregon, and we work as mediators and facilitators on public policy issues ranging from energy to natural resource issues, public health issues, agriculture issues, and we design processes that provide opportunities for people to work collaboratively and constructively together.

And we've responded I guess around the first of the year to a request for proposal put out by FSIS to work on a stakeholder input process on risk-based inspection, and were lucky enough to be selected to assist them with this effort.

Our activities are varied, and this workshop is one of those activities. We have been gathering a lot of information from stakeholders in a variety of ways including the workshop over the next couple of days, interviewing approximately 45 or so stakeholders

in individual interviews as well as group interviews and have been reviewing electronic submissions on FSIS' website, in terms of comments relevant to the couple of the papers that we'll be discussing today, and focusing on a range of -- in those conversations on collecting information on risk-based inspection broadly, as well as the papers that have been posted on the website, and you'll hear a little bit more about those, the concepts in those papers and FSIS' thinking and how it's involved in the presentations today as well as gathering the information over the next couple of days.

Ultimately, we'll be developing a report to present to FSIS. So we'll analyze the information, try and highlight where the thinking of a variety of stakeholders on various concepts associated with RBI and compare and contrast some different -- the different perspectives and competing perspectives on some of those concepts, and as well as present some recommendations for next steps in the stakeholder input process.

The workshop is a very significant

opportunity to gather a lot of input from people as you can see around the room. I think we had about, at last count, 120 people registered here at the site. We also have through webcasting a net meeting that has been made available to sites. I think we're on 25 or 26 sites around the country and you know about 80 people I think at last count, at the end of last week, had registered for that. We anticipate that those numbers have probably gone up. And we have people joining us everywhere from Beltsville, Maryland, Dallas, Texas, Chicago, Illinois, Alameda, California, which is really an early wake up call, and we really appreciate their getting up early and joining us this morning. And an impressive number of people from Springdale, Arkansas, and Jackson, Mississippi are also joining us, and then also several other sites to participate in this session, the workshop over the next couple of days.

And I just wanted to point out two more things briefly, and then come back and talk about the agenda and some other things after Dr. Masters has a chance to welcome all of you.

When you registered and for those on participating by net meeting, you had materials sent out beforehand. Here at the site, they're contained in this packet, tan packet. It has an agenda that is -- the agenda has been posted for a while, but we put it on lovely blue paper for you to be able to pick it out of your packet.

There's also the overview or some PowerPoint presentations that will be given over the course of today and tomorrow. Some of those PowerPoint presentations have been slightly modified, but I still think those will serve as a good guide for you, so you don't have to take copious notes, but -- or you can take copious notes on the slides. So you'll have those at your disposal to use, and then we also have the two papers that we referred to, that have been posted on the website, as well as some information on the expert elicitation that will be discussed as part of the product -- inherent product risk -- product inherent risk, sorry, and then also an evaluation form is in there and some other materials. So we'll get back to some of that information in your packets over

the course of the day, and I just wanted to point that out to you.

So I will be back to talk a little bit more about the agenda and some meeting protocols, but I first want to turn it over to Dr. Masters to welcome all of you.

DR. MASTERS: Thank you, Abby, and good morning everyone. On behalf of FSIS, I want to welcome everyone to this very important two-day meeting. I want to extend a special welcome to our Netcast attendees who are joining us from across the country, and Abby mentioned some of the sites that are participating with us from those remote locations.

I'm happy to be here with you today, to discuss our progress in creating a more robust risk-based inspection system and our vision for the future. I'll let the ladies catch up here.

I'd like to thank our host, RESOLVE, for setting up this meeting. As you may know, USDA sought a third-party facilitator on the recommendations of our National Advisory Committee for Meat and Poultry Inspection, to assist us in getting input from all of

our stakeholders. RESOLVE was selected through a Government contracting process.

At FSIS, we are committed to the idea that an effective food safety and food defense system must be rooted in science. To meet its goal of protecting public health, FSIS will continue to review policies and regulations in light of what science demands.

The more robust risk-based system we envision, is an example of our effort to modernize and enhance food safety and food defense. We are committed to carrying out these changes through a public process. RESOLVE has conducted issue spotting interviews with employees as well as other stakeholders to identify crucial topics in our risk-based inspection effort.

This meeting is an opportunity for you, the stakeholders, to express your views about our vision for a more robust risk-based inspection system. The success of this vision will depend upon the active participation of all our food safety stakeholders.

I want to emphasize that we are here for discussion. I'm going to say that again. We're here

for discussion, not to unveil a finished product.

During this two day meeting, we will present technical papers which discuss two key components of our envisioned, more robust risk-based inspection system, first, measuring establishment risk control, and second, determining a product's inherent risk.

In addition, FSIS will begin a discussion on how these two measures of risk might be used to implement a more robust risk-based inspection system to direct in-plant processing and off-line slaughter inspection activities.

We hope that during the workshop, you come away with a clearer understanding of our vision.

In addition, we want you to present your ideas and suggestions on the key components of a successful risk-based system and its implementation. We welcome your recommendations, and I want to thank you in advance for your participation. Your input and your discussion, both here and at the Netcast locations, will be critical for FSIS. We genuinely want to hear your ideas and your input. I look forward to a productive meeting. Thank you.

MS. DILLEY: A couple of things before we review some meeting protocols, ground rules and agenda.

I wanted to give people in the room, obviously in the time that we have, we don't have time for everybody to go through and given an introduction, but just to give people a sense of the composition of the room, I thought it would be helpful to maybe have you raise your hand in different group so we can get a feel for the diversity of stakeholders in the room.

For those of you that are FSIS employees, if you could just raise your hand. Great.

For those of you who are other Government employees, just a sense. Great. Wonderful.

For those of you, consumer or advocacy groups affiliation. Okay. Good.

And for those of you in the meat and poultry producing and processing industry, a sense of hands. Great.

Members of academia. Great. Good.

Any people who didn't identify with any of those groups. Oh, good. We covered just about

everybody. Okay. Good.

I also did not introduce my colleagues who are also here with me today and will serve as facilitators throughout the day and for the small groups. Paul DeMorgan is over here. He is based in Logan, Utah, but also frequents our Portland Office. I mentioned we have an office there. Kathy Grant and Brad Spangler who are over here are based in our D.C. Office, and I'm affiliated with the D.C. Office but happen to live in Grand Rapids, Michigan and, yes, I am an unabashed Tigers fan. I just wanted to get that out of the way. So those of you who are baseball fans.

So in looking at the -- if you will look at the workshop agenda, I just want to go over a couple of different things.

First of all, in terms of meeting protocols and logistics for fostering a function and productive meeting, the goals that are outlined there are really to try and maximize opportunities for discussion with FSIS, with each other, and to provide ideas and suggestions on a lot of key dimensions of risk-based

inspection. And we're also trying to maximize the number of people who have an opportunity to ask questions, provide comments. Obviously with -- I think we had about 120 as I mentioned, people registered for the workshop here, and then about 80 at the remote sites, those dual goals to present some challenges in terms of trying to maximize those opportunities. And the meeting protocols and ground rules and the agenda hopefully are trying to balance those challenges and get as much information over the next two days, and beyond, as possible.

In terms of just overall protocols on site, we'll have a combination of presentations that will reflect FSIS' latest thinking in terms of some core concepts regarding RBI, and then we also will have an opportunity and time for questions and answers as well as discussion. We really hope to maximize opportunity for discussion, both in large group, in this room, and then also this afternoon the opportunity to get into small groups where you have -- it's a less formalized process.

We will have -- we do have in the room the

two microphones you see standing. So during the Q&A, question and answer period, we'll use those microphones to make sure that you can be heard in terms of asking your questions and giving people an opportunity to participate.

For the remote sites, we are trying to engage them in a couple of different ways. One is to, while we are asking questions, also give them an opportunity to post questions to an e-mail address, and we'll be trying to the best of our ability trying to draw from those questions that are also posed by the remote sites to be able to put that into the mix of questions and comments that are being presented in discussions here.

We also will collect the information, not only that's gathered. We're collecting information in a variety of ways. There are Court Reporters who will be taking extensive notes, degenerating transcripts. We'll have people taking notes, handwritten notes. We as facilitators also will be doing some flip charting. So we will also try and capture the comments that people are raising and the essence of the discussion.

And hopefully in doing that, gather as much information as possible to be able to put into the mix of developing a record of the meeting as well as getting all the good ideas and suggestions and comments that will be presented over the next couple of days.

And subsequent to that, as I think we mentioned before, there is a website on FSIS' website or an opportunity to provide additional comments subsequent to the workshop. So comments can continue past the workshop, and those will be reviewed in addition to the material gathered over these couple of days.

We're also asking the remote sites and have provided them with some suggestions how to hold the small group discussions at their locations, and then pull together information from that and send it on. So we're trying to gather as much material and information over the course of the two days as possible.

In order encourage as productive a meeting as possible, we also wanted to suggest some ground

rules, and we have that on the blue piece of paper for the Agenda, and I just wanted to go over a couple of things.

One is to stay on one conversation. Obviously with a room of 100 plus people, and a lot of you, if not all of you, wanting to comment, it's really important to have one person talking at a time so that everyone can hear the question, and the answer. So that's very important.

Observing time limits is also important. I've been in several meetings where people have started out their comment by saying, I have three questions with three parts to each of those questions. Recognize that there are 100 plus people in the room who have questions as well, and if we could be respectful of trying to keep our comments and questions. We want you to ask them and we encourage you to do that, but also recognize that there are also other people that want to comment as well. So if we can keep to crisp comments, that would be very helpful.

And also, if you would turn off your cell

phones, if you haven't already done that, and pagers or at least put it to vibrate, not stun, but vibrate, that would also be very helpful. Sometimes we have musical accompaniment to comments, and that can be a little distracting. So we would appreciate that.

So in terms of staying in one conversation, it's helpful to have just one person talking at a time.

Also adhering to the agenda. As we mentioned, we have multiple sites participating. They are linked to the meeting between now and when we break at 1:15 for lunch. And in order for them to hear what you hear in terms of the presentations and the substantive information, we need to adhere to that agenda. So that means breaks really need to be 15 minutes. So we need to stick to that agenda so we maximize the opportunity for the remote sites to be as engaged as you all are in the room.

We do have some opportunities over the course of the two days to come back to issues. It's an iterative agenda, and I'll talk a little bit more about that in a minute. We can do some fine tuning as

we go, but we really do need to, for example, the second day we have I think between 2:30 and 3:30, we have identified a time to address other major issues which is kind of a catchall to say, let's take an evaluation of where people really want to talk on issues that has not received as much attention or airing that people would like, and we can come back to some issues and spend some time doing that. So we do have opportunities to do some fine tuning, but in terms of time and the overall agenda, we need to adhere to it as best we can.

And then finally, just being respectful. In the short time we've worked on this topic, it's very obvious that there's a lot of passions surrounding food safety and risk-based inspection, and these issues involve people's careers, their livelihood, and personal and public health issues. Obviously people have very strong feelings around these issues. I think we can express those strong opinions and ideas and do it in a productive manner, disagreeing without being disagreeable, those kinds of things, to pay attention to and being respectful to one another in

having a productive exchange of ideas and points of view.

Any questions about the proposed ground rules before I turn to the agenda? Any different kinds of ground rules that you would find helpful or any additional comments on that? I'm going to pause for just a second. Any questions coming in remotely?

(No response.)

MS. DILLEY: All right. So let me walk through the agenda to talk about how it's structured in order to achieve the goals and outcomes that we've established for the two-day workshop.

In a minute, Dr. Masters will come back up and talk about the vision for risk-based inspection. Schedules will be schedules, and Dr. Raymond is right now, wanted to be here from the beginning. He needed to be in a meeting with I believe it's the Ambassador to Korea. Okay. And so in the interest of being flexible, but trying to stick to the agenda as best we can, Dr. Masters will give her presentation, and then if Dr. Raymond is here, we will turn to him and go to the question and answer period as you see on the

agenda. Alternatively, if he is not here at that time, we're going to go right to the papers and have Matthew Michael give his presentation on product inherent risk, and then we will have Don Anderson give his presentation, and then come back before the lunch break to have Dr. Raymond give his comments, and then have the question and answer discussion around the vision related presentations.

We're trying to be flexible in terms of accommodating people's schedules, but want to get to all of that before the lunch break at 1:15, because again the remote sites are linked to the meeting until that time, and so we want to be sure that they have heard all the presentations and the discussion, Q&A period.

Then we have a lunch break from 1:15 to 2:30, and then I believe there are lots of alternatives to you that are fairly convenient to hopefully get you to have a decent lunch and back here to start up again at 2:30. And we'll have an opportunity for you to ask some additional questions on the presentations regarding product inherent risk

and establishment risk control, and then we will provide some instructions and overview of the small group discussions, and then move you into the small groups so that you can spend the better part of this afternoon, an hour and 45 minutes in those small groups discussing the questions around -- that have been formulated around those two papers, two presentations.

Tomorrow we will come back and start again at 9:30. Sorry, Alameda, those of you on the West Coast.

And, just in terms of the small group discussion, I also wanted to reiterate to the remote sites, you obviously won't be eating lunch at 9:30 or 10:00. So you can do your small groups -- I encourage you to do your small group discussions when convenient for you. I just wanted to make sure you had the opportunity to do that.

Then we'll come back again at 9:30 tomorrow, and reflect on the discussion held over today, and then review the agenda for the day tomorrow. If there is any fine-tuning at that point, we'll talk about it

at that first session. Then we will have the small group reports and group discussion, up to the break at 11:15, and then have another presentation on preliminary ideas on using risk to direct in-plant inspection activities and processing assignments.

And, then take a break for lunch from 12:15 to 1:30, Eastern Time, and then come back and have a group discussion on the presentation, after you had a chance to think about the presentation over lunch, and then some more opportunity for discussion on topics. Again, that's an opportunity to come back and revisit some issues that you would like to spend more time on, not just on implementation, but over the course of the day and a half up to that point, take a break, and then a discussion of assessment of the workshop discussion and ideas for moving forward, and then summary and wrap up, and then we'll adjourn no later than 4:30.

So again just to mention that the agenda is structured to try and maximize as much input opportunity for discussion, questions and answers and comments. Over the course of the two days, we have

some time to come back and have it be iterative a bit, to revisit issues and topics over the two days, and do some fine-tuning.

Any questions or comments on the agenda or anything up to this point? Yes, please. If you can use a -- you can't really use a microphone can you? Let me see if you can --

MS. NESTOR: I can speak pretty loud.

MS. DILLEY: Okay. I just want to make sure that the sites can hear you, and I'm not sure they can hear you without a microphone. So please do. In order for the remote sites, we need you to use a microphone.

MS. NESTOR: Did I understand you to say that at the remote locations, they are also going to be having group discussions?

MS. DILLEY: Yes. We hope so, yes.

MS. NESTOR: Okay. And who is -- will those discussions be recorded and entered into the record? And who's going to be doing -- who will capture the comments in those group discussions?

MS. DILLEY: I believe the people at the

sites, right, the -- is it at the FSIS offices? Yeah, capturing and then forwarding them to the site, the e-mail address that also is how we're fielding questions.

MS. NESTOR: Okay. So FSIS management is going to be recording the comments?

MS. DILLEY: Yes.

MS. NESTOR: Second question, do we know how many inspectors are at those sites? What's the breakdown of inspectors versus managers at those FSIS sites or will the agency be keeping a record of that?

MS. DILLEY: In terms of who all is participating?

MS. NESTOR: Yes.

MS. DILLEY: Yeah, they needed to register and I believe they're capturing names and affiliation of people who are participating at those sites.

COURT REPORTER: You need to identify yourself for the record.

MS. DILLEY: Yeah.

MS. NESTOR: Do I need to go to the mic for that?

MS. DILLEY: You can just --

MS. NESTOR: Felicia Nestor with Food and Water Watch.

MS. DILLEY: Thank you. Felicia Nestor with Food and Water Watch. Thank you.

Any other questions, comments, at this point?

(No response.)

MS. DILLEY: Okay. All right. Then I will turn back to Dr. Masters.

DR. MASTERS: Thank you, Abby. We're verifying we have the right presentation for the Netcast participants.

I appreciate Lisa joining in at the last moment to help with slides.

Today we will begin discussing how we can measure risk in order to implement a more robust risk-based system, but before we delve into this discussion, I would like to acknowledge that we have been exploring the risk-based approach since before 2000. The most significant milestone by the Agency was the implementation of HACCP. We have also

implemented many forms of risk-based pathogen controls that I will address shortly. But you may have also heard about the risk-based strategies for processing inspection by the Agency under different names, like processing inspection optimization systems or PIOS, hazard control coefficients, the HCC, and hazard coefficients or the HC.

I want to make clear that since that time, our thinking has evolved with lessons learned at each step. The current risk-based inspection system we are developing reflects that evolution.

As I mentioned, FSIS has already made progress toward a risk-based approach to food safety, especially with regard to pathogen control. One example, is FSIS' verification sampling program for listeria monocytogenes. Under this initiative, FSIS tailors its verification activities to the interventions that a plant chooses to adopt and to the potential for listeria growth in their products.

In other words, FSIS conducts less sampling in those plants that have the best control for listeria, and more sampling as well as in depth food

safety assessments in the plants that adopt less vigorous control programs.

Based on our progress for listeria, we announce an 11-step program that's a risk-based strategy for *Salmonella* in February. The initiative includes concentrating resources at establishments with higher levels of Salmonella and changes the reporting and utilization of FSIS *Salmonella* verification test results.

Our goal is to further enhance and strengthen our risk-based approach for pathogen control. We are currently developing a risk-based verification strategy for *E. coli* O157:H7. This is pending the completion of a baseline study for ground beef components later this fall.

We are taking this risk-based approach even further by exploring how we can apply risk-based concepts to the processing inspection and off-line slaughter inspection. We envision a system where we will utilize the data we have to determine the level of inspection at processing plants and off-line slaughter assignments. This allocation will rely upon

two measures of risk, inherent risk, or the measure of the inherent risk posed to public health by each type of processed meat and poultry product and risk control, or the measure of the amount of actual risk control achieved by each establishment.

Today you will hear our best thinking about the types of public health data we plan to use to make these risk-based decisions, and we welcome your input on these ideas. For example, what factors would be appropriate and adequate for inclusion in a mathematical formula to determine inspection level? Pathogen testing results, certain noncompliance records, the results of an in depth food safety assessment. How about the number of confirmed illnesses tied to specific products? Within a plant, could different processes be assigned a different level of inspection?

These are questions that we are now exploring, and these are questions that we will be exploring when we talk about the specific papers later this morning.

Tomorrow, we will begin discussing

implementation of risk-based inspection, focusing on how inherent product risk and establishment risk control are tied together. In a few minutes, Dr. Raymond will share some of his thoughts on how this might look conceptually. We will be seeking your input on specific questions in this area as well.

But for now, let's step back and look more broadly for a moment at the Agency's overall vision for our more robust risk-based inspection system. Our risk-based approach must and will be driven by data. We are building a public health data infrastructure to enable us to collect the data that we need, analyze that data and respond to that data in a way that protects public health. We need to get the right data to the right people at the right time to make the right decisions.

Thus, we need to get data and information flowing seamlessly across the Agency. Data must flow in real time and be continually analyzed so potential problems can be detected quickly and resources and be more efficiently used to protect public health. The data must be reliable and securely assessable.

In addition, these data systems must permit strategic decisions to be more traceable, measurable and easily audited.

So what does this really mean? As we move forward as an Agency, we envision a giant feedback loop, in which data can be quickly integrated and analyzed to make effective risk-based decisions in areas such as inspection verification activities, policies, employee training and outreach to industry and consumers.

Data entering the system will come from pathogen testing, in-plant verification, noncompliance records, food safety assessments, traceable food borne illness outbreaks, inquiries to our technical service center, and many other sources, and it will be in one central warehouse so that it can be accessed from many sites and for many purposes.

Under our risk-based inspection system, the in-plant level will be provided by FSIS, will be based on an algorithm or a mathematical formula derived from data representing the inherent product risk and the risk control factor. Again, this is the focus of

today's meeting.

However, all of the data that I just mentioned above, the pathogen testing results, noncompliance records, food safety assessment results, food born illness outbreak information, are all potential contributors to this mathematical formula.

However, the Agency will also be using data more broadly. We will be using data to be proactive to protect public health beyond the in-plant inspection level. All Agency decisions will be driven by data.

I want to share an example to better illustrate what I've been saying. For example, let's look at the traditional approach. FSIS learns about a salmonellosis outbreak from CDC or a state public health agency. If available trace back information implicates a particular establishment, FSIS conducts a food safety assessment to determine compliance with all applicable regulatory requirements. FSIS also takes action against the product and/or establishment as appropriate.

In a risk-based proactive approach, by being

able to analyze all of this data together, FSIS will begin looking at clusters of high risk isolates from FSIS verification samples to see if they come from a particular establishment or from a geographic part of the country. If they were all from a particular establishment, FSIS could then initiate a food safety assessment at that particular establishment before a potential outbreak occurs, rather than as part of an investigation of why an outbreak occurred.

If the cluster of highly pathogenic serotypes (ph.) was from a particular geographic area, but no particular establishment had multiple occurrences, FSIS could immediately schedule more sampling in the area to determine whether an unusual prevalence of a high-risk serotype is occurring. FSIS could do what we'd call Epi trace forward with the information by working with CDC to try and prevent outbreaks from occurring. These concepts are in part what FSIS is beginning to accomplish with the *Salmonella* Federal Register notice that was presented in February of 2006.

I think it's important to note that in these

examples, that under our risk-based inspection system, the level of inspection verification in the plant would continue to be determined from the mathematical formula that was based on inherent product risk and the plant's measure to control risk. The additional data that was used to determine whether to conduct a food safety assessment was an additional data point for verification by those trained in the food safety assessment work methods.

However, FSIS does envision the results of the food safety assessment, as well as the results of the *Salmonella* testing program, would both play an important factor in the algorithm, that would determine the inspection level in the establishment for the in-plant personnel.

Other examples of more broad use of data might be calls to our technical service center that suggests training needs or policy changes. So the giant feedback loop may have a direct or indirect impact on the in-plant inspection level.

In our example, it ultimately had a direct effect. We had to do a food safety assessment, and we

had *Salmonella* results, both of which ultimately had an impact on the inspection level at an establishment.

We recognize that our challenge as an Agency is to anticipate and quickly respond to food safety and food defense challenges before they affect public health. We know that the only way to accomplish this is through the use of real time data. To this end, we are replacing dial up connections with high speed access to all headquarter plants to insure that FSIS is equipped with fully integrated real time communications infrastructure. We anticipate this will be completed early in 2007.

Through this data infrastructure, the agency will have the ability to instantly detect and respond to abnormalities or weaknesses in the system to best insure food safety and food defense. We must be proactive in decisions based on data.

To continue our progress, we are using a transparent and inclusive process to seek input on a wide range of issues, such as what factors should be considered in determining inspection level, and again, that will be a lot of the focus over the next two

days.

We have begun to apply concepts already taken directly from stakeholder comment. For example, early on, the Agency recognized that not all noncompliance records posed significant threats to food safety, and this was validated by many of our stakeholders. Therefore, FSIS presented this concept to NACMPI and asked for their thoughts. We received useful feedback on those NRs that the Agency believes are appropriate to consider food safety, and we also received some input from NACMPI on some specific data analysis we should be doing to validate the ideas that the Agency has, and you'll be hearing more about that at this meeting as well.

And last November, a subcommittee of NACMPI recommended a third party approach to assist us to reach out and gain input from our stakeholders. To accomplish that, we selected the consulting firm, RESOLVE, who you met this morning, to help us gain in put. A NACMPI subcommittee has been providing regular ongoing guidance, and many of the NACMPI committee is here, and we appreciate the work they've been doing.

Also, in order to insure transparency and insure dialogue, we published the two technical papers measuring establishment risk control for risk-based inspection and measuring product inherent risk or risk-based inspection back in July. Both those papers as well as some PowerPoint presentations have been on our website, they remain on our website, and we encourage you, if you have not looked at those, to review those papers. Those are what we'll be discussing over the course of the next two days. Our website is up and we'll continue to take comments on our website.

As I mentioned earlier, RESOLVE has conducted issue spotting interviews with our employees as well as other stakeholders to identify crucial issues and that framed much of the agenda over the next two days.

We have also engaged with our employees by holding feedback sessions or focus groups in loose terms. We've had town hall meetings both in the field as well as with conference calls and Netcast meetings. We've also begun inviting members of our employee

associations to participate at NACMPI. We started that this spring, and we're pleased to say that we have members of our employee organizations at this meeting, as well they'll be staying for our NACMPI later this week.

We also have been publishing articles in our Agency publications, the News and Notes and the Beacon, to try and assist getting the information out for our employees, and so we have been working diligently to try to engage our employees in a variety of realm of ways.

And when this meeting is over, we encourage all of our stakeholders, our employees, our consumers, and industry and other stakeholders to continue to submit comments to our e-mail address that is at our risk-based inspection website.

What we do expect to report from RESOLVE on this stage of what we're doing with risk-based inspection in December, we do expect to continue to engage with RESOLVE and many other aspects of our more robust risk-based inspection. So we do encourage you to continue to stay tuned to that website and continue

to provide us feedback through that process.

We look at this workshop on risk-based inspection and the NACMPI public meeting which will follow this meeting on October 12th and 13th, as more opportunities to listen and gain insight from our employees, consumers, industry and other stakeholders, and we certainly hope everyone will take advantage of these opportunities because we think this has been a great process, and we look forward to everyone working with us through these next few days. We think we all share the same commitment to improving food safety and public health, and we look forward to hearing from you and look forward to a productive few days. Thank you very much.

(Applause.)

MS. DILLEY: Just to let all of you know, we weren't sure -- we knew he was in the car, but we weren't sure where he was. So now he's here, and we will give him a second to get himself in here and just for the remote sites, Dr. Raymond is just arriving. So we are giving him time to actually get in the room and up to the podium and then we'll have his

presentation and then take questions and comments until 11:00 Eastern Time.

We also, I realized, when I looked to my own packet to look for the PowerPoint slides that they're not in there. So we'll make some copies available and I believe the presentations will be posted on the website right after this meeting. So you will have those available to you.

So I guess we'll get his slides going so we have the technical kinks worked out before he starts his presentation. Good morning.

DR. RAYMOND: Hi.

MS. DILLEY: How are you?

DR. RAYMOND: Good. Ready?

MS. DILLEY: I'll turn it right over to you. Yep, you're timing is prefect.

DR. RAYMOND: We try. Really classy. I just have to say that.

Good morning everybody. I'm sorry I'm a little late. We had a meeting with the Secretary and a couple of other people in the Federal Government that make a lot more money than I do, and when they

ask you to be there at 9:30, you be there at 9:30. So we're flexed a little bit but I think the rest of the two days will go uninterrupted, and you'll have our due attention.

I know Barbara has already spoken, and I've read most of her comments, but I just want to echo her thanks for all of you who have come here for this very important 2-day meeting, and for all of those who are joining us at the 30 different locations across the country for the Net Broadcast. I also welcome you and thank you for your participation.

I don't think there's any doubt that this may be the most important project that we've undertaken since I came on board 15 months ago, and I do intend to see it go through fruition, although by the time I'm done with my job, I know there will still be changes being made as we learn and go along the way, as there are with so many. But we do need to work together to build this more robust risk-based inspection system of that I am certain, and I think most of you are, too, and that is why you are here.

Our current system is very strong. If you

look at our incidents of food-borne illnesses and the reductions since 1998, you have to agree that reducing *E. coli* by 29 percent, *Listeria* by 32 percent and *Campylobacter* by 30 percent is an amazing accomplishment. It's an amazing accomplishment. But if you also look at the numbers very carefully, you'll see most of those changes, most of that improvement was made between 1998 and about 2001, and for some things like *Listeria* particularly, we've kind of plateaued out for the last four years. *E. coli* has plateaued out for the last three years.

Things have kind of stagnated, and we need to find a better mouth strap. We need to continue to drive those numbers down because there are too many people getting ill and too many people dying from food-borne illnesses, and that's what we're all about today. We're not looking for more resources or more FTEs. We're trying to take what we have and use those more wisely and more efficiently, bring the advantage of the experience we've got out there.

Another benefit that I think we'll see coming from a more robust risk-based inspection is

taking those 7,000 front line inspectors and allowing them, encouraging them, to use their God given talents, to use their scientific knowledge and background and to gain additional knowledge through training on how to play more of a key role in protecting the food supply of America, and our international trading partners also. We need them to be more active.

I want to -- oh, that's a face made for radio.

(Laughter.)

DR. RAYMOND: Can we go -- there we go. Do we have the ones with A, B, C or just -- it makes a difference. If we can -- never mind, Lisa, we'll just use this. I'm sorry. I had asked Lisa to make some changes, and I didn't get a chance to see them. She did exactly what I asked. I didn't --

What I want to talk about very briefly today. Some of you have seen this matrix. We call it a Nona matrix. Nona is Greek for nine. So Bryce Quick thought we had to have some fancy name on it.

The Y-axis is the inherent product risk,

which is one of the things we're going to talk a lot about today. The X-axis is establishment risk control.

Now we've been spending a lot of time on inherent product risk. We're going to spend a lot of time the next few days talking about inherent product risk, and we're going to take this point here as low risk. This is going to be something like a canned ham, and the top up there is going to be something like ground poultry, and that's part of our job the next couple of days, is to decide where all the 23 different categories of food products will fit into on that-axis.

And then the X-axis for establishment of risk control is another one that we're going to spend a lot of time on today. There's a lot of debate, a lot of controversy, and a lot of work put into this. The Agency kind of stopped what they were doing about a year ago and kind of revamped it, took a different tact at my request, so we would have something that I could sell and I could support, and I think we've got that now. The details we're going to work on this

week with all of you. But for establishment risk control, we will use things like noncompliance reports. We will rank noncompliance reports. There will be some that quite frankly won't enter into this equation because they don't affect public health. There's no risk.

There are others that are extremely risky, and they may have a heavier weight than the ones that are moderately risky for public health. We'll take a look at things like food safety assessments, microbiological testing, test results, for which there is no human element to enter that. We'll take a look at consumer complaints, food defense plans, recalls, and many other issues will be brought up the next couple of days.

Now, for example, my other matrix would have a plant over there in level 5. That would be a plant maybe making ground turkey, that has a history of multiple noncompliance reports being written, had a couple of NOIEs, maybe it flunked its last *Salmonella* set with like 35 percent positive. It just has a bad record. It shows it can't keep the Salmonella out of

its poultry, and it's making a high risk product. So that fits over there in level 5.

Then we'll take the same product, ground poultry, and put it up here on level 3, in the upper left-hand corner, because that plant gets very few noncompliance reports. It's spic and span. It's clean. Management, all the way from the owner to the newest front -- newest processor on the line, they all believe in HACCP, they all believe in SOP, they all believe in food quality and food safety, and they don't get NRs and their last *Salmonella* test had 5 percent positive samples, and they're just a plant you like to eat chicken from.

Level 1 is making canned hams down here, and that plant also doesn't get any NRs and has never had a recall and has never had a consumer complaint, and that's the place where you want to eat meat from. I don't want to eat meat from level 5 plants, and most of America don't know where the level 5 plants are, and our job is to get rid of those level 5 plants and move them to the left by increased attention.

My other matrix would have level 5 would be

plant A, plant B would be up here in the upper left-hand corner, level 3, and plant C would be down here in level 1. And we've got one inspector covering those three plants. That inspector today might spend about two hours at each plant and one hour traveling between each of those plants. So they're all about the same amount of inspection.

And when I talked to some of our inspectors and met with them and had scenarios like this, they all will tell you, if they've been on the job very long, they've got one plant they worry the most about, the one plant they worry the least about, but they don't have a lot of flexibility to spend more time in the plant they worry the most about because they've got PBIS assignments that they have got to be done in all three plants that week. And so they may spend a little more time in plant A, but not a whole lot. They don't have that kind of flexibility, and it's certainly not based on scientific gut feeling. And they tell me it takes about a year to really get confident to get that gut feeling. So when someone fills in for them, they just do each plant for two

hours. When a new inspector comes on, they do each plant for two hours until they get a better feeling for the plants.

We want to do something that's based on science, that we can stand behind, that will assign the inspectors to spend more time in plant A over in level 5 than in plant C down here in level 1. That C maybe only needs 30 minutes a week or a day, and an inspector knows if she goes in there, she isn't going to find anything. The plant's going to have everything lined up, everything in order, everything's been done by the book, and she's going to sign her papers and she's going to go on back to plant A again.

So that's really a high level picture of why we want to get there and how I think we can get there.

And I want to talk for just a minute about the noncompliance reports which is going to be one of the six elements down here in establishment risk control, and the reason we need some help from you all today and tomorrow in trying to decide which NRs should rank the highest on determining the plant's ability to control risks, is because they're not all

the same. I use an analogy of traffic violations, and most of you heard that. So I'm going to change that today because you haven't heard the new one.

The new one is football because it's football season. And when you're playing a football game, you've got two teams playing against each other, and the rules are primarily so that no one gets hurt or at least reduce the risk of someone getting hurt. Football is not a 100 percent safe sport, and are also there so that one team doesn't get an advantage over the other team.

And we can look at plants the same way. So we have these rules. And if someone on the bench says some nasty word that the official hears, he may blow the whistle and stop and he'll provide a warning to the bench that he doesn't want to hear that again. Nobody got hurt. Nobody got an advantage. It's just not good.

Now if someone jumps off side or has motion, they'll blow a whistle, throw a flag, and they'll assess a five-yard penalty. No harm done. Nobody is going to get hurt by that. Somebody might have got a

little bit of an advantage, but probably not much. So five years, play the down over, no big deal.

If someone stopped holding in the line, on the offense, that's a little bit bigger deal. Nobody's going to get hurt, but the team gets a little unfair advantage. So we don't like that. So we assess a 10-yard penalty.

But now if we've got some infraction where there was danger of someone getting hurt, or there's danger of getting hurt, we're going to call a 15-yard penalty. That's roughing the passer. That's roughing the kicker. And why do we do 15-yard penalties for those two, because those people, right after they come to the ball or thrown the pass, they're vulnerable. They're at risk, and so we need to protect them. We need to do more to make sure this game is safe and cut down on the risk of injury. The same as we do when we do a little bit more in the plants.

Now if there's a little skirmish, a little scrimmage, they get up and go pushing and a little shoving, the officials, they don't like that either because that can erupt into a full blown fight, and

that could end in a lot of people getting hurt. So they're going to issue their own little NOIE. They're going to say, if I see that again, I'm going to enforce. So clean up your act today. You don't have until tomorrow.

Now, of course, in all of these penalties, the coach, management, always has the opportunity to ask for a review, called an appeals process in our industry. So someone else can take a look at what the action was and see if it was appropriate or not. The official, they also have the ability to do risk-based inspection during the game, because there are some players who are known to be a little bit dirty. They're known to push the limit. They're known to have taken quarterbacks out for the season with a bad hip. They're going to watch those people a little more closely to make sure the game is a safe as it can be and that those vulnerable populations are protected, and that no one gets an unfair advantage.

That's the NRs, help us. Tell us which NRs are going to cause people to get hurt. Tell us which NRs would be an unfair advantage if they're not

followed. We need your help on that, and we can do that together, I'm sure. I have confidence in it.

We've tried to be open and transparent in this whole process. We really have. We may have made a couple of mistakes along the way for which I've already publicly apologized. We've tried to make up for those errors, of perhaps not being as quite as open as we thought we would be, but today is kind of a culmination about openness and tomorrow and the next two days at NACMPI.

We've been meeting with consumers monthly since Barb and I took our jobs. We've been meeting with industry on a regular basis. We've even started having joint meetings with industry and consumers so they can all hear each other's concerns. We have extensive meetings with our own employees. We have had town hall meetings. We have had four focus groups. We've asked them to participate in this meeting, and also in the last few NACMPI meetings. The web page is open for their comments. We have been out in the field visiting with them individually and Barb and I even flew to Fort Payne, Alabama, and then

drove to Huntsville, so we could meet with Mr. Painter (ph.) personally, and spent the better part of the day discussing risk-based inspection with Mr. Painter, quite some time ago, to let him know where we thought we were going, and get his feedback at a very early stage in this process.

If we can work together for the next couple of days, and come up with constructive criticisms, it would help us build a better mousetrap. So if everybody has a chance to be heard and listened to, so we can all agree, and we need to move forward with this. I don't think there's any disagreement that we can do a better job. The disagreement is exactly how is it going to look, and we need to be -- we need to work together on that.

This meeting is about the Y-axis and X-axis. This meeting is not about inspection. This meeting is not about a single food safety agency. This meeting is about these two axes and if we limit our conversations to that, everyone will get more out of this meeting. If we drift off into something, like budget, which this does not affect, we're going to

waste a lot of people's time who won't get to say as much as they'd like to say. So I ask you all to keep it to the Y-axis and X-axis for the next two days. Make the best out of the time that we can because the other issues, we'll continue to have discussions on them on a regular basis, but they're not what we're looking about today.

I want to say two things. This is not about budget. This will not save the Agency one thin dime. This is not about FTEs. This will not cost anyone their job. It's just that the inspectors will spend more time in plant A than plant C, but that inspector's still got three plants to get to on a daily basis. I don't know how to save money doing that. The Secretary has said this publicly at a conference last week that some of you were at. When the Secretary puts his reputation on the line, he obviously expects us to back that up and we will. So we don't need to get in that discussion either today.

Lastly, before I wrap up and get to the meat of what we're here for two days, I want to talk about the face-mask penalty one more time. Face masks

haven't always been on football helmets. They came on in the late fifties, and when they did, some people began grabbing hold of them to tackle people and people's necks began to get hurt and some people broke their necks and some people even died from that particular use of face mask as a tool.

The NCAA naturally doesn't like that. They formed a committee to take a look at, here's something new, we need to make a rule to protect the runner. Now I can just imagine the first time they got together, somebody thought, we'll, it's a brand new piece of equipment. We ought to just warn them. Someone else is using it intentionally and they're going to hurt somebody, eject them from the game. Somebody said 5-yard penalty. Somebody said 15-yard penalty. And if they would have taken two or three years debating what the right penalty was, somebody would have died. So they came up with a 15-yard penalty. That penalty has evolved over time. They now say 5 yards for accidentally touching the face mask, 15 yards for grabbing hold of it and tackling. They made that change as the implementation became

more available, and we will make changes as we get more information but in the meantime, we need to take what we have today because there are people getting sick today and there are people dying from food-borne illnesses, and I don't want to wait another two years to polish this thing up to where it's perfect because it won't be perfect. Things change in public health, and if you don't change with it, you're moving backwards. And so I want to move with the changes, and I want to create a system that we can be proud of, that we can defend, that will save lives. It won't save a dime. It won't cost one person's job.

So once again, I look forward to sitting in the back and listening for the next couple of days, absorbing as much as we can, taking copious notes, taking all the information we can gather from this meeting, the people on the Netcast and also from those who might prefer to submit their comments electronically to our web page in an anonymous fashion. They will all be treated with an equal amount of respect and sincerity.

So with that, I hope we have a great meeting

for two days. I know some of you will be NACMPI meeting. So for those of you with that kind of perseverance for four days, I congratulate you and thank you, too. So let's go to work.

(Applause.)

MS. DILLEY: Before you retreat to the back of the room, we're going to have you sit here as well as Dr. Masters. We have until 11:00 Eastern Time, some time to ask questions about vision. This was the big picture that gave you the sense of the grid and the inherent product risk and establishment risk control in terms of the major factors generating the inspection level, and we'll talk more about that in different chunks. Shortly we'll talk about the two papers and concepts on the two axes. Right now it's an opportunity to ask Dr. Raymond and Dr. Masters about their presentations on vision and the big picture of risk-based inspection.

If you could please, we encourage the site, the off-site locations, to forward some questions that they have. We also would ask those of you in the room to use the microphones and identify yourself before

asking a question. So with that, for those of you who would like to ask some questions, to use the microphone.

(No response.)

MS. DILLEY: I can't believe there are no questions. You're thinking about it. All right. Please.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority.

MS. DILLEY: Thank you.

MS. KOWALCYK: I just want to go back to Dr. Master's presentation, in which -- well, first of all, I think I can say safely that risk-based inspection is an ideal that most people can agree with, and obviously with limited resources, we need to find an efficient and effective way to allocate those resources to protect public health from food-borne illness.

That said, of course, and I talked to Dr. Raymond and Dr. Masters many times, and my biggest concern here is the data. And I fully understand that we don't have two to three years to wait to have

accurate data, but certainly we need to start going down that road as quickly as possible. How many times has the Agency implemented a program with the idea of polishing it later, and it takes an awfully long time to get the polish out. The microbiological baseline surveys are a perfect example. Those were supposed to be revisited on a continual basis and have recently, 10 years after the fact, been started. So that's my big concern.

But I wanted to talk about Dr. Masters said that the Agency hopes to develop an algorithm, a mathematical model, in which to come up with a -- I guess a measure of risk to be used in this RBI system. How much data do you currently have, and what progress have you made in developing that model? Typically developing a model takes a very long time, and you have to go through not only collecting the data, developing it, and then validating the model. So I was just wondering how far along you were with that process.

MS. DILLEY: So generating the model and collecting data and how long -- how far along?

MS. KOWALCYK: Right. How far along is the development of the algorithm mathematical model and, you know, also when you're doing model development, you also have to update models, and I greatly appreciate the fact that you've put in Internet, high speed Internet access and things like that. I'm just a little concerned as to how far along are you in that process.

DR. MASTERS: That's a great question and a lot of what we'll be talking with Don Anderson and Matthew Michael's papers, because the pieces we see contributing to that algorithm are the inherent risk of the product which will be one component of the algorithm, and then in Don Anderson's paper when we talk about risk control in the establishment, there's many factors we see contributing and some of those are much further developed based on the last NACMPI meeting which is pathogen control for which the Agency has many components of that data already prepared to put into that algorithm. There is the NRs, and we are working through the process of validating which NRs which would be those of public health concern, and

Dr. Raymond expressed some challenge to this audience to help us get that finalized. So we have that piece of information.

We have consumer complaints which the Agency already has data on consumer complaints. And so the validated consumer complaints. Recall data that we would be looking at, Class 1 and Class 2 recall data. Then we're looking at food safety assessments, and questions that we'll be talking to you all and we're trying to get some additional information from this audience today, on food safety assessments any other design components we should be considering.

So we'll be asking you a variety of questions around the data we currently have, and how we should use that to finalize the algorithm. So I think it will become a little bit clearer through Don's presentation today, how we're trying to put that algorithm together with the data that we have as an Agency that we're trying to complete. Don, do you have anything you want to add briefly for the good of the cause?

MR. ANDERSON: This is Don Anderson

speaking. I don't know that I do right now. I will be giving a fairly in depth presentation, and I think that questions are going to come up not only about -- we really sort of got three algorithmic processes, because we're coming up with a measure of inherent risk. We're coming up with a measure of risk control, and then we have some way which may or may not be mathematical to bring it together into this matrix that both Dr. Masters and Dr. Raymond showed you. So I think it would be best to let some of that come out, and then to ask specific questions about things as we go along.

DR. MASTERS: And then, Barbara, if it's not clear on the second day after you've been through those detailed presentations, we have a time window in the second day that you can resurface this question. I think this will be a little bit clearer after we've walked through the presentations.

MS. DILLEY: Okay. Next question? If you can identify yourself and --

MR. MUNSELL: John Munsell from Montana Quality Foods and Processing, as well as the

Foundation for Equality in Regulatory Enforcement.

Dr. Masters, in your presentation, you made several very good statements in regards to you talked about the feedback, the feedback loop. Various components of that loop included pathogen testing, verification testing and traceable outbreaks. You also mentioned about the information needs to flow in real time or quickly, as immediately as possible. Also you made the comment that all Agency decisions would be driven by data, and I fully agree with all your statements.

But I think, how do we apply that to events, previous events? For example, since May of this year, there have been seven *E. coli* related outbreaks on ground beef, and of those seven plants, they're all small plants, and five of those seven plants don't slaughter. Well, since ground beef and *Salmonella* are enteric pathogens, that is emanated within the intestine, and it can be found on hides, and those nonslaughter plants don't have intestines or hides, how can we from a health standpoint, how can the Agency best protect public health. So my suggestion

is simply that a sampling -- the Agency's sampling protocol should be changed that would enable immediate of real time trace backs to the true source of contamination. You know, it's a concern amongst these small plants that they're being made responsible for pathogens discovered that came in from other facilities. So my suggestion is that the whole trace back effort has to be brought up to date.

DR. RAYMOND: Barbara, while you prepare your thoughts for the long question from John, I'm just going to jump on the end of it a little bit and say, first of all, Mr. Munsell, I agree with you. You know, the further we can go upstream, the further we can go up the river to stop the problem from occurring, the better. We don't want to deal with outbreaks. We don't want to deal just a small grinder that bought his product from someplace else. One of the things that this will allow us to do, that we can't do right now, you know, to recall or to take action against a slaughter facility. You have to have everything just. I mean everything has to line up just perfect. To do increased inspection, you don't

have to line everything up just perfect. If we have reason to indicate that the product came from a particular plant, that we can't 100 percent prove, we can still increase the inspection upstream.

DR. MASTERS: And to that end, where we're at today, John, I certainly welcome your input, and I know you sent some comments through our website, and we appreciate that. Where we're at based on our NACMPI meeting, the Agency currently keeps what we call our STEPS database, which is our supplier tracking system. So we do keep that database. The recommendation that we have as an Agency is to incorporate into the inspection level through the algorithm, the information from the STEPS database into the algorithm for inspection level at the supplying plants. So there is some level of consideration being given to incorporating that data into the inspection level at one level. You're suggesting that it be taken to another level. So we would certainly welcome that input, but just to let you know, there is some consideration being given to including that STEPS database that we do currently

have as an Agency.

MS. DILLEY: Next question?

MS. NESTOR: Felicia Nestor, Food and Water Watch. This is an important meeting, and I'm sure that the transcript is going to be available on the website. So I just want to make a couple of comments for the record because, you know, I just want the American public to know that Dr. Raymond's statements about what's going on in plants are not uncontroversial.

Before I say that, I want to say, I've been at some of the public meetings where Dr. Raymond has talked to inspectors, and I have heard the inspectors say, and inspectors have told me privately, they do currently have the flexibility to go from one plant -- to cover the bad plant and not spend so much time at the excellent plant. So they ask me why do we need a change? If the Agency is going to -- is pushing for this change, you have to be certain that this algorithm that you're coming up with is superior to the experience, the day-to-day experience of the front line personnel in those plants.

The second thing I want to take issue with is the scenario that inspectors are in the plants two hours a day. This year we alerted the Agency and, you know, I don't know why it's our job to alert the Agency, but we did alert the Agency that there was an assignment in the Northeast where an inspector was covering 18 plants. It's my understanding that in the focus group meetings, for RBI, that someone mentioned, some front line person mentioned that there was someone covering 26 plants in Philadelphia for 3 weeks. So I talked to inspectors around the country that are doubled and tripled up. They have -- they're covering 12 plants. That is not two hours in a plant.

When you have the inspectors so strapped, they don't have time to write the NRs, which it's becoming the NRs are going to be a very critical part of the Agency's data. So if the inspectors are not in the plant to write the NRs, we're starting off with, you know, faulty data.

Dr. Raymond, you say that this won't save any money, that there's going to be no decrease in FTEs. The fact of the matter is that the Agency is

allowing attrition to cut down on the money you spend on staff, and there is -- in effect, a hiring freeze in many, if not most, if not all of the districts around the country or at least there was until October 1st.

So finally to get to my question here, you know, you're talking about the transparency in this process. Again, you mentioned NRs at the NACMPI meeting in November 2005. You mentioned it at the May 2006 meeting. I just talked to a number of consumers today who have never seen a NR. I don't know whether the academicians that are on the National Advisory Committee have ever seen a NR. I don't know how, you know, in contrast, I would say that every industry representative here has seen at least one NR and has probably been engaged in, in depth discussions with the Agency for years about what are in NRs, why NRs should be written, how they're written, what the categories are. So to ask consumers to come to this meeting and go sort of head to head and give our opinion about what you should do with NRs, when you have refused to describe a NR, to provide a copy of a

NR, you know, it makes, you know, it questions -- it calls into question the legitimacy of this process. How you can ask people who have no expertise, who you're not willing to give any information, for advice on how those NRs should be used, you know, I just don't get it.

I spoke to one inspector who said to me, what, what do they mean by transparency? Do they mean invisible?

MS. DILLEY: Okay. So I heard -- I'm sure there's a lot of comments and questions in some of your statements, and the couple I heard in terms of the key pieces that Dr. Raymond and Dr. Masters may want to respond to is how does this all play out in terms of the inspector level? So how does the algorithm fit with what the inspector is doing in terms of inspection level effort? And then the other piece of it was transparency of data in terms of how decisions are being made and one what information and who has access to that information. So, Dr. Raymond, Dr. Masters.

DR. RAYMOND: I'll start out, just so

everybody in the room does know, that the NRs, samples of NRs are posted on our website and have been posted on our website for quite some time. We can find out exactly how many months or years, but if you want to look up what a NR looks like, it is on the web, number one.

Number two, there's probably some people in this room who don't know what a speeding ticket looks like, but they do know what the effect of the speeding ticket is, and I think most people in this room understand the effect of a NR. Now if I have one group tell me we don't write enough NRs, and I have industry telling me we write way too many NRs, we must be doing it just about right.

Now I won't argue if there are some inspectors that have too many plants on their circuits. We've had these discussions in public many times, Felicia. There are times that we have a shortage. Someone leaves, someone quits, one gets sick, and somebody has to fill in that slot. But just so everybody in the room does know, we did do a hiring freeze on October 1 of 2005, and we still have just as

many front line inspectors working today as we did then because we did not free front line inspectors. The 200 employees that we have fewer today than we did before are central office workers for the most part and district office workers.

MS. DILLEY: Dr. Masters, did you want to comment?

DR. MASTERS: The only thing I would comment is that in working with our in-plant employees, I think it is important for everyone in this room to walk away with a clear understanding that our employees do have the flexibility to work through their assignments today. What Dr. Raymond was sharing, when we have these conversations with our in-plant employees, they do have the flexibility to make some decisions today based on their knowledge of the in-plant environment, as to how they want to allocate their time. They get a PBIS schedule and if they have five plants on their assignment, they're going to be allocated that eight hours across those five plants. And they have the time to do unscheduled procedures. What the in-plant employees we have talked to have

shared with us is that, yes, they are trying to do a level of risk-based inspection based on their knowledge of the facilities. And we credit our inspectors for the good job that they are doing today.

What the employees who have talked to us have said is, it takes time, knowledge and experience to make some of those decisions, and some are able to do it more quickly than others based on the time they have and the experience they have in those facilities. And when someone comes in on relief, they don't have that same time, knowledge and experience to make those kinds of decisions.

What we're suggesting by trying to work through algorithms and to work with an objective system as opposed to a subjective system, is to give our inspection program personnel tools to allow them to have an additional piece of information that takes away the initial first, that piece of information that they have to start with. That wouldn't likely preclude them from still using the knowledge that they have of each operation above and beyond this tool that makes that first cut for them. So when they go in on

a relief assignment, they have an objective cut, so that if you have an A establishment and a C establishment, and they have to make decisions, for example, if they are doubled up, where should I go first? I'm on relief, and I've never been into any of these plants before. We need to give our inspection program personnel all the tools we can to make their jobs easier, and to get them into those establishments that need them to do the inspection the most.

And then over time, when they do unscheduled procedures, obviously they're going to use the knowledge that they have of those operations to continue to do those kinds of things.

But I think if I had to answer the question to an inspection personnel, why do I need this, I think this is just an additional tool above and beyond the innate knowledge that they have gained over time that is very beneficial. We want to provide them another level that allows them to have even better tools when they're trying to make these inspection decisions at the in-plant level.

MS. DILLEY: Okay. We have five minutes

until the break, and we have four people standing at the microphone. So if we could take those questions briefly, and then have some time for response. We also recognize that this was a challenge to begin with in terms of doing this only in 20 minutes. So we'll see if we need to come back to some of these issues a little later this afternoon or tomorrow, but please, why don't you go first, and then we'll move through this as quickly as we can.

MR. SEWARD: Skip Seward, American Meat Institute. I just want to applaud both Dr. Raymond and Dr. Masters for the effort here, and we look forward to working with you as part of the industry to make this a reality. So thank you very much for the public meeting and for your comments.

Many establishments produce multiple products, presumably with different inherent risk profiles, and the risk control surrounding those might be somewhat variable. So could you comment briefly, if you can on how you see the management of those kinds of situations on a risk-based inspection program? Thank you.

DR. MASTERS: The question as I understand it is a plant produces multiple products, and the risk control varies around, not only does the inherent risk vary, but the risk control varies, and there's multiple thoughts. One extreme might be that the inspection level would be geared toward the product with the highest inherent risk, and the worst risk control, and so -- but we'd welcome feedback from everyone participating here as to whether we should have multiple inspection levels or gear it towards the worst case scenario, and that's one of the things we'd like your feedback on, and I think you'll see that very question in one of the presentations later today.

MS. DILLEY: Please identify yourself please?

DR. O'CONNER: Dr. Bob O'Conner. I work at Foster Farms, the Director of Food Safety and Quality.

I also applaud the efforts that both of you and the agencies are moving towards. I think accuracy of data is a very good point, and I would definitely like to see that in the program.

I do want to return real quickly though, to

the sports analogy, Dr. Raymond. I appreciate it. I think it's a good analogy. My one point though is that I think we all know in football or soccer or whatever sport, there are some referees who we would label as bad referees, or bad refs. And if you end up with a game, if you're a soccer coach on Saturday, and you see that same referee who made bad calls in your three previous games, you know, you kind of start out the game on a bad note.

And I guess I would like you to recognize that when it comes to NRs, actually here's one. NRs can be very subjective, and I think the Agency realizes that. I think consumers should realize that as well. When we discuss NRs, I think that's one thing that needs to come out on the table is how subjective a NR can be. And just like a referee, you know, calling a foul or penalty in a game, you get the same effect with NRs. So I think we need to be very careful how much we actually judge an establishment based on things like NRs. For instance, the number of NRs received by an establishment can be very deceiving.

MS. DILLEY: So how decisions are being made and what kind of appeals process.

DR. O'CONNER: And in the appeals process, we don't have instant replay.

MS. DILLEY: Right.

DR. RAYMOND: But you can criticize in the press. If you're the coach, you'll get fined. But we do recognize that, Dr. O'Connor, and that's one of the things that a year ago, when I came on board, when we started looking at this, I realized the human element. We had to try to reduce it as much as possible, but we can't eliminate it any more than you can eliminate the human element of the officials. If you've got an official that continues to make mistakes in your mind's eye at least, you should ask someone to take a look at that, too, the same as they do with our inspectors.

One of the reasons we're trying to pare down the NRs that really count is to get the ones that are just the most obvious. I mean if the temperature in the chiller is not the right temperature, the temperature in the oven is not the right temperature,

there are some things that are irrefutable. Microbiological sampling eliminates human error. We're trying. We recognize that. We recognize that as a significant element that we're trying to -- and that's one of the things that we want to hear about, how do we help reduce the human element. We're going to have humans out there writing NRs. How do we help make it a fair playing field?

MS. DILLEY: If we could go ahead and have the people standing at the mics state your questions and then maybe if there's some duplication, then we can address them, in the time, in the couple of minutes.

MS. BUCK: Hello. My name is Pat Buck, and I'm with Safe Tables Our Priority, and my question is for Dr. Raymond. And, Dr. Raymond, you know, I don't have all the expertise that I really need but you have that grid there with your levels, and I understand, you know, how it's put together with the X-axis and the Y-axis, but what I'm confused about is will there be any, you know, maximum limits which, if you go beyond those, what will then happen? And if there are

maximum limits, how are you going to go about enforcing them? Is that a crucial component of this grid that there will be limits set?

MS. DILLEY: Okay. So the limitations? What are the implications of reaching those limitations and then enforcement.

MS. BUCK: Yeah, and how will we reinforce them.

MS. DILLEY: If we could have the other three people that are standing at the mic just put their -- put your questions on the table, and then we'll come back to those and make sure those are addressed. So, please, go ahead.

MS. MUCKLOW: Rosemary Mucklow with National Meat Association. I always hesitate to disagree with the Administrator in public because it would get me in trouble in the future. But I would suggest that the early efforts to systematize came through the actions in the 1980s with the passage of the Processed Products Inspection Act in 1986, that set up PBIS. And it was a major first step before we got to HACCP. And it assigned a very systematized work process to

inspectors. Before that, they just used to walk around, and you had the guy that watched the ceilings and the guy that watched the floors and so on. We made huge improvements then.

Further, I'd like to suggest, NRs are very publicly available and are frequently requested through the Freedom of Information Act. I'm not suggesting that that activity increase, but they're not an unknown quantity out there, and the union organizing effort is often based on NRs and extracts from the same.

We applaud the Agency as an organization, as my predecessor, Skip Steward, this is a major step forward and that's why I've come all the way from the West Coast to be here today and to contribute. Thank you very much.

MS. DILLEY: Thank you.

MR. KOWALCYK: Michael Kowalcyk, from Safe Tables Our Priority. I'm also a current member of the National Advisory Committee for Meat and Poultry Inspection.

In past committee meetings, we've talked a

lot about data and obviously measuring establishment risk or product inherent risk, you're bringing in data from various sources, and I would like to see from the Agency, if you have anything available. Your current vision is to have that data, how you see that being structured.

In my professional life, I work in database marketing, and I know that any model you build is only as good as the data that goes into it, and a key component of that is the management of that data and the quality assurance of that data to make sure what you have in your system is accurate and timely. I don't know if the Agency has anything right now as far as an ERwin Data Model or some type of schematic that would illustrate what your vision is and how you would manage these massive amounts of data because it looks like a very onerous task.

MS. DILLEY: So data collection, management modeling and where you are and your vision for that, the limits implications and enforcement piece. Okay. So we can -- would either one of you want to respond to those briefly, and then we'll take a break.

UNIDENTIFIED SPEAKER: One question if I may?

MS. DILLEY: One question to throw in. Then why don't you go to the microphone and ask it. Oh, you've got one.

UNIDENTIFIED SPEAKER: He has to read it?

UNIDENTIFIED SPEAKER: Yeah.

MS. DILLEY: Okay.

UNIDENTIFIED SPEAKER: This question is from Neal Westgerties (ph.), USDA. The X-axis establishment risk control appears to be a measure of industry control of risk through the perspective of FSIS. Is this correct? If correct, what can be done to, one, consider risk control due to industry's efforts, that is an industry program perspective? Perhaps an evaluative measure of industry programs? Two, can the proposed X and Y matrix assist in FSIS' response to identified risks? And, three, can it enhance our ability to identify in-plant risks?

DR. RAYMOND: Well, I'll try that one first, and then we'll go backwards for those on the net. That's a good question, and I'm going to throw out

another question because of that question. One of the things that we have been discussing and discussing and struggling with a little bit that we hope to get some guidance from folks today and tomorrow, is when we look at inherent product risk for instance, poultry carries a certain risk. We know what the *Salmonella* rates are on chicken carcasses. How do you then translate that risk to cooked, ready-to-eat chicken product? Is that the plant's control? Is that inherent control by the plant by cooking? Or does it become the inherent risk of the product? There's certain things that some plants use different chemicals in their Jell-Os, et cetera. Is one of those better than another one as far as the plant's ability to control risk? And those are some things we do want to talk about, the NRs and the microbiology for testing and sampling are there, but where do we put in a plant that has a $1 million piece of equipment that detects a pinpoint size of feces on a carcass compared to the plant that doesn't have that particular piece of equipment, or maybe that's not a good example, but there's lots of examples like that.

Plants are innovative. Innovation sometimes it's helpful. Sometimes it turns out not to be worth it. But how do we put those in there on that X-axis?

So it's a good question. I don't have an exact answer for that. Do you have anything to add on that one?

MS. DILLEY: Okay. So either data or the limits implications and enforcement.

DR. RAYMOND: Pat Buck had asked about limits on the grid and, Pat, I'm going to take the license here in interpreting what I think you were asking about.

On the inherent risk of the product, it would be product categories ranked 1 through I think it's 23, but it may be 24. There's a certain number there that they'll be ranked. I mean it's not like the top one gets thrown out and we'll never eat it in America. We just need to make it safer.

As far as the plants, as you move across from the left to the right, I think your question is, at what point do you say that's the limit? After that, the plant can't operate, and I think that's an

excellent question. I had not thought about it from that standpoint. I don't even have -- I can't even begin to give you an intelligent answer other than that's -- I like the question. It's one that needs to be looked at. Somewhere along the line, there should be some kind of limit to say, hum, this is going to generate a food safety assessment. This is going to get an EIAO officer into that plant and, you know, to see if we need to do the next step, the NOIE, et cetera, et cetera. So I think it's a good point, and it's something we'll certainly take into consideration. Is that -- was that the gist?

MS. BUCK: Yes.

DR. RAYMOND: Okay.

MS. DILLEY: Dr. Masters, any on data or --

DR. MASTERS: Yeah. First, Rosemary, you didn't disagree with me. I didn't just get into depth on my history lesson there. So I wouldn't disagree. We've got more systematic with PBIS. Thank you.

On the data, again, we are going to -- Michael will get into the data in the next two presentations. If we have not laid out a complete

plan for everybody in the audience to understand where we're going after we've heard from Matthew and Don, the Agency wants to make sure where we're going. Data is driving the system. So we will have a chance tomorrow afternoon, if people feel like they need more detail, we can try to bring that back tomorrow if people still feel like that's a topic for that general discussion tomorrow. Most of it is in Matthew and Don's papers and presentations, and what they'll be able to answer. If there's still a general sense, we need to lay more out in that area of data and what we're doing with the data, that would certainly be a topic we can spend some more time on tomorrow afternoon. We want people to leave here with the clear perspective of what we're doing with our data.

MS. DILLEY: Okay. So with that, it is now 10 after 11:00, and we need to stick to the 15-minute break. So we will come back at 25 after and start with the product inherent risk presentation right at 25 after. Thank you.

(Off the record.)

(On the record.)

MS. DILLEY: A couple of things before we turn it over to Kathy Grant, to facilitate this portion of the program.

This morning, until lunch, we have two presentations, like we talked about this morning. We've got four big pieces that we're tying to present FSIS' thinking and have some opportunity for questions and comments, and then also time for discussion, and the big pieces of that are the product inherent risk and establishment risk control, both the axes this morning already. We're delving more deeply into those, and providing a richer discussion of those in terms of presentation, also time for questions and answers, after each presentation. That will go until lunch, at 1:15. By the way, at the registration table, there's a list of suggested restaurants just for your convenience, to look over if you need that that are relatively close to the area. We will get started right at 2:30 this afternoon. So we hope that you can go to someplace nearby in order to be back in time to start right at 2:30.

Also, I'll just mention to the remote sites,

we appreciate your identifying yourself when posing a question. We also need you to please add to the e-mail your location, and part of that is helpful to us so that when we select questions or comments from the remote site, so we be sure we're trying to get a sprinkling from all over the country. So if you could supply that information that would be helpful to us as well.

Also at the registration desk is a pair of sunglasses that apparently somebody left. So if these look like yours, or if you're looking for a new pair of sunglasses -- if these are yours, they'll be up at the registration table. So you can get them there.

So I will turn it over now to Kathy Grant.

MS. GRANT: Okay. So we're going to start now and have two presentations on the two papers beginning with the paper on product inherent risk, and then the second presentation will be on measuring establishment risk control.

These handouts are in your packet. We did not have Dr. Masters' or Dr. Raymond's presentations available to make copies to put in your packet.

However, they will be on the website. So you will have access to them. These are in your packet. The first one looks like this. It says Measurement of Inherent Risk in Processed Meat and Poultry Products.

So let's start and have Matthew Michael introduce himself and give his presentation, and then we'll have at least 15 minutes for questions and answers at this time on the questions. We'll have more time later on.

MR. MICHAEL: I'm Matthew Michael, and I'm going to talk today about our current thinking on inherent risk and our work so far in developing a measure of inherent risk. I'm also going to throw out a few of the major outstanding questions we have in developing the measurement.

In my first slides, I've covered issues that Dr. Masters and Dr. Raymond already talked about, but I'm going to go over them again, to provide a specific context for my presentation.

Risk-based inspection. FSIS is developing a new system of inspection which will better allocate Agency resources to control the risks posed to the

public health by meat and poultry products.

RBI and Measures of Risk. Allocation of Agency resources under risk-based inspection, or RBI, at each inspected processing establishment will rely upon two measures of risk.

Inherent risk measure. That's what I'll be talking about today. It's a measure of the inherent risk posed to the public health by each type of processed meat and poultry product, assuming typical process control by the producing establishment.

And also we have the risk control measure, which is the measure of the amount of actual risk control achieved by each establishment, and Don Anderson will be talking about risk control.

I think what may or may not be clear from this definition is that we plan to calculate one or more measures of inherent risk per establishment. How many yet is to be cited, and it was actually the subject of a question that came up earlier. So the idea is that we would calculate measure of compliance and then determine allocation of resources.

Measure of inherent risk provides a relative

value for the risk posed to the public health by each category of processed meat and poultry product produced in an official establishment. Again, we're only talking about processing here.

And it takes into account the species of animal processed, the type of processing which those two components together make up the hazard component, hazard part of our equation, and also takes into account production volume which is our exposure component and the production volume would be collected and used from each official establishment.

The inherent risk formula that we're developing, is based on the general equation that's used to calculate risk which is hazard times exposure equals risk, whereas it's written here, hazard component times component exposure equals risk measure. In our case, our equation is species process value times volume equals inherent risk. And we combine species and process into a single value which represents hazard, the hazard component, and we combined it into a single variable to account for the different risks that products might pose in

combination. For example, all things being equal, raw poultry might pose more risk than raw pork in some situations. If we separate the two species and processes, we had earlier attempts at this, we get double counting and all sorts of things, and a lot of this development work is explained in the paper that's on the Internet.

So we have the species/process value, which is a hazard component, and then we have volume. Volume, we've used as a proxy for exposure. We consider volume -- we're going to assume a direct relationship between volume produced and exposure to the inherent risk posed by the product.

So next I'll talk about how we developed the values for the hazard component or the species/process value.

We determined the initial values for 24 categories of species/process combinations through expert elicitation. Expert elicitation is a method that's commonly used to supplement, integrate and interpret an existing qualitative and quantitative data into a framework for making decisions. The use

of expert elicitation dates back about 20 years. The cites example of its use is probably a Nuclear Regulatory Commission expert elicitation conducted in 1989, where they collected expert opinion regarding risk of accidents at nuclear power plants, some of the most famous -- cited.

A more recent one, that's similar to this one, is EPA conducted an expert elicitation on the effective changes in the level of particulate matter in air pollution on mortality, and notably, the National Research Council actually recommended that the EPA use expert elicitation to develop this data. That is expert elicitation is a little more complex than ours. They're actually estimating bounds of statistical uncertainty but it's a very similar type process, and I think when you review the literature and see that agencies have conducted hundreds of expert elicitations over the past 20 years, in cases where you have a mix of data or you have incomplete data, and you want to consolidate it and use it for decision making.

So we conducted an expert elicitation to

collect values for 24 categories of processed product.

The experts themselves, with whom we talked to, were 23 experts from academia, the Federal Government and industry, and we asked them to score the 24 categories, species/process categories, to reflect the relative risk of illness per serving that each poses to consumers. Now let me just say, it says we asked 23 experts which is true. Actually, we had a contractor conduct this elicitation, and initially the list contained 32 experts. Nine did not respond. So 23 of those that responded. And a list of the experts has been posted in the inherent risk paper that's on the Internet. It's been on there since July I believe.

We asked the experts to provide both the relative ranking of inherent risks and scores -- inherent risks and scores that reflect -- we asked them to provide both the ranking of inherent risks and also scores that reflect a proportional risk. So we said, for example, among these 24 products, pick the one least likely to pose a risk of illness per serving and give it a 1, and then pick the product you feel is

the riskiest and give it a score that is proportionate. So if you think it's 10 times riskier, 100 times riskier or 1,000 times riskier, give it that number. Don't fill in the numbers in between, and by doing this we hoped to get the ranking of risk among these products and also a notion of proportionality of risks.

Experts were given a specific set of assertions, provided to insure that they would each calculate their scores in the same context and also that the scores would be comparable when we used them. I already mentioned, we asked them only to look at risk of illness per serving. We didn't ask them to consider severity of illness for example. We also didn't ask them to consider further processing. We asked them to think about products that would be a finished product when it left the plant, reached the consumer. We did ask them to assume typical processing by the consumer which is good or bad. There's a number of assumptions we gave to the experts to sort of constrain the way they gave us scores and that was necessary to make sure that we get comparable

data. But we asked them to make those assumptions and not consider those factors does not mean we're not going to consider those in creating the measure of inherent risk. And some of my questions pertain to how we work these other factors into the data we have already such as severity, further processing, et cetera.

This is a chart and it's of the median values of the experts per product type. It's also presented in some of the information on the Internet. I think this chart is slightly different in that it's been ranked in descending order. And we see that the raw, nonintact products are up, the high median score was a 10, ready-to-eat products in a bag without subsequent exposure to the environment, they're down at the bottom and the products in between. And then given the assumptions that we gave the expert, this is about what we would expect assuming they're risk of illness per serving, and not severity and not further processing, et cetera. So these are the median scores, and that's what we've been looking at. We've been using the median as measurement of central

tendency, but I have a question about that later whether we should do something else.

And then if you remember back to my earlier slide, our equation which is species/process value times volume, we are collecting volume data right now from -- or we're about to. We will shortly. Our inspection personnel, we're going to collect data from them, in each plant, to give us estimations of volume data for each type of processed product in each establishment, and they're going to give us various ranges of volume, production, amount of production per day, et cetera, and then we're going to use that data -- we're going to use that data to create the exposure variable in our equation.

So now I'm going to move onto some of the outstanding questions we have about our developing equation. The first question has to do with how we've measured the expert scores we've received. We have tentatively decided to use the median of the expert scores in the inherent risk algorithm. Is there an alternative we should consider?

And I will say, we have chosen the median

because there is some literature on expert elicitation that suggests you should use the median. There's been some studies done that show that experts have a median in mind when they participate in expert elicitations, and thus when you aggregate their answers, if you use a median, you probably get closer to what they were considering but, of course, there are other elicitations where you use the mean or the geometric mean, et cetera.

The second question is about thermally processed, commercially sterile products, typically canned products. We didn't include them in the elicitation for scoring, and the reason being that our own in-house people felt that experts would believe they were so much safer than the next safest product, that we would get a very skewed range of answers from our experts and would make it less useful. But, of course, we do want to include them in our measure of inherent risk.

So exactly how should we fit them into the range of species/process values now? And one option would be you could say it was the safest and fit it in

with a 1 and adjust everything else accordingly. You could do a number of things.

And here's a question about some of the assumptions we asked the experts to make. To better ensure comparable expert data, experts were asked not to account for any processing after product leaves the establishment of origin. For example, no cooking at a second establishment or no preparation at retail.

But, of course, this is very typical. A lot of product is further processed in an establishment or produced at retail, and we do want to account for that when we conduct risk-based inspection. The question is, how do we fit that into our algorithm and how do we account for that? So if a processed product is to receive further processing at another establish, how should we account for its inherent risk?

If you have a product, you're producing ground beef, and you know it's going to go to a plant where it's going to be cooked to be ready to eat, which value should we use for that first establishment?

If a processed product is to be further

processed at retail, how should we account for its inherent risk? You know a plant that's producing product that's going to be cooked at retail or by an institution, what value should you use for that plant, or how should you adjust the value it's been given, given the product it's producing?

The fourth question is about our volume. How do we translate the volume data we collect for each type of processed product produced at each establishment into an exposure variable for that establishment? And we're going to be asking inspectors to give us estimates of volume, of production, for all the products produced at these plants, and it's going to give us a number of ranges of volume per type of product per plant. It's a lot a lot of data. And we want to translate that into a factor, the second half of this equation. What's a good way to do that?

And here's a question that was asked previously. Given that most establishments produce more than one type of product, how should inherent risk data for each establishment be presented? We

could do a worst-case scenario, as Dr. Masters mentioned we could. We could do separate values per product. We could do an average or an aggregate, where you're going to get some strange numbers if you do that. You have plants that produce, as you all know, a wide variety of products but this is an important question that we need to answer. How will we present the inherent risk data for plants that produce a variety of products?

And my last question -- severity of illness, and as I mentioned, we asked experts to simply not to consider the severity. This is one of the things we asked them not to consider. The reason being, there's a lot of uncertainty about severity. There are also a lot of factors that some experts might consider that others might not. Some might be thinking about valuation of life and others might not. Some might be looking at different data, et cetera, and, of course, we do want to consider severity of potential illness.

So how should we account for severity of possible illness in calculating the risk inherent to each type of meat or poultry product?

And I believe that's the last question. Yes.

MS. GRANT: Okay. So as I said, we have about 15 minutes, a little bit more than 15 minutes right now, for questions about his presentation. After we finish this part, we'll also have a presentation and about 15 minutes on the other paper, and then later, we'll have an hour to, you know, ask more questions or raise more issues. So if you could think of these 15 minutes as really trying to clarify anything you didn't quite understand about what was said, and we can have a fuller discussion later. And then in the small group discussions, at the end of the day, then we're going to delve into each one of these questions and come up with some answers and see your perspectives on that, how to answer those specific questions.

So again, if we could line up, identify yourself, remind the remote sites to identify where you're located when you send us a question. I actually didn't see who lined up first, but let's start over here.

MS. SMITH DEWAA: This is Caroline Smith Dewaa with the Center for Science in the Public Interest, and I think you're going to find there are a number of questions on this. I want to make clear that I think the exercise is a good one to try to rank meats by the inherent risk posed by those.

I do have concerns that this expert elicitation may not have quite achieved your objective. And one of my questions is in the -- in advising the experts of how to actually do the ranking. How did you advise them? Because I'm just looking at their maximum scores, and one of them -- many of them is 10, is the maximum, the riskiest product was ranked 10. Some of them it's 5. We have one panelist who had 20, another had 25, one had 300,000 as the maximum score, one had 2 -- no, 300 million, another had 200,000. I mean it's -- we have such -- it seems to me very difficult to compare results between the experts when clearly the experts weren't given direction on how to, how to evaluate, how to rank the products so that it could even be comparable between -- from expert to expert.

MS. GRANT: Matthew, before you -- I notice that many of you are realizing that you have in your packets an explanation of the elicitation process, the list of experts, et cetera, for those of you who might not have realized that. I'm just pointing that out to you. Go ahead, Matthew.

MS. SMITH DEWAA: By the way, on pages 1 and 2 of page 27, if you want to see what I'm looking at, I'll be happy to hand it to you.

MR. MICHAEL: The contractor in this case went over the instructions with the experts in groups and in paper, and followed up with them. They did follow up with the two you mentioned. There were two outlier experts that had extraordinarily high scores, and the contractor followed up with them to make sure that they in fact did understand the instructions, and they did. They just had very diverse opinions.

In the case of the other scores, we started a statistical analysis, a cluster analysis, and we see some pretty good agreement among these experts. The different between 10 and 100 might seem huge, but it's not so much -- when you put it in context of the guys

who scored 30 and 200,000, I do consider them to be outliers in this group, that's not to denigrate their opinions, but they're just not obviously within the consensus of this group.

We're fairly confident that the experts did receive good instructions. I think there's a diversity of opinion on these, the risk posed by these products, and we -- one of the reasons we asked them to make some of the assumptions when they were scoring them, was because we expected some diversity in the scoring.

MS. GRANT: Sandra.

MS. ESKIN: Hi. I'm Sandra Eskin, and I'm a consumer member of the National Advisory Committee on Meat and Poultry Inspection. My question goes back to also the expert elicitation. You said you gave them a number of assumptions. Again, one of the questions that you have posed to us deals with how to factor in severity of illness. My question goes to among those assumptions, was the assumption that the risk was to a healthy, middle-aged person? Did any of these -- do you know if any of these experts or did you direct

them to consider the fact that for many groups in the population, children, older consumers, people who have -- who are immune suppressed, food-borne illness is much more of a danger to them. Is that all factored into your expert elicitation?

MR. MICHAEL: It was not factored into the expert elicitation. We did ask them to assume that the people consuming the product would be healthy adults, and we did that intentionally. We planned to factor in severity knowing that the young, the old or the uncompromised are most often affected. But we were really constraining it to try to get comparable data from the experts. The more things they have to consider, for example, you know, maybe some proportion of these consumers are old, maybe some are uncompromised, it's less likely we're going to get comparable data. So we really see these experts as a starting point, and the questions I've asked are on things we need to add in to modify these values to make them reflect severity, to make them reflect further processing, et cetera. We're fairly confident that the numbers are consistent within themselves.

MS. ESKIN: Well, again, I think that is a factor that must be considered.

MR. MATTHEW: Absolutely.

MS. GRANT: Skip.

MR. SEWARD: Skip Seward, American Meat Institute. Matthew, when it comes to the production volume, have you developed a concept further -- far enough yet to have an idea of how you're going to assign a numerical value and how that's going to be broken down or right now it is just a concept?

MR. MICHAEL: No, we've talked about some things, different kinds of rankings, different kinds of proportion but, no, we're still in the process of beginning to collect the data.

MR. SEWARD: Okay. Thank you.

MR. WALDROP: Hi. Chris Waldrop, Consumer Federation of America. Going back to your expert elicitation again, I notice that you said it was made up of academia, Federal Government and people from the industry. I think an element that you're missing here, especially for a public health program, are academic and public health universities, consumer

groups, medical doctors, public health officers, people who come at this from a different perspective, maybe give you different risk rankings or you could at least sort of compare them to what these other groups came up with. And I think also because it's a public health program, it would bring sort of a valuable perspective that needs to be considered when you're bringing this final -- when we come out of the final ranking of risk.

MR. MICHAEL: Okay.

MS. GRANT: Go ahead, Barbara.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority. I also wanted to make a comment on the expert elicitation. One, I have a few questions about the sample size, and how that was determined, just because 23 does not seem like a very big number, and especially when you ended up with outliers and if you look at the distribution, you had probably five or six people that were using clearly a different scale, and when that's one-fourth of your overall data, then that presents a problem.

The other thing is on your slide, talking

about species/process values, the second bullet, it says expert elicitation is commonly used to supplement, integrate and interpret existing qualitative and quantitative data into a framework for making decisions. What quantitative data is the Agency using to integrate in with this expert elicitation to assign risk factors for the different categories?

MR. MICHAEL: With regard to your first question, we did an initial culture analysis on the agreement with the experts, and we're continuing that and, you know, depending on how that comes out, we can further discuss how best to use the values, and it's one of the reasons we asked about using the median value. It's a problem that commonly comes up in expert elicitation is what measure of central tendency do you want to use.

In regard to the other data, I think we plan to use whatever's available and answer at a minimum some of the questions I posed, how do we factor in severity, how do we factor in further processing, how do we factor in intervention? For example, some

products subject to *Listeria* is processed under different processes, and there's data on that. I know there's analysis data available and we plan to use that. How exactly we plan to use that in conjunction with these numbers, it has not been determined. For example, some products subject to *Listeria* is processed under different processes, and there's data on that. I know there's analysis data available and we plan to use that. How exactly we plan to use that in conjunction with these numbers, it has not been determined.

MS. KOWALCYK: I'm sorry. Just one more follow up question to that. It would be very nice to know exactly what data you have in your possession now and what data you're going to be collecting in the future, fill in those blanks.

MR. MICHAEL: Okay.

MS. GRANT: I think everybody in this line was up before.

MR. KOWALCYK: Michael Kowalcyk, Safe Tables Our Priority. I just wanted to follow up on the gentleman's question about the volume measures. It

seems like right now in the paper that was presented on the website, it's very a very simplistic measure, 2, 1 1/2, 1. I'm glad to see the Agency is investigating how they're going to account for that.

Another concern is where you have an establishment that processes more than one species in a plant, let's say you have a plant that processes two species, if the Agency is taking a public health approach, shouldn't it be recommended that they default to the riskier of those two species, the riskiest of multiple species in computing the inherent risk score because of cross-contamination issues, process issues. Those are very complicated issues. So I hope the Agency is aware of that.

MR. MICHAEL: It could be. As you probably know, there's just such a variety of types of plants for processing of products. We even have plants that grind raw product, ship raw ground product and ship canned product. And so using the volume of those products, it's a proxy for exposure, and then trying to factor them in, you know, it's very complicated. I think we'll consider all of those.

MS. GRANT: Okay.

MR. REINHARD: Bob Reinhard, Sara Lee Corporation. My question is related to what was put out in the July 19, 2006 information on risk-based inspection related to the Y-axis. There were questions on plant interventions that are not being asked and I assume that it's going to be open for discussion in the breakouts. So I'll go ahead and allow that to happen at that point in time. But there were questions that were put out, and it is important that we comment on.

My second comment is related to volume, and it is, it is true that an exposure will have a public health offense. I don't believe, and we don't believe in this industry, that volume should play a part on necessary the Y-axis, that that's a plant control volume, and if you took that out and considered moving that to the X-axis, you could differentiate and get a similar product based on volume along the X-axis, knowing that that directly affects public health and exposure, and not cloud the issue on the Y-axis of which products are more or less risky.

And then my second comment related to that is the use of attribution data wasn't used, and that we assume and the instructions were that the expert panel use that or consider that when looking at exposure and illness per serving, we would encourage FSIS to go back in the future, if they continue to use this model, and improve it using the attribution data out there on actual public health --

MR. MICHAEL: I think -- with regard to your first question, I think Don is going to talk about intervention in his presentation on risk control. The second comment is very interesting, and the third one, I assume, I'm certain some of the experts did consider attribution data. You can see it from the Excel charts we put on the Internet that some experts did record their comments explaining why they gave certain scores. Others did not.

MS. GRANT: Okay.

MS. DONLEY: I'm Nancy Donley with STOP, Safe Tables Our Priority. I just have an issue to raise to everyone as far as the volume component. I'm a little bit concerned that, you know, that with what

was brought up here, where you have multiple types of product going through a plant, that's one issue, but I will say this, that I don't understand where if we're looking at product, as purely product, that a volume works into it at all because pathogens frankly do not discriminate based on plant size or amount of volume that goes through the plant. I understand how with a plant that's producing, you know, 100 times what another plant is, as if there's going to be an exposure down the line to the public, but it does not factor into the inherent risk of the product itself.

And it's just a -- I was sitting here thinking, if you have a product that has a very high risk factor, but is coming from a very small plant, let's just say, and then you have a plant that is making a product, a fully cooked product that is not exposed to any -- that's cooked in the bag, but has a huge amount of volume going out of there, how do you weigh that?

MR. MICHAEL: I think, you know, there are numerous combinations of scores you could come out with, both within the inherent risk measure and in

combination with the risk control measure, and I think what you spoke about in regard to hazard and volume is true, and that's probably why both of those factors are in the equation, hazardous. It takes care of the inherent hazard to public health and serving volumes per plant.

MS. GRANT: Let me move over to this side.

MS. SCOTT: Jenny Scott, Food Products Association. And this is back to volume again. Clearly this is a contingent issue, and I'm wondering if the agency has considered using volume as a Z-axis in a three dimensional approach. If you think about the brand that was laid out there, volume really has the biggest impact on public health, if we're talking about an inherently high risk product that has very poor controls and has much less of an impact if you're down at that other corner. So I'd like to suggest you consider that approach.

MR. MICHAEL: Thanks.

MS. GRANT: Okay.

MS. BUCK: I'm Pat Buck from Safe Tables Our Priority, and I was just wondering if you could

briefly outline for us, especially those of us that don't understand, the whole formula, how you came up with the -- what did you use for your hazard control and your species/process? Did you actually have raw data that you used on this or was this something that is just sort of a, you know, conjecture, you know, like an expert opinion that we know species has some problems. So those two issues then are considered higher risk. I mean what did you -- how did you actually come up with this formula?

MR. MICHAEL: The instrument we gave the experts which is posted on the Internet is the 24 categories of products, and I think with the exception of canned product which we excluded intentionally, we tried to account for combinations that would reflect every type of product out there. We couldn't get as specific as one might like just because you have to have some generality to have reasonable numbers but I mean we had 24 products. So we have raw, nonintact chicken -- poultry, raw, nonintact beef, et cetera. And then also the experts were given lists of sample products just to make clear what we meant by each of

those categories.

MS. BUCK: Was there any attempt to make or to be made to see how much of this product was actually produced of these various subtypes so that when you would consider in, you know, the other factors, it would --

MR. MICHAEL: That's what we're doing now with the -- survey.

MS. GRANT: Okay.

DR. HENRY: Craig Henry, Food Products Association. My question is relative to the experts. Was your intent to get a randomized opinion about the risk associated with various products or was it targeted at a specific set of experts based on their credentials that are widely recognized and accepted? And then secondly, tied into that, does the Agency have prior experience in applying expert elicitations to other regulatory actions and/or risk assessments?

MR. MICHAEL: In regard to your first question, no, we didn't want to randomize opinions. We wanted expert opinions, hence the name, and the experts were picked based on their expertise in

processed products, PLG, the factors listed in the paper. There was an expert elicitation used for a very small *E. coli* project by OPHS years ago. There was a previous expert elicitation used in this project in 2001, and it's been replaced by this one. Other than that, I don't know of our Agency using it, though there are multiple examples of other federal agencies using expert elicitation to make policy. The ones I listed, quite a few from Nuclear Regulatory Commission, EPA, NOAA has done quite a few on wind speed and tornadoes, one of which we used as a model for this one.

MS. GRANT: Okay. We have two more over here.

DR. LEECH: I'm Irene Leech, and I'm one of the consumer members on the committee. It sounds like you plan to make this numerical assessment maybe once a year or I'm not sure. I wondered if one way to consider it might be by the day or by the week, if you're making decisions about where the risk is, particularly for plants that don't do the same thing every day, that that might be something to consider.

MR. MICHAEL: You would hope inherent risk didn't change that often, you know.

DR. LEECH: Well, if you're changing --

MR. MICHAEL: But if they're changing the products they produce, yes, absolutely. Yeah.

MS. GRANT: Okay.

MR. MUNSELL: I'm John Munsell. First of all, during the break, Jenny from Food Products Association gracefully told me that I made a misstatement in my earlier comment. I said since May of this year, there were seven food-borne outbreaks related to *E. coli*. It's seven recalls. There's certainly a difference between the two. So, Jenny, thank you for the clarification.

I'd like to briefly talk about the volume variable, that it was initially suggested of assigning a value of 1, 1 1/2 and 2, you're familiar with that, the fact that the Agency is willing to revisit that now. I commend you for revisiting that. There are some very small plants, sell less than $1 million revenue a year. Some sell hundreds of millions in revenue a year. So that two to one relationship is

not accurate, and the way it should be, 2,000 to 1, maybe that will skew the results but it certainly needs to be substantially different than 2 to 1. A good example is this spinach outbreak. I think last Saturday there were 199 sicknesses in 26 states. Some very small spinach producers probably don't have 199 customers today. I respectfully suggest that.

MR. MICHAEL: Thank you. I think you've illustrated how difficult a problem it is translating volume into the variable.

MS. GRANT: Caroline.

MS. SMITH DEWAAL: I just want to come back to one point that was raised earlier. I can't find the specific piece of paper that says this, but I recall reading in the discussion of the summary of the expert elicitation, that you advised the experts that while they were not to consider severity, nothing would be done with the data without applying a severity component to their results. I'd like to know where -- when and how FSIS proposes to apply that severity element to this expert elicitation or is this -- I mean one way to look at this is to back out and

say, well, this is just one of how we're going to do this important job of determining inherent risk, and now we need to move onto getting more expert elicitations of public health components, getting the product attribution which has been raised today, making sure severity is considered.

I just want to know what your next steps are, because we do have very significant concerns about the product of this expert elicitation.

MR. MICHAEL: I think in regard to your first question, I don't believe we, if I understood, we told the experts we would be including severity later. We just told them not to consider it. We didn't explain to them one of the factors we would be using. We didn't need to, but we are going to consider severity. I don't know what the timeframe for that is, but that's one of the questions that we have today. It's another difficult problem. How do we factor severity into allocation resources -- risk?

MS. GRANT: Barbara and then one last question that's coming up, and I think we'll be right on time to move onto the next paper.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority. I wanted to kind of follow up on something Caroline had said and also something that was brought up earlier, and that's the importance of attribution data in the assignment of inherent risk in processed meat and poultry products. I would hope that this would be done on a continuous basis, that these product risks would be updated continually, not just yearly.

One reason that it's extremely important that we have a product tracing system in place that gives us good complete, not anecdotal, attribution data, is that there are new and emerging food-borne pathogens that are coming about all the time, and certainly various strains of existing ones. And while a product may not seem to have a significant public health risk at this time, it doesn't mean that in five years there isn't a problem. And, of course, if you had attribution data that you were looking at on a regular basis, complete attribution data, not anecdotal, you would be able to identify new and emerging pathogens much quicker and -- but we don't

have that system in place.

I would hope that in the development of this algorithm, we would take that into consideration.

MS. GRANT: Go ahead.

MS. DONLEY: Nancy Donley, STOP, Safe Tables Our Priority. This has been really, really helpful, and to listen and just the issues that have been raised, and -- but what is really, really pointed out, is we are not ready to move forward with this process until there's been so many questions asked, just as in this 10 minute or 15 minute questioning period, and the answers coming back, yeah, we're working on this, and I believe that you're trying to answer these questions. But the idea of rolling out anything that is this important and impacts public health and safety so tremendously, it's very premature to be trying to embark down this path without getting these questions answered.

MS. GRANT: Okay. Thank you. While Don Anderson is coming up, getting ready to give you his presentation, let me just remind you I understand that there's no questions from the remote sites. So that's

why we're not including any. But for those of you at the remote sites, if any of you are having any difficulties, I'll just remind you of the number that you can call to get assistance. It's 1-800-967-6433.

Okay. Don.

MR. ANDERSON: All right. Thank you very much. I'm Don Anderson, of course, with the Food Safety and Inspection Service, and I'm going to talk now about the X-axis. We've been talking a lot about the Y-axis, Matthew has, and now we'll talk about the X-axis some.

Just a quick reminder, to keep everybody on the same page here. As Drs. Masters and Raymond have already explained, FSIS is developing this new RBI system to better allocate Agency resource, to control the risks posed to public health by different types of establishments. And they have also explained, and Matthew has just elaborated, on one of the two measures that we're using.

Inherent risk measure is the so-called Y-axis, and that goes to the inherent risk of the product processes in establishments, and I can tell

that some of the confusion has been about, you know, the volume and the inherent risk. It's true I think that products, products have inherent risks, and the inherent risk of a product does not depend on its volume. But the inherent risk imposed by an establishment that produces a product does depend in part on its volume.

What I'll be talking about though again is risk control, which is a measure of how well establishments control the risks that we think are inherently present in the products that they produce.

These are what we're calling the six components of our establishment risk control measure. So we intend to use an algorithm to come up with a single measure of how well establishments control risks. That's that rectangular box in the middle. What are the six things that we're going to be looking at? Well, we're going to talk about them in turn and in depth, but what we're considering are what we call system design features, pathogen control in commerce, enforcement actions, food defense and system implementation.

So these are what we consider to be six important factors that enter into the establishment risk control measure. These are the six components, and we'll talk about each in turn.

Let's talk first about system design for a few minutes. The objective of our food safety system design component is to gauge the efficacy or sometimes we refer to it as the robustness of the design of the establishment's food safety system.

How good is their system in design and to some extent, in implementation?

We have at least a couple of types of data or information that we think have a bearing on this. First, and foremost, surely are what we call food safety assessments or FSA findings. We've heard a lot about food safety assessments. Food safety assessments are in depth examinations of an establishment's food safety systems. They generally take place over the course of days rather than just a few hours, and they are conducted by what we call EIAO trained personnel. They're especially trained personnel, and the acronym is not important. I could

relate it, but they're EIAO trained personnel and they go into establishments and kind of look at food safety system design, features of the program from top to bottom. They look at their plans. They look at records. They walk through and see if things are actually implemented the way they're supposed to be. So they're basically a comprehensive look at the establishment food safety system.

Another piece of information that we're considering bringing into the design measure is what we're calling 9 C.F.R. 430 RTELM control alternatives. Now what are those?

The alternatives, these LM control alternatives 1, 2 and 3, have, in fact, already been mentioned earlier this morning by Dr. Masters in her presentation. These are basically -- these are examinations or judgments of how well establishments control LM, *Listeria monocytogenes*, in ready-to-eat products, and whether an establishment is alternative 1, 2 or 3, basically depends on what types of controls they have in place to protect RTE products from *Listeria* contamination before they're shipped. We

think there may be other factors, other kind of design components that we should also consider and that will be a question that we'll be asking you at the conclusion of this presentation, the rest of today and tomorrow.

So let's turn to the second component, which is food safety implementation. Food safety implementation is a different look at the establishments and how they control hazards. It actually looks at how well they implement the food safety systems that they have. Remember the design looks at how good are their standard operating procedures? How good is their HACCP? How good are their prerequisite programs? What this is supposed to look at is how consistently or how well they actually carry out those programs in practice on a day-to-day basis.

We've heard a lot about NRs. We're going to hear a lot more about NRs. Basically what happens is this? When an inspector performs an inspection procedure, they are looking for what are called noncompliances or what we sometimes call -- they end

up writing noncompliance records. And FSIS is required by law to document all regulatory noncompliances. If an inspector performs a procedure and observes noncompliance, they are required to write a NR, and the inspectors and FSIS will continue to document NRs of all types. All regulatory noncompliances would continue to be documented under RBI. That's not something that we're talking about changing.

What we are saying or what we are believing and we will be asking your input on this, we do believe that some NRs or some types of NRs are more related or more predictive, however you want to think about this, to public health than other types of NRs, basically that some NRs are more important than other NRs, not because they're more noncompliant but because they go more directly to an indication of how well the establishment is controlling hazards that pose problems to the public, public health problems. So that's what we mean when we talk about significant NRs.

Let's look at that a little more because

it's a very important question. When we talked to the National Advisory Committee on Meat and Poultry Inspection, I'm going to say it was April, it may have been May most recently, we received some input on NACMPI regarding NRs with public health significance, which ones NACMPI thinks are most important.

So what we're doing now at FSIS is going through a methodical process of considering different types and descriptions of NRs to try to identify those that we think are most important from a public health standpoint. So, for example, consider NRs, noncompliances, that cite 416.15, or 417.3, which are HACCP corrective actions. What those two NRs basically have in common is that a problem at some point was identified in the establishment, in either sanitation or HACCP, and a NR was written before, and then we -- in subsequent actions, we find that a problem is recurring and basically we observe that corrective actions are not in place, have not been put in place, to prevent the recurrence of that problem. So that's what we mean by these corrective action problems. And we believe that those are probably the

types of NRs or examples, some of the examples of what would be considered more public health significant NRs.

Others might be noncompliances for which a regulatory control action was taken, maybe product was tagged or detained or something like that, or a piece of their equipment was tagged. In other words, it rose to the level where we were concerned enough that we took kind of an in-place regulatory action, a control action. Another possibility are NRs that are issued for inadequate validation or verification processes in the establishment. These are just a few examples.

The question came up earlier that maybe will help, too, how do we know what's a significant or insignificant or not so significant NR? When noncompliances are observed for floors that are not clean or product contact conveyor belts that are not clean, those are both -- those can both rise to the level of regulatory noncompliance, but perhaps NRs for unsanitary food contact surfaces are more important than NRs for noncontact surfaces, from a public health

standpoint. So these are several examples, and there are many more we could go into.

So we're currently going through a process of reviewing NRs to try to identify and validate these categories.

We're onto the third component now. Remember that figure, we've got six components that come into our risk control measure.

This third component again is extremely important and a fairly complicated one, and that is pathogen control. And what we're looking at here is actual agency data on how well establishments control pathogens in their operations.

Let's go through these. RTE, ready-to-eat, testing program results are basically the findings of our several ready-to-eat testing programs that the Agency has. We test ready-to-eat products for *Listeria*, for *Salmonella*, and for certain types of ready-to-eat products that contain beef, we also test them for *E. coli* O157:H7. That's what we mean by our ready-to-eat testing program results. We test products. Those tests come back from the laboratories

as either positive or negative results, and that's what we mean by that.

The *E. coli* O157:H7 testing program, of course, is basically our raw beef, basically our raw ground beef testing program. Dr. Masters mentioned this as well earlier in her presentation.

The third category is the *Salmonella* verification category. The *Salmonella* verification category is a fairly new system. I believe you may have mentioned it was published I want to say February, is that correct, on or about February. The *Salmonella* verification category that is assigned to an establishment is, without getting into too many complexities, basically looks at two things. The Salmonella verification category for an establishment is based on recent *Salmonella* set test results, but it's also based on the presence of certain public health concerns serotypes in those *Salmonella* results. So we look not only at the prevalence of *Salmonella* and recent tests in an establishment, but we also look for the presence of certain serotypes that are of public health concern.

The next to the last category or data element here are again something that Dr. Masters referred to earlier and, in fact, this is an example of I think Dr. Raymond called it our upstream, upstream example, and this is our STEPS program which is suppliers to establishments with *E. coli* O157:H7 positive test results.

Now what does that mean? Remember, in the second point here, that FSIS conducts *E. coli* O157:H7 testing in a lot of establishments, in over 1,000 establishments that produce raw ground beef products. Think of it as a ground beef testing program. It's not that simple, but for the illustration, that works.

When an establishment, when we take a ground beef sample from an establishment, send it to a laboratory and we get that result back, and it says that the ground beef tested positive for *E. coli* O157:H7, of course, we take a number of actions at that point, but one of the things, one of the things we do is we enter certain information into what's called our STEPS database, our suppliers' database, and we may find over a period of time, we may find

that a certain establishment is a trend supplier or basically an intact supplier to multiple establishments that themselves have had positive *E. coli* O157:H7 tests. So this is actually saying that with our data, and with our pathogen control measures, we not only want to consider whether we need to increase inspection in an establishment with an O157:H7 positive, but also whether we need to increase our level of scrutiny in establishments that supply product to those establishments. So this again is an example of an upstream effect.

Finally, we have an agricultural marketing -- there is an agricultural marketing service or AMS school lunch testing program, and our plan would be to bring the AMS information testing program results into our measure of risk control as well. It's very similar to the O157:H7 testing program, but what really differs is who's doing the testing and where the testing is done, but it's essentially the same kind of test as I understand it.

The fourth component is in commerce findings, and there's been a lot of talk about this as

well. The objective here is to -- is again to measure how well establishments prevent, actually prevent the shipping of products that contain hazards, and there are at least three factors that we're considering here.

One is, as probably many of you know, that it's very straightforward on FSIS' web page for consumers to find out how to report to the Agency consumer complaints, and we have a system, a consumer complaint monitoring system, and it's electronic database, that we use to track consumer complaints. Now a consumer complaint investigation system is a fairly complicated one, but suffice it to say, that what we're focusing on now, but we want input from you on this, is we're focusing on what we call significant public health verified, and by that we mean traced back, validated consumer complaints. So we wouldn't, we wouldn't automatically conclude that just because an establishment has had a consumer complaint filed, if you will, against it, that they necessary need greater inspection, but if we do an investigation of that consumer complaint, can trace it back to a

particular establishment, if we can find at the establishment other information that corroborates that, and if that was a public health complaint in the first place, then that's the kind of indicator that we would probably want to include.

Recalls, Class 1 and Class 2 recalls are the types of public health recalls. If I remember correctly, the Class 1 recalls are some sense more significant, a greater significant type of public health recall. Class 2 recalls are also public health recalls. There's a third type of recall which are nonpublic health recalls, that we don't necessarily think we would want to include in our measure of public health on a risk control effectiveness, but again, we want your input on that.

Finally we have in commerce public control actions. These are detentions and seizures. They are basically when FSIS has cause to in some sense physically control product, to keep it from being further distributed once it has entered commerce.

The fifth component, enforcement actions, and again, our objective here is to capture

enforcement related indicators of loss of process control.

Now we've talked a lot about recalls and NRs and food safety assessments and positive test results, and all of those things can directly or indirectly lead to enforcement actions. But what we're talking about here is that occasionally there are enforcement actions that are taken in establishments that aren't really captured very well, or at least very immediately anywhere else in our system. So these might be, for example, we've talked about NOIEs, and we've talked about NOIEs, I'll spell it out, a Notice of Intended Enforcement. A Notice of Intended Enforcement or a NOIE as we sometimes call them, sometimes result from FSAs but sometimes they don't. And that would be an example here. Or sometimes NOIEs are kind of a seemingly logical conclusion of a repetitive set of NRs, and again, we could capture those somewhere else in the system. So what we're talking about here are NOIEs that aren't captured elsewhere, but we would also include enforcement actions such as injunctive actions, consent decrees,

and this is a mouthful, but the reinstitution of inspection. In other words, we re-institute inspection after a failure to meet a corrective action under deferral. This is basically, as I understand it, an establishment is put on notice that they may lose -- be suspended, we may suspend inspection in that establishment and then they respond as they are officially allowed to, they respond that, hold off, we're going to put a corrective action in place and we're going to take care of this problem, and if they do, that's good, but if they don't, that's not good. So we have to capture those types of enforcement actions as well or those types of activities that are sort of in this enforcement realm.

The last component is a food defense component, and the objective here is to measure how well establishments protect their operations from intentional harm, what we call food defense.

The four measures that we look at there or are considering looking at are what we call product process vulnerability. Product process vulnerability is in a lot of ways very analogous to the inherent

risk notion. The inherent risk goes to kind of how inherently risky a product or process is by -- in some sense by nature. But we're talking about something here that's not nature. It's an intentional human introduced harm here, and we believe and it's FSIS beliefs, through a vulnerability assessments, that some products and processes are more vulnerable to intentional harm than others. So we would want to look at that.

Again, we would also want to look at product production volume in an establishment, which we believe is a good proxy for exposure. Food defense plan efficacy, remember that establishments are supposed to have what we call food defense plans. Actually I guess that's not right. I guess they are food guidelines, and plants, as I understand it, are not required to have food defense plans but there are industry guidelines for food defense and FSIS has been conducting work, call it survey work. It's technically a little different but work to find out which establishments have plans and how good their plans are. So we have data on that. So that goes to

the plan efficacy.

And finally, food defense verification results. Many of you will know that FSIS conducts procedures, inspection procedures in establishments to see how well on a day-to-day basis, how well establishments are actually implementing recommendations, kind of food guidelines and recommendations, how well are they implementing -- in some sense, how well are they implementing those plans. Those inspection procedures are called O8 procedures and data on those come straight from the performance based inspection system or PBIS.

So let's look at the questions that we want this group to think about over the next couple of days. Are these six components that we've laid out, and summarized I believe it's on slide 4 of your presentation, are these six components appropriate, which means should they be there, and are they adequate, which means should others be there? So we want to get your ideas on the adequacy and appropriateness of those six components.

Secondly, we would like to know if some of

these components, like food implementation or, excuse me, food safety implementation or food safety system design or pathogen control or any of them, are some of these more important? Are they more important to our measure of risk control, and thus should some of these components be weighed more than others of our components when we come up with our measure of risk control.

The third question that we'd like to ask your input on, is whether there is other useful information about establishment risk control that FSIS is not considering?

Now one suggestion or one idea has already come up in the earlier presentation, and that was the question about intervention. At one point, and it's probably reflected in the inherent risk paper, that one of the things in establishments that we think is important is the presence and the efficacy or validity of certain types of intervention, things that are put in place by the establishment to reduce hazards. We believe that that's an important piece of information. We think that we will probably bring that component

into our design component, we think we can probably capture that, in our food safety assessment process, but there may be other types of useful information that we haven't talked about yet that need to be brought into our measure of establishment risk control that we aren't even considering. And so we want your ideas about that.

Our fourth question is, are there other ways besides food safety assessments to evaluate establishment food safety system design? Remember food safety assessments are these EIAO, PIAO, trained personnel evaluations of how well establishments have robustness and validity of their food safety designs. We want to know if there are other ways to assess the robustness of establishment food safety system.

The fifth question that we would like to ask, and we've already asked it several times today, is, are the NRs, the noncompliance reports, FSIS is currently considering for public health-related issues, are they inclusive, that is, are we considering the right ones or are there other types of NRs that FSIS should be considering?

The last question, and this is a fairly quick one I think, is, what is an appropriate look-back window? It's just a few words, but it's a very important question. We talked a lot about the Agency needs to look at data. We need to be looking at valid data and reliable data, and these data include NRs, looking at NRs, food safety assessment results, pathogen results, et cetera, et cetera, et cetera.

Well, what this question goes to is, okay, if we're going to look at data, to come up with a measure of how well establishments control hazards, should be looking at the data for the last week of an establishment or the last month or the last six months or the last year? That's what we refer to as an appropriate look-back window.

We've been talking most frequently at the Agency about using a six-month look-back window, and that's for a lot of different reasons that I could go into, but we're trying to get your ideas and we're looking at data to identify what an appropriate or proper look-back window is. Whether it's six months, a shorter period of time or a longer period of time.

That concludes my brief talk here. Those are the six questions that I want to ask you. Some of you may have other questions, and I'll sit here and try to answer whatever questions you may have. Thank you.

MS. GRANT: Okay. Thanks, Don. Again, just line up and at the remote sites, type in your questions if you have any. You lined up first. We'll start over here.

MS. SIEMENS: Hi. Angie Siemens with Cargill. Could you give us some insight on how you would take food safety assessments which today I looked at the qualitative data and transfer it into quantitative data for this model that you put together because it's not scored today. How do you anticipate putting that in, in a numerical format?

MR. ANDERSON: Okay. That's a good and fair question. I would say that it's partly accurate to characterize as I understand it that the FSA process is a qualitative process, and when a FSA is conducted, the EIAO trained personnel at the conclusion of the food safety assessment complete what I think is called

a Form 5000-8, which is a form that captures the salient information that they found during the conduct of the food safety assessment, and it does contain a sometimes rather lengthy narrative of information that the inspector found but the FSA also has some information in it that can be summarized.

Numerical might not be the right way to describe it, but categorically, and that is that at the conclusion of a food safety assessment, the EIAO sends I believe to the district office the Form 5000-8, and based on their food safety assessment findings, they make a recommendation based on that finding. That recommendation could be that they look at this establishment for three days, top to bottom, and everything is under control, we're done here. No further action is necessary.

In other cases they might say, well, things are in pretty good control in this establishment. Things are fine. We did identify a noncompliance or two during the course of the FSA, and the inspection personnel were instructed to write NRs to document that finding. So basically that's a finding that

things were generally in pretty good shape, but basically you've got a rationing up of finding.

Another finding, again, this is a categorical, not a numerical finding, a categorical conclusion of the FSA could be that we found substantial enough problems or concerns with this establishment that we believe that the establishment should be put on notice as to what those findings were and they need to correct those problems if they want to remain under inspection. It's a letter of notification basically.

Or in some extreme cases, an establishment may be suspended directly at the conclusion of a food safety assessment.

So these are categorical findings. That information is in Agency databases, not always in machine-readable forms as we would like. So that's something that we have to work at, but I think it's pretty clear to try to just a couple more sentences, the point of your question is that some findings would indicate the numerical in the algorithm that the establishment has good risk control processes, while

other findings like a letter, a 30 day letter, or suspension, will obviously indicate that that establishment, or maybe NRs, that that establishment has some food safety issues that need to be addressed, and so that would affect their score in the algorithm and lead us all that's equal to a higher level inspection of that establishment.

MS. GRANT: Felicia.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Dr. Raymond mentioned before that there's a website, that on the Agency's website, there are examples of NRs, and just to prepare for tomorrow's subgroup meetings, maybe you could -- someone from FSIS could write the URL address up there later so that we can.

Okay. I spoke to someone who works in a plant and said there's over 20 HACCP plans and that the EIA came in and reviewed 3 of them. You said that the FSAs do a comprehensive look at the plant. How does FSIS determine how many of the HACCP plans should be looked at in a plant that has a lot of HACCP plans? And how often? What's the range between FSAs

currently at these plants? I heard that the EAIO, because of budget constraints, have been sort of lost in the offices. So are we talking a year between FSAs, two years, what's the range?

MR. ANDERSON: Yeah, Dr. Masters has indicated she'd like to start with that, and we may have to ask somebody else for some information about it, the FSA process in terms of if an establishment has produced six different products with six different HACCP plans, whether or not all six processes are looked at or not, I don't know the answer to that question.

DR. MASTERS: Food safety assessment is intended to be a complete look at the entire process, food safety process conducted in an establishment. So the EAIO trained individual is trained to look at all systems, HACCP, SSOPs, sanitation performance standards and any testing that's done by that establishment, as well as the prerequisite programs that are being conducted in the facility.

So if a plant has multiple HACCP plans, the decision on how many to look at varies, depending on

if all 20 HACCP plans were related to the same process category such as O36, they may look at a representative number. If all 20 HACCP plans were for different of the 8 HACCP categories, they may look at a different number of those HACCP plans, because the EAIO trained individuals are to look at a representative number of plans because the idea is to look at the entire food safety system, in action within the establishment. So they are to look at a representative number of plans across the process categories.

MS. NESTOR: Okay. And what is a representative number? Is that a proportion?

DR. MASTERS: Again, they're going to make those determinations depending on how many plans are operating per process category. So it is only going to be a proportion. If they have process categories that are being conducted in a plant, and they have multiple plans for process category, they're going to look at a few plans per process category. They may look at them and see that they're identical for each process category in which case then they'll look at a

couple of them. If they see that they're very different for each process category, within a process category, and they look at all of them. And those are decisions that they're trained to make during their training.

MS. NESTOR: And do you know the length, the time between FSAs?

DR. MASTERS: On average, we are finding that it is about three years between FSAs in an individual establishment, unless those are done for cause.

MS. NESTOR: Okay. I have a question about the NRs. Because of the shortages, the inspectors can't get to a number of the plants or don't have time to write the NRs. How will you identify which plants have had a less than standard form of inspection and, you know, take that into account. In other words, the lack of NRs at that plant might reflect that an inspector has not had an adequate amount of time to write the NRs.

MR. ANDERSON: We obviously -- I stated at the outset that inspectors are required to write

regulatory noncompliances when they see regulatory noncompliances. Now apparently some inspectors have said that they don't always have time to write NRs. I'm not sure how I would answer that question except that inspectors are supposed to write NRs when they observe regulatory noncompliances.

I'm not saying that -- necessarily that they always do. I'm saying that they're supposed to, and I know the Agency is working hard in a lot of different ways to facilitate that. One of the things that -- some of these things may be technological. We made improvements I know actually in recent weeks that will increase the ability or the ease with which inspectors will be able to document noncompliances, with the increase in the number of high-speed lines and those kind of things that we have.

But it is a complicated process. This sort of gets back to the analogy and the referee and some referees may be better than other referees, but some referees may have different resources available to them than other referees do. It would be hard to referee games, and we're asking most of our inspectors

to inspect more than one establishment.

What we're trying to do with risk-based inspection though, remember, we're trying to do a risk-based inspection say, we have a population of establishments out there, that we are required by law to inspect every day and we do our best to do that, and now we have a certain set of rules by which we do that. What we're trying to do with risk-based inspection is to improve the game going in. We're trying to make the allocation of inspection resources and the direction that we suggest they go in, an improved system in the first place, so that if they are able to spend less time in some establishments, not no time, but if they're not available to spend as much time in some establishments as they are in others, we want them to spend more time in the establishments that have higher inherent risks or poorer risk control. That's really what we're saying.

MS. NESTOR: Yeah, I understand that that's your goal. I mean it's been reiterated over and over again. The question is, USDA's OIG recommended to you several times that you refurbish your PBIS program so

that you can document when inspectors did not perform an inspection task because they didn't have the time. Will you be doing that?

DR. MASTERS: That is something that we said we would take under advisement under our new system, yes.

MR. ANDERSON: And there's a point of clarification. When inspectors are assigned to perform tasks, and they don't perform them, they do get coded as not performed. We do know when inspectors don't perform tasks that they were scheduled to perform. We also know when they perform tasks that weren't scheduled but they perform them because they thought they were important to do from a public health standpoint. We don't always know why they didn't perform.

MS. GRANT: Felicia, I know you probably have some additional questions, but I think you can see that we've got almost five people on each side. So if you want to get back in line, that would be great. Go ahead.

MS. SCOTT: Thank you. Jenny Scott with

Food Products Association. With respect to NRs again, even within the categories you list, which I will agree generally are appropriate with respect to public health, there's going to be different degrees of impact on public health. For example, we have a member who has gotten a NR for verification activity. The only disagreement is the frequency of which that verification activity is performed, daily versus weeks. So there's really limited impact on public health. So is there a way to consider that?

And secondly, how do we -- how will this algorithm address NRs that are under appeal?

MR. ANDERSON: Let me answer the second question first. It's most immediate to some of the work that we have been doing already. It is true that when a NR -- it's true that we don't have instant replay but we do have an appeal process, and establishments do not infrequently appeal NRs, goes through a process. And if the NR is appealed, the NR stays in the PBIS system but it shows that it was appealed and in effect overturned. And again, we would like your ideas on this but my instinct would be

that if the Agency makes an official determination that a NR that was once written was not an appropriate NR, and it seems to me we would not want to include that in our measure of risk control.

DR. MASTERS: And on verification, and whether or not we should look at varying degrees, that's another area that we welcome input during this process. The Agency is open to the idea that there may be verification NRs that have one degree of concern, and verification NRs that might have a different degree of concern. And so that is something we hope that we'll get some input on during the workshops this afternoon.

MR. MUNSELL: John Munsell. I'd like to address briefly two issues. One is the NRs and, Dr. Masters and Dr. Raymond, I have nothing but praise for you folks for your willingness to address the fact that currently NRs don't assign a relative degree of severity, and years ago this system did allow that. So I praise you for your willingness to address it.

To answer the previous question here, as an alternative, I suggest another report, and we might

call it for example an administrative shortcoming report. That would address the issues that have absolutely no impact on a plant's ability to produce consistently wholesome food. Now that's not meant to circumvent or insulate a plant's responsibility to address those issues. So I think even those administrative shortcoming reports could be linked together. So that if a plant did not address the issue, and the administrative reports could be linked together, then they could lead to a NR. So there still has to be accountability.

The other issue I wanted to talk about is on the slide you have up here now on how to determine risk control. A couple of issues are pathogen control and in-commerce findings. Let me go to that issue I brought up earlier about since May, there have been seven or eight recalls from very small plants, five of which do not slaughter. My question is, did those five plants introduce the *E. coli* or *Salmonella* into their product? In all probability, no. But are those plants responsible? Is the Agency assessing liability of those five plants for the detection of the pathogen

at the plant? Well, yes. The leading question with those five plants, has the Agency implemented an aggressive trace back to a true origin of contamination? Well, that's not for me to answer.

But my conclusion is this. The rule on data collection, and we talked about this before, the real time data collection and expedited trace back to the origin of contamination, rather than placing all liability on the down line plants that are the destination of the previously contaminated meat is very important.

So my conclusion is that until the Agency aggressively pursues real time data collection at down line, further processing plants, and the use of adverse microbial test results and in-commerce findings and recalls and the risk determine algorithm, may inappropriately reflect an incorrect risk assessment at the down line plant, at the supplier plant.

MS. GRANT: Tony. I'm sorry. Do you want to make any comments on that?

MR. ANDERSON: We'll take that as a comment

I guess rather than question. That's noted. Thank you.

MS. GRANT: Tony.

MR. CORBO: Tony Corbo from Food and Water Watch. This past weekend I spent most of my time reviewing six hours of audio tapes of the -- what the Agency now is actively calling employee feedback sessions. They were in no shape or form focus groups. In one of those tapes, an individual brought up the fact that several years ago, the Agency conducted case studies using I believe he termed it a hazard control coefficient. And when asked what happened to all of the data that was generated from that, there was no response.

So question number one, is that information still available? Since obviously you would have started, you know, this process a few years ago.

The other issues that came up in both sessions was on the issue of consumer complaints, that the Agency does not have access to all the consumer complaints. The folks in the feedback sessions indicated that companies, the firms get most of the

consumer complaints, and there was an issue as to what access FSIS has to that data.

So number one, you know, the first question is what happened to the case study? Number two, access to consumer complaints.

MR. ANDERSON: Okay. In that order, what's been referred to as the HCC, hazard control coefficient, and it was on one of Dr. Masters' slides, can probably be thought of as a very early developmental and a precursor to this measure of risk control in the following sense.

Remember that as you see on the slide, we have six components of risk control that we think we want to bring into our measure of establishment risk.

The old hazard control coefficient had just two. It had pathogen findings and it had NRs. So it had the pathogen control component, and it had the implementation component. Furthermore, in the implementation component, there was a much simpler kind of variation. Basically what was the old, as it was called, HCC, treated all the regulatory noncompliances equally. A NR was a NR was a NR. That

measure was developmental. It was partly an illustration. I think it has proven over time that the Agency can track this kind of information in something like real time from other electronic databases, that we can build algorithms and that that information can be useful to us. It's never been used to allocate inspection resources. It's never been used in policy ways. It was really more of an illustrative tool, but it is a very -- it is kind of a very simple version of the establishment risk control measure, but again, it has only two of these components. It doesn't have six components.

The second question about consumer complaints, it is true, I was referring to a consumer complaint monitoring system tracks consumer complaints that come into the Agency. We have talked long and hard about the possibility, the feasibility, and we have to think more about how we would do this, and we need more input from you about how we might do this or whether it's important.

We are aware that complaints presumably go directly to corporations sometimes. It's a different

kind of consumer complaint, but whether we should or how we might include that in a measure of this control, I don't think we can speak to that right now, and we would like your suggestions.

MS. GRANT: Barbara.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority. I have several questions, and I'll try to keep them to a minimum.

The first question that I have is looking at this charge, I would like to know, you know, you're going to have to develop data collection systems for each one of those six circles and then figure out a way to integrate all of those issues into some sort of database that you are able to analyze, and that I want to make sure you understand is a monumental and time consuming project that you are facing in doing that.

The second thing, under pathogen control, what -- in your list, there was really no place in there for input of testing results, and I wonder how input of testing was going to -- results were going to be considered in pathogen control?

And secondly, although I probably ask more

questions, in-commerce findings, I'm very disturbed by the first bullet under in-commerce findings. Significant public health verified, track back, invalidated consumer complaints. One, I find it a little startling that attribution data from food-borne illness cases is not considered as part of this model, in determining establishment risk. And under the -- and I submit myself, that I can certainly tell you that the current system we have for product tracing in this country is by no means efficient or timely and is pretty much set up to prevent you from verifying and validating a consumer complaint, and what constitutes a consumer complaint? Isn't it also just a food-borne illness that occurs in the field? And I can certainly give a personal example about this if necessary.

MR. ANDERSON: There are three or four different questions there. I'll try to answer them in order but again, the first comment about data collection, data -- you used the word develop data collection system is a monumental task. I'm not going to say we don't have a monumental task ahead of us. I am going to say that many of these data are already

captured, and are machine readable from existing data systems.

The performance-based inspection system is an electronically readable database that captures NRs in establishments with regulatory citations and other kinds of information, what procedure was performed, what was the finding, what day -- that's an electronic data system that exists today. So we don't really need to develop a new PBIS system necessary. Do we need to make some improvements in our PBIS system? We probably do. So we don't need to develop a new system.

Our data on pathogen findings are captured in what we've started calling recently, as I understand it, our N2K system. We referred to it in the past more as a prep system. It's a prep database. So again, there is an electronic database that tracks all our pathogen control data.

Our food safety assessment findings, our FSA data, is probably one of our weaker points. We collect that information. It is readable, but it is not always entirely machine readable. So that's an

area that we do have to work on.

The consumer complaint monitoring system, which is in-commerce, and the recall database, which is another in-commerce component, those are for the most part reliable machine-readable databases.

So I don't think that -- again, I don't want to make lightly of what our data development challenges are, but also I don't want people to have the opinion that we don't have electronic data systems for capturing a lot of this because we do.

The second question was about in-plant testing, and it is true again in pathogen control, I was referring to the O157:H7, the *Salmonella* in the ready-to-eat program data that the Agency collects and sends to our own laboratories for analysis. It is also true that a lot of establishments conduct their own testing program.

One of the things we have talked about, again in our groups today, it may be important to, and I would think you would argue that it is, by the nature of your question, that it may be important to capture or to at least be aware of which

establishments are doing their own testing, and if possible what are their test results showing. One possible way to capture that that we thought about would be an expanded food safety assessment process. So when we conduct FSAs, we would go directly to, you know, what types of in-plant testing do they do and what have been the results of their testing.

Your other question I think had to do basically with -- we use the word incidents, the attribution data, as most of you know and I think you may have referred to it yourself, the Center for Disease Control is the agency that is directly responsible for tracking food-borne illnesses in the United States, and you're all familiar with the pyramid system and the mead (ph.) studies and all that.

We do believe, we are aware that illness incidence data and whether that incidence is a food-borne illness didn't require hospitalization or did require hospitalization, or actually resulted in death, we are not -- again, we are not trying to discount the importance of that data. What we are

trying to consider is how can we capture that information from existing data systems, whether they're at FSIS or CDC or anywhere else, how can we capture that information in a reliable way and bring it into our measure of risk control. This is a substantial challenge that we have.

MS. GRANT: We only have a couple of minutes left before we have to stop and break for lunch. We have five people in line. How about if you just raise your question. We will -- after lunch, we will have another hour to come back and we can have more questions and more discussion, but can we just at least set them out on the table. I'm particularly interested in the remote sites since they're not going to be with us for that second part of the conversation. So just raise the question.

MR. BERNARD: Thank you. Dane Bernard with Keystone Foods. As a follow on point to Ms. Kowalcyk's question about in-plant testing results, we do a lot of testing. That data has been available to inspectors certainly. If the Agency is to consider that data, which I hope the answer is a

positive one, would that change in any way the ranking or the weighting of each of the categories? For example, if you're not going to have good system design, system implementation, you're probably not going to be effective in pathogen control, but if your data -- if you, if you follow that course and statistically derive an ample document, good pathogen control, would that give you a different weighting in terms of your algorithm? Thank you.

MS. GRANT: Chris.

MR. WALDROP: Chris Waldrop, Consumer Federation of America. I had a question about the look-back window and whether that meant that every six months or so you were actually going to look at all these different elements and sort of look and see whether those same levels of risk controls and the establishment risk are the same as it was six months ago, and if that's not what you meant, then I'd recommend you incorporate some sort of continual improvement into your system like that.

MS. GRANT: We have a question from a remote site.

UNIDENTIFIED SPEAKER: This is an anonymously submitted question. Is the agency planning on utilizing the plant's own HACCP data when determining risks?

MS. GRANT: Okay.

MR. REINHARD: Bob Reinhard, Sara Lee Corporation. My question revolves around the same question that's been coming up and everyone has a concern, and that's the quality of data. And my question is this. Has FSIS considered developing a questionnaire in which establishments are allowed to in essence determine their own establishment risk control and then also use their own data within that questionnaire to go back to be used, because in a truly transparent model, all the variables in the algorithm would be known, the establishment would be known what they can put in for each one. Then in turn they could respond to FSIS, this is what level of control I have and this is other data that I also have that we want to make available for you to use in your determination.

MS. GRANT: Okay.

MS. MUCKLOW: Rosemary Mucklow, National Meat Association. We've been looking forward to the day when you would make the perfect inspector, multiply him 6,000 times, so that every time they look at the situation, they see the same thing. Consistency is very difficult when you've got 6,000 people out there, many of them working on their own.

And for that reason, and also for seasonality, I would suggest when you say look-back window, you might want to hear in that look-back window, one week, one month is certainly too short, and given the ranges of *Salmonella* that runs up and down depending on seasonality, you don't capture it unless you have a full year. So I would suggest when you look at that look-back window, that you extend the time.

MS. GRANT: Okay. That was a bunch of questions, using HACCP data, a suggestion about --

MS. MUCKLOW: I'm sorry. I forgot my other piece.

MS. GRANT: Okay.

MS. MUCKLOW: If you're going to make this

system work, you've got to improve the timeliness of the appeal system. An inspector sees a NR and he writes it today. You can have appeals going on for six months. This system ain't going to work if you've got appeals dragging on like that. To get to the -- system, they need to be much, much faster or the data is not going to be good for you.

MS. GRANT: I don't know if you want to comment on that. Most of them were comments but there are a couple of questions in there.

MR. ANDERSON: Yeah. Don't get me started. Let's not address these now. We're going to have a lot of time over the next day and a half, and people know me well.

MS. GRANT: All right. That's great, and Don is absolutely right. There will be other opportunities. So according to the schedule, we want to have you all back here at 2:30. I think there's some real good places you can go.

I want to officially sign off for today with the Netcast participants and encourage you to do the small group discussions on your own and e-mail us the

results, or if you don't get them within the meeting time, you can also use the FSIS e-mail to give us your response.

So back at 2:30 sharp, and we'll continue this conversation.

(Whereupon, at 1:15 p.m., a luncheon recess was taken.)

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

(2:30 p.m.)

MS. GRANT: Let me just remind people what we want to do this afternoon. First of all, we have an hour set aside, and I've asked Don and Matthew to be up here, because we have an hour set aside if there are some additional questions or comments people want to make on either one of the papers. And I want to go back to the four or five questions or comments that were left lingering when we broke, in particular, the one from a remote site. But then if there are other questions or comments, we can take them.

At some point, if it seems to make sense to break into the small groups and it's not too early to get into the specific questions, we'll just do that, because the small groups have 12 questions to try to answer, and that is a lot to accomplish in the time we have allotted. So it wouldn't be a bad thing to break into the small groups early.

So I wanted to start with -- Don, I'm just going to tell you what I remember some of the questions were. The one from the remote site was

specifically will you be using plant HACCP data? What we plan to do, when the remote sites come back online tomorrow morning is provide them with the answer to this question, but maybe you could answer that question for the group right now, and we'll provide the answer tomorrow.

MR. ANDERSON: Okay. I'll try to address that. Will we be using the plant HACCP data? I'm not sure I know exactly what that means. Establishments have HACCP plans. They have HACCP systems. We, of course, perform HACCP inspection procedures in establishments. I'm sure, I'm confident that part of the FSA process, the food safety assessment process, of course, looks closely at the HACCP plan or as somebody pointed out, there may be multiple HACCP plans. So we certainly look at the rigor of each establishment's HACCP plan or HACCP plans in the FSA process. Inspectors, of course, also have to have available to them various records that the establishment is required to keep.

And I, you know, maybe one way to answer that I guess is with an example. Some of our

inspection procedures, as I understand it, include looking at HACCP records, and the things that the establishments themselves are doing, and there are certain regulatory requirements that industry must meet that are related to the operation, both the content of and the implementation of their HACCP systems, and if they are noncompliant with those, we certainly document those as we've talked about, NRs.

Without knowing more about the question or the context of the question, I'm not sure I could give a better answer.

MS. GRANT: Okay. I'm going to repeat what I remember about the other questions, but if the people who asked them want to adjust what I say, please feel free.

There was a question about using in-plant test results. There was a comment about establishments using -- developing their own questionnaire and then using their own data, if you remember that comment, if you want to respond to that.

I think it was Rosemary raised a question about consistency and the human factors.

And then there was another question or comment about the look back window, would there be continuous adjustments to that.

If I didn't get those right, please feel free to get back up at that mic and, if there are any other questions, please feel free to line up, and I'll take them in order.

MR. ANDERSON: Regarding the -- I did want to address the look back period. One of the points that I wanted to clarify, whatever the period of time is, whatever the window is for the look back period, by look back period, we don't mean that we would just go in and take a snapshot of the data every six months or one year or two years. We mean that we would -- that that's the amount of data that we would look at every time we took a snapshot of the data, and I think we would anticipate that we would fairly frequently re-look at the data, and the idea would be we would have a moving window of data probably that we would be examining. No, we wouldn't just look at the data, you know, every so many months. That wasn't our intent. So I'm glad that that question came up again.

MS. GRANT: Then there was -- Dave Bernard raised the comment of or the suggestion of -- that establishments might develop their own questionnaire and use their own data or --

MR. ANDERSON: I took that as more of a comment. I'm not sure how we would implement that or what the authority would be to do that or anything.

MS. GRANT: And a question about using in-plant test results? Did you already address that?

MR. ANDERSON: Well, again, we know that, we know that a lot of firms do in-plant testing, and as I understand it, our inspection personnel do have the authority and the right to look at that data, but how we would capture that data and bring it into a measure of risk control, I don't think that's something that we've really talked about. Ideas would be welcomed.

MS. GRANT: Then I'm just reminded that I think it was Rosemary raised a question about the timeliness of appeals, of the appeals process?

MR. ANDERSON: Again, I would take that as a comment, but I think it's a valid point.

MS. GRANT: Okay. So we have one person

lined up with an additional question. Go ahead.

MR. POTTER: Thank you. I'm Bill Potter --

MS. MUCKLOW: Consistency is the other issue I raised.

MS. GRANT: Don, can you hear that?

MR. ANDERSON: Consistency of:

MS. GRANT: The human factor.

MS. MUCKLOW: Human variability between inspectors.

MS. GRANT: Well, it's something that's come up several times. In fact, Dr. Raymond was one of the first to bring it up I think in his football analogy that consistency, as you pointed out, consistency is bound to be an issue with as many employees that we have. I do know that we have a very sophisticated and elaborate training system, and we do correlation activities and all those kinds of things. We have IPS programs in place, and so I'm not sure what to say about that except maybe we do need to improve the consistency.

MS. MUCKLOW: Thank you.

MR. ANDERSON: Okay. Noted. Go ahead.

MR. POTTER: Hi. I'm Bill Potter with George's, and I also, as others have said, wanted to tell you we appreciate those of us from industry, the open forum and the ability to provide feedback.

My question is related to the presentation on inherent product risk, and how to measure that, and I thought the panel of experts was very qualified and would commend the Agency on soliciting their input.

However, the panelists, if you kind of drill through that, I kind of did that at the break sessions, the panelists had some pretty diverging opinions about inherent product risk. I was just looking, for example, at the category of raw intact chicken versus ready-to-eat, fully cooked poultry, and one panelist, panelist 3, for example, said that raw intact chicken had a score of 600 whereas ready-to-eat had a score of 10,000. To me that says that that panelist thought that the ready-to-eat, fully cooked product was much more riskier. Panelist 10 had about the same score for those two categories, scoring one 2.2 and the other one 2.5, and then panelist 13 had the opposite opinion, whereas that panelist said that

raw intact chicken had a score of 100 and the ready-to-eat, fully cooked poultry was only a risk of 1.

So I guess my question would be -- well, first a comment. Obviously, the panelists considered the subsequent step of the consumers cooking and further handing of the product to be significant in this risk but they see it in different ways obviously.

So I guess my question is could the Agency do further and extensive studies to try to determine relative risk? Because those of us in industry want to make real, real sure, that we all have a really good understanding of which of those products the Agency feels like are higher in relative risk than the others.

MR. MICHAEL: I will say we are continuing to look at the scores given to us by the experts, and as I mentioned earlier, we did an initial informal analysis, a cost analysis. I'm not a statistician. I couldn't explain all the things we did. We found a significant amount of agreement among the experts in terms of ranking in some cases, in terms of proportionality in others, but we are continuing to

look at it. This is, you know, getting a really wide range of numerical answers is something, of course, that we want to try to constrain when we give people the instrument, but it's something you encounter anytime you do an expert elicitation, regardless of whether you give them a range, or in our case, we gave them a lower bound but no upper bound. You're always going to get different answers, and you need to determine how to make -- which measure of central tendency to use, how to generalize that data, and I think we still have a lot of options on how to use this data, how to interpret it, but we are still looking at it.

MS. GRANT: Michael?

MR. KOWALCYK: Michael Kowalcyk with Safe Tables Our Priority. In looking at the establishment risk control paper, it brought back a lot of memories from the last NACMPI meeting about these questions were posed to that committee, and I think the committee came back, my fellow committee members can correct me if I'm wrong, but that we requested that the Agency provide more detailed information about the

actual data that would go into the system. When you look at this system here, with these spokes around the center of this tire here, it looks like a scheme for a database that you use to manage your workforce.

To really address these questions, as far as applying weights and look back periods and things like that, it would be -- it would help those in industry as well as consumer groups as well as academicians to better understand what the data is, how it's currently structured, where you're gaps are today. I know someone mentioned taking qualitative data and transforming it to quantitative data that may cause revisiting, how NRs are structured as well as how FSAs are done. Those types of details, unfortunately if those aren't transparent up front, there could be a lot of misinterpretation of the risk-based inspection process that's built on said data.

So if the Agency can share anything at this time for this meeting or for the committee meeting later in the week, it would be greatly appreciated. Can you speak to that? Are there any more specifics than what we had in the spring and what we appear to

have today?

MR. ANDERSON: Well, again, I would say that this is part of a continuing public process that we're getting information on these kinds of things. We're still at the point now where we're trying to make sure that we have all of the right components, that there aren't any components that were missing, if there's some components that are more important than others. I think on many of the components, which I probably went into more detail than some people might have liked and less than other people might have liked, on pathogen control, there are a lot of different variables or elements that enter into it.

So I think what we're still trying to do here is see if we're getting the big picture right before we get down into more details. So I'm not sure what -- if I can add anymore. I mean I can try to answer more specific questions when they come up, but that's a pretty broad question I guess that you're asking.

MR. KOWALCYK: Okay. Thank you.

MS. GRANT: Okay. Felicia.

MS. NESTOR: Felicia Nestor, Food and Water Watch. You just mentioned that as a continuing public process, does that mean you have another public meeting scheduled after this one?

MR. ANDERSON: I don't know the answer to that.

MS. NESTOR: So in other words, there may be another public meeting after this before implementation? It's still an open question?

MR. ANDERSON: I don't know the answer.

MS. NESTOR: Does anybody know the answer?

(No response.)

MS. NESTOR: I mean whether this is the last public meeting on this seems like a significant issue. So if there is an answer to it.

(No response.)

MS. NESTOR: I guess we don't have an answer. Okay.

In the implementation box, you mentioned some, some specific things that could be in an and/or that would be considered food safety, and you mentioned the 416 and the 417. Are these definite

factors that the Agency has decided upon or you're just considering these or what?

MR. ANDERSON: I would say the latter. I would say we're considering them.

MS. NESTOR: Okay. And when it says those for which regulatory control action was taken, how do you determine that from an NR? Would it be in the blurb or is there some, is there some category on here that's checked off every time any regulatory control action is taken?

MR. ANDERSON: One of the, one of the ways that we're analyzing NRs is we're actually conducting text search analyses of the NR narratives, which is difficult and it's painstaking work, but we think that if we can identify certain types or characteristics of NRs that are really predictive and if it meant we needed to make a change to the system, we would entertain that. It would allow us to do that more efficiently.

MS. NESTOR: So for regulatory control action, you're going to be searching for specific words that would tip you off that that might have

occurred?

MR. ANDERSON: That would be one of the ways to try to do that, yes.

MS. NESTOR: Okay. And then those issued for inadequate validation or verification, I'm assuming that would be the monitoring NRs. Is that right? Or would that be a word search as well?

MR. ANDERSON: Reg cites, yeah. I can't -- I brought my red book with me. I didn't bring it up to the table, but we have a regulatory -- we have a particular regulatory requirement for that, and it would be a particular reg cite.

See, one of the things that we didn't -- maybe didn't go into as much this morning is that FSIS in December of 2005, had a new feature to FSIS that permits --

UNIDENTIFIED SPEAKER: PBIS

MR. ANDERSON: -- PBIS, that permits and, in fact, I think requires an inspector when they're documenting their regulatory noncompliance to select one or more specific reg cites that are being violated, and that has -- since December, that has

substantially increased our ability to analyze data because we can count NRs now that are documenting specific noncompliance and specific regulatory requirements.

MS. NESTOR: Okay. So that's starting to explain to me. You're talking about relevant regulations. That there is a category on the NR that's called relevant regulations.

MR. ANDERSON: Yes.

MS. NESTOR: Okay. And so you're saying that every single NR now is categorized where they have to --

MR. ANDERSON: Yes.

UNIDENTIFIED SPEAKER: Actually there was a relevant regulations field before. It's just there wasn't a drop down menu and the data wasn't constrained. It was entered in ways that made it harder to search. Now that we have the drop down menu, we can do very consistent searches, for example, for various violations of 417. So the validation violation, corrective action violation, et cetera.

MS. NESTOR: Uh-huh.

UNIDENTIFIED SPEAKER: And every inspector now will enter that data the exact same way.

MR. ANDERSON: And they can enter more than one regulatory requirement if there was more than one reg cite, if you will, that was noncompliant. He can actually enter multiple reg cites anew.

MS. NESTOR: And have you been reviewing these to make sure that it actually comports with the blurb in the NR? I mean how is this drop down system working? Is it working extremely well, pretty well? Have you done a review?

MR. ANDERSON: I think that's maybe a bit more a side benefit, part of the work we're doing here because by doing some of the text string analysis that we're doing, we can do text string analysis by NRs by reg cite, and that should give us some insight into some of that kind of consistency and validity. So I think that will permit us to do that.

MS. NESTOR: Okay. So the way you're going to deal with NRs is through this kind of computer system rather than like an individual review of NRs?

MR. ANDERSON: Yes, because I think what we

ultimately understand here is that a risk-based inspection system, that's going to be a data driven, a real time inspection system, we can't be, you know, people can't be sitting down and reading all the NRs and putting them in one category or another. That needs to be automated to the extent possible.

MS. NESTOR: Thank you.

MS. GRANT: Craig.

DR. HENRY: Craig Henry, Food Products Association. Considering all of the debate that is involved today regarding the expert elicitation from the inherent risk, it seems that it would be appropriate when you look at the Agency using the National Advisory Committee, not only on meat and poultry inspection, but the microbiological criteria for food, certainly would have merit for a review and to have them make their elicitation on the ranking of the products appropriately since it does take into account I believe all stakeholders. And if that's not an option or is an option, we'd certainly like to hear about that, and relative to your wheel, could you comment briefly on how food defense got figured into

this, into your decision making factors.

MR. ANDERSON: I know what you mean by the wheel now, but what do you mean how it got factored in.

DR. HENRY: Well, food defense seems like a new wrinkle coming into the scheme of public health, and in this case, food safety. Food defense is just a new one which I guess was news to us as being a major factor to be brought into this relative to establishment of risk controls.

MR. ANDERSON: Well, again, remember one of the questions that we ask is are the six factors appropriate and we also ask if we think some factors are more important than others, you know, should they be given more weight in our algorithm. So I don't know whether you're asking a question or expressing an opinion. I mean I'm trying to --

DR. HENRY: Well, it seems as though it was then arbitrarily brought in or did FSIS have a rationale for including that in part of the factors that should be considered for establishment of risk control?

MR. ANDERSON: Well, I think it's our current thinking, is that how well an establishment protects its operations from food defense threats which are -- clearly the nature of it is inherently public health. That's a factor that we should be considering bringing into our measure. Exactly how we do it, we haven't decided yet.

DR. HENRY: Okay. And what about the option on having NACMCF address the elicitation method, the ranking of the products?

MR. ANDERSON: I can't answer you yes or no but we will take that comment into consideration.

DR. HENRY: Okay. Thank you.

MS. GRANT: John.

MR. MUNSELL: John Munsell. I have a question in regards to the usefulness of plant and generated microbiological testing results in your equation in the algorithm.

Most small and very small plants do not have their own in-plant samples or lab facilities. Some do, you know, for generic purposes but most don't to make a definite determination for positive *E. coli* or

which type of *Salmonella* serotype. I know that the Agency provided me a list here several years ago of -- from an Agency publication of a variety of labs in the country that plants should consider, which we have always used.

So assuming that a small or any size plant would send a sample into one of those labs, does the Agency consider the results from those non-USDA labs to be valid?

MR. ANDERSON: Again, I want to make it clear that what we're talking about, what we've been talking about in our presentation, in our measure of establishment risk control, what we had addressed is the Agency's own laboratory test results, our own testing program. Now others have brought up -- this is maybe the third time that somebody's brought up is the possibility that we should somehow consider the results of the industry testing they do themselves, and now you've taken it down even another level, which I'm not saying isn't valid, but it's still a deeper question of, okay, if we were to consider industry test results, would we treat industry test results

that we tested at some other lab, depending on which lab it was tested, and I guess I just don't know the answer to that.

MR. MUNSELL: Well, I'd like to suggest that since those labs are listed in the USDA publication, that they must be valid labs, and if the USDA would simply accept those lab results as valid, I would suggest that the USDA should give perhaps equal weight or relevance to those test results as it does the results from USDA labs. For one thing, it would provide quite an enticement to plants to increase their own testing if they can be a part of this system to prove what the actual risk is at that plant. If the Agency refuses to accept the validity of those results, then the plants would respond, well, why should we waste this expenditure if the Agency refuses to accept it?

MS. GRANT: Dr. Raymond.

DR. RAYMOND: I want to address Craig's question about NACMCF, just so everybody knows. I think technically I chair the NACMCF committee, but in practical purposes, Bob Bracket (ph.) from the FDA --

and myself kind of co-chair it, FDA and USDA and many other U.S. federal agencies sit on the advisory committee for NACMCF and about twice a year, we get together as an advisory committee and entertain requests for work for the NACMCF committee and depending what they've got on their plate, we may task them with one task, sometimes maybe with two tasks, but it is formed by a -- and, Craig, I think that's the reason no one can give you a definite answer. We certainly could bring it to the NACMCF Advisory Committee with the request that this be considered as a project for NACMCF. It may or may not, you know, work that time. They meet twice a year basically and, you know, have to work into that schedule also to get it done. I'm certainly not going to say we wouldn't consider requesting that the Advisory Committee put that on as one of the projects, to get it done probably. Barbara, you sit on that. How long does it on average take from the time you get tasked with something? One year, year and a half. So, Craig, at best, we're probably talking two and a half years before NACMCF could come back with some

recommendations. Not that it couldn't be done. Not that we couldn't in two and a half years take a look at that Y-axis and say, well, we're going to slide some things around based on NACMCF, but I don't think we'll postpone our RBI to get NACMCF to do it.

DR. O'CONNER: Dr. Bob O'Conner, Foster Farms. The issue of NRs has come up quite a bit, and I would say I live on the ground floor of noncompliance reports, because I have quality control managers who work for me. I deal with a lot of NRs, a lot of appeals, that process. It's a very long process by the way.

I think there's been a lot of valid points brought out relative to using NRs in your analysis or analyzing NRs, and what I hear you saying is you're going to be looking at a lot of that electronically. It would almost be impossible for you to drill down into every individual NR, and I would say validate the substance of it. That's going to be very difficult for you to do.

But one thing is on every noncompliance report, the inspection employee does list their name.

And I think as part of your analysis, you might want to look at the names of the inspectors who have written in their names. And then I would look at the numbers of NRs written by various inspectors and look at those trends and maybe analyze why certain inspectors rank so high in so many NRs. And I think in some cases, you'll find that it's very valid. And then I think in other cases, you're going to find it's very invalid and very biased. So that's a suggestion as part of your use of NRs.

MS. GRANT: Okay. Any other questions on either one of the papers? Any other comments?

MS. DILLEY: I just want to take a run at, I think it was Felicia who asked the question about is this the only public meeting, and I think the reason that that's a hard one to answer, there's kind of two levels of answering that.

One is tomorrow we're going to come back to so what next steps discussion, and some of that's based on the next day between now and that discussion of what comes out of this, what the group recommends and some ideas that you're going to put forward.

The other piece of that is looking at other avenues for public participation. The stakeholder input process I believe is beyond just this meeting. And there are lots of avenues to do that. People have mentioned NACMCF, NACMPI, lots of other kinds of avenues to do that.

So one of the questions is, taking what comes out of this and other avenues of providing input, and looking at what would be the best vehicles, whether that's a public meeting or doing it through a subcommittee of NACMPI or NACMCF, a lot of acronyms in this -- on this topic, but other avenues. And one of the things I think will come out of part of that discussion tomorrow, but also beyond that, additional comments that come in from the remote sites and through the electronic means on papers and reviewing the material from this workshop, is making some decisions. We're going to write a report, too, as part of our task is to put some options out there in terms of how to stakeholder input can be gathered beyond this. So it's not a very satisfying question to you possibly right now, in terms of is this the one

and only. We don't know yet is kind of the short answer. So I would participate like it's one of the best opportunities to get your comments in, but the door is still open in terms of what comes after this. It's going to require some reflection and thinking about what information comes out of this discussion and other avenues of gathering input.

MS. GRANT: There's another question.

MS. NESTOR: I don't have so much a question. She kind of answered it, but I think all of us have come here to give our input on a very complex and large problem, namely, you know, food safety in America, and I really would be quite upset if I thought this was the only public forum because I feel totally like overwhelmed. We just have way too many topics to be discussed, for it to even be done remotely in two days of public testimony. And I would sort of like to know how many other people agree with that in this room right now.

MS. DILLEY: That is a point well taken, and I think the question is, let's come back to that question again tomorrow and see how we can do in the

sessions that we have planned for today and tomorrow and I think that's part of the input that we're looking for from everyone.

MS. DONLEY: This is Nancy Donley from STOP. I guess, and this is going to go back -- take a step back to this morning's conversation on the whole vision of this. I have a question. What does FSIS envision coming out of this meeting? I think that would be very, very helpful for me to at least know what is it that we in this public meeting are being charged with doing? What is it that you're really asking from us, and what are you going to do with what we give to you?

MS. KOWALCYK: Actually -- this is Barbara Kowalcyk. I would like to follow up from Safe Tables Our Priority. I would like to follow up and just take Nancy's comment which was very well taken and appropriate, one step further.

The directive seems to have been that we're supposed to spend these two days really getting into the details of these two papers but yet earlier, I believe it was Don Anderson's response was really

we're here to look at the big picture, and it certainly raises the question, we're getting conflicting messages. Are we here to look at the big picture of risk-based inspection, or are we here to get into the details?

If we are here to get into the details, we obviously need more information to actually delve in there and give you some feedback.

If we're here to look at the big picture, then should we be limiting this conversation to these two papers?

It's just -- I'm getting a mixed message.

DR. MASTERS: This is Barb Masters. We tried to give you a sense of the bigger picture in our opening remarks to let you know where we were heading from an overall perspective, how data can play out in may ways in the Agency. Then to bring you back, to let you know that most of what we need from you over the course of the next two days, did relate back to these two papers and how we could begin to implement these two papers specifically for processing and for off-line slaughter positions.

These two papers, we have had on the website since July and have done some issue spotting with some of our stakeholders to gain what we hope to be a substantive and useful agenda, and with that, we have put some very specific questions along with each of the papers so that you would have a sense of the kind of information we still need from you, the stakeholders, to help us move forward.

In these workshops, we hope to obtain answers to those questions from our stakeholders and start to come to some consensus around those questions as we move forward.

A lot of the questions you're asking, I think when you get in your small groups, you will see were really around the questions we were asking, and you are really starting to give us, from where I was sitting comments around the questions that we were asking.

So I felt you were starting to get into some of the questions that we were asking with the comments that you were providing to the Agency, and I found it quite helpful to listen to you, and I think when you

get in your small groups, you have already begun to do some of the work that we were asking you to do with your comments.

We're hopeful that by getting into your small groups and working through the questions, you will have given us ideas around those questions as well as quite possibly new ideas that we didn't think to ask which will be very useful to us.

So tomorrow, we can get those thoughts brought back to the Agency, and then we can share with you, at least our preliminary ideas for a vision of how we see these two papers coming together with your input. We will try to bring a few of the pieces that you have asked for in the form of an example NR, the URL to get to that. I heard somebody ask, could you chart out for us the data pieces that you already have in that data warehouse. We can certainly try to put those on charts for you if that's useful to you, and if that's helpful, we'll be glad to do that while you're in your workshops so that you can see that as you move forward.

But we really do need your answers to these

questions which in some ways you were starting to do with your own questions, your comments that you're giving for us, to help move us forward and looking at these two papers and how they relate in coming together for implementing our more robust risk-based inspection for processing inspection assignments and off-line slaughter inspection assignments.

MS. GRANT: Caroline.

MS. SMITH DEWAAL: Thank you, and I beg your tolerance on this. I wasn't going to take the mic, but I will not be here to participate in most of the small groups, so I won't be here tomorrow.

I think Craig Henry has really raised an important question on the expert elicitation. And I've heard the Under Secretary come in and say we don't have two and a half years, but you need to take the time to do it right, and we, you know, in leaving this meeting this afternoon, I just need to share with you that I don't have confidence in that piece of this work. I have not spent as much time delving into the plant based thing, the plant based component of the algorithm but I think there are people in this room,

both on the industry side and on the consumer side who can comment on that, but I just -- I thought I'd tell the Agency that what I hope comes out is a plan for how you plan to move forward with, with the product ranking in a way that's trustworthy to everyone, and if it is not through the NACMCF, you need another vehicle because what you've got right now isn't ready for prime time.

DR. MASTERS: Caroline, I think that's a good example. Where we ask some questions, we shared with you what we have. We asked for some additional help, how we could start getting input on how we could, in fact, look at measures to insure that we were considering severity, and if an answer that comes out of this group is to have somebody like NACMCF, be a body that helped us do that, or another body, to make this a work that could move forward, then that's a way of answering that question that might not only answer that question but give this body of individuals some assurances around the whole body of work. I think that's what I'm saying, but what I was hearing allowed me to believe that you were starting to answer

some of the questions while you were providing some of the comments.

So I was hearing things maybe differently in the front of the room than you might have intending to present them from the back of the room. But I believe you were starting to answer some of the questions with some of your comments.

We recognize there's questions still to be answered, and how you might present a comment could help us move forward in many realms. So I think that's a good example of how you might choose to answer a question to help us move forward. Does that make sense?

(No response.)

DR. MASTERS: So we may ask it about severity and you may choose to suggest that not only around severity, but around the whole process may take it to the whole next level, Caroline.

MS. SMITH DEWAAL: I just -- Barb, I appreciate your focusing on severity, and that's certainly an important question but in delving down into the actual expert elicitation, there was not

substantial agreement. There wasn't even agreement on how to rank it, and I think that's a flawed tool. And you need to come in with the public health, a public health tool that either -- I mean either start over, throw it out and start over or use that as a base, but bring other public health experts and, you know, I might suggest a ratio of 22 public health experts to 1 industry expert for your next panel. You did not deliver a baseline product that is at all trustworthy to us. It did not appear to be substantial agreement among the experts, and I think you need to go back and rethink that. That is not ready for prime time.

And maybe I'm -- I'm not just answering you on severity. I need to be very clear about that. I'm not just saying look at this on severity. I'm saying look at the answers that you have come up with and make it balanced and make it something that we can trust, because it's not that way yet.

DR. MASTERS: I appreciate that, and I don't think that's what I was suggesting you were saying. Thank you.

MS. GRANT: Nancy.

MS. DONLEY: This is kind of as a follow up to what I was saying earlier, is as far as I can determine from what I've read is that the Agency has been going down this path of risk-based inspection since about 2000. And most of it, which none of us has seen anything until July when these two papers were put up, and so there's been a process, an ongoing process for years that we haven't been privy to.

You used a word, Dr. Masters, that really causes me grave concern, and that is the word consensus. I do not see how we can be given the materials that we've been given, and can we give you some specific points on the papers? Yes. But we cannot give you our best thinking with what we've been given. Those papers beg more questions than they do provide information for us to be able to really respond in a meaningful way.

I don't think there's any way that five -- we can be given five, six years worth of work and be asked in a two-day session, to come out with a consensus among all of us. I just think that that is just -- I'm not prepared to do that. And I really

don't know who really could honestly say they could.

And I also think that after having built a model going forward for five years, six years now, that you can't honestly tell us what your next steps are going to be. I find that hard to believe.

MS. DILLEY: I appreciate your input. I do think it's important to understand, we have had public meetings on our processing inspection optimization system, and have talked about the HCC and the HC with our consumer groups. So I don't want anyone to suggest that we haven't had public forums on these other documents.

And as to not being able to speak to our next steps, I think it's important to understand that Matthew and Don are being open to hearing from our stakeholders, and they don't have perceived next steps because we've asked them to allow the public process to play forward.

So I appreciate your comments, and I don't want to take away from your comments, but we don't have definitive next steps because we are allowing this process to play out, and we are looking for that

public input.

Just two other things. Do you think we will all come back to the question of what are the next steps, and we talked about that earlier, and we do have a place for that in the agenda tomorrow. So we need to come back and revisit that question.

The other is whenever a facilitator hears the word consensus, we kind of go -- and the expectation is not to come out of this meeting with consensus in terms of saying, do we have consensus, and it's impossible with the amount of information you have.

I think what we are -- what the charge is, is to get as much information and input on these concepts. We recognized from the beginning that two days on these big chunks of information is a lot to ask. No doubt about it. We're not looking for consensus. We're looking for as much input as possible. So I do want to be clear about that because it's important to distinguish what you're being asked to do.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables

Our Priority. I have a couple of comments.

First of all, I am still a bit confused as to whether or not we're supposed to be looking at the big picture versus the details. If we are looking at big picture, then there are other things that we should be talking about such as does the Agency even have the legal authority to implement risk-based inspection and will this get challenged in Court, but I'll stay away from that for now.

The other thing I wanted to follow up on was Caroline's comment on the expert elicitation. And I agree completely with her. I think that the expert elicitation that you do have, when it comes to product risk, has some very significant problems in the fact that, you know, participants were told to ignore -- to assume healthy populations. They were told to ignore severity of illness, and personally I believe that's probably why you got large scores is because people thought that was absolutely ridiculous. Had I been asked to fill that out, I probably would have done something similar just to send the message that you cannot think about that in a vacuum.

I think that you do have a challenge ahead of you, and something that Dr. Raymond has brought up many times, is that the plant, if I believe in level 5 is not the plant that anyone wants to eat meat from, there are certain steps that you can take in the intermediary to certainly reduce the risk of people eating meat from a plant in level 5.

You need to start somewhere, and I understand the Agency doesn't want to wait two and a half years until it collects all the perfect data, and the expert elicitations could potentially provide a baseline if there was any assurance that the Agency would then move towards a data driven system. I have absolutely no faith, based on what I have seen with the microbiological baseline surveys and the other things, that the Agency will go back and fix this system after it gets implemented, and that's what my concern is, and that's why I have significant problems agreeing to this expert elicitation because it needs to come from data. An expert elicitation is a very subjective opinion, and you do not have nearly enough sample sizes to -- and I don't see how bring NACMCF

and NACMPI will even correct that.

DR. MASTERS: Just so everyone is clear, we are talking about the two papers for the workshop this afternoon and about the specific questions that we have framed out for those two papers for this afternoon.

MR. HENDRICKS: Lamar Hendricks. I'm an industry consultant. I've worked in the industry for 40 some years.

I think we're making this a little too complicated. I think we're getting away from the picture. I believe, and the gentleman from Safe Tables mentioned it. We have a wheel. We have a design. We have an enforcement piece. All I think we're looking for is how to assign different weights to determine whether inspection needs to be double here versus twice here or whatever. That's all I think we're charged with here. I think you guys have gone out and done interviews with industry experts, consumer experts, and had input from all of these people. I think let's not over complicate this thing. Let's see where we go. Let's go through some

workshops, answer some questions and then come back and find out what's happened here or how much weight we can put on enforcement activities.

When we were talking earlier about comprehensive food safety assessments, we have a tool in place. It was tough for the industry to comply with all of the directives, the notices, the EIOs, the NOIEs and everything else, but we -- we've still got a lot of work to do but we're doing it. We're making safe product, but what we need to get down to is, okay, our plant here is down in that bottom quadrant. We don't need the inspector there all the time because we have a real good facility, whereas this product has a higher risk, and that's where we need to assign those inspectors.

So that's my input, but I just don't think we need to over complicate this thing. Thank you.

MS. DILLEY: Let me just say one more thing and make a suggestion, and then we'll take Felicia and Barb's comments.

Barb, to your question of are we being asked to look at the big picture and small picture? You're

asking to do both. We started with a vision piece. We're trying to get into -- we want to get and will get into the small groups to wrestle with some of the questions. That's at obviously a more detailed level, but we also have time, we haven't even touched on the implementation piece. That's tomorrow.

Unfortunately, you have disaggregate and then re-aggregate it to see, do the piece, to get a little deeper into the different dimensions of it, and then step back and that's why we have some time allocated tomorrow. I know an hour isn't much, but it is some time to surface at least additional issues that need to be raised. And I think when you're being asked to put input on, drilling down, how do you think through volume, this equation, and then take a big picture question and say, how do you get an expert elicitation or the basic calculation to have some validity, et cetera? You're providing comments at both levels. Those are -- so you are -- it's a big charge, and we knew that coming in and it is hard. I think the problem is we want to get to doing it, and then come back and say, okay, so what? Then we have

to ask the big question that both you and Felicia and Nancy have been asking, and others, so what next after that? And we don't have the answer to that. We won't be able to answer that question I don't think until or at least take another run at it tomorrow afternoon.

So we're doing all sorts of those pieces together, and then we need to step back and say, okay, what's the information that we gathered, and what do people want to see in terms of next steps and a stakeholder input process.

So I'd like to take Felicia and Barb's questions, you're standing at the mic. Dr. Raymond, you have a comment as well, and then I really would like to get into the small groups to be able to spend some time talking about those two pieces, and the questions that have been posed. Felicia.

MS. NESTOR: Felicia Nestor, Food and Water Watch. I have a couple of more questions about this diagram with everything around the central hub, and I just wanted, you know, to figure out how much data you actually have. How many plants, how may processing plants that might be subject to this risk-based

inspection right now get no Government sampling?

MR. ANDERSON: The question was about the number of establishments, I think you're asking that do and don't have laboratory test results?

MS. NESTOR: Yeah.

MR. ANDERSON: It is true that a lot of establishments produce products that by virtue of the fact that they're not ready to eat or they're not raw ground beef product or they're product that's not subject to some *Salmonella* program. It is true that we have a lot of establishments, I believe it's between 1500 and 2,000, I look back to Loren to give a nod, but we do have over 1,000 plants, maybe 1500, that by the nature of the work they do, they're not subject to any of the Agency's sampling requirements.

MS. NESTOR: Can you give me an authoritative percentage of the number of plants that are going to be subject to this RBI that don't -- I mean I, you know, it makes a difference whether it's 10 percent of the plants that are going to be subject to RBI or it's 50 percent.

MR. ANDERSON: Oh, I'm sorry. Yeah, well,

we currently have approximately between --

UNIDENTIFIED SPEAKER: 25 percent.

MR. ANDERSON: 45.

UNIDENTIFIED SPEAKER: 25.

MR. ANDERSON: -- 25 percent sounds about right, because we've got about 5500 plants under active federal establishment, you know, inspection.

MS. NESTOR: And those are processing plants you're talking about, not slaughter plants that wouldn't be subject to this?

MR. ANDERSON: Well --

MS. NESTOR: Barb's shaking her head yes. So --

MR. ANDERSON: Yeah, we have slaughter establishments that also do processing --

MS. NESTOR: Right.

MR. ANDERSON: -- combination establishments but we're not talking about slaughter inspection here. We're talking about processing.

MS. NESTOR: Okay. How many companies would you say are identified each year by the USDA's complaint system? Because that's another, that's

another data collection point you have, is the in-commerce findings.

MR. ANDERSON: I don't know the answer to the consumer complaint number. I know there are hundreds. Maybe there are over 1,000 consumer complaints. I know recalls, there's only been approximately I believe, because I checked the other day, there's been 15 Class 1 and Class 2 recalls since January 1st.

MS. NESTOR: So you're talking about 1,000 complaints that actually identify a plant. So that's data that --

MR. ANDERSON: I do not have an authoritative answer to that question, no. On consumer complaints, I don't.

MS. NESTOR: Okay.

MS. GRANT: Felicia, how many more questions do you have? I don't want to cut you off on one hand, but on the other hand, we really do need to get into the smaller groups.

MS. NESTOR: Yeah, I don't actually have other questions. I was just going to read a couple of

little statements that I got from inspectors since we don't have any inspectors here on NRs. I mean I know the Agency invited Stan Painter (ph.) but unfortunately they didn't give him his authorization code. So he's not here. So we have no inspectors here.

MS. GRANT: Okay. I'm trying to think of the best way to do that, for the public record, to be able to do that tomorrow or I'm just worried about --

MS. NESTOR: I can do it tomorrow. I just thought it was relevant to the question of NRs today, but I can do it tomorrow.

MS. GRANT: Okay. You had a response to that question?

UNIDENTIFIED SPEAKER: Just an answer to your question about consumer complaints. There are about 5,000 consumer complaints in the system, and your question was how many individual establishments that represents, I don't know. It's smaller than 5,000. I don't have the exact number.

MS. NESTOR: Okay.

UNIDENTIFIED SPEAKER: And each of those

complaints is referable to a particular establishment.

MS. NESTOR: It is?

UNIDENTIFIED SPEAKER: Right. We have to have an establishment number.

MS. NESTOR: But you have no idea what it is?

UNIDENTIFIED SPEAKER: What the total number of establishments represented?

MS. NESTOR: Each year. I mean, I'm just wondering what kind of --

UNIDENTIFIED SPEAKER: That's over about a five year period of time.

MS. NESTOR: All right. So I'm trying to figure out what kind of source of information is this going to be. If you've got the data coming in from all these different points, food safety assessments are done once every three years on average, 25 percent of the plants get no pathogen control, we don't know what percentage of the plants there's any in-commerce findings on, the NRs are not written at a number of plants because of shortages, and the Agency doesn't know why. So I mean I think these are important piece

of information.

MS. DILLEY: They are important pieces of information. I think what you're trying to do is a gap analysis right now which I think has been offered to do some of that between now and tomorrow. To come back to the question, I think your questions are right on target, and I think part of the conversation this afternoon is how do we collect this information? What are the best types of information you need to collect, and then where do we have that information and we here don't we have that information. We're kind of doing it in bits and pieces, and we need to pull it altogether. Barb, you have a comment?

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority. I just wanted to follow up on the gentleman's comment earlier, I think that the purpose we are -- the reason we are here is we're trying to give the Agency feedback as to where they should allocate resources in an efficient and effective manner to prevent food borne illness.

I do not take this as lightly as maybe some others do, but the problem is if we do not -- if we

are not very careful about how we classify these plants, my concern is what if a level 5 plant gets misclassified into a level 1 plant. That will have a profound effect on public health because there will not be inspectors there on a regular basis. So what we need to do when we are looking, going through this process of trying to figure out the algorithm for which cell plants fall into, you need to take the most conservative approach in order to protect public health. So I take this very seriously because one of my gravest fears is a level 5 plant is going to be misclassified into a level 1 plant, and when is the next opportunity for that plant to get shot back up to level 5. So I think this is a very important public health task that we are faced with.

DR. RAYMOND: Dr. Raymond. Barb, first of all, I don't think a level 5 could get misclassified as a level 1. First of all, the product they make would have to go from a very risky product to a very safe product, and even though we may disagree on expert elicitation, who those individuals were, et cetera, I don't think too many of us have too much

disagreement on the list that has been compiled of the 24 food products, and that's one thing I would task this group to come up with.

For instance, the consensus of these 23 scientists said ready-to-eat meat, fully cooked without subsequent exposure to the environment is the safest of the 23. This group of scientists also said that the riskiest of the 23 is raw ground, comminuted, otherwise nonintact chicken and turkey, and again, I don't think too many of us would disagree wildly with that. The question is where do we put the other 22 in between, and I don't care if number 16 becomes 17 or 17 because 15, because we're splitting hairs here, that won't move you from a 5 to a 3 to a 1.

Same with the plants. All of our poultry plants are doing *Salmonella* testing. They can't move from a 5 to a 1, just based on *Salmonella* testing alone. They're either going to be at a 1 with less than 5 percent, or they're going to be in 5 with more than 20 percent or they're going to fall somewhere in between. They just can't get around that. There are 1,000 plants, 1500 plants, maybe that don't have

microbiological testing or producing product for which we do not microbiologically test. They're not ready to eat. They're not ground poultry. They're not ground beef.

Now there's a reason that we don't do testing in those plants. It's not a gap. It's not a gap. Consumer complaints is a small part of this whole overall thing that we cannot ignore. It's not one-sixth of the whole spoke. It's not going to carry one-sixth of the weight. It's not that big of a deal, but it's a deal that we cannot ignore. Someone complains they got glass in their ground beef, we should know that, and the plant should be held -- with that and have a different inspection. Not everyone of these is 100 percent for every plant.

I would ask you to take a look at the 24 types of raw and processed meat and tell us where we are wrong with our expert elicitation. Caroline, I talked to you earlier in a private meeting. If you want to give me a list of 20 public health scientists that are willing to take a look at this, and 1 from industry, Dane will be happy to be that person. And

I'll facilitate that meeting. That won't take us two and a half years. You know, you and I had the conversation, you had some ideas, I had some ideas. I don't think either one of us are right on who it should be, but you come up with the names, we'll do that.

When I said two and a half years from NACMCF, that's on the good side, two and a half years, and I don't want to wait two and a half years, you know, people playing football, tackle them by the face masks right now. We need to move and do the best we can which is better than we're doing. I think everybody in this room agrees we can do a better job. This is public health. This is lives saved. That's what it is. And we need to get off the dime and move, and I will use the word consensus. Barb will use the word consensus. Our facilitators won't, but that's okay. We need to stop the harping about what we haven't done right in the last 10 years, and we need to talk about what can we do with the resources we have, how can we better utilize them to get the biggest bang for the buck, built the best mouse trap,

and let's get this thing moving forward with your input. That's why we're here today. That's why we've been having monthly meetings with industry and with consumers, quarterly meetings with the two together. NACMPI has been meeting on this. We've been doing this for the whole last year.

Now I'm not going to go back to 2001. I wasn't here. Barb wasn't here then. Bryce Quick wasn't here then. Dr. Mann, our Deputy Under Secretary. None of us were in our positions back then. We all came in about 14 months ago. And we've tried to change things in the last 14 months to get this on the table for open discussion, and that's what we're having. I encourage you to keep it up tonight and tomorrow.

MS. DILLEY: Carol -- and then Paul's coming up to do the instructions for the small groups.

MS. TUCKER-FOREMAN: Dr. Raymond, I have a real problem. I'm Carol Tucker-Foreman with Consumer Federation. I have a real problem with your -- with the structure of your comment. In fact, as we all know, if you do not have the right information, it is

quite possible that at the end of the process you will have something that's worse. You'll have unintended negative consequences.

We all have serious reservations, not just about the process on the expert elicitation but about the fact that the National Academy of Sciences and every other document that I have checked since I first saw these things, says that this is one way to collect data, not the preferred way. Okay, to use if it is joined with other ways to get the data, in the case here, food attribution data would seem to be essential.

Well, now you're going to tell me you don't have time to do food attribution data. I want to tell you that I spend the last weekend going through all of the documents back to 2000. In 2001, there was a discussion, the Agency went to the Congress and said, it's a Dilley. It said this was a way to avoid inspector shortages. That's how it described risk-based inspection. But they said we need risk attribution or we need food attribution data. FDA said it. CDC said it. Everybody said it. It's been

talked about but nobody's done anything about it.

Now it's hard for me to have you come and say, you have to sign off on this because we don't have anymore time when we've made no effort to get what every expert source that I have checked said is the preferred source of data for this kind of decision making.

It is possible to come out with something worse than what we have.

MR. DeMORGAN: I think I introduced myself previously, Paul DeMorgan with RESOLVE. I think, you know, I'm sure it was a little bit challenging for some of you to kind of listen to that back and forth. At the same time, I think it's better to get that out now in front of everybody and have the conversation because that is the underlying concern here. And in speaking with FSIS staff and others at FSIS, I think the reality is that's what needed to come out, what was wanted to come out of this conversation.

So to Barb and to others about the big picture, little picture, I think what we've just been talking about, not little picture, but big picture,

specific papers, that we've been talking over the last half an hour now, is big picture related for the most part. And as Abby has said, we do have an opportunity, and I would encourage everybody to reflect on tonight and think -- or reflect on today and this evening, and think about what kind of additional thoughts. I've heard a number of good options or ideas at least in terms of, and I know it's not the only concern that's out there, but with respect to the expert elicitation, some ideas. I think we just heard that Caroline is going to come up with 20 names and that could be one of those options, but there have been some others.

So those kinds of ideas are going to be helpful, and RESOLVE, as those of you who kind of were interviewed, I know there are some of you out there, understand, we are developing a report, kind of a summary if you will of the steps that we've taken, that have included the interviews that have included this meeting and some other conversations we've been having, and part of that is going to kind of be a capturing of, some of the key concerns as well as our

recommendations in terms of, from a process perspective or at least options that FSIS can take under advisement and then do what they will.

So tomorrow afternoon we do have an opportunity for you to get some of those feedback in after you heard from Dr. Masters and Dr. Raymond.

What I want to turn us to now is to shift gears a little bit and transition us into the conversation in the breakout or small group discussions that we're going to be in for the rest of the afternoon. It's going to be a little bit challenging. There are some logistical issues, but once we get started, I think we'll be fine.

What I'm going to need to do, and I apologize and if we would have had complete information, i.e., who was here, and what organization, we might have been able to go through and kind of parse out and allocate you into all separate groups. Instead what we've done or what we've decided we're going to do is just count off one to four, and go around and around, and that way, whoever you're sitting next to, you won't be in that

next group. We realize that many of you sit with your friends and folks that you want to chat with off-line. So in this instance, you won't be able to. Maybe that isn't always the case, Carol, but -- so we'll do that in just a moment.

Let me just give you a quick sense of what we're going to do though. Each of -- there's four groups. The first two groups are going to look at product inherent risk, that paper and those six questions first. Each group will get a chance to look at both papers and the six questions but we also realize that embedded within those questions, underlying those questions are a lot of conversation, and if we started all the groups on the product inherent risk paper, we might not get you -- any of the groups might not get into sufficient depth of the six questions associated with establishment risk control.

So the first two groups, group 1 and group 2, will take a look at product inherent risk first. They'll spend some time talking about the six questions, and then depending on the time that that we

-- we didn't pick up any extra time in this session. So we'll see if there's any additional comments on that paper that people feel they didn't get out as it relates to those questions. But after about a half an hour or so talking about the one paper and those six questions, we'll spend a quick second talking the highlights, and then transition to the second paper and the second set of six questions.

I think as Dr. Masters has mentioned, at least from my hearing, a lot of what you've been talking about has already been started, you get into that, has engendered a lot of good comments already. So hopefully people feel that was as well, but I'm sure there's going to be some more specifics as it relates to those questions.

We do need to prepare -- just so that all of you get to share the kind of wealth, the benefit of each other's ideas, we will be sharing some brief group reports. And so the specific facilitators will work you through that or help you with that before you adjourn this afternoon at 5:30.

Tomorrow, you will -- each group will have

about 10 minutes or so to present their thoughts. We'll have kind of a PowerPoint scheme that just answers the six questions, and we'll kind of go through that relatively quickly. We'll also have the opportunity to see if any of the groups from out in the Net meeting world were able to submit any comments on that kind of stuff.

I think that really is it in terms of the specifics of the notes. The only thing I would add now --

(Away from microphone - counting off).

MR. DeMORGAN: Okay. Great. So Group 1, raise your hand. Okay. Good. You're going to be with Kathy. Kathy, you want to stand up for just a second, in Room 302. All the other rooms are upstairs. So 1, 2, 3, you're upstairs. Go up the escalator, as you come off the escalator, it will be the first one on the left.

Group 2, raise your hands. You're going to be in Room 317, which I think is on the right.

Group 3, raise your hands. This is Brad, and that's going to be Room 303.

Group 4, you stay here.

(Whereupon, at 3:35 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:

RISK-BASED INSPECTION (RBI) PUBLIC WORKSHOP

Arlington, Virginia

October 10, 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 J. Atkinson, Jr., Reporter

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