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 11, 2006
9:30 a.m.

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

FACILITATOR: ABBY DILLEY, RESOLVE
PAUL DeMORGAN, RESOLVE

PARTICIPANTS:

DR. RICHARD RAYMOND
DR. BARBARA MASTERS
MR. BOBBY PALESANO
DR. DAVID GOLDMAN
DR. KEN PETERSON
MS. JENNY SCOTT
MS. BARBARA KOWALCYK
DR. CRAIG HENRY
MR. BOB REINHARD
MR. MARK SCHAD
MR. BRAD SPANGLER, RESOLVE

I-N-D-E-X

I-N-D-E-X

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

(9:45 a.m.)

MR. DeMORGAN: I know that the participants were able to engage in a lot more of the discussion that is really valuable in these types of meetings, and they're hard to find when the group is this big. So hopefully people enjoyed that opportunity and maybe we'll have more of those in the future around these issues. But that was a good discussion.

And what we're going to do now is hear about the results of those, and clearly one -- I think from what I heard, it was logical and in retrospect a good idea to split and have two groups look at one paper and two groups look at the other paper first, because some of the groups didn't even get to the second paper, and I know in Group 2, we didn't have enough time on the second paper. I'm sure people would have liked that.

What we're going to do is we're going to spend 10 minutes or so, if you need that much time. I don't think in every instance you will, 10 minutes presenting, and we're going to go Group 1 first, and

then we're going to kind of switch order because of a presenter issue, and go to Group 3, Group 4 and then Group 2. And then we'll do the remote sites last. So we'll do each of those.

Each one has approximately 15 minutes total. So the idea was you get at least up to 10 minutes to present, and then 5 minutes for discussion, question, anybody else in the group can offer any additional thoughts first, and then any questions, discussions, et cetera, and I know for those folks who were in Group 2 who didn't get to talk about the establishment risk control paper, they may have some -- in as much detail, they may have some additional thoughts they want to add to the presenters from Groups 3 and 4. So we'll kind of play it by that.

So with that, the first group is going to be, let's see -- Jenny Scott, with FPA and that group looked at product inherent risk. So take it away. Let me get the -- and if you could just go forward.

MS. SCOTT: Good morning. We had some good discussion in Group 1. We didn't get through all of the two sets of questions, but it certainly was a rich

discussion, and time was short enough we didn't come to consensus on everything, but we threw out some good points for the Agency to consider.

With respect to inherent risk, first of all, we didn't feel that we could talk about that without first commenting on the expert elicitation. And we thought that this elicitation was a good start, but we recognized that there were -- there was limited input here, and we felt that it would be appropriate to take this before another group of experts. So we'd like to take Dick up on his offer to get Dane involved with some public health experts and look at this some more.

We also thought that if these experts had been put into a room together, they might have come to a better agreement on rankings, and they could have explained their rationale for why they were ranking things a certain way because we think that they made a lot of assumptions in doing what they did that didn't come across in the written information that was presented.

We also think that there are data out there that maybe can be used to validate these rankings.

So, for example, if we look at some of -- where some of the illnesses are coming from, is that substantiated by the rankings that they listed.

So getting to the specific question that was posed as to whether the median was the best score to use for this, because of the range in numbers, certainly the median is the best measure of central tendency for what they have now, and we thought we might get a better picture if they could do something like normalizing the data, to a scale of say 1 to 100.

There was also consideration given to maybe they ought to re-look at this. It was proposed that consideration be given for looking at the likelihood of the hazard and the severity of the occurrence and the likelihood of mishandling, and I'm going to come back to that at the end of this presentation.

It was a little hard for some people to say whether or not median was the best number to use, without knowing a little bit about the context in which the experts made their rankings. So again more information and maybe getting people into a room to hash this out would be useful.

With respect to the second question about thermally processed, commercially sterile products, we were in total agreement that they should be included in the list of products, that they are inspected products, but we also felt that because of the controls that are in place there, they really do fit in as the lowest risk product.

On question 3, we broke this down into parts A and B. One related to whether or not the product was further processed at another federally inspected establishment, and secondly whether or not it was going to retail.

If we're talking about processing product at another establishment, then we felt that the product at the initial establishment probably shouldn't be inspected as if it had the higher risk. In most instances, these products are going to be shipped to another facility and given another treatment that would then reduce the risk but maybe this needs to be addressed on a case-by-case basis.

Other people felt that maybe the best way of looking at the risk of the product was just when it

left the door. It's being shipped, the final assessment is being made, the pre-shipment review was done, and that's a product leaving the establishment and maybe risk was best established there. So again this is something that if we would have had more discussion, we might have had been able to come to consensus.

The risk really depended on a number of factors, included the intended use of the product, the likelihood of mishandling, and whether or not the second establishment is employing a lethality step. So that's why we suggested maybe case by case.

On 3B, with respect to product going to retail, we were in agreement that the risk of the product should be assigned based on the product risk at the plant, without consideration for how it was going to be treated at retail because the controls and the oversight at retail are not the same as a further -- a USDA inspected establishment.

On question 4, with respect to translating the volume data into the exposure variable, the group liked the idea of looking at a third access for

volume. They didn't think that volume was inherently part of product risk, and so it possibly could go into establishment controls or have its own component.

We got into a little bit of the detail on how this would be assessed at the plant, looking at the plant profile that establishments fill out in estimating the volume on once per year, and that's something that would be addressed later with -- probably with Bobby's talk on how this gets implemented.

On question number 5, accounting for establishments that produce more than one product. A lot of people thought that for public health reasons, it would be important to look at the most risky product and establish the product inherent risk for that plant based on that. In other instances -- but we need to consider the fact that some of these products may be produced on an intermittent basis, and it certainly wouldn't be fair to give a plant a higher inherent risk ranking based on a product that they produce maybe once or twice a month. So that needs to be considered.

And it was thought the Agency might be able to flag the production of these low volume, high risk items, and have inspection in place at that time.

We also felt that they could consider mapping where all of the products of a plant fell on the grid and making an assessment on where most of the products fall. If they're trending towards the riskier products, then you might consider them higher risk. If they're trending toward the less risky products, maybe less risk.

Turning to severity. The group was unanimous in agreeing that severity does need to be factored into these equations, particularly as it relates to vulnerable populations. We felt that the Agency has a lot of experience in doing risk assessments and the experts on staff who can help them with this, and CDC has some data related to illnesses that could be used in assessing severity. This might be a factor that would be used to adjust the initial rankings.

We also thought in looking at the responses from the experts in the elicitation, that some of them

probably did consider severity in making some of their assessments, and this might be why there's some high numbers for raw products.

Turning to the establishment risk control which we addressed very quickly, on whether or not the components were -- that were listed around that circle were the right components and all needed to be included, we were in unanimous agreement that food defense should not be a factor in determining how to allocate inspector resources. We did feel that this was a very important item for plants to address, but it should not be part of the system design here.

The other components in general seem appropriate but there was some concern expressed about the data that support them, and wanting to see a bit more information about that, and I think we're going to see some of that today.

On question number 2, whether or not the components should be weighted. Comments were made that if you don't have data that accurately reflects reality, then it's hard to make an accurate determination of risk, and it was hard to answer this

question because there were some concerns expressed about the reliability of the data for the individual components, but it was in general felt that pathogen control data are likely to be more objective and certainly are clearly tied to public health impact, and that FSIS may actually be limiting itself if industry data did not play a role in consideration here.

We also felt very strongly that system design had a more important role than some of the others, could be a fairly objective measurement, and if validated interventions are part of the system design, then the design should be weighted higher because of public health impact.

With respect to other useful information for this exercise, we certainly felt the public health data were very important, and it might be possible to sync these up with geographic data. The data needs to tie to a system to indicate a decrease in food-borne illness.

We also considered that attribution data from CDC and the Agency are very important, and they

may figure into both inherent risk and the establishment risk control.

On other ways than FSAs to assess the design of the system, we felt that PBIS data could be used in assessing both design and implementation. We think it's important to capture some of the positive aspects that are in PBIS, not just the negative aspects as captured in NRs. We thought that information from local inspectors and supervisors and management personnel could be useful, and it might be possible to integrate some third party audits in there, like using industry data. That would be a little complicated but certainly it's a tool that can and should be used where available.

Whether the NRs are inclusive, we think that NRs need to be looked at very carefully. We need to focus on the NRs that are being used, and recognize that even within specific areas where generally they would be considered important, they need to be specifically tailored to be food safety related. Some are clearly more food safety related than others.

And on the look-back period, there was

discussion on whether or not it should be a year because of accounting for seasonality. We certainly felt that this ought to be a rolling window, that with an automated system, it would be possible to update the data on plants and reassess where they stood on an ongoing basis, and certainly we wanted to make sure that if a plant implements new technology that has a pathogen reduction effect, then it would be important to make sure that this plant isn't stuck with the rating that they had before they implemented this intervention. And also in considering with a one year design, that clearly data from more recent periods are more significant than data from a year ago.

And finally I said I would come back to this inherent risk index that was discussed, it was suggested that there would be this likelihood of a food safety hazard, the severity of the hazard, the likelihood of consumer mishandling and the volume factor that all could be ranked on a 1 to 10 scale. It was recognized that this goes beyond simply product inherent risk across the entire system. It is probably more of a plant specific situation, but it's

something for the Agency to consider.

Any comments from the group about anything I left out? Mike.

MR. KOWALCYK: Michael Kowalcyk with Safe Tables Our Priority. I think going back to the question of NRs, we wanted to get through all the questions during our allotted time, and I just want the group to understand that we spent very little time talking about NRs and that there really is no consensus, and that's something that really needs to be looked at seriously.

Also in the look-back period, there was some valid points raised about new interventions that are introduced let's say three months ago and not penalizing an establishment for things that happened 10 months ago.

For lack of detail into what the model would actually look like, you would maybe -- you could expect some type of recency component in any predictive model, if we're talking about a predictive model and that should capture that. So I guess looking at the data structure, when the Agency is

looking at putting together this database, dates would certainly be an important aspect of that because you should be able to utilize recency. So I think that kind of begs further analysis into how this model would be specified.

MS. SCOTT: So being very transparent as to the algorithms that are developed is very important.

MR. KOWALCYK: Absolutely.

MS. SCOTT: Okay. Anyone else have any questions or comments?

(No response.)

MS. SCOTT: Thank you.

MR. DeMORGAN: Great. Quick round of applause for group one.

(Applause.)

MR. DeMORGAN: Thanks very much. So I know that the group was asked if they had any other comments. Anybody else have a question or reaction at this point? I mean I think at some level obviously it will be helpful to go through all of them.

UNIDENTIFIED SPEAKER: Will the findings of all the groups be available?

MR. DeMORGAN: Pardon me.

UNIDENTIFIED SPEAKER: Will the findings of all the groups be available?

MR. DeMORGAN: Yeah, the results of these will be in the summary, exactly what format that will be, but these -- I mean these are all on the web already for the Webcast folks. So whoever is on for those folks will be made available.

Okay. We did have the Group 2 presenters come or our second presenter was able to make it. So what I think we'll do is just because they're focusing on that first paper as well, let's have them go next, and then we'll go to Groups 3 and 4. So we have two presenters for this group, and it's Barbara Kowalcyk and Craig Henry. So let me just get this up. And if you guys could use the forward arrow.

MS. KOWALCYK: As Paul said, we're from the second group, and we'll be alternating slides. We spent most of our time on the first paper, and as Paul said, we really didn't get too much discussion on the second paper but did a little bit.

In response to question one under product

inherent risk, there was a lot of desire from the group to re-examine the ranking, and specifically for the expert elicitation. You know, was everybody using the same scale, the same science when they were determining their rankings, when they were doing the expert elicitation. There was a lot of feeling from the group that there was some problems with assumptions. Was it really correct to remove severity from the analysis and only consider healthy populations? The other question that kept coming up was, was the expertise represented broad enough? Should other groups have been consulted, and how would that have happened? And we also wondered why the paper did not include the experts' rationale. It seems that some of the experts did provide their rationale in the comment section, but others did not, and it would have been useful information.

The other thing that came up in terms of question 1 and the expert -- well, specifically in using the median ranking, was we weren't really sure what FSIS had done to validate the median? Was this really a good surrogate to use in determining

rankings, and we weren't really sure what FSIS intended to do with that number.

Basically if you're going to come up with a ranking model, you're going to want to validate that model and get results to make sure that it is a good approximation toward what is really going on in the workplace. Unfortunately, we don't really have a whole lot of mechanisms to get the attribution data that you would need. In other words, if you are going to validate, you would want to see if those rankings -- those products are really causing the most food-borne illness and our highest risk, and really the group felt that there weren't a whole lot of mechanisms in place to get that attribution data.

DR. HENRY: Okay. As far as question 2 is concerned, fairly straightforward, relative to low acid canned foods, commercial sterile canned product, if you will, interesting discussion. We had a very good discussion within the group. Fortunately we had Dane Bernard in our group who had served, as you know, as part of the expert elicitation. And in this we ranked it, the discussion was the product itself has

an inherent high risk. However, as noted here, you must take into consideration the degree of control with the process that's generally used throughout the country. And if the process breaks down, then you're going to have a major problem. But, you know, if you don't rank it high, then there wouldn't be any inspection. That was the other concern.

Well, logically and as we all acknowledged, you go back and look at either the attribution data or just look at the instance of illness that are arising from this type of product, and it's virtually non-existent which really I think attests to the value of the process and the fact that that process has to be taken into consideration when you really look at this product ultimately at the end of the day.

So that's something that I think the Agency needs to consider again when you're looking at product inherent risk between what comes in and what is actually coming out of the process.

MS. KOWALCYK: For question number 3, did we need to factor in for other establishments? We felt that it really -- we did not need -- you do not need

to factor in what happens if the product is going to be processed further at other establishments, except for the assumption in the expert elicitation, page 8, bullet number 2, that the experts were asked to actually assume that consumers were going to deal with it appropriately and there was a lot of feeling in the group that each plant should really stand alone. How it was going to be dealt with at another -- further down the line shouldn't really play an impact.

And there was another part to this that was raised, and that was you need to consider physical and chemical concerns as well as biological concerns when you look at each one of these plans.

DR. HENRY: Okay. On question 4, which dealt with a volume issue, looking at the volume issue, there's an immediate take, well, it should be one on one, larger volume, larger inspection, and conversely in the opposite direction. However, you also need to consider the complexity of the system that exists out there, and the number of products within the plant. So there needs to be some type of weighting that's going to have to be considered.

For that question, there was general agreement I think that the minimum amount of inspection at every plant, dependent upon volume, or regardless of volume, there should be inspection, and I don't think anyone just expects inspection to go away, if you have a minimal amount or if you have a very, very small plant.

On high-risk levels, like number 5, in this case, does it matter about volume, needing a lot of inspection. I think more specifically as we discussed it, that really says if you have plant that's producing a product with high inherent risk, and they have poor controls, then you should have the appropriate amount or proportional amount of inspection at that plant which I think is what Dr. Raymond alluded to yesterday.

MS. KOWALCYK: In regards to question number 5 which was, you know, if a plant was producing multiple kinds of products, you know, how should they be ranked. The options that we came up with was to, one, take the riskiest product and apply to the full establishment. This would give you the most

conservative approach in terms of public health. So if a plant is producing three products, and one of them is the highest risk, that's what should be applied to the whole establishment.

The other one, the other option that was discussed was if you allocate resources to risk, suppose a plant is producing three products, and the highest riskiest product is their lowest volume, should that be taken into account, and then really be assigned to the whole plant? Of course, you then bring up cross-contamination issues, the fact that you have a riskier product in the plant, even though it may be produced at smaller volumes, you could have cross-contamination, but those were the two concepts that we were really getting at in our group.

DR. HENRY: Okay. Stepping from risk and get more direct to the point of severity. I think that the severity point was really well aligned and so much of what we've already delivered, I think you heard from Jenny from Group 1, it's almost kind of like a ditto, but severity shouldn't have been removed from the ranking considerations, and the fact is, it's

very, very difficult to reconcile it no matter how you approach it, especially if it's only aligned with the idea of the product by itself.

But it should have been included in the first ranking, if you would have wanted them to do it, but because of that difficulty, we think it should be a two-step process. You know, look at the product and then consider the severity, and it's almost like you go through the hazard analysis of what is the product you're producing, and who is it intended for, what is the target population that you're going for, and when you do that, then you also must consider, you know, mixed products, a wide range in products such as supposed you're using a finished TV dinner or meal where you've got some type of fresh vegetable in there that may have been blanched, as opposed to a fully cooked ready-to-eat chicken or beef type product mixed into an entrée. So those need to be really properly broken out and weighted as you go through the process of trying to bring severity to bear, but it does have merit here.

MS. KOWALCYK: As I said earlier, we did

have a little bit of time to get to the second paper, and we really just spend a lot of time on question 1 in the few minutes we had.

Some of the issues that were identified in our group was that there was overlap in the wheel, such as NOIEs and NRs, you could potentially get doubled up. Somebody might have an NOIE, and then also get a NR for the same thing. So it was kind of -- I think somebody in the group used the term double dipping.

The other thing that really came across strongly in the group was that we need an accurate picture of inspection, and there's a major problem if inspection is not occurring at plants. So that would put the onus back on FSIS to make sure that there were appropriate levels of inspection, so that we can get an accurate picture.

The third issue that was raised was the lack of consumer information, and there was a concern in the group about what it meant to be verified and validated consumer complaints, and where did food-borne illnesses fit into this, and how was this

defined and what did it include? Did it really truly mean that you had to have a traceable product to its source?

The fourth point is food defense. There was pretty much consensus in the group that it didn't need to be included. We weren't really sure why it was included, and if it is included, it should at least have a very low priority, which I believe the first group found as well.

Okay. I'm going to skip down and do the data collection. One thing that we did spend some time discussing in the group was the fact that you are going to have missing data when you look at the different spokes on this wheel. And the Agency will have to come up with a way to factor in missing data. How are they going to handle that?

There's a variety of ways that you could do that. A lot of statisticians spend a lot of time working on that.

You could also improve NRs, the process, the forms, and I'm sure for each part of the wheel, to be more statistically significant. You still need to --

you want to be able to at the end of the day have all the data that you needed collected, and the entire system needs to be a living, breathing thing, that is that you need to have that continuous loop I believe it was in Dr. Masters' or Dr. Raymond's slide show yesterday, where you have that continuous loop where you keep feeding back and improving the system, and keep feeding back and improving the system. So this isn't just a one shot deal.

DR. HENRY: Jumping back up to subjectivity, it was just clearly noted, and the Agency has already acknowledged as well as the NACMPI has recommended, you know, a re-analysis or evaluation of the NR system, but because of the subjective, you know, we acknowledge there is the possibility that you could have good plants categorized as bad or vice versa, especially if you're just taking them for face value. And I think stepping forward with that, as the Agency attempts to analyze those NRs, we try to figure out which ones are most applicable, and there was some debate within our group about which ones should be considered. You know, we just need to be cognizant of

that because you do want to get the proper attribution of value from this part of the criteria for any of these plants going forward.

And I guess lastly, we thank Paul for his help yesterday. He did a great job facilitating, and certainly did a great job of capturing our bullets for us. Thank you.

(Applause.)

MR. DeMORGAN: All right. Thank you both. So anybody from that group want to add anything, clarification or major points that you think need to be conveyed at this time?

(No response.)

MR. DeMORGAN: Okay. Is there any questions from others to that group? Yes, sir. Name and --

MR. SEWARD: Skip Seward, AMI. When we talk about severity and in relationship to the product inherent risk, it seems like it's almost a subset because when you talk about severity, I assume we're talking about the specific hazard that may be associated with that particular product subsequent to its production or as part of its production. So it

seems like we sort of missed that point a little bit. I just want to make in my mind, anyway, that's a critical parameter that's almost a subset of the product depending on the particular hazard that's associated with that product.

MR. DeMORGAN: Okay. Any -- okay. Anybody else? Comments?

(No response.)

MR. DeMORGAN: Okay. Let's then turn to Group 3, and this is one of the groups that looked at establishment risk control. I'll get that one up here. Just introduce yourself.

MR. REINHARD: My name is Bob Reinhard from Sara Lee, and I was asked to get up and speak on behalf of our group. So I want to thank Brad because he did a good job as a facilitator and I thought we had some very good dialogue.

We set ours up a little bit different, and what we did is when you see the items that are in red, I'm going to call this there were really no major objections by any of the stakeholders to what's being said, instead of saying that we agreed or that there

was consensus because little words can make a different in that, but there were really no major objections, and if I do misspeak on anything, or if anybody wants to make a correction in my group, feel free to stand up and do it.

Looking at the first thing, and our group only got through establishment risk control. We did not get to the other part, the X-axis, the other paper.

The first question was components appropriate and adequate. It was unanimous in the group or there was consensus or there was what I said before, I guess that there were no real objections, that food defense really shouldn't be a component of RBI. And then what we have listed underneath this would be the other comments that were made by stakeholders and put in, food defense should be examined but not as part of daily inspection process, handled through other FSIS activities, RBI should drive food defense.

Another comment that was made on this part related to components appropriate and adequate was

that in commerce should be rolled into enforcement and become one component, and a suggestion was made to add intended use of products as a component.

Another thing that there was no major objection on was this, and that was that some classes of consumer complaints, lack supportive data and instead of can, I want to say may therefore be unreliable. The group agreed that this may be difficult to use within the model, and maybe that we needed to have further discussion on it, and that we needed detailed categories of consumer complaints for the public.

Should the components be weighted was the next question, and our group agreed or there wasn't any major objection. The answer is yes, they do need to but we were unable to get any further than that because we needed a little bit more thinking from FSIS and stakeholders. There would be a lot of questions on that.

Some comments were that in-commerce findings were food-borne illness outbreaks should be weighed more, and food safety system design and implementation

should be weighed more than other components. And the weighing should be flexible, enable to incorporate new information, meaning even if you -- what I believe was discussed by this person, was that even if you have a minor -- a category that's minorly weighted, and you have a major issue within that category, then the model would have to be flexible enough for that to be appropriately handled or vice versa, if you had a category that was heavily weighted, and you had a minor issue, that that minor issue wouldn't trump out because of the weighting. So that the system was not necessarily a guess a straight line equation of this is where you fall, but it had to be more fluid than that.

Establishment risk controls, for FSIS to consider. I think the group considered food safety hazards and all food safety interventions in all types of products should be considered. There was a need to clearly define what interventions are. Am I on the right one? Yeah. Consider differences in scale among plants, meaning an intervention in one plant would have a different scale effect than an intervention in

another, and it's important for the purposes of RBI to consider interventions. Look at plant data to see whether it supports the process they currently use.

The next question was other ways than FSA to evidence food safety system design. At this point, I think the group had no major objections that FSIS should use industry data within the RBI model, and that it would strengthen it potentially.

Comments that were made were establishments collect more data more frequently than FSIS and sometimes more than regs required. This data needs to be considered. The next comment that was made was FSIS collects information, re: establishment's chosen control measures and the possibility of a questionnaire on implementation and design, with an option for industry to provide the data to FSIS and therefore help differentiate themselves on the X-axis if they choose to use that data.

Data sharing could be mandatory was made as a comment and rewards for good plants and penalties for bad plants would be how that summarized.

Again, just to restate, the things in red

are what we generally agreed on and then the rest are just comments underneath those.

More on evaluating food safety system design. The comment was made that FSAs are expensive and inefficient, and put the burden on FSIS and the taxpayers, and that some -- the comment was also made that some plants then gain an economic advantage in essence by consistently skating on the edge of acceptable was added, and we'll get that in the record, but I'll have anything look at this and make sure there wasn't anything right -- wrong.

Another comment that was made is another approach is needed. Plants are required to validate HACCP is working, could generate more information about whether the system is working. Establishments ought to take on costs was one of the comments, and that was that they require more FSIS oversight because they're not doing things correctly, and cost would be appropriately put to them. And then the next comment was, if a plant does well, you could add incentives.

Others, NRs, we didn't get into the NR discussion. We didn't have enough time is really the

reason, just for the same reason we didn't get into the other axis and the other questions.

Appropriate looking back period, the only thing that was discussed here was that hold data long enough to make an adequate assessment and a clear determination. We didn't have any other real comments here because I don't think we were able to go through all the steps to figure out what that would mean, and it would take a long time.

Other inputs and comments and these are just put in here for -- some in the form of a question, some just in the form of a comment.

FSIS ought to identify its own weak spots; need to include input and expertise of inspectors in the development of RBI; inspectors should not get involved with out-of-plant/in-commerce findings; may not be a penalty to be inspected more, it's a reallocation. Inspection could get decreased if you were doing a good job. FSIS might need to go back to Congress to gain authority over shipping decisions, and I'm not quite sure of the specifics on that. So if anyone in the group wants to comment, they can.

Then a couple of questions. What does in-commerce mean? Will there be an appeal process for levels assigned to an establishment? And will there be a venue or vehicle for expedited re-assessment? Which I think some of the other groups talked about what that would be, either if there was an event or there was a new intervention.

So does anybody in my group have anything to clarify or to comment on?

UNIDENTIFIED SPEAKER: I thought you did a fairly good job of capturing some of the things that we focused on. We looked at as many of the big pictures issues as we did as a detail, would be one thing that I think we should have, you know, brought to the attention.

The other thing is that when you're trying to talk about the specific questions as to what did I and some of the consumer representatives there feel was really, really important, we felt it was significant that the Agency does not always have the authority that it needs to carry out some of the jobs it's required to do. And that was what that one

comment was about.

The other thing that I think was -- I think was a consensus of the group was that we all felt that this was a very complex issue, the whole, you know, thing, and that continued discussions of these types would probably be necessary for bringing the industry and the Government and the consumer groups into a unified idea or approach on risk-based inspection.

MR. DeMORGAN: Anybody else from that group have any clarification or comments?

(No response.)

MR. DeMORGAN: Okay. Great. Thanks, Bob.

(Applause.)

MR. DeMORGAN: We do have a couple of questions as well. And just to make sure we have time, we'll take a couple of minutes but, Felicia, a question?

MS. NESTOR: Felicia Nestor, Food and Water Watch. I actually have one comment and one question.

I think if you're going to consider industry data, it has to be mandatory that the industry submits all its data because we already know that the industry

can game the system. They take, you know, 10 sample sets and they report only the data that's favorable to them. So I would anticipate that FSIS has to watch out for that.

The question I have is I don't know -- what did you mean exactly by combining in-commerce and enforcement in one factor?

MR. REINHARD: Well, I wouldn't want to speak for the group, but since that was mine, I can speak to it. The idea would be that the in-commerce results, if there's a significant event, would lead to an enforcement action. If there's a validated or verified food-borne outbreak, that leads to an enforcement action, therefore instead of having a separate standalone spoke on the wheel to handle that, you could roll that in under enforcement action and just handle it at that level, because what was put together by FSIS, was to show that they would look at consumer complaints, they would look at recalls, they would look at these things, and the issues really let to, in my opinion, that if there was an enforcement action, and it wasn't done properly or an event

occurred, that it would make an effect on the rating on that axis. So that was all. It was just a location question.

MR. DeMORGAN: Thank. Yeah.

MR. KOWALCYK: Michael Kowalcyk from Safe Tables Our Priority. Bob, I have a couple of questions.

I think one is more directed towards FSIS relating to industry data. NACMPI was addressing this issue probably about a year and a half ago about industry data and what was called a data repository and we had some pretty lively discussion about how that would be collected and managed and the legal ramifications and it was really those that are in this room that may have been on that subcommittee that would recall, it was a very complicated issue, and I guess this is a question to the Agency as to what the status of that process is. If this is to be considered an input into some type of scorecard for lack of a better word, it would be nice to see an update, if not today, maybe at the committee meeting later this week.

Another comment about industry data, it was mentioned in your presentation about rewarding, sharing of that information. I mean I understand -- I mean you should encourage all stakeholders to share information so that we get the best product available. However, if you're going to use a scientific methodology to come up with a robust scorecard, you can't override what the data is telling you. The data should only be what that plant's process is and other elements that are identified. There shouldn't be a flag in there to say, well, Mike's processing plant shared data, he gets bumped up in score. That should not be the intention of that. That's far from scientific.

Another comment is about pathogen testing data. I know in Group 1, we discussed that, and we were in general agreement that pathogen testing data is -- should be your most objective measure, and if we require more of it, then that fine, we require more of it. Was that discussed in your group and was it really mentioned in your presentation?

MR. REINHARD: I don't remember us going

into the details about pathogen data. If somebody in the group has something different than that, there was not.

MR. DeMORGAN: And I would just note that there is going to be, at some point today, we haven't quite figured out the perfect timing, but we'll figure that out, and we'll all know at the same time, and -- but there's going to be a presentation on data that FSIS is going to give, that will, if not answer all these questions, at least set the stage for additional conversation if needed at that time. So our intention is to make sure it happens no later than the 2:30 item which is kind of the open, catch basin for kind of key issues, but it might come up a little earlier depending on if we have time after the next presentation, the next two -- there's still two presentations to day.

Okay. Thanks to Group 3. Let's see. So let's turn our attention then to Group 4, and again looking at the establishment risk control paper. Great. And Mark Schad is going to make that presentation.

MR. SCHAD: I want to thank the group. We had a very good discussion, and thank you, Abby, for facilitating this. We only focused on the established risk control due to time constraints. We thought we'd just concentrate on that and do the best job we could on that. We discussed the six questions with some additional questions, ideas and comments, detail levels of components, other questions, big picture issues, command and control roles and responsibility, data integrity, quantitative and qualitative and how we got into a discussion like that was the question came up, well, what was the most important parts of these six pieces of the wheel, if you want to call it that, and most of the discussion -- the first item that came up was the food safety system design, and that's how we got into a discussion on the roles of who was responsible. Was it industry? Was it Government? And so like I said, we had a lot of discussion about that.

So question number one, are these six components appropriate and adequate? We didn't really answer that yes or no. We did come up with, there was

some input on some suggested gaps that there was in there. One of them is attribution data. Are we adequately capturing consumer complaints that do not go to FSIS? There was input in there that there are some happenings or complaints out there that do not get reported that FSIS does not know about it. For the plants that do not have pathogen testing programs, how is this considered into the equation?

And there was a question that was brought up, we spend a lot of time on this. The question is, if we're going to use an algorithm or an equation as the driving concept, should non-quantitative information be removed, and that had a lot to do with the food system design or the FSAs. There was some people in the group and I thought it was logical input, that it's not a quantitative thing, this food safety assessment, and we're trying to apply it into a quantitative algorithm or formula.

Are some components more important than others, and how should they be weighted? And, of course, the answer there was, yes, some are more important than others and, first of all, we got some

that we felt were less important. One is food safety defense. It's an important issue but should be minimized as a component in this equation. But there are also many people in the group, just so I can say that to everybody as a whole, there was many people in the group that said it should be eliminated entirely. But I think as a consensus of the group, minimally is at the very maximum -- that's a poor choice of word -- minimally at the most.

Okay. Enforcement actions. This is an important issue but can it be folded into design implementation? And the discussion here revolved about, okay, on these NOIEs and the NRs and stuff like that, if we have a good food safety system, and there's good food safety system implementation, isn't that taking care a lot of these NOIEs and NRs, that they should have never happened anyway.

And the comment was made, a lack of enforcement actions does not equal no food safety issues or need for review and possible improvements.

Okay. The question here, some components more important than others. We pretty much agreed as

a group that the food safety system design and the system implementation are very important and should be closely linked and we really thought those two were the ones that should be most heavily weighted. Some think these two components are the most important. From these two, the other components will flow. I remember one person made the comment that instead of being a circular thing, maybe it's more of a linear thing, that if the food safety system is a good one, implemented correctly, then the other ones like pathogen control and in-commerce findings will take care of themselves.

So questions that were raised. If the algorithm is key, should qualitative data be used? That kind of goes back to the question about the food safety system design and the FSAs. This is a quantitative approach or quantitative -- I'm sorry -- a qualitative evaluation where we're trying to plug that into a quantitative algorithm.

How and in what way is qualitative information and data factored in? Data driven system is important and how do we achieve this? And also in

reviewing only paperwork, NRs, is not sufficient. Need to go into the plants to see what is happening firsthand. And I remember the comment being made there, there's nothing like getting that look, hands on look at the plant.

Are some components more important than others? Pathogen control and in-commerce components are also very important, but we did not draw any conclusions about the relative importance. We focused more on aspects of these components. Such as on pathogen control, not all plants have pathogen testing programs and how is this taken into consideration in the equation? In-commerce, inclusion of attribution data. Some thought that this data ought to be the primary driver of the system.

Question 3, is there other useful information about establishment risk control that FSIS is not considering? And as a group, we answered that as, yes, the consumer complaints that I mentioned before that were not directed to the FSIS, that the Agency does not know about, the attribution data, like such from CDC, and if I can refer back to earlier

slides of question 1, that was the gaps that I talked about earlier, are there other ways besides food safety assessments to evaluate establishment food safety system design? And again, we talked about the discussion that we had on command and control. What was brought up there that was -- one or two individuals thought that maybe the Agency should come in there and just say, here is your HACCP plan and actually design the HACCP plan for the plant, but the industry felt and that's pretty much as a consensus we came to, it's industry's responsibility to -- for food safety and industry knows its plant better than the Agency does, and so the Agency should be responsible.

So there were discussions on command and control, whether the current system has too much or too little, whether a more robust RBI system should have more or less and the roles and responsibilities of industry and Government. Some thing there's not enough command and control in the current system, more should be incorporated, and that industry should design systems, HACCP and Government should validate, combination gives consumers more confidence.

Other things the current system has too much command and control. It should be reduced, and industry should have the lead role with designing in-plant system as if their reputation is at stake. Their responsibility to produce safe food and product, and they have the best ideas for designing the system. Government should verify the design and validation of the implementation.

Question 4, are there other ways besides food safety assessments, to evaluate establishment food safety system design? Well, we do have the FSAs already to represent information at hand. I remember the comment being made by one of the members of the group that the food safety assessments and NRs is something we already have on hand. So let's -- whether we like it or not, let's use those.

There was a discussion of how and when and in what way quantitative and qualitative data are considered. I guess you can tell by the group that that issue kept on coming up. We have qualitative data out there, and we kept using that example of the food safety system. How do we plug that into a

quantitative algorithm?

If algorithm is driving the baseline of inspection level, then qualitative information should be removed. Use only quantitative data that can have a numerical value. At some point in the evaluation of establishment food safety system design and implementation, someone needs to go to the plant and look at what is happening and data only analysis is not only adequate. Again, that's the hands on approach.

Question 5, are the NRs FSIS is considering public health related inclusive or are there others that FSIS should be considering? Again, NRs are tools that represent data in hand, but there was concern that we do need to speed up the appeal process. Those of us in industry know that when you do appeal a NR, there are several layers or several steps that you ultimately can go through, and it is very time consuming, and the input here was, is there another way where we can speed up the appeals process instead of going through a number of layers, just go through to a separate portion of the Agency and get the

decision made one way or the other more quickly. And one input was, appealed NRs should not be considered in the equation until it is resolved.

FSIS is on the right track and needs to evolve the approach more, need to have a clear process how to determine which NRs are health related and which are not.

And question 6, what is the appropriate look-back period? Clarification that this represents a moving window for data collection, perhaps a baseline could be a year and adjustments can be made up or down as appropriate based on seasonality, types of products and I think in the et cetera category we can put in intervention. So we just discussed this a little bit. We did get a clarification from Don Anderson, and we appreciate that, that there should be like a rolling window and we pretty much as a group decided on one year, but that would only be looked at like maybe once a month or maybe we'll look at some time period there and just look at the previous 12 months. We would drop off the last -- if we used one month as an example, we would drop off the last month

and just look at the most recent 12 months, and then say a plant did come up with an intervention or change its food safety system design, then the -- it should be looked at. That establishment should be looked at again.

MR. DeMORGAN: Okay. Thanks. Anybody else from that group want to add anything to what Mark said?

MS. DONLEY: Yeah, Nancy Donley from STOP. Is it possible, can we get back up the slide -- the one on the NRs. I just kind of want to make the point of what was made with all the other groups is that there was not necessarily consensus on all these things, and in ways we have sometimes showed both sides of the issues, but I would just like to say that there's a couple of things, for instance, on this that, you know, I would -- that these were all points that were made but not necessarily that we all agreeing upon. I just think that's pretty important to point out.

But the one thing that I just didn't quite make it onto this one that I do really want to point

out, and we have -- our discussion was very lively. We were really broad and all over the place, and I really have to congratulate you on getting it onto slides. I was thinking, I couldn't do that task.

But the one thing with the NRs that I kind of equate it right now, is we've got a bit of a Swiss cheese problem. There's just so many holes right now in the NR system, and that we're missing so much information, and that there really needs to be a focused look on NRs, how there can be better tracking of what actually is happening, and also the fact that right now we have an incomplete picture because there are cases when NRs are not being written up. When they are, they're in a way right now that we can't capture the information that's needed from them, and this whole thing needs to be looked at a lot more closely.

MR. DeMORGAN: Anybody else from Group 4, do you have any comments?

(No response.)

MR. DeMORGAN: Okay. Thanks, Mark.

(Applause.)

MR. DeMORGAN: Are there any comments or questions for that group, and I would ask that if you could keep the comments to a minimum only because we will get to -- when we've done all five of the presentations, we'll get to overarching if there's more questions, so just keep them focused. Thanks.

MR. KOWALCYK: Michael Kowalcyk from Safe Tables Our Priority. I guess that's been kind of an overwhelming theme, and I don't want to take too much time, but the question I have, I think it again goes not to the group to the Agency, and I think this is why the groups are struggling, and I think using qualitative data and putting it over into a quantitative model, is presenting quite a bit of difficulty, and the question I had yesterday, what is this data going to look like, and then does that mean that the FSAs are going to be standardized in such a way that would make quantitative data a product of those as well as the NRs? I mean right now there's a lot of talk about food safety related, non-food safety related. Well, do we really have enough evidence to prove that if you have a plant that has several non-

food safety related NRs, there could be some correlation with a food safety problem downstream. And I think that whole quagmire of taking qualitative data and moving into the quantitative realm is something that for whatever committee is going to be charged at looking at this, for us to give our best products back to the Agency, I would hope that the Agency would provide us with enough information as to where they plan on going with this.

MR. DeMORGAN: Okay. Great. Thanks. And again, we will -- as I said, we will have a presentation on data, and again it may not answer all of your questions and the other that are out there, but it'll help kick off that conversation about data. So thank you. Yes.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority. I just had a question on question number 4. It seemed like there was -- too bad we can't have the slide up, but it seems like -- next slide I believe. Yes, here.

I didn't really understand the difference between the two points except that one group obviously

thinks there's not enough command and control, and the other group thinks there's too much, but it seems like there's almost agreement that the industry should be designing the HACCP system and the Government should be coming in and verifying and validating that. And it seems like the difference here is how much command and control does that give the Agency, and I was just -- I didn't know if somebody in the group could give a little bit of feedback, if I have that correct.

The other -- this is just another comment. I have in question 5, there was -- about NRs, there was a comment that appealed NRs should not be considered in the equation until resolved, and I would have real concerns about that just because you could actually have everyone appealing all their NRs so they would never get into the system. So that just really raised a big red flag for me.

MR. DeMORGAN: Okay. So there was a specific question about the kind of variation between those two sub-bullets on the question 4 slide, first one, for those of you in that meeting, Is there any response to that? Or was it just --

MS. RICE: I was in Group 4.

MR. DeMORGAN: Could you just mention your name?

MS. RICE: Kim Rice. I was in Group 4 and, you know, and a quarter to whoever guesses who is on which side in that debate about command and control, but there was agreement that industry, I believe, Nancy, you can correct me, but I believe there was agreement that industry is responsible for designing and implementing their HACCP programs, and that the Agency should come in and verify. The discussion started with the Agency should provide hazard analysis for plants, and plants should start from there, and we discussed that, you know, a hazard analysis is based on a flow diagram, and every plant's flow is different. And so you can't walk in and say, okay, for every poultry slaughterer out there, here is the flow diagram, because not all facilities are set up the same.

So the hazard analysis has to be based on the flow, the programs that are in place, et cetera. It can't simply be the Agency coming in and saying,

this is what your hazard analysis is going to look like. Does that answer your question?

MR. DeMORGAN: Okay. Great. He said yes.

Okay. Thanks to that group again. And before we move to the presentation on the remote sites, there was -- we were getting a couple of remote questions that come in slightly delayed.

So for Group 3, there was a clarification question. So this is basically what it says. What was the basis of the comment about an economic advantage for refusing FSAs? There was a sub-bullet on, I can't remember which slide it was. So is anybody from that group able to help answer that question? Bob, any chance? I can bring that slide real quickly. So is anybody from that group able to answer that question?

MS. RIGGINS: Judy Riggins, OFO. I wasn't in the group but I can tell you from experience, I'm not aware of any plant having refused a food safety assessment, and if a plant were to refuse a food safety assessment, we have tools that we can use to gain entry in instances where we believe that it’s

important to conduct that food safety assessment. So I'm not sure on what basis that statement was made, but I just want you to know that as a practice, as an ongoing practice, we have not had any instances where a plant refused an FSA.

MR. DeMORGAN: Okay. Thanks for the clarification. Yes, name and organization.

MS. BUCK: This is Pat Buck.

MR. DeMORGAN: And were you in the group?

MS. BUCK: Yes.

MR. DeMORGAN: Okay. Great.

MS. BUCK: Pat Buck from Safe Tables Our Priority. And when I saw that up, I was a little confused by it myself. Bob assures me that this was a typo error, and that he says instead of refusing FSAs, that by consistently skating on the edge of acceptable.

We had a lot of discussion in our group about the idea that one of the objective goals of risk-based inspection was to get rid of that bottom 20 percent of the plants that are doing very, very poorly. I feel very strongly that many of the people

that are here today from industry are the ones that are representative of what I call the really good industrial, you know, food producers, and yet we have to recognize that there is that bottom 20 percent and how does FSIS account for that, and how do they handle that, and how do we bring them up to snuff.

So one of the things that I think out of that discussion that people were concerned about, was that there is an economic advantage to not following all of the better safe food practices by industry. They don't have to put those other interventions in place.

MR. DeMORGAN: Great. Thank you for that clarification and also for the other one as well. So thanks for the question from the remote site. A very good question, a good catch if you will.

There was one other comment that came in again to Group 3. Brad, do you just want to mention that?

MR. SPANGLER: This is from Glenn Mott, Gerber Poultry. He submitted this comment. The implications of the statement, some companies do

multiple testing and only report the good cannot go unchallenged. As strange as it may seem to some, producers do not stay in business by moving product by gaining and maintaining -- do not stay in business by moving product but by gaining and maintaining customers. This is done by producing safe, wholesome and desirable product. It is of great importance for companies to know their systems and end results in order to produce good product. This would be true event in the absence of PBIS, RBI or any Government intervention.

MR. DeMORGAN: Okay. Great. Thanks. So anything -- any comments on that? Somebody's already stood up, and then we're going to move to the remote site's presentation. Yeah.

MR. REINHARD: I'm Bob Reinhard. Sara Lee Corporation. These were just comments by different people in the group and stakeholders. They weren't necessarily something that everyone or anyone else agreed with in that. So the comments then that were made were made by that individual, and if they'd like to address it, they can, but I just wanted to make

sure that that's known. Everything underneath our bullet points besides those things in red, which there was some kind of no objection to as I said before, is then just a comment by any of the stakeholders in the room, and just listed directly as that.

MR. DeMORGAN: And I don't think that that was in response to the presentation, but to a subsequent comment to your presentation. So the point taken though. I think that's important to recognize.

MS. BUCK: This isn't --

MR. DeMORGAN: Pat.

MS. BUCK: Yes, Pat Buck from Safe Tables Our Priority. He handled that very well, but I think the other thing that FSIS should take into account, I like the presentation that Group 2 did where they had two different people from the presentation working together to put out the ideas. I thought it was bit much for one person to have to capture, you know, the whole thing. And in the future, I would definitely use two people as a collaborative effort.

MR. DeMORGAN: Okay. Thank you. Okay. Let's move on then. We have one final presentation.

As we said, we did receive answers to the questions from four remote sites. So for all of you out there on the web, we really appreciate that. And what we did was rather than try to summarize and put into place slides that incorporated, because they weren't as in depth of the written responses, I'm sure the conversations were very good. And Abby Dilley is going to kind of walk through this for you relatively quickly, and then we'll spend the remaining time kind of talking about common themes. So --

MS. DILLEY: Just again, obviously I can't elaborate on these because I didn't have an opportunity to ask for questions of clarification, and hopefully I've just captured and compiled the comments as they came in.

Okay. So there were three sites that sent in reports. In Springdale, Arkansas, they did two small group discussions and send in two reports which is great. And Chicago and Palmyra, Pennsylvania also send in reports. So that's where this information came from. And just to walk through the questions. All of the groups discussed both papers.

So on the alternative to using the median scores, just consider throwing out the outliers. Plant historical data should be used. NRs should not be used because they are too subjective.

Moving forward, data should drive inherent risk. Weight of each factor should be known. Need to base inherent risk algorithms more on data than on compliance.

On question 2, in terms of how should thermally processed, commercially sterile products be considered? A couple of questions. How will low water activity, shelf stable products fit into this range of species/process and what values will they be given? This category should be considered in the lowest risk, level 1, and two comments along those lines from different groups. These products should be considered GRAS. Should be included by its own species/process.

Okay. Question 3, if further processing is conducted, how should this be considered. Consider the inherent risk of product as shipped from establish. Each facility should stand on its own.

Again, this echoes some of the other comments from other groups. Retails should stand on its own. Retail, sorry, should stand on its own. The further from the producer, the higher the risk. Risk should be part of the calculation for the establishment that is doing the further processing.

And obviously I'm reading these directly but I just want to make sure that the remote sites know that they've got the slides as well. I just want to go through and highlight them.

Translate volume data by product group and process. Weight factors by species, product and type. Depends on each produce produced and with good HACCP plans with good critical control points. Take it out of the algorithm. Consider it as a apparently factor and triangulate it with X and Y axes. I think that was also suggested yesterday, came up yesterday in some of the discussion.

Question 5, how should establishments that produce multiple products, how should that be considered? By product group. That came up in two of the reports. The median approach is the most

practical. If the worst case scenario is used, it needs to be modified by frequency of production and volume, or a third approach would be to go to the product production or slaughter in the greatest volume.

Weight risk scores based on annual production by product type, and give examples.

How should we account for severity? Should be paired up with exposure proxy in some way. Another comment was do not need to consider severity of illness. See each type of meat or poultry products at this time, and then another comment, a political issue, give a strong push to *E. coli* O157:H7.

Appropriate and adequate -- we'll shift to the second paper. Six components and whether they're appropriate and adequate. NRs should not be a weighted factor because they are subjective opinions. Okay for now. Perhaps include some training for industry, FSIS and consumers. Components are appropriate and adequate. Another comment, although important, food defense does not seem appropriate in this category. Need to be careful about including

enforcement action after an EA. An establishment often adopts better food safety controls.

Weighted more than others, that question. Appeals should be considered fully before utilizing the equation. One view is that food safety design and food safety implementation are the two most important. Should consider sampling. Pathogen testing is part of system design rather than a separate category. Decisions should be based on industry and FSIS agreement. Pathogen control and system design are the most important. I missed that one. It said to compile it but that was also stated up above. Pathogen control system design, in commerce, food defense should have more consideration. So again I'm trying to lump all these together.

Is there other useful information? In-plant microbiological testing, third party audits if applicable, and overall comment of let's keep it simple. Should add implementation of food safety system, HACCP deviations and SSOP deficiencies involving product and contamination.

And then there was a question, in the

interest to clarify, on page 9 of the presentation yesterday, what does this mean? FSIS is currently reviewing NRs to validate these categories, and just a request for more information on that.

Are there other ways besides FSAs to evaluate establishment food safety system design? The current FSA method is becoming very effective and seems to be working well. Look at end results. Microbiological data, consumer complaints, for now okay. NRs should be identified as food safety related or not. Be careful not to go back to the minor, major, critical system. Corporate company audits if applicable and company FSAs.

Question 5, the NRs, noncompliance records should not be considered at all. Perhaps we should go back to the minor, major, critical system. Obviously that was in contrast to just before. And we actually did talk about that in our group as well. No, there are not other considerations other than public health related NRs for FSIS to consider.

And then finally, what is an appropriate look-back period? A one year look-back period would

smooth out fluctuations. This would require an assessment of a one year period's records. It may have a considerable impact on the time it takes to do an assessment. One year seems to be a common theme here with different explanations for that. It takes into account seasonality. There were two comments along those lines, and then at least one year on the shelf life date, if it is longer. So I believe that was the end.

So hopefully remote sites, we have captured appropriate your comments on the two papers and thanks again for submitting them.

MR. DeMORGAN: Okay. Any -- recognizing you can't really ask any questions directly, any comments or reactions to that just right off the top of your head?

(No response.)

MR. DeMORGAN: Okay. So it's about 11:00, just a little bit. We've got until 11:15. So we've got about 15 minutes here to kind of just -- I mean clearly from my perspective at least, you know, it's a little bit difficult without having the slides in

front of me and looking at all five of them and kind of seeing what --

MS. DONLEY: Can I ask a basic question? Sorry. Regarding --

MR. DeMORGAN: Would you mention your name please?

MS. DONLEY: Nancy Donley, sorry. Nancy Donley from STOP. The small groups, the off sites, do we know, I can kind of guess in some cases, but do we know what the make up was of these small groups? Is there some way we can --

MR. DeMORGAN: At present we don't. We know that there were 23 remote locations that were signed up, and I'm fairly certain that that's the number, and then we will be getting information on the participants from each of those but we don't have it right now.

MS. DONLEY: If it's 1 or 20 or if it's --

MR. DeMORGAN: Yeah. Either the number or the specific individuals but we're getting that information. Yeah. So it will be available.

MR. SPANGLER: --

MR. DeMORGAN: Okay. Related to the remote presentations?

MR. SPANGLER: Yes.

MR. DeMORGAN: Okay. So we'll turn to Brad to just offer some of the comments that are coming in from the remote locations.

MR. SPANGLER: I'm not exactly sure -- this is from Palmyra. The comment is that you stated our position wrong. We feel that minor, major and critical should be used.

MR. DeMORGAN: Okay. So it was stated both ways. So --

MR. SPANGLER: I'm not sure if it was part of the record.

MR. DeMORGAN: Well, I think just to be clear for you and for the remote, we did not do any editing. We just -- we got four reports sent to us under each of the questions. We pulled that information, put it on the list. So while one group may have said and we saw that, one group did say they shouldn't be and one group did say they should. So that may clarify -- he may have sent it as soon as it

was said. So --

MR. SPANGLER: And I would like to remind the Net meeting participants, to please include your name, e-mail and location when you send comments. Thank you.

MR. DeMORGAN: Is that it? Okay. Okay. So as I was saying, it's a little difficult without all the slides and eventually you'll see those in hard copy if you want, and obviously FSIS will be that and will be using it in the context of our report, but clearly there were some common, you know, I don't want to say themes necessarily, but some common areas where there seemed to be some agreement around issues. There definitely seemed to be agreement around some concerns that were out there, and I would say there also seemed to be some agreement around suggestions for FSIS to consider, to address those concerns. So from our perspective as the facilitation team, that's one of the key things that we're hoping to get out of this, is to understand where there's any kind of agreement about things that FSIS might want to consider to do, to address the broad concerns that

people have. It's only one of the things, but it did seem as if though there were some of those.

And I guess what we'd like to do in the last 10 minutes or so, before we break, is just see if any of you have, now that you've heard five sets of presentations, any observations about common themes or suggestions, et cetera, that you thought were particularly interesting or instructive that you may not have been thinking about when you walked into the room yesterday morning.

DR. HENRY: Craig Henry, Food Products Association. I think that as you alluded to already, Paul, that I see at this point for the process that was intended with this public meeting, that there is now a lot of fingerprints all over the concept and the potential value of moving with risk-based inspection. We have a lot of stakeholders with concerns on various issues about parts of the process.

Certainly the expert elicitation can be enhanced. The foundation is there, and it needs to be tweaked. So you get a few more puts of input.

I think one thing that certainly stands out

through all five groups almost was that food defense just doesn't quite fit this model under these circumstances, and that's something that the Agency can move forward with. But the path forward certainly becomes a little more clear now that we have the input from so many of the stakeholders both here as well as what's on line.

So I think to see what the implementation phase might look like to FSIS is going to be excellent for this afternoon, but hats off to the facilitation team, and hats off to the Agency for, you know, establishing this meeting and allow total stakeholder input to make the process a little more transparent. Thank you.

MR. DeMORGAN: Okay. Thanks. And recognizing that we will be having more conversations about the data piece which I understand is a big question and concern and issue that people have some ideas and thoughts about. Yes.

MS. SCOTT: Jenny Scott, Food Products Association. One comment was made in one of the presentations and I want to come back to that. I

thought it was very interesting, and I don't think we fully considered that. Maybe the Agency should take a closer look at that.

We've all struggled with how to give an inherent risk rating for product in a plant that is producing multiple products. And one of the groups suggested weighting the risk scores by the product, the type and the volume and putting some other things in there, but basically not just coming to the lowest denominator in there. And I think that that bears some investigation, and see how that would work in some of these plants that, you know, certainly you could give more weighting to higher risk products but certainly maybe plants shouldn't drop to that lowest level or the highest risk.

MR. DeMORGAN: Okay. Yeah.

MS. ESKIN: Sandra Eskin. I'm one of the Consumer Reps Advisory Committee. I just wanted to add to the comment that was first made about sort of where we're at. I would differ to some degree to saying that the expert elicitation just needs to be tweaked. I think there's a lot more that needs to be

done, and I think there are other issues not only around inherent risk but also obviously establishment control. Again, the last Advisory Committee meeting, the Committee specifically directed or asked FSIS to go back and undertake a comprehensive review of the NRs and that's been discussed here. I'll be curious to see how much progress has been made to date on that tomorrow at our meeting.

But again, while we've had an opportunity to identify lots of issues, spot lots of issues, I think we are not ready yet to move forward and a lot more work needs to be done.

MR. DeMORGAN: Okay. Thank you. Yeah.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority. I would like to echo Sandy's comments. The thing that struck me was that we were raising just as many questions as we were answering.

The other thing that kind of struck me is that several groups brought up the gap of lack of attribution data as a gap in the system, and it seems to me that getting that attributions data input, collecting it, and insuring the validity of it, and

making sure it's a comprehensive database is going to take an awful lot of work and an awful lot of time. The third point I wanted to do is kind of follow up on Jenny Scott's comment. If you're going to take this from a public health approach, where you're going to really put public health as a priority in developing a risk-based inspection, you would want to assume the worst case scenario in terms of highest risk product because that has the most potential to impact public health.

MR. DeMORGAN: Thanks. Sir.

DR. BLAIR: Joe Blair with the HACCP Consulting Group. While I agree that we should use as much quantitative data as possible, I don't think we can totally neglect to look at some of the qualitative data. We can't throw that baby completely out with the bath.

MR. DeMORGAN: Okay. Good. So I think I would also just note that the range of data questions I think is going to help in terms of both the presentation of that and then framing up the conversation of it as needed. So -- yes.

MS. MUCKLOW: Rosemary Mucklow, National Meat Association. I would certainly echo the comments made by Dr. Craig Henry and when I came in here yesterday morning, I thought, oh, you know, what's this going to be, and I do commend the Agency and its staff expertise yesterday and the way in which RESOLVE has helped to bring all of this into a large landscape picture, and I think that has been significantly helpful.

One of the things that we have not maybe raised is that some of the smallest official establishments under USDA inspection make a large range of products with various risks. Some of the largest facilities are dedicated to a single product with one level of risk. We have huge variability out there among different kinds of establishments in terms of what they are producing as safe food, and that's one of the -- I didn't see us raise that question this morning, and it is again significant that the Agency has dedicated resources in its outreach to small and very small facilities, and as that progresses, we're going to -- they're going to learn a great deal more

and have more information about the complexity of many of the very small operations, and how they fit into this magical matrix, but you've certainly given us a great deal of food for thought, and thank you for the dedicated work.

MR. DeMORGAN: Okay. Maybe one last, maybe two if someone else but -- yeah.

MS. NESTOR: Felicia Nestor, Food and Water Watch. I just also want to take issue with the concept that because we're all here, we all have our fingerprints on this. For my part, I've been at the National Advisory Committee meetings and asking questions at those meetings. I've been asking questions in the monthly meetings with FSIS, and have yet to get satisfactory answers to some of my questions. So given the fact that this was announced as a public meeting where the Agency was going to be announcing some things about RBI, a good portion of the reason that I am here is in the hope that we might actually get some substantive answers to some of these questions.

So, you know, while I think it's important

that we're all participating and raising issues, I wouldn't -- I think it would be a mistake to interpret our presence as, you know, that we are fully invested in the Agency's plan to push this thing ahead rapidly.

MR. DeMORGAN: Thanks. My sense as a facilitator is that there has been, and I totally -- I understand those points and other ones made in response to the fingerprints question. I think it is clear that a lot of useful questions have been raised, some across the board, by all -- in essence by almost all the stakeholders raising the same questions. And in some instances, giving some potential answers to FSIS, and really out of any public workshop, the proof is in what happens next. And so I think your point's well taken. The point that people -- it's great that people have been willing to engage in the conversations, small groups in particular, in terms of conversations here is a little bit more comment oriented, and we will get at the end of the day, as we've said, some time to think about, and there may not be full answers at that time, there probably won't be full answers, but it will just be a discussion

about what are the appropriate next steps needed from -- first of all, you'll hear from FSIS and then your own comments and thoughts about that.

Okay. Thank you all. The remote groups, anything from them before we go to the break?

(No response.)

MR. DeMORGAN: They will be with us all day. So we can build that in if we need to when we get back.

It's 11:15. For the sake of staying on time, and for the folks on the Net, please be back at 11:30. When we come back, we'll have a presentation on implementation before lunch. We'll then break for lunch and be back for discussion subsequently. Thank you.

(Off the record.)

(On the record.)

MS. MUCKLOW: I asked if I could just say something very briefly, not to the issue of the meeting. Joe Blair, you're getting in my way.

(Laughter.)

DR. BLAIR: Yes, ma'am.

MS. MUCKLOW: Thank you. You know, we're here to make a lot of observations and to contribute, and I don't think there's probably a person in this room who couldn't give a testimonial to the hardness of the seat upon which they are sitting. (Laughter.) The breaks don't come soon enough. Even for those of us that are well endowed in the rear portion of our body, they are very hard. I would like to point out to you, that the RESOLVE people are smarter than we are because if you will notice very quietly as I have noticed, they have padded seats on those first two tables. So their little posteriors don't get nearly so tired as ours do sitting on the hard seats. Just wanted to point that out and make sure you all noticed it.

(Laughter.)

MS. DILLEY: Well, now that I've sat on my padded seat for a break, I'm ready to go. So we'll keep you here until the lunch break, maybe even longer.

Just a couple of things. I want to note that apparently some of the remote sites have been

trying to send reports. We have from the small groups that we didn't receive last night, we now have a report from Jackson and Dallas, right, and just again to request that if you are trying to send something and you're sending an e-mail through the live link, you need to send your e-mail address and your location so that we can reach you to respond because through the live link, we don't have a return -- we can't just hit reply. So please do that, and if you still have not been able to get your report through, do that. What well try to do over lunch is add the reports to the compilation so at least we have it all in one place, and make sure we capture those.

There also were a couple of questions that came in from the remote sites, and I believe one is very relevant to the next -- well, one was consider redesigning the FSAs to include scores and therefore have more significance as quantitative data. So again coming back to that issue.

The next question is a good transition into the next presentation, and some of the discussion later this afternoon, and the question is, what is

FSIS' timeline vision for further design and implementation. And so just to put that out there, and not to necessarily respond to that right now but throw that in the mix, as coming from the remote site. So we want to be sure and capture some of the questions that are coming from the remote sites.

From now until the lunch break, at 12:15, we are going to have a presentation by Bobby Palesano to give preliminary ideas on using risk to direct in-plant inspection activities and processing assignments, and then we'll take -- after his presentation, we'll take an opportunity for questions of clarification and some discussed up until taking a lunch break.

We do then have time allocated after lunch to pick that discussed back up should we need up to an hour. If we don't need all that time, we could move perhaps to the data discussion and presentation, but I just want to point out that we've got a couple of possibilities and we do have a fair amount of time allocated for this particular portion of the agenda. And then we'll have again some opportunity to come

back and talk about next steps, and an overview of some of the two days, and then conclude by 4:30.

So with that, and as you can see, we have up here Bobby's presentation. So here he comes walking down, and he will give his presentation.

MR. PALESANO: Thank you. I'm Bobby Palesano. I'm with the Policy Office, and I have been given the opportunity to present to you using risk to direct in-plant processing and off-line slaughter inspection activities.

Before we start, I need to make you aware that the presentation that you have in your packet has been updated a time or two since you received that information, and that is a test of my flexibility and presentation challenges that I have. So just to let you know, there are some additional slides that have been added. There are some that have been taken out, and the reason for some of these revisions is because that we heard some concerns and feedback yesterday, and we wanted to update that information just to show that we could.

(Laughter.)

With that, I would like to say to all of the folks that are on Netcast, that you do have the correct presentation, at least it was correct at the time that I started.

With that, we will walk through our preliminary thoughts on this, and I would like to emphasize to you that it appeared to some of you that we had our thoughts laid out quite well in other areas. I think as we walk through this area, you will see that this presentation or this particular topic is very early in the design and development. We encourage your thoughts and comments. Obviously the way I understand the purpose of this meeting is so that we can engage all of the stakeholders, getting your thoughts and idea so that we can incorporate them into the design of our BS.

Now some things that we probably need to now right up front, I heard some discussion yesterday and I thought, well, at least I've got one slide that says something different than what I thought I was hearing. I want everyone to understand that the statutes actually require us to have daily inspections in all

facilities. We do not anticipate changing the statute. I believe you heard our Under Secretary indicate that he would like to get something implemented while he is here, if we open the statutes. I don't think we would have much shot at that. So keep in mind that we are staying within the statutes. All processing establishments continue to have daily inspections.

Again, I want to emphasize to you that we are not dealing with slaughter inspection or carcass by carcass inspection, but this presentation deals with processing and off-line slaughter inspection activities.

Implementation of risk-based inspection will be, we believe to be a multiphased process. We believe that it will be complex enough that we should implement it incrementally to allow for training of our inspection personnel for them to familiar themselves with the new system. And we also are hearing that we need to spend some time programming a computerized risk-based system, and as you all know, that kind of leads into the data presentation.

Now I've heard a lot of terms and for the sake of this particular presentation, I would like for you to understand that we are referencing some of the blocks that Dr. Raymond had up on the screen yesterday as inspection levels. And as you should know by now, we are using inherent risk and the establishment's ability to control that risk as the measures to determine the level of inspection.

Noncompliance records, I think I probably heard more discussed on that than any other topic. They will continue to be utilized, at least that's the way we see it, for regulatory noncompliance. Again, all regularly noncompliance or all NRs will not be treated equally when we make the determination of the plant's ability to control risks.

We figure or plan to turn the scheduler off at some point. That will be one of the phases of implementation. And during that period of time, our inspection personnel will familiarize themselves with situations that could be predictive indicators. For the sake of those that may not know what that term means, we have given some examples of situations that

we feel like could be predictive indicators that would require some additional verification or inspection.

Our first question is should we use predictive indicators?

And the second question is how would we capture predictive indicators?

Third question, what are other examples of predictive indicators?

Again, we are saying that the inherent risk and risk control are combined to calculate an inspection level for each establishment. There's been a lot of discussion about how those numbers or values have been determined and how we would use those. Obviously as we work through that, it will impact on how we implement this portion.

Again, this is the chart that I believe you saw yesterday. Again, if you look at the X and Y axis, you can tell that we, in fact, have put some numbers in some blocks to indicate the level of inspection associated depending on the inherent risk and the risk control.

The next question, how many level of

inspection are optimal?

How do plants move from one level to another?

How frequently should we evaluate data to make decision on the plant moving from one level to another.

One of the changes -- another change we made in the presentation from yesterday is we included a noncompliance record. This record -- it does not have any data entered into it, but it does show the form that inspectors complete when they find regulatory noncompliance in an establishment.

We also put the link where you can find a sample NR. This link will take you to the Food Safety Regulatory Essentials Training, and at that time you can find example noncompliance records that have been completed for training purposes.

Questions?

MS. DILLEY: So questions, clarification. If you have questions that are just clarification, then possibly we can go to the comments or questions that Bobby had in his presentation, but initial

reactions or questions or clarification?

MS. DONLEY: This is Nancy Donley from STOP. Can you just please elaborate a little bit more on what you mean by levels of inspection?

MR. PALESANO: Is this on?

MS. DILLEY: Yeah.

MR. PALESANO: While we're speaking about a level of inspection would depend, as I think what most of you have referred to as a risk level, we're referring to the level of inspection. To utilize the chart, if you look down in the lower left-hand column, or lower left-hand corner, excuse me, you saw the number 1. That would be an establishment that had the lowest inherent risk and the best risk control. So that particular establishment would have a lesser inspection coverage than one that was in the supper right-hand corner which would be level 5.

MS. DONLEY: It's Nancy Donley again. Could you just please tell us, walk us through the -- maybe walk us through the levels a little bit as far as what does level 1 inspection look like, how much is there, and so forth?

MS. DILLEY: So basically --

MS. DONLEY: And what's a minimum?

MS. DILLEY: What's an inspection coverage mean per level?

MS. DONLEY: Correct.

MS. DILLEY: Get a feel for that.

MS. DONLEY: And what's the minimum, certainly.

MR. PALESANO: Okay. And, Nancy, I will tell you this, that at this point in time, we are very early in the process, and we do not have those worked out at this time. Obviously if the folks here in the room want to give us those ideas, we would love those ideas.

UNIDENTIFIED SPEAKER: Bobby, could you please provide us a definition of off-line slaughter?

MR. PALESANO: I will do my best. In a slaughter facility, as some of you know, there are verification activities that occur that are related to Sanitation Standard Operating Procedures, as well as HACCP procedures that must be verified. Our on-line or slaughter food inspectors do carcass by carcass

inspection, and at this time they do not conduct those off-line verification activities.

MS. DILLEY: Please.

MR. CORBO: Tony Corbo, Food and Water Watch. We've seen in the media the concept of electronic inspection being proposed. Is that something that is considered in the level 1 inspection at this point?

MR. PALESANO: I think at this time, we would consider any type of verification activity that would work into what we would classify as meeting the definition of daily inspection. I don't think that electronic verification of records from a remote site at this point in time without rulemaking would apply.

MR. CORBO: And we've also heard dates being thrown out like first quarter of 2007, spring of 2007. You're saying that you're still at the very beginning stages of looking at implementation. So what is the truth here?

MR. PALESANO: Well, the truth is, Tony, that when -- during my presentation, I mentioned to you that we are going to implement this incrementally.

One of the phases of implementing this might be to turn the scheduler off. Obviously there would not need to be a lot of training. There would need to be some training apply before we turn the scheduler off, but that might occur very early. The next step might be something else that would occur later.

MS. DILLEY: So the question is trying to understand in a multiphase process what that looks like in terms of parsed out and at what point some things come online and when. Sandra.

MS. ESKIN: I'm Sandra Eskin. Bobby, you mentioned again the term predictive indicators. Could you elaborate? The way I understand it, could you define it and give examples. The way I understand it is there are events that may happen that would cause an inspector to perhaps enhance inspection or change level or just look more carefully. I don't understand exactly what you mean by that.

MR. PALESANO: Okay. The example I gave or one of the examples that's in the presentation is construction in a RTE facility. Currently in today's inspection, when we capture a result, an inspector

performs a procedure. They perform it, and it's recorded as performed or they record it as non-compliant. We believe that a predictive indicator to use that term in quotes, would be a situation that has the potential to raise the risk level or cause a concern. Obviously a RTE construction does raise the possibility that products, RTE products could be contaminated with Lm. That does not mean that there's regulatory noncompliance at that particular time.

MS. DILLEY: So it is basically something that requires you to take an extra look. Is that how you are using it?

MR. PALESANO: Pardon me.

MS. DILLEY: From behind you. I was just trying to make sure I understand that. Predictive indicators as you're using it is something that would make you take an extra look. It may not be a constant in the equation, but it's something that says we may need to look at what's going on at the plant to see if a closer look is necessary.

MR. PALESANO: That is correct. And it does not change the level, the inspection level at the

establishment. I believe I omitted that, but it does not change the level.

MS. DILLEY: Okay. Felicia and then Carol.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Okay. About this multiphase implementation process, how long has the Agency been contemplating doing this in phases?

MR. PALESANO: I don't know the exact time, but I know --

MS. NESTOR: Ballpark is good.

MR. PALESANO: Pardon me.

MS. NESTOR: Ballpark is good.

MR. PALESANO: Within the past few months, we've been talking about multiphase implementation.

MS. NESTOR: Okay. And what are the phases that you're contemplating?

MR. PALESANO: At this time, I don't think we even have them defined. We just believe that the concept is complex enough that it will take multiphases to get it fully implemented.

MS. NESTOR: And can you -- so you have no idea what the contours are at all, so that you could

describe the different -- what the different phases might be?

MR. PALESANO: No, we do not at this time.

MS. NESTOR: It's a complete morphis (ph.), nothing.

MR. PALESANO: No, we do not.

MS. NESTOR: No definition. Okay. In this slide you say that the one phase you're considering or no, another slide, is turning the scheduler off. I want to understand what that means. So inspectors go into plants on a daily basis and they have a schedule of inspection tasks that they are to perform in each plant. One of the phases you're considering is you will turn the scheduler off, meaning that inspectors throughout plants in the country will have no assigned inspection tasks. And how long will that go on for?

MR. PALESANO: Well, obviously under risk-based inspection, we are striving to insure that when we establish the minimum inspection that would go into each level, that we are doing the right thing while we are there to insure that what we have captured so far is, in fact, authenticated.

MS. DILLEY: Okay.

MS. NESTOR: That didn't answer my question at all.

MS. DILLEY: Well, what part of it do you want clarification on? We've got three other people standing in line over here.

MS. NESTOR: Yeah, I asked whether inspectors will be assigned to go out to the plants with no assigned inspection tasks under PBIS, and for how long will that go on for?

MR. PALESANO: When we turn the scheduler off, we don't anticipate turning the scheduler back on. What we anticipate doing, maybe I didn't answer you evidently clearly, was that we have different inspection levels that will be determined based on the two factors that were discussed yesterday. We envision that there would be minimum verification activities that would occur within each level that is assigned to each establishment. But they would not be scheduled by the PBIS system. So if you're a level 1, and we decide that you would do a particular verification, you would do that without the schedule

telling you to do it.

MS. NESTOR: So you're saying that permanently your concept is to do away with the current PBIS tasks?

MR. PALESANO: Yes, that is the proposal at this time.

MS. NESTOR: Thank you.

MS. DILLEY: Carol.

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation. I think that the last three questions of mine will be the third, indicate that we have a really basic problem here. I have not heard yet a definition of risk-based inspection. I don't have a definition for predictive indicator. I don't have a definition for daily inspection.

Now my English teacher would not allow me to define a term by giving you examples until after I had said this is what the term means, and then you can give an example. We have only examples. We have no definition for any of the terms that are being used.

Now I know the Agency -- I know you all know what you're looking for, and I suspect that a lot of

people here from the industry know what you're looking for. If I don't understand it, I think it's pretty likely that most of the American public won't and I think you have an obligation to have something that is more specific than you'll know it when you see it. It is very hard to go forward and have a discussion without definitions of basic terms.

I don't know what daily inspection is right now. It sounds like you're going to change the definition of daily inspection. I need to know what that will be. As Felicia pointed out, we don't know what multiphase means, and it's very hard for us to, for me at least, to participate in a meaningful way when I don't have the language and definitions for the terms.

MS. DILLEY: So clarify of definitions and concepts.

MS. TUCKER-FOREMAN: Yeah, and the thing is, we then get into this problem of, well, you don't have these definitions because you're just starting, but then we're told that it's going to begin very soon. So please, I need a roadmap.

MS. DILLEY: Okay.

MS. DILLEY: Kathy, comments from the remote sites?

MR. SPANGLER: This is from Ron Fouche, Palmyra. Today FSIS formed 5404 (798), the NR form, does not allow the form writer, i.e. the inspector, to indicate the type of inspection. It is suggested that not many of the current NRs are really food safety problems. Would it thus not be better to allow the IIC the opportunity to make this decision on the type of inspection?

MS. DILLEY: Bobby, do you want to take that one?

MR. PALESANO: I guess this kind of falls into the whole category of looking at NRs, and we're hoping as an Agency to get a lot of ideas here as to how we can make the NR system better. I think in every group that I listened to yesterday, it seemed like there was a lot of interest and a lot of ideas that come forward on how we can improve the NR system.

Again, I don't think, as Don pointed out yesterday, that we have reached the final conclusion

as to how that will be done.

MS. DILLEY: Dane.

MR. BERNARD: Thank you. Dane Bernard from Keystone. There may be no need for the question at the moment, and by the way, Bobby, if you've shared exactly what the Agency wants out of this with others in industry, I'm going to be mad at you.

NRs, food safety NRs has been talked about as a categorization that you may look at, and just for those who haven't lived through this, if you're standard operating procedure for opening a bag includes ripping the outer layer before you dump it, and you don't do that, you may be a NR for that, that's classified as a food safety NR. At the same time, if we were ever to undercook chicken, we would get a NR, a food safety NR for that, and obviously the risks imparted by those actions is vastly different.

It almost occurs to me that if you're going to do this, you're going to have to take a sampling of NRs and actually have somebody that understands that concept go through and categorize these in a more -- it's almost an expert system is what I'm saying. So I

don't know if you have that in mind as you go through this or not, but thanks.

MR. PALESANO: Thank you, Dane.

MS. DILLEY: Please.

MR. PAINTER: Stan Painter with the National Joint Council of Food Inspection Locals.

Currently the inspectors are being told covering multiple assignments to go in the front door, wave at them as you go through and go out the back door. Would that be considered minimal inspection?

MR. PALESANO: I'm not familiar, Stan, with the term minimal inspection as it relates to that activity. Again, for the sake of risk-based inspection, what we plan to define based on the inherent risk and the establishment's ability to control risk, some minimal inspection activities and again, at this process, we are hoping to flush out what would be the most important inspection activities to occur while we are in those establishments.

MR. PAINTER: I have one other question. Can you explain how team inspection will fit into risk-based inspection?

MR. PALESANO: Team inspection is a different function that is outside the parameters of this particular meeting, Stan. I believe that if we implement risk-based inspection, we can implement risk-based inspection with or without teams.

MR. PAINTER: Thank you.

MS. DILLEY: Barb.

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

I had -- I guess I want a clarification on the question about how many levels of inspection are optimal. In the chart you had shown, and we've seen several times in the past two days, there are five levels of inspection currently included on there. How is the five levels originally -- how was that decided upon? Was this a statistical analysis or was it a subjective opinion that we just pick five to begin with.

MS. DILLEY: So basically, is there meaning behind the five levels in the chart?

MS. KOWALCYK: Well, and then, you know, how many levels of inspection are optimal? Do you want a

subjective opinion as to how many are optimal or are you looking for input on how to have a science based method of arriving at the number of optimal levels of inspection?

MR. PALESANO: Obviously the more science based the decision could be, the better off we would be as an Agency as we move forward. That is correct.

MS. KOWALCYK: Right, but what I'm asking is was the decision just to start at five? Was that a subjective opinion or was there any analysis done to even get to the five starting point?

MR. PALESANO: No, we only put those numbers into those blocks to show everyone here at the meeting what it could look like and five was the example that we used.

MS. KOWALCYK: Okay. Thanks.

MS. DILLEY: So there's no particular value to the number 5 or 5 levels. Okay. Please.

MR. MUNSELL: I'm John Munsell. And I feel real awkward in trying to say what I'm attempting to say here, but --

MS. DILLEY: Give it a go.

MR. MUNSELL: Okay. In recent years if I've seen what I have perceived to be problems with Agency policies, I've certainly been very outspoken and having said that, I'm listening, especially this morning to comments. There appears to be a lot of criticism towards the Agency, and I think we need to, the industry and all of us in this room, need to cool our heels in our criticism of the Agency on their implementation of this RBI.

Obviously, the comments that have been made by everyone in this room yesterday and today, we're not all in agreement ourselves. Obviously the Agency is still searching for answers, and we can see that the Agency is transparent, and I cannot give enough credit to Dr. Raymond and Dr. Masters for their aggressiveness in promoting this, and they don't want to wait for five years, and I appreciate that.

Plants don't like bureaucratic delays. So I can understand that, realizing that even we're not in agreement, there's a lot yet to be worked out, and I agree with Bobby, that this has to be incrementally implemented, and just kind of make decisions as we go.

I think it would be a big mistake to try to implement it too quickly. I would sure recommend that the Agency conduct one, maybe two more stakeholder input public sessions like this to review the progress that it's made to date, but I for one am pleased with the gradual approach that the Agency is taking.

MS. DILLEY: Okay. Kathy, were there other comments by remote sites? And that will probably be the last comment before we wrap up for lunch.

MR. SPANGLER: This is a question from Joseph Reldime (ph.), FSIS. When the scheduler is turned off, how will the Agency monitor the inspection procedures? Will verification of said procedures be added to the FLSDDs?

MR. PALESANO: Again, that's a good question that we have not worked through. Obviously it will be the Office of Field Operation to put management controls in place to insure that inspection personnel are performing the activities as the system as designed.

MS. DILLEY: Okay. So just a couple of things before we break. We will come back after lunch

at 1:30, to pick up this discussion, and I think just in terms of -- a couple of the last comments in terms of the implementation piece, the concept of a multiphase process, it sounds from comments needs to be linked up with this roadmap concept.

So I think what the Agency is asking for, is additional input into some of that, and certainly there's been others that it would really be helpful to know what that roadmap looks like, and the thinking up to this point. I think you're getting some of that thinking up to this point, and I think what maybe we can do is talk a little bit more about some of the questions such as what would -- I think it was posed as a question, what would the minimal level look like, and maybe even tabling that question for -- and get some input on that because I think people are trying to struggle what is a level -- what does it mean to be in a level, what does that look like, what is the inspection look like, and then you could maybe link some of those other questions into that in terms of how does a plant move from one level to another and some of the other questions that were in there.

In terms of predictive indicators, I think obviously some terminology and clarification of terminology needs to happen. What about the concept? I mean the concept that you have kind of a basis level, but there may be some things, what do you call them? Predictive indicators or something else in terms of requiring, taking a closer look, and what are some examples of issues. Bobby put some examples in his slide but are there other things that should be considered in requiring an extra look when you have kind of a baseline level.

So coming back and getting into tailoring some of those questions conceptually. Hopefully that will then lead to a clearer roadmap and clearer definitions, and I think that will help transition into some of the discussion this afternoon in terms of next steps and what would be helpful in terms of additional clarity around concepts and a roadmap and how these phases are developing, et cetera, and I'm sure we'll pick some of those issues back up this afternoon.

We also have some time later to come back.

We do want to get to the data presentation that was requested and FSIS has put some things together to present and discuss. So we'll come back to that issue this afternoon as well.

I think that's it for now. Again, the suggestions, we'd like to start right back up here at 1:30. So if you could please be as expeditious in your lunch as you were yesterday, that would be extremely helpful to maximize our time in session. So we will see you at 1:30, and thank you very much.

(Whereupon, at 12:15 p.m., a luncheon recess was taken.)

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

(1:30 p.m.)

MS. DILLEY: So thanks again for getting back here in a timely manner, and I believe we have our remote sites plugged in. Brad, right? Remote sites are up and going. Okay. Good. As far as you know.

All right. Just a couple of things about review of the agenda, where we are right now. We're going to pick up the implementation discussion, the preliminary ideas on using risk to direct in-plant inspection activities and processing assignments. Bobby has a couple of comments of clarification he wants to add to the mix, and then come back and pick up some of that discussed, look at some of the questions again and some other pieces of that presentation and concepts.

Then we're going to have an opportunity to come back as I mentioned earlier before, we took the lunch break, some additional sites were trying to get in their small group reports from yesterday and we've taken them and compiled them, and we're going to take about 10 minutes to go over that new compilation to be

sure that they have the opportunity to put their comments in front of you.

And then after that, we will move to a discussion of data as we've been mentioning a couple of times, and at the request of some folks yesterday, FSIS has put together some comments on that, and that will provide an opportunity to launch into some of the data issues for further discussion this afternoon. And we're going to take a break at 3:30 and come back for some summary comments, assessment of the discussion and ideas for moving forward, and then have a summary and wrap up and be adjourned by no later than 4:30. So that kind of gives you a sense of the overall flow of the afternoon. Any questions about that before we get started.

All right. One other thing I wanted to mention. In your packets and the remote sites have forms as well for some feedback. We have a participant evaluation. If you could take some time to give us some comments, that would be great, and you can give it to one of the RESOLVE staff, either Paul, Kathy, Brad or myself, or put them out on the table

out front, registration table, and we'll collect all those, and we always appreciate some lessons learned and some feedback from people. So please do take a couple of minutes to do that.

All right. Then I will turn it back to Bobby for some comments and then we'll get into the discussion.

MR. PALESANO: Okay. There were a couple of things I omitted to clarify well enough for people to understand and the first thing I would like to talk about a little bit is there was some discussion on predictive indicators, and I would like for everyone to know that the term as well as the examples for predictive indicator actually came from the last NACMPI meeting. So we actually took those from the NACMPI recommendations. So that term, as well as the examples, came from that least meeting.

Another thing I would like to mention briefly is about the multistage implementation just so that everyone knows that my back pocket is quite empty. What the multistage really means will depend on what we get at this meeting from you as far as how

we move forward. So, you know, it depends on all of your comments that we pick up, as far as how many stages and the timeline that we will be implementing this on.

Again, I want to emphasize to all of you that as we move forward with this, today's meeting will provide us a lot of input as we lay out our plan for implementing this. So, again, I want to emphasize to all of you, and I appreciate all the comments that we have received thus far, and encourage other comments as we move through this afternoon and it will have a tremendous impact on how we move forward and how we implement and what the inspection activities might look like in that new environment. Keep in mind that tomorrow if you think all of my opportunities are for today, you would be mistaken. I get to present this material with the feedback that I receive today to the NACMPI group tomorrow and probably will be modifying my presentation based on the input today so that I can present to them the information that reflects what the group presented to us.

MS. DILLEY: Okay. So just in terms of the

big chunks of the overall presentation here, we have predictive indicators, we have the inspection level and questions around that, and then also the multistage implementation. So I'm wondering if we could engage a discussion over the next little bit in terms of kind of taking each one of those categories and get some additional input or raising the question, well, what do you think about predictive indicators, and some of the questions were in Bobby's presentation in terms of should they be using them, what do they look like, and I know there are a lot of questions about what exactly does that mean, and I think we're trying to get some clarity around the definition, and then talk about some discussion about whether the concept makes a lot of sense in terms of using those two, to take an extra look someplace.

So, Tony, you have a question, a comment?

MR. CORBO: I have a comment. Tony Corbo, Food and Water Watch.

I'm going to go back on a follow up to a question that Stan Painter asked, and I'm not -- I don't want this to stand, just left out there. You

know, the issue of team inspection and how that comes into play, I don't want to get into an elaborate discussion of that, but, but the Agency in its presentation of its budget for FY 2007 to the Congress, indicated that team inspection would be used as a vehicle to implement risk-based inspection. Number two, in a direct question that was posed by Congressman Maurice Hinchey of New York, when he specifically asked in writing and you responded in writing back to him, how was team inspection going to be used as a vehicle to implement RBI, you responded, "Team inspection will be used to implement risk-based inspection . . . " and you went through a whole paragraph.

So I am not going to let this stand that you can have one or the other and not -- the thing is that you're using that as a vehicle. So I just don't want that to be left out there saying that team inspection is not playing a role. It is playing a role.

MS. DILLEY: Okay. So I think the question from that is are they linked, and you've cited examples where it's been stated as being linked, and

so in what way is team inspection being used to implement RBI? Is that fair statement of your question, Tony?

MR. CORBO: Yes.

MS. DILLEY: Okay. So, Bobby, do you want to respond to that?

MR. PALESANO: I will just respond again, Tony, by stating that the RBI implementation strategy that we are trying to lay out is not designed around team inspection. It can be implemented with or without team inspection.

MS. DILLEY: Chris.

MR. WALDORP: You had laid out, not laid out, but sort of --

MS. DILLEY: Can you identify yourself? Sorry. Even though I know who you are --

MR. WALDORP: Chris Waldorp, Consumer Federation of America.

You talked about this multiphased process to kind of ease us into risk-based inspection, and I wondered if the Agency had given any consideration to doing this on a pilot project basis because a lot of

time, you know, things look good on paper. It seems to work in our head but when we actually get it out in the field, it doesn't necessarily work according to the way we thought it would or we find new things that we didn't even think about. So I was wondering if the Agency had given any thought to doing that instead of this phase system?

MR. PALESANO: Yes. That, that has been discussed and obviously again we appreciate those comments and certainly appreciate those, but as you indicate, sometimes we can draw something up on paper that doesn't work the way we think it does, and certainly we have talked about that. It is very early on, and we don't have any plans obviously to implement a pilot next week because we don't have the system designed yet.

MS. DILLEY: Okay. Nancy.

MS. DONLEY: This is Nancy Donley from STOP. Has the Agency done any thinking or set any discussion about making some measurements with implementing an RBI system as far as comparing it to a PBIS system at this point in time? Have you set any goals and

measurements where you can assess how this program stacks up against what we currently have?

MR. PALESANO: I think it's a little bit early in the process for us to try to do that. Obviously one of the things that would make that very difficult to measure is that we do not have the new system in place at this time. So we couldn't measure the outcomes compared to what we're doing today.

We have looked at the existing data on occasion, and I believe there will be some discussion about the data systems, and how we're using the present data later on this afternoon, but we can't compare present data to the new data because we don't have the new data yet.

Obviously part of implementing risk-based inspection would be the evaluation of that system to insure that it is providing us the desired outcomes, Nancy.

MS. DONLEY: But have you identified any data points that you could then identify that this is being done under this certain set of circumstances and then measure? Obviously you don't have the data for

the new system, but to make a comparison? So if you identify this point A and that -- under PBIS and this point A under RBI, is it good, bad, an improvement?

MR. PALESANO: Yeah. At this point in time, we do not have that criteria established for that. Obviously we would expect the new system to be better than the existing system. At this particular time, I want to reemphasize to everybody, we are so early in the process we have not come up with that criteria, Nancy.

MS. DONLEY: And I appreciate that. What I would like to suggest then is that the Agency establish some sort of criteria, start developing the data as a current system, and then measuring it as you start implementing RBIS.

MR. PALESANO: That's a great suggestion.

MS. DONLEY: So that you can have a comparison and really see, is this the right path we're going down.

MR. PALESANO: I think that's a great suggestion, keeping in mind, and I would encourage everyone to remember that we're going to be hoping

that you will help us design the new system. When you design a new system, it's not always easy to compare one set of data to another but that's an excellent suggestion, and we certainly will take that into consideration, and we thank you.

MS. DILLEY: So some means of measuring effectiveness of how the new system and some potential for evaluating it with what currently exists versus the new system, when you have that data. There's two parts to that.

MS. DONLEY: Exactly, and I think that would dove point very nicely into what Chris Waldrop brought up before, is to do this as a pilot study and to see if this --

MS. DILLEY: Collect data and evaluate it.

MS. DONLEY: Exactly.

MS. DILLEY: Question. Comment.

MR. MAIER: My name is Wolf Maier for the European Commission. I appreciate this event very much and the transparency of FSIS to inform people about their plans. There is one dimension, however, that I haven't heard about yet which is the impact on

international trade, potential impact on international trade. I mean if inspection practices will change in a certain establishment, this might have an impact on the export, because the importer might insist that things continue to be the same and so just this dimension should be kept in mind. Likewise, authorities struggle worldwide to look at ways worldwide to use their resources more efficiently and get inspection capacity more efficiently allocated to where the risks really are, in order to pick up the cases more efficiently.

We do the same in Europe, and -- now we might go down the road of implementing risk-based inspection in facilities in Europe which may have an impact on how you look at these establishments in -- countries. So that's a question which I would like to raise. I mean I am aware that I am in -- to a certain extent, we have exactly that same issue to discuss with FSIS, that establishments are changing their inspection practices and we should do a better job to be more active in informing you guys about it. But what do you think about this dimension? Do you have

plans of informing your trade partners about implementation and to avoid, to minimize any impact on trade?

MS. DILLEY: So a question about how you're thinking about -- RBI, risk-based inspection in terms of its impact and interaction at international trade level. Bobby, do you want to --

MR. PALESANO: Yeah, I will address that a little bit. Obviously if we implement risk-based inspection in this country, I believe what we look for in countries that are importing or exporting products to us is that they have a system that is equivalent to ours, and certainly that would not change at all under the new system in my estimation.

Obviously as Dr. Masters and some of the people mentioned yesterday, we plan to use risk in all of our management Agency wide.

MR. MAIER: I appreciate you used the word equivalent rather than identical. So I appreciate that. Thank you.

MS. DILLEY: Thank you. Other questions or comments. On the screen, and we talked a little bit

about predictive indicators I guess and Bobby's mentioned that he's bringing the same presentation and putting some of these questions to the National Advisory Committee on Meat and Poultry Inspection over the next couple of days, some of you are part of that. So you will be able to carry on that discussion. I guess anymore thinking or feedback to FSIS about that as a concept in terms of having kind of a level, inspection level but then wanting to have some means or mechanisms that may trigger a closer look, and I'm hoping I'm characterizing that right, Bobby. If I'm not, I'm sure you'll correct me. But additional thoughts? Mike.

MR. KOWALCYK: Michael Kowalcyk, from Safe Tables Our Priority.

Yes, it is correct that use of predictive indicators was discussed at the last Committee meeting. In thinking of how in practice, I mean there's a lot of discussion that this should really be a management tool for the Agency to allocate resources as efficiently as possible to maximize public health, okay, using predictive indicators, whatever they may

be, and that's my first question has FSIS been able to narrow down a list of what they would define as indicator variables that they would want to have in this management tool that would enable the agency to, based on your comment about replacing the schedule process, almost real time allocation of resources so that adds an additional wrinkle as to what data you could use because you would have to make sure that that data is refreshed and is consistent throughout your inspected establishments, and that gets really into the details of it. But I just want to get a sense of where the Agency is with narrowing down a list of predictive indicators or even a wish list of things that you want to be able to use that based on your expert elicitation and knowledge within the Agency and industry and academia, what data elements do you need, and this probably gets into the next presentation, or at least I hope we address it, is what do you have? Do you have a universe of variables that can be investigated and how reliable do you think those data elements are?

MS. DILLEY: So you've got a lot of

questions in there, and I --

MR. KOWALCYK: It really is do you have a list of predictive indicators that you're thinking about right now?

MS. DILLEY: Right. It sounds like have you done some prioritization --

MR. KOWALCYK: Yes.

MS. DILLEY: -- on what you could use to develop those predictive indicators? And one dimension you mentioned is the real time aspect of it, how rapidly could you pick that up and make real time decision.

MR. KOWALCYK: Yes. Can it be applied out in the field?

MS. DILLEY: Okay.

MR. PALESANO: The answer to your first question is very easy. Obviously I would say no is the short answer. We do not have a list of predictive indicators that we have designed. One of the questions that we have asked this group is, you know, should we use predictive indicators? Another question was, you know, what are they or how do we record

those?

The second thing that I think is kind of underlying, and I'm not trying to read into your question, but it is important to understand that if we use predictive indicators, those predictive indicators, since they are not regulatory noncompliance, would not necessarily fit into what Don spoke about yesterday as far as the establishment risk control, but they are factors that could impact on the risk at a particular establishment. Did I answer most of your questions?

MR. KOWALCYK: Yeah. That begs another question which is should you get a list from this group or from the Committee tomorrow, what strategy does the Agency have or are you still trying to formulate a strategy? Say, okay, I've got 10 variables that we feel are really important, experts in the audience feel are really important, what steps is the Agency planning on taking with that information? What type of project do you have in mind or is that still too early to determine?

MR. PALESANO: Okay. Well, I guess I will

give you my opinion which I don't know if I'm authorized to do that, but I will anyway. Actually what we plan to use that information for is for the local inspection personnel so that, you know, it will not change from one level of inspection to another, but if the inspection personnel that visits that establishment on a particular day and one of the examples was RTE, and they determine that there is construction going on in that establishment, then the inspection personnel that are assigned to that particular establishment might want to insure that they check that area of the establishment to insure that the appropriate controls are being implemented by the establishment so that it does not create a food safety hazard.

MR. KOWALCYK: Okay. Now based on the fact that the Agency wants us to be a living, breathing thing, back to Dr. Masters' presentation with the circular feedback loop, does the Agency plan on having a mechanism to capture that information from the local inspectors, where if I've got plant A that has construction, are there plans to be able to capture

that information and database it somewhere so that way that may not be a predictive indicator. There's construction, but it might not have any impact on food safety. The sense I'm getting is that no one knows the answer to a lot of these questions. There's needs to be a significant amount of work remaining to determine what is important.

MR. PALESANO: Not at this time, Mike, and I know, you know, you think we have the answers. Again, I want to emphasize that we don't have the answers. We are asking the question and one of the questions was should we use predictive indicators, and again we asked another question how should we capture that information?

And again, the example we had, construction, could have an impact in RTE. It may not have any impact in another situation, and if the establishment is actually controlling everything and actually doing everything they should do to ensure that their product is not being contaminated, it may not have anything to do with risk, but again our responsibility at FSIS is to verify that.

MR. KOWALCYK: Thank you.

MR. PALESANO: You're welcome.

MS. DILLEY: Kathy, some comments from the remote sites?

MR. SPANGLER: We have three new questions. The first two came from the same person, anonymous questions from Springdale, Arkansas, an establishment representative. Question 1, will on-line slaughter, carcass by carcass inspection be implemented into RBI eventually? And question 2, when the PBIS scheduler is turned off, will off-line inspectors only perform tasks based on the RBI factors or will the inspectors be able to choose tasks that they feel are necessary based on the establishment's risk level and/or situations of concern that could arise within a facility, e.g. construction, RTE area, et cetera?

MR. PALESANO: Okay. I'm going to answer the second question first. We anticipate as I mentioned this morning, that there would be some type of minimum inspection activity associated with the establishment at their particular level. Obviously inspection personnel would always have the latitude

based on what they see at their -- during their visit at the establishment to do more than the minimum inspection activities.

The first question that you asked is would RBI cover carcass-by-carcass inspection. I believe that risk based inspection will apply to all operations at some point in time. However, today at this meeting, we are discussing RBI in processing and off-line activity.

MS. DILLEY: One more question you had, Brad?

MR. SPANGLER: Yes.

MS. DILLEY: Somebody's cell phone's going off.

MR. SPANGLER: Another remote site question from Glenn Mott, Gerber Poultry, risk assessment is inherent in HACCP PHAs. What exactly is different between the proposed new systems of RBI and the current existing systems of the PBIS? We have had some discussion here in Reynoldsburg but the current discussions do not seem to be much more than correcting shortcomings of the current PBIS. Is there

really anything new here?

MR. PALESANO: Well, obviously we think there is something new here or we would not be pursuing this from a public health perspective. Obviously one of the things that we want to determine as we move forward with risk-based inspection is try to determine if we're looking at the right things to make a determination that we, in fact, further protect public health. We have presently set up a list of procedures in our inspection system procedures guide that are -- that lays out the procedures that an inspector will do in a global sense. At this particular time what we are looking for is to design inspection activities that will actually tell us whether or not there are things occurring at the establishment that could impact on the risk of products in that particular establishment.

MS. DILLEY: Okay. Thanks. John.

MR. MUNSELL: John Munsell. Mr. Palesano, I think you're asking us to help you answer that question. Should you use predictive indicators? And you use the example of new plant construction,

specifically in a RTE facility. Regardless of the type of facility, I would think that the opportunity would always be there for the inspector or veterinarian to tactfully approach the plant management who are going through plant construction and say have you considered this, not telling him he has to do something, but have you considered this? So I think they would always have that input.

But to answer your question, first of all I thought, well, what is a predictive indicator? So I wrote a few down here. One would be in-plant training. Does that plant have any kind of in-plant training of employees? If not, it might indicate something.

What if it's an old plant and the plant management is not putting any improvements into this old facility. It still just barely passes inspection, or perhaps most important, the attitude of plant management. For example, is plant management cordial and cooperative? Or are they permanently argumentative? Is the plant management helpful or willing to indeed partner with the Agency? Or is the

plant management obnoxious and independent permanently?

So, should we use predictive indicators? I'd say no, because the answers to these options that I just brought up are so subjective in nature. They're not based in regulatory requirements. I think of an inspector that we had on occasion at our plant, nobody got along with, nor did he get along with anybody in the entire state. Can you imagine how he would --

MS. DILLEY: A lonely person.

MR. MUNSELL: What kind of predictive indicators would he show at every plant? So my suggestion is no, you don't use them because it's too subjective.

MS. DILLEY: So, John, the way you were capturing that, one of the things you mentioned was, how would I define it, and it sounds like you're using it as a catchall for kind of the qualitative or the subjective information and your sense is that if that's what it is, then you would not use predictive indicators. That's how you would respond to that

question.

MR. MUNSELL: Right, because, Bobby, correct me if I'm wrong, but didn't you say something about these things would be totally outside of the realm of regulations. So a plant might be fully within all the regulations, but what other things?

MR. PALESANO: That's correct.

MS. DILLEY: Okay. Thank you. Barb, you had a comment and then Danielle, do you have a -- okay.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority. I guess I'm going to respectfully disagree with Mr. Munsell. I think we should use predictive indicators. However, it kind of depends on what those predictive indicators are going to be used for. If they're being -- if you're looking at indicators that are predictive of a plant --

MS. DILLEY: Sorry remote sites. That was a dropped microphone.

MS. KOWALCYK: Sorry about that. It depends on what they're going to be used for. So if the purpose here is to predict whether or not a plant is

going to produce safer food or predict whether or not this is something that could impact public health and therefore increase the risk of food-borne illness, then, yes, it is very appropriate. I don't understand then if that's the case, why it would not be included in the establishment risk.

I mean what role does this have to play if it's a predictive indicator? My statistical mind is sitting there thinking, predictive indicators are different components you put in when you're developing a model, and they're going to have a predictive impact, and you're going to have a coefficient for them, and some of them will be subjective, and you'll try and develop -- you'll try and fit them into the model in a quantitative way. But what is the point of the predictive indicators? Not only that, but once you've gotten a list, I mean asking this group for a list of predictive indicators is a very subjective mechanism for doing that. You would then have your list and then actually go back and do some validation. Does this actually predict good outcome or if you're trying to predict bad outcome, does it actually bad

outcome?

So I guess it comes back to what Carol said earlier. We need a definition of what predictive indicator is, and how that's going to be used, and you need to really -- you need to kind of set up what your goals are, and I think that comes back to Nancy's comment earlier, too.

MS. DILLEY: So what they are and what they're used for and then some evaluation as to whether they're accomplishing that goal. Danielle, you had some comments.

MR. SPANGLER: I have another anonymous question from the remote site. If an inspector has a patrol assignment where all plants fall in the level 1 for risk, will this affect the MAW for that assignment?

MR. PALESANO: No, I don't -- I'm not going -- I don't know what that's referencing actually.

MS. DILLEY: You don't understand the question or --

MR. PALESANO: No, we're not going into

assignment of work.

MS. DILLEY: Okay.

UNIDENTIFIED SPEAKER: What's MAW?

MR. PALESANO: Methods of assigning work. MAW.

MS. DILLEY: Okay. I'm sorry. Go ahead. One more. Go ahead.

MR. SPANGLER: This question is from Katie Hannigan (ph.), Farmland Foods, Omaha, Nebraska. Will inspectors assigned to a level 5 plant be required to have a higher level of training than an inspector assigned to a level 1 plant?

MR. PALESANO: No, the inspection personnel will be trained adequately to do the activities that they are assigned to do. They will not be trained differently for the levels of inspection.

MS. DILLEY: Go ahead.

MS. KARWEIK: Kim Karweik. I also am confused with the term predictive indicators. It really has a negative connotation, just the two terms together. And one of the things I can't help but notice is that the examples given by the Agency are

all in the codified regulations as reasons for doing reassessments in our HACCP plans or food safety systems. So as predictive indicators, are they truly -- I don't think you can say any of those are equal to an increased risk in food safety. What they are an indicator of is that if you're not going to reassess your HACCP plant because you're doing construction, then maybe there's some flaw in your food safety system, but I don't believe that it is equal to being a food safety risk. I think it speaks to how fully well developed your system is designed and how well you implement it. If you do have a construction project, did you follow the construction part of your food safety system as you defined it.

MS. DILLEY: Stan.

MR. PAINTER: Stan Painter with the National Joint Council. I would like to address three questions that were asked that were never answered. One of the gentlemen here to my right asked you regarding exports, and you answered the question regarded imported product, that it would have to be the same or equal -- equal to or better than what we

have, but you never addressed how exports will be factored into RBI regarding what an inspector will be doing in the field. That's the first thing we didn't get an answer to.

The next thing was the question was asked by someone over the computer regarding RBI and slaughter. You said currently we're looking at RBI in processing, and the question was are we looking at RBI for some point in the future regarding slaughter?

And the last one I have was the question regarding MAW that was asked, and you said we're not getting into that. Does that mean we're not -- it's not going to affect MAW in the way it's implemented or it's not going to be addressed?

MR. PALESANO: Okay. I'll start with your last question first, Stanley. At this point in time, it will not affect measure of assigning work. That's the answer to the first question. Keep in mind that we have to go -- anytime there is impact on our bargaining unit employees, that has to be worked out with the bargaining unit. So before any measures of assigning work are changed, that will have to take

place.

The other --

MR. PAINTER: Is that a yes or a no?

MR. PALESANO: It won't affect assigning work until that agreement has been worked out with the bargaining unit.

MR. PAINTER: So that is a yes.

MS. DILLEY: So that's a could I think. That's what I'm hearing.

MR. PALESANO: It will not affect the method of assigning work until the bargaining unit and management have reached an agreement. Or, you know, I'm not going to tell you that it's going to affect a method of assigning work when it doesn't comply with the contractual agreement with the bargaining unit.

MR. PAINTER: Well, there has to be a chance in order for the process to take place that you're referring to. So, you know, if there's no change, there would be no need or not statutory obligation.

MR. PALESANO: Well, let me go back to what we said earlier today, Stan, and keep in mind that at this point in time, since we have not defined the

inspection activities, it will be really difficult to even know what the inspection assignment would look like, but if it does affect the method of assigning work, obviously the bargaining unit will have to go through their process. Okay.

MR. PAINTER: Okay.

MS. DILLEY: So the second question was link with RBI the slaughter. Coming back to that --

MR. PAINTER: Yes.

MS. DILLEY: -- question.

MR. PALESANO: The second question that deals with RBI and slaughter, we will be discussing that particular issue at the NACMPI meeting. We'll be starting some discussion with that tomorrow. This meeting actually is for risk-based inspection in processing and off-line slaughter assignments.

MR. PAINTER: And I understand that, but the question was, was there a vision for slaughter? So I think I'm hearing you say yes.

MR. PALESANO: Risk-based inspection will be implemented to some degree or at least considered to some degree in all establishments.

MR. PAINTER: To some degree, meaning slaughter.

MR. PALESANO: Slaughter will not look exactly the way processing does, I would not imagine. I don't know that because I don't have the processing RBI designed yet, and we haven't even started the discussion on slaughter.

MS. DILLEY: Okay. So then -- and then I think your third question, Stan, as I understand it, it was the next step from the question that was raised about international impact and international trade. I think Bobby answered that in terms of yes, it's being considered, but your question was how that might affect -- that discussion might affect on the ground assignments, not assignments of work, but with the inspectors doing on ground. So it's kind of that dimension of it.

MR. PAINTER: In regards to the exports, how will exports come into play with RBI as far as what's going to happen as far as the inspection task being performed.

MR. PALESANO: At this particular time, for

the group that have had some discussion on processing and off-line slaughter activities, we have not gotten into export assignment. I believe that export is dealt with through another means of inspection. I would envision that some type of RBI would impact or would actually relate to export, but at this point in time, I have no concept of what that would look like, Stanley.

MS. DILLEY: Okay. Pat.

MS. BUCK: Pat Buck from Safe Tables Our Priority. I've been listening to this discussion about the, you know, predictive indicators, and to the questions about exports and imports and about the problems earlier this morning that we had on the expert elicitation yesterday and some of these other things. And the thing that's become very clear to me is that there's a lot of complex issues here for which FSIS does not have a plan, and they're asking all of us, consumer groups as well as industry, to come up with some suggestions.

I'd like to sort of throw that back to FSIS though. What is FSIS' plan to ask for additional

resources, whether those are, you know, internal in depth studies or projects that you want to design or, you know, more public meetings like this that would help you come up with what I call a detailed operational plan. You can't put a plan in place unless you have some of the details worked out. This is a very big food safety system. Do you have -- FSIS --

MR. PALESANO: I would anticipate that Dr. Masters and Dr. Raymond will probably address some of those issues later this afternoon.

MS. BUCK: Yes, I would hope they would because they need the additional resources to carry out what they've embarked upon.

MR. PALESANO: Thank you.

MS. DILLEY: Rosemary.

MS. MUCKLOW: Rosemary Mucklow, National Meat Association. Let's see if I can shed a little light on the confusion that I hear in the questions and answers.

It is a rare and unusual experience that the Agency comes to us with some very preliminary

information and asks for our input. We are not used to this experience.

(Laughter.)

MS. MUCKLOW: We are used to you coming out with a proposed rule and we can all get out our shooters and go after you all because you didn't get this right, you didn't get that right, you didn't get something else right, and we try to straighten you out, and sometimes we don't do it that well, as we didn't do with the HACCP rule.

And so then you had some public meetings. They were an unforgettable experience for those of us that were there in the cafeteria in the South Building because the Agency was so poor, it couldn't afford George Mason University for us to meet. So we all met in the crowded space for six days, over two weeks, and there are a number of people here who will remember it, and we thrashed out a lot of issues before you finally wrote a final rule.

Today's event, and I have to commend USDA for this, is that you have presented Matthew Michael or Michael Matthew, whatever his name is, and Don

Anderson and Bobby and whoever, and you've told us what you're thinking about, and you said, here's some questions we need answered, and we don't know how to answer that. Because this is so unusual, and it is commendable.

I didn't get up here to say that but as I listen to all of the to and fro, I just felt I had to say this because I think it kind of puts a perspective on why I've come from the West Coast to spend two days on these hard seats doing this. You know, it's just, it's just very unusual, and I appreciate your frankness and the thought that has gone into the initial thinking on this.

We talk about definitions, and we've talked a lot about predictive indicators. Now there's some people that really don't want to drive down the road when I'm driving down the road in my standard shift car. They think I'm not capable of both driving and moving gears and so on all at once. If I'm going to go down the road and I'm going to turn left, I've been told under the driving code, I'm supposed to put the indicator on. That is an indicator that I'm going to

make a left turn. It's very simple English. It is a predictive indicator if you will. If I don't have it turned up and I make that left turn and I hit something in the intersection, the cop's going to nail me for it, and if I make the left turn in front of something coming the other way, it's not difficult. A dictionary will help to explain to me what a predictive indicator is. It's not what a USDA inspector thinks of plant management or worse yet, what the plant management thinks of the USDA inspector. That is a subjective thing, and there are a lot of things wrong with that.

But there's some very good clear predictive indicators, and when I'm on that long trek home tonight, I'll try to think of some for you that will fit your models and make something work that are clear and definite without any subjective judgment.

But I appreciate that you have brought to us these ideas at this early stage and that you are open to our thoughts and comments. That is one of the most commendable things that this Agency has ever done, and it's a lot better than those sweaty meetings we had in

the cafeteria in September 1995.

(Applause.)

MS. DILLEY: Okay. There are two people at the mics. And we have five minutes to wrap up the discussion on implementation and move to some other agenda items including data and some other things.

We have not spent as much time -- we have talked about predictive indicators. We've talked a little bit about the phased approach, and we've talked a little bit about the levels, but I just wanted to make sure that if you have comments on that, we'll try and get more airing of the level concepts and some of the questions around those that were in the presentation. So I'm not sure who was first but, Felicia, why don't you go ahead, and then we'll go over here.

MS. NESTOR: Felicia Nestor, Food and Water Watch. To Rosemary's comment about, you know, it's commendable what the Agency is doing. I'll tell you, I was at the NACMPI in November 2005, and in the May 2006, and I know that the Agency has approached the Union and the basic issue has been we're going to RBI.

We have absolutely no idea what we're doing. What do you think we should do? We're not going to give you any details about what we might do, but just pick it out of the air, what do you think we should do?

I think that's a really silly process, and it still boggles my mind that even today with Dr. Raymond saying, we're going to be implementing this thing in 2007, the Agency can still come here and say, we have absolutely no idea, no idea whatsoever, how we're going to do inspection in 6,000 plants with 6,000 inspectors. We have no idea whatsoever, but we do know we're throwing out PBIS.

So let me ask these questions. Will -- do you know the answer to this? Will the Agency still do pre-op sanitation in every plant?

MR. PALESANO: At this point in time, we are hoping from this particular meeting that this group will help us define the inspection activities that will be used in risk-based inspection.

MS. NESTOR: Okay. So I shouldn't go down the rest of my list about operational sanitation because you're going to give me the same answer. And

to that I say, again, this seems really ridiculous. I don't know how many people --

MS. DILLEY: Felicia, can we us -- I recognize the way you characterize things, it does sound ridiculous, but I don't think that's the way it's being characterized by the Agency. They're trying to at least get some input.

MS. NESTOR: I'm sure it's not the way it's being characterized by the Agency.

MS. DILLEY: So can you stick to the question as opposed to characterizing the way it's being done.

MS. NESTOR: I doubt that there are very many -- I think that's actually appropriate for the consumers to make comments.

MS. DILLEY: Some people have interpreted it that way, and Rosemary's given another dimension of it. So I think if we can --

MS. NESTOR: And you allowed her perspective on it, right?

MS. DILLEY: Yes, I did. You're right.

MS. NESTOR: Okay. Thank you.

MS. DILLEY: And I think you characterized it that way, and I want to move to the questions.

MS. NESTOR: I would like to continue with my question. Thank you.

MS. DILLEY: Yeah.

MS. NESTOR: I doubt that there are very many people in this meeting that have done inspection in a FSIS plant. I know you've got thousands of inspectors out there that have, and yet you haven't had a meeting where the inspectors can come and give you their input about how they think inspection should be done. I doubt that there are very many in this room now that could tell you the different inspection tasks that are done in a plant right now. So I would suggest that you ask your inspectors before you implement this program since you seem to have very few ideas already in front of you.

One final question, and this is about the levels. What will you do in a situation where, using Dr. Raymond's example, plants A, B and C, what do you do in a place where an inspector has plants A, B and C, and he's favoring one plant because it's the worst

plant, and then all of a sudden, one of the other plants goes bad or has a recall or fails significantly in its food safety tasks? What happens if all three plants go bad? Then what will happen? Will you hire another inspector to that location?

MR. PALESANO: I believe your question deals with inspection levels, and how inspectors would cover those particular assignments under those circumstances that were defined. In my brief involvement in this, and where we are in the development of that, Felicia, I believe that if the inspection load became more than one inspector could cover, then obviously the Agency would have to make arrangements to see that an inspector in an adjoining area could cover that particular assignment. Obviously we haven't thought that through, but in my estimation, that is probably one way that that would work in today's world.

MR. HENDRICKS: Lamar Hendricks.

MS. DILLEY: Two more comments. We're getting close.

MR. HENDRICKS: Okay. I can make them quick. Predictive indicators, you don't need them

outside of the regulatory requirements. You have everything you need inside of a complete food safety system. You don't need other predictive indicators outside of the current regulatory requirements.

How the plants move from one level to another? Let's give the inspectors some credit. I've worked with them for 100 years. Inspectors have a great deal of pride, the majority of them. They know when plans perform properly or don't perform properly. Give them some credit. We already currently have a form of risk-based inspection in our system today. The inspector in that plant makes a determination when he comes in and looks at data, at NRs, at plant sampling, at pathogen results, he makes decisions based on those things. He makes a risk-based decision. It's already somewhat in place. It needs to be formalized.

So a suggestion down the road how the plants move from one level to another, perhaps there's a template that addresses whatever inspectors there are so that you communicate with your inspector, the plants communicates with the inspector, I don't care

if it's a template that you fill out yes, no, yes, no, to give him some indication of what's happening in that plant, be it construction, be it a change in the process, the addition of a microbial inhibitor or something of that nature. Thank you.

MS. DILLEY: Okay. One more comment. Two more.

DR. RYBOLT: Michael Rybolt, National Turkey Federation. I think Lamar kind of hit a little bit of what I was going to address. Sticking to the question on how the plants move from one level to another, currently with the *Listeria* RTE program, you do have questionnaires that plants can fill out and send into the headquarters to move alternatives. You could use something similar to that to move from one level to the next. And I appreciate the Agency having this meeting today.

MS. DILLEY: Carol.

MS. TUCKER-FOREMAN: Rosemary's right. This is an unusual way for FSIS to approach things, and it is -- it's good. I think it will end up with a better product in the end. We appreciate being asked in

advance before the Agency gets things locked in, but I'm running into a problem about I'm getting two sets of answers here. On the one hand, you say that the Agency is just now beginning this, and you want our views on such things as predictive indicators. But then, Bobby, when we just started, you said, well, you should know about predictive indicators because we talked to the Advisory Committee about them last year.

So is this new or is it not new? I'm not sure because I've communicated with the Agency a couple of times since we started this, and each time I get a response back, well, what's wrong with you that you're not aware of all these documents that we've published, and we've already said these things. So are we just starting or have you already made these decisions as you've indicated?

You say you're just starting but several of us have noted the need for data particularly data about risk from particularly foods, which the Agency does not have. We don't know which foods are associated with which illnesses. That I believe is essential to determining risk. The Agency seems to be

saying there is not enough time to go and get this information that I think is really basic.

Now because I went back and looked at all the documents that I was referred to, I found one from March 2, 2001, the report to Congress on risk-based inspection, and it refers to it as the inspector optimization system, and says that the Agency is going to move into a risk-based inspection system in order to avoid future shortages in inspection personnel, and this is in response to criticism from the Congress about some shortages. It goes on in great detail about this.

I haven't heard anything since we've been here suggesting that this system was -- had the purpose of avoiding inspector shortages. I think exactly the opposite has been said since we've been here. So -- but I was referred to this document and I don't think it's ever been withdrawn.

Finally, in this document, it says that the Agency is compiling data and intends to hold a public meeting later in the spring of 2001. I think this is the first time there's been a public meeting on it.

So I keep finding a disconnect between this is brand new or this is something that I should have known about five years ago.

MS. DILLEY: Going back to your work plan, a plan of work, some clarity around that, too.

Dane, one last comment briefly, and then --

MR. BERNARD: I'll address the last two questions as one, and it's how does one plant -- how do you move from one level to another in frequency? I think the HACCP model is a guide. It says we've got to reassess once a year based on the data if nothing changes. If something changes, in terms of your product mix, the way you process, et cetera, that we should do it as often as necessary and keep up with the changes, and I think in terms of categorization of plants, that's a very good model. So I just wanted to make that comment.

MS. DILLEY: Okay. So thank you all for comments on this section. We're going to transition to come back to some of the reports that have been submitted from the remote sites so we can be sure and capture some of that, make you aware of some of that

information, and then go to the data presentation discussion. So I'll turn it over to Paul.

MR. DeMORGAN: Okay. As has been mentioned, during -- I think there were some technological challenges overnight at some level. It's a euphemism. Anyway, and then we received a couple of others this morning from some remote groups.

So just in the interest and recognizing that this is not going to have much opportunity for discussion, and there are some common things, we did attempt to look through these. We just wanted to give those folks some -- for conducting those sessions and for sending in their comments, and at least what we explained to all the remote sites, that these report outs, just like the four that came from this session, will be kind of addendums if you will to our final report as information. So you'll be able to see these on your own and exactly which site they came from and correlate it over to kind of who was those sites as needed.

So in addition to the four that you saw earlier, there were five other sites that sent in

reports. These are the five of them. I will note that this slide show doesn't represent the Madison, Wisconsin because they sent in notes and so they were kind of big blocks of paragraphs and we just didn't have time over lunch to kind of pull out and identify the highlights of those, but again, you'll get to see those if you wish subsequent to this meeting.

So with request to question 1, so this was the question about the median of the expert scores, they spent some time talking as did the groups earlier from this area, said about the expert elicitation as well, felt that more food based experts from industry and consumer focused food groups should have been used to score. And the median score seems to be the best to use in the algorithm. Can't think of another alternative that could have been used. However, definite parameters should have been used in scoring. Feel that they possibly should perform another algorithm, increase the sample size and scope. Epidemiology should be included and CDC results and data should have been included. So some similar themes, a couple of different ideas coming in from

those groups.

Question 2, regarding the thermally-processed, commercially sterile products. Should be considered but received the lowest risk which we did hear from at least one of the groups. Should have a standard but should have their own processed defined. Did not feel that we, so we might know who was talking about that one, should be subjected to their standard. Canned products should not be considered in an equation or at a minimum handled completely separately from other products, and should be a separate matrix. So a couple of different ideas and themes coming out of that one.

Three, regarding the further processing of another establishment or further process to retail, just not really a question, but is the product post-lethality exposed or not, something to be considered. Does the producing establishment verify food safety procedures at their retail customers? Feel that for further processing in another establishment, this is addressed in each individual's HACCP plan and in terms of further process at retail, don't feel this should

come back to the initial supply plant. And then finally on this one, they have a product further processed at another FSIS state inspected facility should have less of a risk assigned to it than if it were going to retail, the rational being that the product is going into another HACCP program and can be further evaluated for risk at that establishment.

Okay. Question 4, I'm not going to read all the text on this one because everyone will get tired of hearing me. This has to do with the volume data. It does talk about a couple of different factors there in that first bullet. The second bullet talks about braking down volumes into each of the individual processes, individual HACCP categories. Could consider multiplying the steps of the process times the volume. So a couple of different ideas than the ones I think we heard from the other groups. Processes that inhibit risk should be taken into consideration. And then just a note about the fact that more volume doesn't necessarily mean more risk. And then another comment, risk control by volume, risk should be weighted against volume of product

processed. So that one was one of the ones that did come out of the earlier sessions.

Question 5, the question about multiple products. One factor to consider was the product produced seasonally. Ultimately inherent risk should be based on percentage of total production if that was to be a consideration. Feel that a higher number of steps in the process. So this goes to the complexity which was raised, then the higher risk steps should be weighted more heavily. Maybe inherent risk data should be based on processed categories as opposed to actual products produced, and some questions, how would FSIS evaluate a plant that produces a very high risk product once a month, but a low risk product every day. Would it be based on the volume of the product risk, which we've had some answers to, but there's lots of different scenarios. And then just a worst case scenario would be another one that you might want to choose.

In terms of question 6, about severity of illness, put value on pathogens based on reported CDC incidents is one way to possibly incorporate it into

there. We can't predict the severity of illness when calculating risks. We can only react to the data available to us is what another group said. Another group said severity of illness should be left out of the equation altogether, and added some rationale for that, and then depending on the consuming population and infective dose of pathogen. So that was comments from those four areas related to product inherent risk.

Moving onto the establishment risk control paper, regarding whether the six components are appropriate and accurate, a couple of people said, yes. One group said we feel that it depends on how these are defined, how they're weighted, getting to question 2. And then another group added, what about plant construction? So something we were just talking about at some level.

Okay. Question 2, regarding weighting, are some more important than others? All components are equally important in considering risk control. None should be weighted more than others. That's the first time I think we've heard that one. Yes, we feel that

components are more important, ranked in the following order, pathogen control, in-commerce findings, et cetera, down the line with food defense being last. And then in-commerce should be weighted more heavily.

Question 3, is there other useful information about establishment risk control that FSIS is not considering? Can't think of it is what one group said. Feel these are valid factors if implemented properly. Okay. Extras in establishments is doing to go above and beyond, i.e. environmental testing, HEPA filters, product flow, could be some other ideas, intervention strategies and quantification of pathogen numbers.

Question 4, other ways besides food safety assessments to evaluate establishment, food safety system design, would industry share a third party audits as a possible method, concerned that this could promote an escalation in the amount of NRs written, would like to see a standardized matrix to evaluate FSAs, as seen with third party audits. This would make FSAs more objective in their findings, and then another suggestion related to others, third level

audits, audits need to be standardized, supplier audits.

Question 5, are the NRs that FSIS is considering public health related inclusive or should there be others that they should be considering? The first group said, in essence, yes, and second, another group or maybe the same, another point, NRs should be carefully weighted on its merits, not just what regulatory reference is assigned to it.

And finally, what's an appropriate look-back period, six months, one year or six months to one year. So similar messages that we had heard before.

So I recognize that was pretty quick. We again appreciate the folks at the different locations for getting us that information. Sorry to Madison that we couldn't integrate their comments directly into the PowerPoint, but those will be included as an attachment, and any kind of quick reactions or thoughts to that from anybody recognizing that I'm probably not encouraging them.

(Laughter.)

(No response.)

MR. DeMORGAN: Okay. So as we've alluded to almost all day, we are going to have a brief presentation on data and some of the thinking that was spurred yesterday by comments related to that broad issue, and clearly we've heard a number of times already today some additional questions as it relates to data. We've also heard that some of these questions are going to be looked at in other venues like the NACMPI meeting, but what we wanted to do in the remaining 45 minutes or so of the open session -- when are we going to the break? 3:30.

MS. DILLEY: 3:30.

MR. DeMORGAN: Yeah. So the remaining 45 minutes is to ask Dr. Masters to come up and give a brief presentation here. Let's see if I can find that. There we go. Is that it? And for those of you on the phone, it's a one slide show if you will, and it's being put up here, and it's also being handed out to those of you in the audience. So I'll turn it over to Barb, and then we'll turn to Dr. Goldman for one brief which Barb can introduce him in terms of what that is.

DR. MASTERS: Thank you. And before we get started, I wanted to go back briefly and make a comment on a couple of things that were just addressed, that I think are worthy of just bringing together on the discussion we just finished. They were addressed yesterday and I think they warrant repeating again today because I think they're just such important topics.

In my opening remarks yesterday, I talked about the fact that we as an Agency have started with risk-based inspection prior to 2000, long before myself, before Mr. Quick, Dr. Raymond and others were in place. And that we've been evolving over time, that we did have processing inspection optimization systems. There was a public meeting on that. We had hazard control coefficient, hazard coefficients, and the thinking has evolved since that time, and we've had lessons learned from each of those steps. And that our current thinking now reflects that evolution, and I think it really is important to make those comments, and that most importantly, and Dr. Raymond really emphasized this point yesterday, that where we

are today in our evolution is that risk-based inspection, as we're talking about it today, does not, does not include addressing inspection shortages. So I really want to make sure that we're all talking about it from that same place today because we are, through this evolution in a very different place than we were in previous version.

We haven't taken those papers away because they do reflect some of the evolution that has occurred over time, and some of the basis for our thinking. But I think it's important that people have come in at different stages in our meeting, to make those points and reemphasize them.

I also wanted to thank my staff that's had their opportunity in the hot seat. I think they're doing a great job. To reflect the fact that, while the presentation that Mr. Palesano was giving, reflects our very initial thoughts on implementation. We are building that presentation on implementation and the staff working on that, from presentations that we've been working on a little bit longer. The measures of product inherent risk and the measures of

risk control, which you've seen those papers since July on our website, and we've been talking to NACMPI from our last two meetings. And we are trying to build the foundation for that implementation paper from those other papers.

So our process has been iterative. So to the frustration of, is it new or has it been around a while, we are trying to build it from those building blocks. So I hope that helps put some context to is it new or has it been there into some perspective. So I'll leave it and take your questions in a minute, Carol, but I did want to put some perspective to the fact that while we have a group working on implementation, they are trying to build it from the building blocks that we've had at NACMPI, and from those papers that have been on the web for some time, and also to reemphasize that where we are today and the risk-based inspection system we're talking about, has been built over evolution, over time, and it is not about addressing shortages, and that's the most key point that I wanted to get on the table.

Data is something that I really tried to

build into my presentation yesterday and to talk about the fact that we as an Agency believe that data has got to drive our risk-based inspection system. But I will also tell you that when I took over my role as Administrator, and when Mr. Quick took over his role as Deputy Administrator, we recognized that we as an Agency have got to use our data differently than we have been using it for a long time. And I think our management council, most of them are sitting in this room, will tell you a big focus of what we've been doing as an Agency is really looking at how we use our data, differently than we have in the past.

We collect data in many forms as an Agency, and what we've challenged -- and what Bryce and I have challenged our managers to do, is just start analyzing that data and responding to that data in a proactive way. And so we took our managers and we called we had our own data summit, to start looking at the stovepipes of data that we had as an Agency and start putting them into what we will call a data warehouse.

For the purposes of this slide, because we were trying to take it from the risk control slide

that Mr. Anderson presented, the risk control component is actually a subset of the data warehouse. It is not equivalent to the data warehouse. We as an Agency have significant more information in our data warehouse, but the risk control is going to be a subfactor of our data warehouse. We spent much of last year building our data warehouse and getting it together, and I see some our IT people in the back of the room shaking their head and smiling, because that was much of what they did last year.

At our NACMPI meeting last time, we talked about our public health data infrastructure and applies architecture, and for the techies in the room, some of that probably is very comfortable words for them. For those of us that are non-techies, it's how do we get all of our data talking to one another and having the same look and feel so that if the in-plant person types in the plant's name, establishment number, for a pathogen form, it's already in there for a NR. It's already in there for a consumer complaint if they've got one. So in the warehouse, all of it is in the same form. That's what we talk about when we

have a data warehouse.

So we try to put together what we as an Agency already have in our data warehouse, and then we try to put together those things that are already electronic and now we're working towards putting them in the data warehouse, that you can try to get a sense of where we're at, so that you can see the work ahead of us when we start trying to put together the mathematical formulas.

When we look at pathogen control and something that you all thought was very critical moving forward, if we make decisions around pathogen control and including it in risk control. So we'll focus on risk control for now.

We already have electronically in our data warehouse, our ready-to-eat data, our *E. coli* O157:H7 data, our *Salmonella* data and our supplier tracking data. So all of that is data that we already have as an Agency that we capture.

Data that we also mentioned that we thought was important was AMS testing data. That's electronic, but it's not yet part of our data

warehouse. That is something that we would like to get into our data warehouse but that does not yet enter into our data warehouse.

When we look at our systems design information, we at this point had mentioned things we thought relatively important to our system design, or which alternatives, if a plant is making ready-to-eat products a plant is in. Right now plants making ready-to-eat products fill out a form and indicate which alternative they're in. That is already housed in our data warehouse. That's electronic now and the plants fill that out electronically. And that's housed in our data warehouse.

Food safety outcomes on the other hand, well, it's electronic and the EIAO officers or the EIAO trained public health veterinarians fill that out electronically. That is not housed in our data warehouse. So some of the things -- and I heard conversation around this at this meeting, and we got some good ideas, are if we determine it appropriate to consider the enforcement action as the outcome that would get scored because it's taking that qualitative

data, making it quantitative, that would be the component that we would have to make and put into our data warehouse. Or if we determine what intervention a company is using is important data from that food safety assessment to capture, those are the kind of pieces of data that we're going to have to look at capturing from our food safety assessments. It's already electronic. We have to determine which pieces, and that's some of what we had hoped to get through this meeting is which questions we want to capture from that particular piece of data.

NRs, and I encourage those of you that are interested, the very detailed NR description is going to happen tomorrow at the NACMPI meeting because there was a challenge to the Agency to do some validation on NRs and which ones were public health concerns. So that discussion will take place at NACMPI. But we implemented drop down menus last December on our NRs relative to the regulatory citations. So we are validating right now through data analysis which NRs have a correlation to public health. We're doing that two ways. One, through the drop down menu of

regulatory citations.

So we're looking at, for example, 417.3 or 416.15 which are corrective action NRs, just as an example, trying to see how they correlate to situations that had an adverse action such as a recall or an outbreak, trying to see where there are correlations to public health. We're also looking at NRs that had key words and how they might have correlated to public health. If we're able to validate that all of our regulatory citations are working to get us to the adverse actions, then that will be what are already in the warehouse and we already have what we need and validate NRs with adverse public health outcomes.

If we find that we need a combination of the reg citations and key words, then we will have to do some more programming on our NRs to get drop down menus with the key words to assist our inspection program personnel to always use the same key words. So those are things we're trying to validate right now based on the recommendation we had gotten from NACMPI at the last meeting. So we're trying to do the

validation both ways with the reg cites and with the key words. So we'll have a full report out on that at the NACMPI next time -- tomorrow.

Food defense, we already have in our warehouse our product process vulnerability, production volume, food defense plan and our results for our weights for those plants that have food defense plans I should say. And again, depending on, based on the feedback that we got at this session, obviously that was a fairly common theme both here as well as at our Netcast locations, how important is that and should we do that differently or include that as part of the risk control factor, but that's some information that we already have electronically.

Enforcement actions are currently electronic. If an inspection program personnel writes an NOIE, that is electronic but it's not currently captured in our data warehouse. So that's a piece of information that we will have to add into our data warehouse, and we're trying to capture again the concept of taking a qualitative piece of information. The NOIE is not a quantitative document. It's a

qualitative document and trying to make some sense out of how does that become a quantitative piece of information, is something that we're looking at, but that is certainly something that is electronic.

And then our in-commerce data and Dr. Goldman is going to come up and share with you our consumer complaint tracking system that we have as an Agency and walk you through that screen.

We also have our recalls, our class 1 and class 2 recalls that are certainly electronic at this point and in our data warehouse.

And then product control actions is another area that we would have some work to do around if it's determined appropriate to capture when we take a product control action in commerce, which would be a detention. That's different than a product control action in the plant which would be captured on a NR. Here we're talking detentions, seizures, injunctions at the in-commerce level that would be taken by our program investigators in the field. So that would be at retail.

So those are the pieces of data that we

currently have that we are tracking, getting into a data warehouse to work around, to give you a better sense of what we have and how much progress we've made in the last year.

So I'll be glad to answer any questions, but this is FSIS data with the exception of the AMS testing that we're working -- AMS currently shares their test results with us who take action against those AMS testing results, but they're not currently in our data warehouse.

So hopefully this gives you a little better perspective. Sandy.

MS. ESKIN: I have two questions.

DR. MASTERS: Sure.

MS. ESKIN: The Advisory Committee directed or asked FSIS I think three years ago to discuss with industry their data and the other question is, what type of progress have you made toward that, and secondly, there's also a recommendation regarding data that state agencies collect. I don't see that up there on the board, and what type of actions has the Agency taken toward that.

DR. MASTERS: The data depository idea that we've been working back and forth at the NACMPI meetings with industry, we've continued to explore that idea and have not made significant progress on getting a data depository put together. And I would suggest at least at the risk control level and the comments we've heard today as far as using industry data as I understood them, and it was a question I was going to ask later, as I understood the use of in-plant data for risk control, most of the comments I heard were related to in plant for one plant which would be different than some of the difficulties we were running into at NACMPI for a data depository. So as I understood the comments we were hearing at this meeting, if a plant had data and they were sharing it, that would be a separate subset of data for that individual establishment that may be easier to -- it's not on this chart. I agree with you Sandy. Okay. So I was hearing at least in the group I was in, that individual plants would share their own data relative to their plant to factor into their score, if you want to call it a score, to help impact their inspection

level.

MS. ESKIN: NACMPI --

DR. MASTERS: Which is different than what -- okay. And so Sandy is suggesting that's different than what NACMPI was talking about with the Agency which was a data depository at a much higher, broader level. FSIS is still very interested in having that data depository. At every NACMPI meeting we talk about that. We ask for ideas on that. We ask for input on that, and we still relish the idea of having a data depository with industry, and have not yet been able to achieve that level of trying to have that data depository.

But I also heard ideas at this meeting of maybe getting to a different level of having industry data which is having individual plant data which might help us achieve gaining individual plant data for risk control, but they're two separate ideas, Sandy.

But we are still very interested in the data depository, and it does come up at each and every NACMPI meeting, yes.

MR. DeMORGAN: And did you speak to the

state data?

DR. MASTERS: The state data, I would say it's here and it's not here in that when we have information from a state, and David's going to talk a little bit about this when he comes up, but where we get state data, it's primarily related to pathogens or outbreaks, and if we have that data, it would be electronic but not in our warehouse at this point. And so we do use state data where we have that data.

MR. DeMORGAN: Okay. Thanks. Tony.

MR. CORBO: Tony Corbo from Food and Water Watch. Dr. Masters, in the latest semi-annual report to Congress that was filed by the USDA, Office of Inspector General, one of the items that they listed as a project that they were going to undertake over the next six months, was a review of the sampling procedures of your pathogen control enforcement program. I don't know if there's any one here from the IG's office who can, in the audience, who can give us an update in terms of where that analysis is or whether the Agency has been contacted on that project?

MR. DeMORGAN: So you don't have an answer.

Is there anybody in the audience that could respond to Tony's question?

MR. CORBO: It would seem that that is a very important report to have in hand to see the quality of the data that the Agency has in hand.

MR. DeMORGAN: Okay. And I think, Tony, implicitly in there, you're raising maybe a higher level, and we've heard throughout the couple of days about the number of issues with no so much this, but what are some of the underlying or overlying, whatever you want to look at, issues, one of them is the quality of the data and Tony's identifying one place where you could get some of that. Phil.

MR. DERFLER: Phil Derfler from FSIS. I just wanted to supplement what Barb said about the data warehouse. Mike Taylor at the University of Maryland is working on this, and we are involved in the effort, and so there is ongoing effort to try and pull this together.

DR. MASTERS: Thank you, Phil.

MR. DeMORGAN: Yeah, Barb.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables

Our Priority. I think we've heard several times this morning from several of the groups that one of the gaps is attribution data which, of course, is evident yet here again. What sort of plans -- I understand you're trying to develop this repository and that you have state data there sort of but sort of not. What plans does the Agency have to proactively try and get attribution data into this model since it's come out repeatedly in documents prior to this meeting and then again in the group summaries that probably the most important piece of data is sadly missing from your chart?

DR. MASTERS: Not sadly missing. Dr. Goldman is going to address attribution data. So I'm going to defer to Dr. Goldman on that question. If you have questions on this chart, I will answer these, and then Dr. Goldman is going to walk through consumer complaint monitoring. He's going to walk through outbreak data and he's going to walk through how we use information from our CDC and others. So Dr. Goldman is going to walk through all of our public health data.

MS. KOWALCYK: The other thing I had is you made a statement earlier saying that you had charged a lot of your managers with going back and analyzing the data. And it would be useful to know what sorts of questions were being asked. I mean you just don't start analyzing data. You usually have a goal or an objective, and it would be useful to know, one, what sorts of questions and information was the Agency looking for? Two, did you have the data you needed to get those answers, what were your outcomes because I think that that will certainly help us potentially identify more gaps in your system.

DR. MASTERS: Okay.

MR. SEWARD: Skip Seward, American Meat Institute. Barb, thanks for the explanation. A lot of work's been done at the Agency and I commend you on pulling together all this information and the data. Great job.

I believe that part of the AMS school lunch program, they use a lot of statistical process control in the analysis of their data, and I wondered whether or not the Agency's considered expanding the use of

statistical process control, both -- not only for plant data but obviously in the data that you collect to better determine, according to a set of rules, whether or not systems are in control or out of control and that kind of thing as a way to analyze that data. I know it's difficult when you pull individual samples from establishments and you don't have necessarily the frequency that you need, but have the people that you work with on the data side looked at ways to look at the data to better predict whether or not the system is in control or out of control?

DR. MASTERS: I think it's a good comment. Right now what each program area is doing, it's a little bit of what Barbara is asking as well, is each program area has been challenged, put management controls in place, using the data that they have, and it may be most useful when we finish this, after David gets through, since we don't have time, is to have Ken Peterson come up and talk a little bit about what they're doing with the data. I'm looking to see if Ken's here. Ken's here. Talk to the management control system as theirs is the most automated that

we've put in place. We talked about it a little bit at the last NACMPI meeting. He has put together their automated management control system, including dashboards and indicators of how he's using the data to look around, procedures performed, procedures not performed, which procedures he's looking at and how he's using that data, and he can very quickly walk through that. And that's the challenge we've put in place for each of our program managers.

Field operations is a good example because it relates directly to most of the folks in this room, and a lot of what we're getting at, at the in-plant level. So I may defer to both of you and to let Ken kind of walk through a quick example of how he's using that data and the way he's analyzing that data at the in-plant level.

MR. SEWARD: Okay. Thank you.

MR. DeMORGAN: And I think what I'd like to suggest, Barb, is if we turn and I'll ask Michael, do you think you've got to ask the question now or do you want to go through those two presentations first? Either way is fine. You'll be first after they

finish, but if you have another question for Dr. Masters, that's fine, too. It's up to you.

MR. KOWALCYK: I can wait.

MR. DeMORGAN: Okay. It would just be nice to get that and then we'll be done, and then we'll just have X amount of time, but you'll definitely -- it may only be Michael that has a chance to ask a question depending on how long the presentation is, but you'll definitely get that change.

MR. KOWALCYK: Sure.

DR. GOLDMAN: All right. I was asked to put together a very brief example of in-commerce data and in this case, I'm going to walk you through a little bit about our consumer complaint monitoring system, show you a series of screen shots which constitutes our intake form if you will, and then end up with one pie chart of data just to give you a flavor for the kinds of complaints we get. And then I'll try to address some other issues that have come up in the previous two days.

So yesterday when I was put on the spot about how many complaints we had in the system, I'm

gratified to know that I was pretty much in the ballpark. We do have 5,046 complaints in the system. For those who may not know, the CCMS as we now know it, was a creation that was a result of an OIG investigation which found that the Agency was not handling consumer complaints in a consistent way. So there was a decision made to centralize that and automate that. So you'll see that in just a minute when I do the screen shots.

So this system as we know it has been in place for five years, roughly 1,000 complaints a year. Every complaint right now is triage, which is a term we use. In other words, it's examined by a headquarters staff member, and they go through a series of steps in order to investigate that complaint further. We work very closely with the Office of Field Operations, and in particular, the EIAOs in each district office who are assigned further activities or investigations depending on the nature of the complaint. And so there's actually a directive that outlines in essence our SOP for investigating complaints.

If you look at the third bullet then, about 16 percent of the complaints that are in the system currently have warranted some further investigation of in-plant practices. And typically what that means is an EIO going in and looking at the plant practices that may have resulted in the complaint that was lodged.

And there was another question yesterday about how many establishments have been put into the system and so there's the answer there, 989 of our establishments of the roughly 6,000 have had a complaint registered in our system.

Okay. The screen shot is actually three different slides because it's such a long intake form, and I'm just going to walk through this very briefly, and not go through every data field, but for those of you who haven't seen it, and it's probably most of you, we try to gather some what we call demographic information, you know, where was the case reported, if we can get the information about the complainant, then we try to enter that. And the reason we do that is we send each and every complainant a letter at the end of

the process, once the case is closed out, either to say your case has been investigated and we've found such and such, or else to say your case has been investigated and we didn't find anything necessarily to address the complaint that you lodged.

Here's kind of the meat of the system, and you should also know that currently the complaints come in through primarily two mechanisms. One is there's a complaint that's registered at the district office. So someone will call a district office because it's close by and they can find it in the blue pages of the phone book, and they'll talk to someone on the district staff and register the complaint, and that person will actually enter the data.

The other mechanism is the meat and poultry hotline. A lot of people call in to register the complaints through the meat and poultry hotline.

And as you can see, we try to gather information that helps us characterize the nature of the complaint and tries to get some details about that complaint. You can see there's some kind of free text fields here, that would help us determine what the

pathogen may be, if it's a pathogen that's causing an illness or what the agent may be, if it's a toxin or a chemical contaminant. And as you'll see in just a minute, a lot of the complaints are about foreign objects or foreign materials. So again there's some free text fields about trying to describe that foreign material.

Then finally, we end up, and this is the third and last of the screen shots, we end up trying to gather information about the product. So to the best of the complainant's ability, try to describe the product that they believe has led to their illness or injury, and we try to capture this information as best we can. The establishment number is required field. Otherwise, the complaint won't register in the system unless we have the establishment number. So currently that's the way the system is set up.

We also try to capture the point of purchase, and I'll get to that a little bit more in a minute but, you know, we try to capture as much data as is available that can be provided by the complainant.

And this is just an example of the kinds of complaints we get. This happens to be 2005 data. I don't know what the denominator is. I don't know the number of complaints, but again roughly 1,000 or so, and you can see the nature of the complaints. They're categorized as soon as they come in according to the data fields that are checked off and -- on the intake form that you saw a minute ago. And so you can see the majority historically have been about foreign materials or foreign objects.

Sometimes there are complaints of illness and there are a series of questions asked of the complainant to determine whether or not that illness has already been evaluated by their physician, has been reported to the public health department, in their locality. So not all the complaints, in fact, probably a minority, a small minority of the complaints are actually lab confirmed illness but we do capture that information when it's available. And, of course, those illnesses that are lab confirmed become part of the reportable illnesses that come up from the local health departments to the state health

departments and ultimately to CDC.

So that's, that's all of the slides I had.

I did want to mention that there are some enhancements coming to the CCMS which I think you should be aware of that will help us use the data a little bit more easily than we're able to do right now. There will, in the very near future, be what we're calling CCMS II, in which there will be a web interface for a person to enter their complaint directly into the system.

Another activity that we've been engaged in discussing for some time and would like to move forward is the ability to capture state-based complaints. We realize and recognize that 5,000 complaints is just a small tip of the iceberg, in terms of the number of complaints that are out there. So we are trying to develop ways that we can capture state-based complaints. So I think those are two enhancements you should know.

The other thing that will happen with the new CCMS system is that there is a customized software application that was developed by a contractor to help

us recognize unusual situations that we wouldn't otherwise recognize by simply having our headquarters staff review each and every complaint. They can do some rudimentary searches right now, but this customized application will allow us to enrich the data and analysis that we can do on the consumer complaints.

So that's really all I was going to say about CCMS.

I do want to address the issue of attribution because it came up yesterday and again today. The Agency has for several years, even preceding my time here which is now four and a half years, been actively engaged with the CDC, our partners in Food Net, to try to help us with attribution information. For those who may not know, 1 of the 3 objectives of Food Net are the original objectives from 10 years ago, was to get attribution information. It has not yet succeeded in doing that.

Part of what I've realized is we've been engaged in this process is that it's a much more complicated issue than probably most people imagined,

but there is good new on the horizon. And just as a point of information, I want to let you know that co-incidentally the various efforts on attribution that have been developed both within the Government, through academia, and even through a private non-profit, the Food Safety Research Consortium, there will be five presentations of attribution models at the upcoming Society for Risk Analysis in December in Baltimore. I think the SRA is an appropriate venue for a discussion of these various models, and certainly -- actually the FSIS is co-hosting that session. So you can tell we're very interested in the outcome and the presentations that will be presented. And they run the gamut. They're various types of attribution models. So all of them will be presented.

FSIS has been very interested in the work of John Painter at CDC who has been trying to conduct what we call the outbreak attribution model. We have been waiting and waiting for that. He will present his findings at that meeting. And interestingly, there will be a discussion of another way of getting an attribution using expert elicitation. So we'll be

interested in hearing how they were able to arrive at some results with that.

So I just wanted to give you some hope that there is some information out there on attribution. It is very difficult and has proven to be difficult but it's on its way.

The last thing that I wanted to mention is that the Agency very much does use both outbreak data and sporadic illness data. I mentioned a minute ago, Food Net, that we were one of the original contributors to the Food Net project going back 10 years now. Food Net, of course, publishes annually the rates of illness for food-borne pathogens. The Agency uses that information and that information by the way is primarily sporadic data but it also includes outbreak cases, and so because Food Net is limited to 10 sites across the country, it's subject to some data variation in the sense that if to use a real recent example, if the number of cases of *E. coli* O157:H7 suddenly increased in Food Net, we might look to the recent spinach outbreak or other produce related outbreaks, and this is why the attribution

information is so important. We need to know. This Agency needs to know as well as FDA if we make a change in our regulatory policy, it's having an effect on the product we regulate. Right now we have an idea and we have a better idea for ***E. coli*** than we do for *Listeria*, for example, but we need that information.

And we use outbreak information. We use outbreak information for enforcement. Sometimes it leads to a request for voluntary recall. We use outbreak information for regulatory policy changes. There are two very recent examples of that. One is more recent than the other but one is the discovery of *Salmonella* species, various species in stuff poultry products. The Agency made some regulatory policy changes as a result of that discovery. And a little bit older, but another good example is we've used outbreak data from *E. coli* O157 in mechanically tenderized beef products as a way of changing our regulatory policy calling to the industry's attention the need to reexamine HACCP plans for this possible pathogen or this hazard.

And finally we use outbreak data sometimes

to issue a public health alert. Sometimes we don't have all the information we need to put it into a nice package and lead to a definitive action, and sometimes the best that we can do and the very important thing to do is to issue a public health alert to alert people that we have this amount of information and that they should be warned about a particular pathogen in a particular product.

The last thing I would say is that there are sporadic cases. There are outbreak cases, and there's some overlap and most of you're familiar that PFGE is now allowing us to increase the overlap, that is recognized amongst what we once considered sporadic cases, those that might be linked together through some common exposure and FSIS is a contributor to PulseNet. We are very keenly aware of PulseNet. We have people in our Athens Lab who follow PulseNet uploads on a daily basis. So I just wanted to mention that as another data related activity that FSIS participates in. Thanks.

MR. DeMORGAN: Dr. Masters, you had mentioned that you had wanted to ask one other person

in your staff to maybe offer a few comments. Do you want to do that now and then we'll go to Michael's question and then realistically there won't be a whole lot of time unfortunately left, but we'll do what we can.

And Ken, if you could just introduce yourself for the folks on the phone and in the room.

DR. PETERSON: Okay. Good afternoon. Ken Peterson with FSIS, Office of Field Operations. And first I want to thank Barb. We appreciate these unscripted opportunities.

(Laughter.)

DR. PETERSON: But there's some questions on how we're using some data and what we're doing with some of our data.

With Field Operations, about a year and a half ago, we implemented some management controls and then we began the process of automating those management controls meaning I have some Agency data. I want that data to automatically populate my management controls so that people don't have to manually enter data. And so we contracted out and had

that done.

But why do we have management control? Because I get asked, the Agency gets asked, but for Field Operations, of course, I get asked what are you delivering for public health protection for $680 million of taxpayer money, for inspection and enforcement?

And so we're obligated to describe what we're doing, and if we're not doing it, what we're doing to make sure it gets back on track. So that's where management controls help me and, of course, then in that way helps the Agency.

So the management controls we have, I'll start with a few that I think are maybe less germane to the group but they're important to the Agency. For example, management controls for enforcement activities. If we take an enforcement action, I want that case filed in the database, industry is welcome to challenge that particular enforcement action, but I want the case file in my hands so that I can move it to a Court if I need to do that, and so we'll do that 24/7. So I have some expectations for uploading

enforcement case files.

I have some management control expectations on the recall front for what the Agency goes, as you well know, some -- a variety of pathogen sampling. When those sample results come in, we get some, what's called presumptive results. They're not confirmed, but they're almost confirmed. And I want to make sure that that product is, in fact, held. The inspector indicates that it's held when they pull the sample, but at the presumptive stage, that's a day or two before it confirms, I want to know 24/7 for a fact that that product has been held. And so when the districts get a presumptive positive, typically they're late in the week or on the weekends, we confirm, in fact, that the product is under the establishments control. If not, then we're going to want to start looking for it, so that we don't have to wait for it to confirm, and then, you know, still have product in commerce and lose a couple of days. So we have some of those kinds of management controls.

And then we have programmatic management controls that I think get to the data folks are

interested in. PBIS data which is scheduled procedures performed. We assign work. I want to know that that work's getting done, and if it's not getting done, then why is that, and do we have good reason? Do we have bad reasons? Are there reasons that we can fix? And if they are reasons that we can fix, then we want to fix them so that scheduled work can get done. And we look at that for SSOP procedures, sanitation performance standards, HACCP procedures, that kind of thing. So we look at scheduled work.

Lab samples, Dr. Goldman's program requests that FO collects samples. They have reasons for making those requests. They have other Agency data based on the plant profile. The plant profiles are in PBIS. So they go through some work to make sure that the right samples are asked of the right inspector. I don't like to waste their time asking for samples that aren't appropriate for that establishment. And then once we get to that point, was the sample collected, and so I want to know that for example, that management control is -- I want to know that 95 percent of those requested samples were, in fact,

submitted. And if there's reasons why not, then we need to fix it.

Inspectors can pull samples for residue sample in the plant for animals that come down the line. They may want to pull a particular residue sample. I want to know that the plant was notified that we pulled a residue sample so that they can hold the product, and I want to know that the inspector, you know, told the plant, here's the sample we took, and if you want to hold it, it's up to you but we think it's a good idea. So we track that kind of information. That last piece is a good example of some information that I don't currently have automated, and the only way I can find out whether a random, meaning a non-sample, the only way I can find out whether the inspector told the plant is through my supervisory activities. And that's very -- that's not timely. So we want to track that performance standard automatically and so we're looking at, well, should we revise our sample submission form and just put a checkbox on there, and then I could automate that. That kind of information would go into the data

warehouse. I can populate the data warehouse and then pull that information out automatically and we can get it real time.

So that's I think pretty high level, but that's what we're doing with data that we have today. What you saw in the data warehouse, we have E80RS (ph.) data, which is for this purpose, mainly some -- handling data. We have Agency pathogen sampling data that's generated through OPHS. We have PBIS data. That gets into the data warehouse. Then we program the procedures to pull that out into automated reports, and I have some standard reports that the districts look at, and we're just to the point now that that's data getting robust enough that we're really able to analyze it. It's been running since about June. So I have some automatic reports that I expect the districts to look at and pay attention to, and then the districts and I can generate custom reports, and as we get into the next year, I intend to, by definition the districts will, closely look at our custom reports. What is happening with the data you have? What does it tell you? What does it tell

you about what you're accomplishing? What does it tell you about potential vulnerabilities? And, are you managing that information? That's what I'll expect them to do. That's in the data warehouse. They pull those custom reports out of the data warehouse, and it gets displayed in a variety of ways automatically.

So that's what we started. As Barb indicated, other program areas will be kind of dovetailing into that automated data system with their own data sets that are Agency data sets that go into the data warehouse so that we can cross-populate those data sets.

MR. DeMORGAN: Great. Okay. Thanks, Ken, for coming down and doing that off the top of your head. I look at the clock and it's 3:30 which is when we're supposed to take our break. So, Mike, clearly you can get up and ask a question because that was -- obviously you deferred and there's no problem with that. I think then what I'd like to do is just see what level -- how many other folks feel like they need to, on this issue, recognizing that it's late, and we

do have one other agenda item and we are going to break right after Michael. So we're going to break after Michael. We'll just see how many other comments have to come in and whether they'll fit. Maybe if it's a couple, maybe we can do them right after the break, and then turn to Dr. Masters and Dr. Raymond for their last presentation. Michael.

MR. KOWALCYK: Fortunately, Mr. Peterson covered one of my major questions, how this data is managed and populated in your current uses for it. I think you addressed some of the concerns I had.

Is it safe to say this current data structure, where you have these data elements in green, is it -- do you have a comprehensive set for all federally inspect plants that would fall within the proposed RBI system, or is there still plans that you do not have information on, even the profiles from PBIS? Are you still in the process of gathering that information or do you have a complete set?

DR. PETERSON: For the official establishments, I would have -- because I'm assigning work in the plant, I have to know what they do, what

the plant does, if they slaughter, process and what kind of activities do they have. For all 5500 federal establishments that are subject to HACCP and SSOP regulations, we would have the complete data that we need.

MR. KOWALCYK: Okay. And then the second question I had in looking at the system design and enforcement action and the systems implementation, and there's been a lot of discussion about NRs, FSAs, NOIEs, is the Agency currently going over those documents to see what elements that you can pull from those documents into this database and, if so, where are you in that process and is there any consideration to modifying those documents to make them fit more within this overall scheme that's proposed with the risk control warehouse?

DR. MASTERS: Yes. And I thought that's why it would be helpful to put down what we have here, and again, they're already electronic, and we believe that we needed to ask some of the questions we asked at this meeting, and to get some further clarification around, for example, and we got some good information

for example on food defense. If people came back to us and said enforcement actions are not an important part of you moving forward with the risk control, then we would not spend additional time working around that. We've got a lot of information that enforcement actions likely are an important component, and then there was some sub-questions. So we'll be going back to look at the report to refine how we move forward in putting them into the warehouse in a useful way. We felt this public process was an important step to getting that refinement before we move forward and getting it into the warehouse.

MR. KOWALCYK: Thanks.

MR. DeMORGAN: Okay. So let me just ask quickly, how many people feel like you need to ask a question or make a comment on the data piece of this at this point? One, two. Okay.

Dr. Masters, I would suggest maybe we take our break, make sure you get your presentation together for the next session up on the slide. When we come back, take those two comments on that and then turn to your presentation. Is that acceptable?

DR. MASTERS: Yes.

MR. DeMORGAN: Okay. Carol, Barbara, thank you. We'll go to you two when we come back from the break. Dr. Masters, is 10 minutes enough time from your perspective? Is your presentation in place?

DR. MASTERS: I don't have slides.

MR. DeMORGAN: Oh, you don't. Okay. Okay. So, folks, if we could just try and keep it to 10 minutes, we'll get back at quarter till. Thank you very much.

(Off the record.)

(On the record.)

MS. DILLEY: We had interest in having one or two more comments on the previous presentation, and then the next agenda item is to go to the assessment of workshop discussion and ideas for moving forward, and Dr. Raymond and Dr. Masters are going to start that conversation, and then we will definitely have you -- we'll definitely adjourn by 4:30.

And just another quick reminder that you do have the evaluation forms in your packets. So please take some time to fill that out and give it to one of

the facilitators or up at the registration table, we'd appreciate that additional input.

Barb, I believe you were next to comment.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority. At the risk of sounding repetitious, I'm going to come back again to attribution data, and it was a very interesting presentation by Dr. Goldman and by Ken Peterson, and I appreciated that.

I'm still very much concerned about the lack of attribution data that's going to go into this model, and I'd like to for a minute quote the July 2004 FSIS Fulfilling the Vision Updates and Initiatives on Protecting Public Health. In that, the Agency identified the challenges for achieving the next level of food safety are the needs for, one, anticipating and predicting risk through enhanced data integration which, of course, was talked about extensively today, improving application of risk into regulatory and enforcement activities. Again, we've talked about that today. An improved association of product -- program outcomes to public health surveillance data, and then the fourth item was

improving food safety beyond our borders.

Further I'd like to quote, the industry perspective on risk based inspections, its components and its execution by industry and regulatory authorities dated December 2, 2005, and I quote, "Keys to successful risk-based inspection are getting the right criteria for assessing the risk, sharing relevant data amongst the stakeholders and having clear links between food-borne illness and specific products." We have repeatedly heard that today from all of the -- I think all of the small groups basically came back to the same thing. And I do appreciate that through your consumer complaint system, you do have some attribution data but it is not nearly sufficient.

I thought that one question that Ken Peterson raised in kind of getting to answering my initial question, is what questions are you looking to answer when you analyze your data, and the one he brought up is, you know, he frequently gets asked what impact are our programs having on public health given the amount of money taxpayers are spending on this

activity. And I think that comes right back to public health attribution data.

The problem is the Agency -- for those of you that don't know, my husband, Michael and I lost our two and a half year old son, Kevin, to an *E. coli* O157:H7 infection in August 2001. I can tell you from personal experience, and I have talked to many, many victims since then, that no one in the Government or very few people in the Government, all the way from the state and local health departments through the CDC and the USDA are there to help you find the source of your illness.

In fact, our son's case, his PFGE pattern, matched that of a meat recall in the same time period from a plant in the same state in which we were living. Now we could never conclusively conclude that that recalled meat is what caused his illness but it took us nine months of threatened lawsuits, getting our congressional representatives involved, and getting an attorney involved to even find -- get complete PFGE patterns for the 2001 *E. coli* recalls.

What measures is the Agency going to take to

proactively help victims find the sources of their illness so that you can then have complete attribution data to drive this very important system?

MS. DILLEY: So what measures can the Agency take so that victims can find the source of the problem and take action? Dr. Masters or Dr. Raymond, you want to respond to that question, that particular question?

DR. MASTERS: At this point I would comment by saying and I had it in my closing remarks, certainly I appreciate that all groups did bring up attribution data, and I think it's clear that the Agency has heard the need to build in attribution data as one of the measures that we consider in looking at risk control. And so I was pleased, as I'm sure others are, that David mentioned the December meeting and how we build the attribution data into the risk control model, and we welcome ideas beyond the need to look at attribution data, but we welcome your ideas also to have a more specific take that attribution data and build it into the model. Because I had noted it as one of the things in my things that really stuck

in my mind rather than trying to recap the entire meeting. That was clearly one of the things that I had noted.

So beyond just marking it as one of the high level things that we need to take away from the meeting, we'd welcome additional thoughts on how we should build it into the model, how we should weight it into the model and more specifically how we should use it in the model. So we welcome thoughts on that as we move forward.

MS. DILLEY: There was a mention of that workshop in Baltimore in December, and is that part of the discussion do you think, the factors in terms of how attribution data is --

DR. MASTERS: Yes.

MS. DILLEY: Okay. Carol, I believe.

MS. TUCKER-FOREMAN: I'm going to pass.

MS. DILLEY: You're going to pass. Okay. So transitioning to assessment and workshop discussion and ideas for moving forward, and Dr. Raymond and Dr. Masters wanted to get that conversation started, and then we'll open it up a little bit more in terms

of other thoughts on moving forward. So I'll turn it over to the two of you.

DR. RAYMOND: Thank you. First of all, I want to thank everybody that came and everybody that's on the Net link from the 23 sites across the country for coming to this workshop for the past few days and contributing. You have helped us tremendously in our effort and in our commitment to do this in an open and transparent way, the best that we can. I think that this has demonstrated that attempt, and it has been very fruitful and beneficial for us.

We've heard many ways that FSIS might enhance it's risk-based inspection program, which we'll use to build a better program, and while we won't all agree on all of the individual elements, I do know that we still all show the same commitment to make the food, meat, poultry and egg supply -- egg product supply in this country the safest that it could be. I would repeat one more time that in the last seven years, I've seen the *E. coli* food-borne illness rates go down 29 percent and *Listeria* down 32 percent, and that's because of the activities of

industry and it's because of activities of the Food Safety and Inspection Service Agency and its policies, and it's because of education of consumers on safe preparation, handling and cooking of meat and poultry products. We've got a long ways to go. We can't sit and rest on our laurels.

I also mentioned in my opening comments that we haven't seen much change in the last three years in *Listeria* and in *E. coli* and in *Campylobacter*, that we seem to have plateaued, and we need to do something to move the plateau downward.

I want to point out before I'm done, that there will be more additional opportunities for all of you to comment. The website will stay open up until at least we get the report from RESOLVE. RESOLVE by contract will have a report to us in December. I don't know the exact date. Abby, is there a data date?

MS. DILLEY: December.

DR. RAYMOND: It just says December. I'll also make a commitment to all of you that when we do get that report from RESOLVE, it will be posted on our

web page. It will be open and public and transparent, and you'll all get to see it, and you can even comment on the report if you want.

Will there be another public meeting like that? We had that question raised yesterday. I don't know yet because I don't know what the RESOLVE report is going to say. I don't know what the NACMPI Committee is going to say. If we need another meeting, we'll have another meeting. It may be a technical meeting. It may be an open meeting like this. We'll make that decision as we move forward with the process.

I think a lot of people believe that Government is incapable of taking proactive steps. A lot of people think the Government only reacts when there's a crisis. When there's an *E. coli* outbreak in spinach, everybody has a correctly for the FDA to do a better job. They weren't crying for the FDA to do that much of a better job three weeks ago. I don't want the plants in section 5 to create a crisis that I have to react to. I took the job to prevent illness, not to recall product. I took the job to prevent

illness, not to figure out how more quickly take an outbreak and link it to a plant. I want to prevent illness. I want number 5 up there on my graph the other day to present a Jack-in-the-box crisis or spinach crisis, and that's why I want to move forward with this.

I know we can do it. We've done it in public health for years. It's just not very easy to do it sometimes, but it can be done. I'm convinced of that.

A couple of reflections I want to make from my past experiences. For 27 years, I practiced family medicine, most of them in a rural area in Nebraska. I made decisions every day based on the information I had at hand. I sometimes changed those decisions as information became available. I didn't have MRIs. I didn't have CAT scanners. I didn't have a laboratory that could do a CPK on a guy with chest pain. So if a 20 year old came in with chest pain, I figured they drank too much coffee or too much alcohol and heartburn and gave them something to take that while I waited for the tests to come in. When a 75 year old

suffered a fall or car accident and came in with chest pain, I figured he had a pneumothorax or some other trauma. We took appropriate studies but did appropriate procedures to keep them in good health while we got the tests back, but when the 55-year-old guy that smoked came in with chest pain, and looked bad, we treated him for a cardiac. We treated him as a heart attack before I had proof he had a heart attack. I couldn't wait. He was going to die or he was going to lose cardiac muscle. You do the best you can with the stuff you got, and then you wait for the other stuff to come in, and then you alter.

Public health is no different. Public health, the example there is, the spinach *E. coli* outbreak, if the FDA would have waited until they narrowed the source of that product to Salinas Valley in California, more people would have got sick, more people would have died. They took the information they had at hand and told everybody in this country, get rid of the spinach in your refrigerator. That hurt industry, but they did what was right to protect the public's health. And then as the information

became available, they said, okay, this type of spinach is okay. You can buy it now. You can buy it from Colorado and you can buy it from the East Coast. They adjusted it as the information became available, and that's what we'll do with risk-based inspection. But to wait any longer, I think is foolish.

The CDC tells us that 73 million people get food-borne infections every year. They tell us that 325,000 land in the hospital and 5,000 die every year. That's 200,000 people got sick today and 14 people died today from a food-borne illness.

Now I took an oath as a physician way back in '72, the first to do no harm, and I think to sit here and watch 200,000 people get sick and 14 die every day and not try to make progress, that is doing harm. And my commitment is to move this forward. We'll save lives. We'll save people from getting ill.

So once again, I thank you all for your contributions. I think you've helped us build a better mousetrap these last two days, and I'll know we'll continue to get input from you all, and I look forward to that. I look forward to the day we can

roll this out and prove that it works. Barb.

DR. MASTERS: Thank you, Dr. Raymond. I too want to thank everyone for their participation, particularly those in the room as well as those that are at Net locations. I think it was particularly great that those at the Net locations actually did the small group workshops and provided their feedback to us, and I want to assure them that we will be taking those comments and looking at those just as carefully as we look at those that were here with us on site, because I think it's great that they took the time to do those small group workshops.

I think we had a lot of great discussion, and we really want to get into that deeper and really study what we thought, but we got a lot of thoughtful answers, not only to our questions, but beyond the questions that were asked of the group, I think we got a lot of good input and suggestions from you all and I think that's really exciting. We made a lot of progress, and I think that's very helpful to us.

We've been trying to make our public meetings as useful as we can, and inclusive as we can

which is why we included the remote sites, so that we could get as many people involved as we could. So we appreciate those that helped facilitate the remote sites as well.

I really appreciate RESOLVE and the work that you did to facilitate this meeting. I think you were very, very helpful and we appreciate the work that you did.

I don't want to try to recap all of the discussions that we had for the past two days, because obviously myself, my staff, are going to have to spend a lot of time getting into the report when we receive the report. But just sitting down and jotting down notes and things that really stuck in my mind, I think there were some themes that came out, that any of us that were sitting in the room probably could say quickly. These were some themes that were pretty constant from the few days that the staff can go back and begin to look at and start working on even short of getting that report which is exciting when you leave a meeting like this, that you can already have some marching orders to start working on.

I think it's clear that there is a lot of interest in reexamining the process and rationale behind the expert elicitation and how we can start working towards that. And I think we're going to have to look at the information we receive from this meeting, and how we can move forward with that. And so I think there were some idea on how we can take that process and move that forward. And so we'll be looking at that very carefully.

I think on the components for risk control, it was interesting that each of the groups, both on site as well as remotely, looked at food defense very differently than they looked at all of the other categories. And that was something that I think came out very clearly when you looked at all of the information that we got back. So we'll have to look at that.

I think we clearly saw that food safety system design and implementation as well as pathogen control are very, very important. And we also saw some agreement, I'm trying to think of the word Bob used this morning, he didn't use the word consensus,

but there was general agreement from the group around the use of industry data. And I think that was very helpful to us as an Agency to consider that and how we might include that information.

I think we heard loudly and clearly, and this gets to the point that Barb was just talking about, about the need to include attribution data in the measures of risk control. And we heard from Dr. Goldman about a meeting coming up in December, which should help us move that cause forward. And so I think that was something we heard very loudly from pretty much all of the groups, on how we should look at attribution data in some way of our measures of risk control. So that was one of the notes I took.

And then we heard some from many of the groups about the challenge of converting qualitative data, which many of our factors and our measures of risk control, food safety assessments, NRs, enforcement actions, are pretty much qualitative measures. And how do we convert those to quantitative measures as you try to move forward with a model? And so that's something I think we're going to have to

look at.

And then volume, I think we got some really interesting perspectives on the use of volume. We had been tying it to our formula on inherent risk, but I think there were some really unique ideas that were brought forward to the Agency as whether or not you want to take it out, and use it as an independent measure or make it into like a prism almost having the three factors. And so I think that was a unique and different perspective that was put forward to the Agency, and it came from a couple of different groups. And so I think that was useful and helpful information.

So those are some of the themes that I saw that were useful and helpful that we can start exploring even before we get the report, that seem to have at least some consensus at least within the groups that were presenting the material this morning.

I think everyone here should know that we welcome and invite you to come to the Advisory Committee meeting which is tomorrow and Friday in the back of the cafeteria. Dr. Raymond and myself have

really worked hard to make those meetings open meetings. While we have the Advisory Committee participants that have a big job and a big role that they play, we have tried to insure that those are more open meetings and that even within the subcommittees, the subcommittee chairs have allowed the participation of those that sit in the room. We would encourage you to come to those meetings.

We are going to be taking the implementation that was presented at a very high level here, and continuing some discussion on that at the NACMPI. And we'll also be presenting at a very high level, how we might begin to look at risk, a risk-based approach to slaughter inspections. So again, continuing some discussions.

We'll also be having a more detailed discussion on the analysis of NRs that the subcommittee asked for at the last meeting. So some of the preliminary information I presented today will be delved into much more deeply tomorrow at the NACMPI. So if you've not been to a subcommittee meeting or our meeting in the last year, I'd encourage

you to come. I think you'll find them to be very inclusive, including of the audience and you will have an opportunity to hear the dialogue and participate in the dialogue even in the subcommittee meetings.

I would suggest that as Dr. Raymond did, we will leave our website up. If you go to our FSIS website, you can type in risk-based inspection. We're trying to post all documents related to risk-based inspection in that one location, and so you can comment at that location. We'd encourage you to do so, and then when the final report is prepared by RESOLVE, that is a location that we will put that report. And so we appreciate all of you that have taken the time to comment and would encourage you based on what you've heard at this meeting, what you hear at NACMPI, to continue to comment to the Agency. Because again, everything we heard at this meeting was extremely helpful and extremely useful in helping us move forward.

So again, we appreciate all the time and attention you've given to this, and we'll look forward to the continued dialogue and discussion. So thank

you very, very much.

DR. RAYMOND: Abby, while you're coming up, I just said early yesterday morning, but I'll just say it again, for those of you who do serve on the NACMPI Committee and have been here for two days, I really, really admire your commitment to learn as much as you can about risk-based, so that the next two days' meetings will obviously continue to be constructive. And for those of you who will be attending the next couple of days as the public, I also thank you for the -- four days of doing this can get a little long. So for the NACMPI members especially who didn't have to be here today, and there's several of you here in the audience, I really thank you for your commitment today. You'll add a lot to your group discussions tomorrow and Friday I know.

MS. DILLEY: Okay. Any just brief comments in terms of ideas or suggestions you haven't already heard or been stated in terms of moving forward? Sandy. We'll just take a couple of comments and then we'll wrap up.

MS. ESKIN: Just one quick question. Again,

excuse my voice. According to the public to the Federal Register notice, we have until October 27th to file comments. Would you consider adjusting that to sometime up until 30 days or whatever after the RESOLVE report gets filed, because it sounds like there's a lot of issues that that's also going to raise. So again, right now the official comment deadline is October 27th.

DR. RAYMOND: We've discussed it Sandy. This isn't a rulemaking process. So there's no official, you know, there's no official time. One of the reasons I said, and Barbara said also, we're going to leave it open is because that things will be coming forward. I'm not going to give you a date that we shut it off because like technically, we don't even have to have it open but we do want to continue to receive comments and we do want to put the RESOLVE report on the web, and I would think it would be prudent for us to continue to leave it open after that for some time period. I just -- we haven't talked about it at the committee yet.

MS. DILLEY: Rosemary.

MS. MUCKLOW: I'd like to thank you and thank RESOLVE who I think have done an excellent job and your staff, and particularly your commitment to spend so much time interacting with the industry and the patience of your staff because it's been hard. We want you to tell us and yet we want to give our ideas.

I would just say to you, Dr. Raymond, that we are pleased to be engaged in trying to make a better mousetrap with you but in the words of Bill Buckner from Excel, don't ever forget that nature is working every day to make a better mouse.

DR. RAYMOND: Right. Thanks, Rosemary.

MS. DILLEY: One last comment.

MR. LEONARD: Thank you. My name is Rod Leonard, and I'm with the Community Nutrition Institute. I want to thank Rosemary again for indicating and showing us what a great advocate she is for industry, having worked with her for years and years and years.

Dr. Raymond and Administrator Masters, I have the feeling at the end of the two days that the train is leaving the station, that I have a difficult

time, however, in determining whether I see the engine coming or the caboose going. So I do want to thank you for your very creative rhetoric. The idea of having predictive indicators I think is a very useful concept, and I have taken some -- what I consider to be predictive indicators that we've been discussing here the last two days. One is that there's going to be a change in the definition of daily inspection. Two, that we're going to eliminate PBIS and we're going to turn off the scheduler. Three, we're going to reduce the field inspection staff and we're going to continue to expand the headquarters staff. We're going to expand risk-based inspection to slaughter inspection, and we are going to reduce the field inspection capabilities for inspection relating to slaughter, and again expand headquarters staff.

And in all of this, because we can't spend more money, it means that we're going to freeze the budget creep that every agency experiences. But again, thank you for the opportunity to participate.

MS. DILLEY: I know people are taking a lot away, both information-wise as well as questions and

there's been a lot of discussion over the last couple of days. I just wanted to make a couple of observations and also speak to the RESOLVE report and just a question in terms of some of the information -- actually a question to me at the break.

First of all, the theme that's kind of been running through my head in my just brief look back at the two days, that's sticking in my mind and, Dr. Masters, if I misquote this, I'm sure you'll correct me, but getting the right information to the right people at the right time to make the right decisions to protect public health, and I think there's no -- every person in this room feels very strongly about that, and obviously when we talked a bit at the beginning about how much passion there is around that issue, and that there are differences of opinion, in terms of how that could be done best. We talked a lot about and I think a strong theme in terms of what came out of the two days is how complex the system is to try and do exactly that. And it's a very complex process to try and refine and reshape and make it a better system.

There was a lot of discussion about what is being done to design and implement RBI, how, when and the opportunity to review that, kind of an understanding of the logic flow, in terms of decision making, et cetera. And how it all fits together, and I think we've talked a lot about the different components and different opportunities to do that, not only at the workshop, but then there's the NACMPI meeting tomorrow and some other venues taking on pieces of that question and discussion.

This is related to some of the work that we are doing. Someone came up to me at the break and said I thought you were going to present some of the information from your interviews because we've talked about the fact that we're interviewing stakeholders and then we have this workshop, and we'll produce a report to FSIS in December. And it's also relevant to gathering additional information and taking advantage of the electronic communication to do that. Kind of the flow of that has been, we've interviewed about 45 people individually and in groups, and then this was also meant to be a similar kind of process to gather

lots of information. So we're very enthusiastic about how many people signed up as well as the remote sites, to be able to again pull lots more information and input both at the substantive level and at the procedural level, in terms of what next steps because what we will presenting in that report, is trying to consolidate some of that information, where there's a difference of opinion, why, analysis of different pieces of that in terms of what we're gathering from those conversations and the workshop and what we receive electronically. And then making some recommendations for potential next steps. So that will be available on the website in December, and I'm sure it will prompt more comments I imagine, and we'll look forward to engaging in that discussion as well in terms of reaction to some of our observations and recommendations.

I think it was a monumental task to take on some very big pieces, and a lot of information over the two days and just want to lend my appreciate for all of you staying with it to the end over the two days, and many of you have two more days of meetings

and appreciate your involvement in the discussions and contributing so much.

So, I don't know, Dr. Raymond, Dr. Masters, if you have any other comments before we officially adjourn?

DR. RAYMOND: None here.

MS. DILLEY: Okay. Any other questions, comments?

DR. RAYMOND: Our two day meeting got done 10 minutes early. I think that's pretty good.

MS. DILLEY: Yeah, 10 minutes early. That's right.

Thank you so much.

(Whereupon, at 4:20 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 11, 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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Keith McGuire, Reporter

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