UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE:

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TRANSCRIPT OF PROCEEDINGS

BEFORE: DR. GARRY MCKEE, FOOD SAFETY AND INSPECTION SERVICE (FSIS) ADMINISTRATOR

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P R O C E E D I N G S

November 6, 2003

MR. TYNAN: Good morning. We just checked with Dr. McKee's office. He has been a little bit delayed. He is on his way. I know some of you have some travel commitments, so I thought perhaps, if you have no objection, we might kind of condense the recap and say we had a nice day yesterday. I know I did. I know I learned quite a bit from the discussion and, certainly, I won't go through all the topical areas. It seems the discussions last night with the subcommittees went very well. In fact, they went more than the two hours. So I thought this morning, what we might do is just get into the committee reports. I am apologizing in advance because I am going to be your typist for the morning, so I have two hats. I am going to be the secretary as well as the typist. I won't exactly vouch for my skills in that regard, but why don't we get into Committee Number 1 and start the discussion. If I could ask the Chairperson -- do we have the Chairperson? Dr. Carpenter. Okay. On second thought, we will wait just a moment. Why don't we skip over to Number 2 and we

will go that way. I am sorry. Why don't we continue with Number 2 since you are up, Michael, and we will do -- I am sorry. I was telling somebody, in the Army they used to do that to us when you start to fall asleep. They throw some kind of a picture up to catch your eye. We might as well go back to Number 1. Okay. I apologize. That is all right. We will go ahead and get started, if that is okay with you, Dr. McKee? Okay. So why don't we go ahead and we will do Number 1.

DR. CARPENTER: Okay. The deliberations of our Committee started with Tab 9, when Philip gave us a background yesterday on what we should do on the best use of data to support risk-based inspection. The Committee members went over the three questions that are in the second page of Tab 9, what reliable sources of data should the agency ensure that is utilized to help achieve Dr. Murano's vision. The Subcommittee identified these suggestions in association with that question. Identify the range of sources of data both quantitative and qualitative that the agency utilizes -- or could utilize in its work. The Committee focused on two sources: (1) industry data; and (2) data collected by state agencies and derived from state sponsored

research. Regarding industry data, we felt that the industry has the potential to provide a greater amount of useful data, but that the potential is not being fully realized. We acknowledged that obstacles to greater data sharing exist and recommend the agency work with industry to address these obstacles and facilitate increased data sharing. It should occur on a regular basis, periodic public meetings or other forum. Regarding state data, there is one source that FSIS is not currently utilizing; that is the state data. The Subcommittee recommends that in order to get this important data -- there are some words missing right there -- that they work with state agencies to develop a process for regular data sharing. It was our feeling that there certainly is a great deal of information within the industry. There may be reluctance in sharing those data because there is the potential -- at least a perceived potential, that those data may be used in an adverse way in the industry. So there would be a need to -- we used the word “anonymize” the data so that it could be used in a way that would contribute. Committee members, any other -- Subcommittee members -- excuse

me -- additions here? Okay. Robert, should we go onto Number 2? (2) Is there data the agency is collecting, that it could be collecting, which FSIS is not taking full advantage? The recommendations were that, as indicated by the first bullet point here -- the more detailed correlations of farm to table data that would augment food safety policy development and public health outcomes should be pursued. The data accrued should be from data bases of other USDA agencies and non-USDA agencies, such as the FDA, CDC, the states, and other agencies. The second point, we had a considerable amount of discussion about this. Correlation meetings that had been sponsored by the agency in the past, it was felt there was effective use of the data that came out of the meetings, as inspection practices were evaluating each of the districts. Although it might be perceived that these events, these meetings, were resource intensive, the meetings did have considerable feedback, as it was discussed, and it was beneficial, and it was felt there was a need for meetings to be conducted more frequently and on a more regular basis. And I believe -- I mean, Joe Harris has outlined how these occurred, and they have occurred like in the last

two to three years at several of the districts throughout the country. (3) Are there methods of analysis the agency may not be using or that the agency should be using that would enhance its ability to anticipate hazards? Unfortunately, the Subcommittee just was not aware -- none of the members were aware of the specific data analysis methods that the agency could be using to enhance its ability to anticipate hazards. There likely are methodologies out there within the private and public sector we felt that FSIS should be hosting; technical conference, conferences related to the subject, so that such an open forum of interested parties might be used to fully explore that issue regarding methods for efficient data analysis. So those were our deliberations, a summary of what is the best use of data to support risk-based inspection. We were fortunate to have Philip as our resource person and had great support from FSIS staff to get this done. Any questions?

MR. TYNAN: If I might ask, when you are asking questions, if, again, you could identify yourself for purposes of the transcriber? Dr. Govro.

DR. GOVRO: In your discussion, did you

consider the possibility of approaching the country of Canada to get access to any of the data that they might have given that they have a different listeria standard than we do? Would that be appropriate?

DR. CARPENTER: I don't -- we didn't. We didn't think about it. That is a very good point, though, Michael.

DR. GOVRO: Given that one of the problems with listeria data is that nobody wants to sample for it and collect it, it seems like you have a prime opportunity there with an actual quantified standard that you might be able to collect some information there.

DR. CARPENTER: Good suggestion. Thank you. Jill, is there a question from you, Dr. Hollingsworth?

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. In the past, there has been some discussions with the Department about setting up, for lack of a better name, we call it an event analysis approach. And the concept was that when there is some type of a problem, either a recurring food safety problem in a plant, recurring pathogen findings, high levels of pathogens, or an outbreak or some type of a

trace back to a particular facility or even a particular region of the country, that FSIS would put together a team that would go out and actually collect data solely for the purpose of determining why did this occur, what could have prevented it, why did it happen here and not in another location, and actually use each event, if you will, as a means of collecting data, and analyzing, and then trying to find preventive measures. Did this group discuss that at all or were you even -- perhaps you were not even aware that those discussions had been going on, actually, for a number of years now.

DR. CARPENTER: We covered areas of inspection that involved practices at good plants and not so good plants and how those data -- but not relative to a particular incident, which I think is your question, so the answer to that would be, you know, not specifically.

MR. KOWALCYK: Michael Kowalcyk from Stop [ph]. In your discussion about sources of data, I guess, you mentioned state agencies. Was any discussion had about data from the states participating in the Food Net Program? And also, was any discussion had about sources of data and academic world research that is going on at land grant universities, things of that

nature?

DR. CARPENTER: I believe -- we didn't talk about Food Net, specifically, but I think -- Sandra?

MS. ESKIN: Yeah. We didn't just focus on Food Net, states participating in Food Net. I mean, our understanding was they would be subsumed in the general category of state data. As far as academia, I think we just chose to focus on these two. As it says, we talked about all the others. I guess the view was, in some way, research that was ongoing at universities, specifically, land grant universities, would be funded perhaps some by industry and other sources. But we just chose to focus on these two: (1) because industry seemed to be the most -- would be the source of the greatest amount of data probably; and (2) the states, something that Phil acknowledged that the agency hasn't really pursued.

MR. KOWALCYK: Thank you.

DR. CARPENTER: You are welcome. Any other discussion? Dr. Hollingsworth.

Dr. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. On the third one, I have noticed in your answer you say that you are unaware of specific

methods that the agency should be using. I guess I am not sure what methods the agency is currently using, and I am not sure how much information you might have had on that. I am not sure in this question if it is a question of what is the agency doing now, what could the agency be doing. I am not aware of all of the data that they currently have and how they might be using that data to make decisions. And I am looking at the answer and wondering if that should be expanded to not only host a technical conference, but also a conference to lay out what data sets they have, how they might currently be using it, and then seek suggestions on how it might be expanded or used more. That may be what is inherent in this answer, but I wasn't sure if I was seeing that.

DR. CARPENTER: Well, we actually discussed extensively beyond the use of data sets, Dr. Hollingsworth; in particular, the methodologies for data analysis. I mean, there was some mention made at some aspects of the industry that have programs that take data and manipulate it in a way that are somewhat predictive, we believe, but that these simply, you know, perhaps are proprietary and are not shared, or cannot be

shared, or won't be shared. But if there was a possibility to enter into a dialogue at a forum, there may be discussion that would bring out what are the best programs for data analysis manipulation that could then be used by FSIS for predicting adverse outcomes or incidents.

MS. ESKIN: And just to amplify that answer or directly address the point you made, Jill, we did discuss, specifically, in context of Number 2, we had an idea of what some of the data was that FSIS currently uses, but none of us had any sort of very complete set, and that also went to Number 3. So obviously, you have to know sort of what they have got now before you can analyze, before you can determine what they need, and what they do with that data before you can analyze what else could be done. So the answer is yes.

DR. CARPENTER: Kevin.

MR. ELFERING: The one question that I have, I guess in my mind I can vision what risk-based inspection is. Were you given any direction at all what the agency considers to be risk based? To me, some of this would mean that there is possibly some product that is produced out there would maybe even need less

inspection. Is there any direction at all that this might eliminate the need for daily inspection in some processing facilities?

DR. CARPENTER: I know we weren't given that direction, but I imagine that could evolve from this kind of activity. Dr. McKee or Robert, any comment on that, what the intent is?

DR. MCKEE: Let me comment on that. The Canadians have looked at risk-based inspection and have done quite a bit of work, looking at, you know, whether there should be continuous inspection. Our federal law requires that that be done in this country but, certainly, the risk and the time and effort that you put on that is clearly part of that. I think the team inspection that we are looking at currently tries to address some of those issues as well. So we are looking at it. The statute precludes us from going there right away, but we are getting data, the Canadians are looking at that model as well.

DR. CARPENTER: Thank you. Any other discussion points? If not, it is up to you, Robert.

MR. TYNAN: Are there any additions or modifications to the report, or is it generally

acceptable as it is written?

DS. JOHNSON: Alice Johnson, NTF. We are going to add the comment that Michael made about the benchmark in Canada or looking at Canada as far as data they may have?

DR. CARPENTER: Okay. What section, Dr. Johnson, would you like to add that into?

MR. GOVRO: Under the first question.

DR. CARPENTER: As just an ending statement in that paragraph?

MR. GOVRO: You might explore the possibility of finding out what data is available from Canada or other countries.

DR. CARPENTER: Who is doing the wordsmithing here? Robert? Okay.

MR. TYNAN: I am sorry. I was distracted, which is not unusual for me under any circumstances, but I had a valid reason this time.

DR. CARPENTER: Right at the end of the paragraph where the cursor is now, Michael suggested that reference be made to -- expand upon it, Michael.

MR. GOVRO: That FSIS explore the possibility of obtaining data from other countries which may have

different standards.

MR. TYNAN: I am sorry -- the possibility of...

DR. CARPENTER: It should be the last statement, Robert -- of obtaining data from other countries.

MR. TYNAN: Such as Canada?

DR. CARPENTER: Such as Canada. Good. Thank you. Dr. Hollingsworth.

DR. HOLLINGSWORTH: Do you -- would there be value in the report if there was perhaps an expansion on the information that is currently available, as far as the data that we all know is being collected, and then leave open -- here is the information, the data that is known to have been collected or is being collected. And then here is sources that maybe you do or don't know if it is being used by the agency. I guess...

DR. CARPENTER: Are you speaking to Question 2, Data that are being collected or ought to be collected?

DR. HOLLINGSWORTH: Yes. I guess I am not sure here if the focus was just on what methods of analysis should be incorporated and taken advantage of,

like you mentioned predictive and analytical tools and all, but is there also an emphasis here in addition to the analytical part of it, also just the collection of data and the sources of data? Did the group actually look at identifying what data is there? There is sort of a brief mention of it in Number 1, very generically, but I guess what I am wondering is would it be useful to identify where, specifically, data should be -- or where the agency should go to use data that already exists?

DR. CARPENTER: I think in discussing Number 2 we are trying to get our arms around the data that already are collected.

MS. ESKIN: Right. And when we asked our resources from FSIS and they didn't know -- I mean, the assumption is that the audience for these recommendations knows what data there is out there. But it would be useful to say, okay, this is what we understand, are we missing something. So we clearly would like that information, but it wasn't available. We asked. It wasn't available last night.

DR. HOLLINGSWORTH: Oh. Okay. Thank you.

DR. CARPENTER: Good point, though. Dr. Johnson.

DR. JOHNSON: Should we maybe put something in our recommendations that request the agency outline the available data...

MS. ESKIN: Yes.

DR. JOHNSON: ...so that there is some sort of list?

DR. CARPENTER: Okay. So you would like to make that admission of the end of 2?

DR. JOHNSON: I think at the beginning of 2.

DR. CARPENTER: The beginning of 2. Okay. Robert, back up to the beginning of 2, right at the end of this -- right there?

DR. JOHNSON: Even at the very beginning.

DR. CARPENTER: The very beginning?

DR. JOHNSON: The very beginning.

DR. CARPENTER: Okay. Right there. Do you want to paraphrase that, Dr. Johnson?

DR. JOHNSON: I think it is imperative that Kevin help me with the wording on this. Kevin would come up with some great words for us last night. The subcommittee recommends...

DR. CARPENTER: Your microphone has to be on.

DR. JOHNSON: Alice Johnson, National Turkey

Federation. Subcommittee recommends FSIS evaluate current data -- outline and evaluate current data.

DR. CARPENTER: Outline and evaluate. Okay.

DR. JOHNSON: All right. Outline and evaluate data currently collected. And Sandra, there is some way we have got to have -- the agency needs to have like a reference, a database of all the data they are collecting, or some sort of reference so that they can go back and look and evaluate if they are using...

MS. ESKIN: How about needs to establish -- you are saying databases?

DR. JOHNSON: I don't know if that is...

MS. ESKIN: Of currently available data. And that first sentence, you can take out the first "current" before data because we have "current" later in the sentence. That is fine. Does that address what you...

DR. JOHNSON: Yes. And I am sorry, I can't read that far. Do you know how much this laser surgery cost, and I can't read that?

DR. CARPENTER: The Subcommittee recommends that FSIS outline and evaluate data that it is currently collecting. The agency needs to establish databases of

currently available data.

DR. HOLLINGSWORTH: I think somebody used the term, maybe, FSIS needs to make available a registry of all current data that they collect, that there needs to be some source of being able to see what data do they have so that then the recommendation can go beyond that and say, here is what you have, here is additional data that is out there that you should try to tap into, and then here are analytical tools that can be used to take advantage of all of that data. But I think the first thing that we are looking for here is to provide that registry, or a list seems almost too simple.

MS. ESKIN: A set of databases there.

DR. HOLLINGSWORTH: Yeah, just the set of data. That is fine.

DR. CARPENTER: So the substitute term for establish databases would be registry or does that cover the bases?

DR. HOLLINGSWORTH: No. I think databases is fine.

DR. CARPENTER: Okay. Now, Kevin, are we going to make additions to this based on Alice's suggestion? You are okay. Anyone else? Any other

additions to direct to Robert to insert at what we are looking at? Hearing none, I assume we have consensus on what this should say, question number 1 -- from the Subcommittee Number 1.

MR. TYNAN: Shall I hit save?

DR. CARPENTER: Yes. Thank you for all those inputs.

MR. TYNAN: If you will allow me one moment to do a technical thing and save this, we will be in good shape. Okay. Mr. Govro, would you like to address Subcommittee Number 2 and the Talmadge-Aiken plants?

MR. GOVRO: Yes. And if you don't mind, I think I will do it sitting right here. Mike Govro with the Department of Agriculture, and I was the Subcommittee Chair for Question Number 2, the issue, Procedures for Conducting Inspection in Talmadge-Aiken Plants. It is not listed on our document here, but our Committee consisted of myself, Dr. Logue, Dr. Hollingsworth, Dr. Leech, and Dr. Jan. We also had in attendance Dr. Masters from USDA, as well as Cheryl

Hicks and Bill Leese. And in the audience we had Mr. Corbo and Mr. Shire. Our three questions were, “How would you define a role for Talmadge-Aiken in today’s public health regulatory environment?” Question Number 2, “Under what conditions would Talmadge-Aiken be appropriate in this environment?” And Question Number 3, “What measures of effectiveness should FSIS use to determine the value of a given Talmadge-Aiken arrangement?” Before I get into what we produced, I would like to express a bit of frustration on the part of the Committee with this question and the way it was presented. This seems to be a fairly complex question regarding internal management in the agency. We spent a great deal of time last night seeking an explanation from the USDA representatives on what this question was actually about and what background information we needed to make informed discussion about this question. And I thought perhaps it might have been more appropriate to consider the question of the agency’s decision to move to a team management approach in a briefing, and then at a later time, discuss the question of how all that plays out with regard to issues like Talmadge-Aiken. Or at the very least, get the material to us earlier so that

we had a chance to consider it. We did just get this material on Friday. At least a couple of us didn't even know we were on this particular question until we arrived, and at that time, it was really too late to do our homework. This is a group of volunteers. We are here because we want to provide input, and getting such late notice makes it very difficult for us to inform ourselves on the questions. So with that, we are going to go ahead and get into the questions. Rather than consider each of these questions separately and provide individual answers to each one, we sort of considered them altogether as a whole and came up with some thoughts, and I am going to go through those. The agency asked the Subcommittee to look at this issue based on FSIS's decision to move to a team inspection approach within the next few years, and that creates some problems for the Talmadge-Aiken arrangements because, basically, of the change in management structure. But the Subcommittee did determine that there is a role for Talmadge-Aiken where it is most efficient. But the current paradigm of allowing only cross utilization or Talmadge-Aiken within each state should be discarded, and two different approaches were

suggested by the Subcommittee for this. Those options were creating mixed teams or simply having two separate teams. And the Committee recommended that a single state should be able to utilize both approaches and that the agency should have the freedom to make those decisions based on what was most efficient. In the mixed team concept, we thought this might work best in situations where plants were near borders and it was necessary to cross state lines for the team to function most efficiently. Individual plant -- let me see, I am trying to figure out our bullet here on this one. Individual plant covered by state, but federal employees are in the area, this might be best for cross utilization concept, which involves 100 percent reimbursement and reporting to a federal supervisor. In the separate team concept, this might work best where there were no other federal plants in the area, mostly state plants. We were working with a nice little map that Dr. Masters drew us last night on a napkin of the panhandle of Oklahoma -- of Texas. It was very high tech. In this case, a federal plant located near other state plants might become part of a state team using the TA concept, and in that case, there would be 50 percent

fund and reporting to a state supervisor. Making decisions about which system would be best would depend on the outcome of the new work assignment system and what you come up with risk-based inspections. The Committee did consider an approach with mixed teams with two separate supervisors for those team members but rejected that idea because duplication was an issue. The discussion was centered around creating efficiencies for the agency and we defined those as maximizing inspection time and minimizing travel time, making the best use of your personnel resources, saving time, and ultimately, dollars. The outcomes again would be the optimal use of your resources. Of course, meeting your statutory regulatory requirements, producing measurable results, and using risk based allocation. And that is pretty much our report. I would like to thank the members from USDA and the USDA staff for sticking with us last night and sort of walking us through this process so that we could come up with at least something for you.

MR. TYNAN: Is there discussion regarding the report -- questions, comments, concerns? Dr. Jan.

DR. JAN: I was on the Committee last night, and when we left, I couldn't stop thinking about these things. I did have some other things that came to mind that I would to at least bring up here and have the Committee or Subcommittee consider. One other area -- I am, basically, satisfied with our responses and approach, but one area that we really didn't address, maybe we should have, and I think going back to where we say making decisions depending on the outcome of a new work assignment system -- go back. That first, under the separate team bullets, when we are talking about how to make a decision on which plants or how to decide whether or not they would be T/A or Federal, I think one other consideration we talked about, dependent on the outcome of the work assignment system and being risk based, which is absolutely necessary, we need to know what that is going to look like. But as FSIS develops or works the risk based, I think it would be wise to have a second consideration, and that being plant size, because I think we need to add one more bullet down at outcomes, and that should be that we would allow success of very small plants. And what I am talking about is very small plants are a different caliber of people

running it than the very large plants, and when you try to have an inspector having to deal with the resources of the very large plants, and then turn around and go into a small plant and deal with the small plant that has no resources, there is a different mindset. And sometimes that mindset doesn't -- isn't conducive to very small businesses meeting the regulatory requirements; not that they don't want to, but when they need that little extra, you know, this is what you need to do other than -- you know, here is NOIE and you do it. And you have to have those different, because that is just different types of levels you are dealing with. So I think it would be wise to consider plant size and maybe establish a jurisdiction that the very small plants, or maybe even under the current definition, make a new definition, micro plants, at some level where -- like a micro size. In State Government we use micro business, so I don't know that we have a standard, but FSIS has developed $2.5 million as a kind of a cutoff between small and very small. If that encompasses too many, maybe cut it back down, but some of these that have graduated from a state plant that are kind of in a precarious situation, they are taking risks, trying to

reach out and expand their markets, and then to throw them in with the sharks, so to speak, where they have to compete for attention and they have to compete for guidance with these big companies -- I think it would be better to consider that maybe these ought to at least be considered as T/A, allow the state -- not to get away from the team concept, but allow the state who have traditionally been better equipped because of just their relationships and because of the group they work with, better equipped to help these people through these troubled waters or these choppy waters, and allow them to move on. And then when they grow up beyond that, then they can let them kind of swim around with the big fish. Well, that is just my comments, and I would like to see something of that added here.

DR. MCKEE: Let me just comment for the Advisory Committee, in that we do have efforts and programs to address large -- very small plants, and our training and education for new directives and so forth is focused very intently. For instance, the Listeria Monocytogenes Ruling that came out, we had meetings all across the country for very small plants so we could get them up to speed. So we go an extra mile, basically, to

engage, because we know there are some issues with those folks in implementing some of our new directives for food safety. But clearly, when we talk about our process, the foremost focus has to be how do we protect public health, and you can get just as sick from a large plant as you can from a small plant. So understanding that and the challenges that exist, I think it behooves us to focus resources on doing that rather than as an option to say, you know, we are going to give you a break because you are small. So I think we have to be careful as an agency when we have regulatory responsibility to protect the public health that it be consistent across the board in whatever we do. But clearly, the identification of resources and focus on some of those areas is something that we are interested in as well, and I just wanted to point that out to the Committee.

DR. JAN: Well, I am sorry to hear you say that we give them breaks, because we don't give them breaks where food safety is a concern. The requirements are the same whether it is large or small, and we appreciate -- and although they do appreciate those

outreach programs. But some of these small plants that you are talking about and their livelihoods, the last outreach program with the Listeria Monocytogenes Ruling, the nearest available meeting was in New Mexico for Texas plants. There is a lot of places that they don't have anybody to run the plants if they have to take off and go, and they have to miss two days of work, no production for two days, because they are trying to learn about LM. But if they have people that are a day-to-day contact, and they can pick up a phone and call me or the Director to get advice, and I can go somewhere and try to get the right answer if I don't have it. A lot of times I can give them the answer they need so we can help, not to diminish from the requirements from food safety. We are a public health agency. We have been -- my program in Texas has been in public health longer than FSIS. We have always been in the Department of Health, so we have always had a public health focus and that is number one. But there is, also, something to say for survival of the small companies. And if you force them out of business because they are not getting the answers they need, where do they go? They are going to start selling as probably retail. I know it is no

longer your issue, but there is still a public health issue, and we need to make sure that those people have the ability to survive and produce a safe product, and have the regulatory oversight that they need. And I think that at least a consideration of size is probably critical, you know. That is certainly my feeling. Even if it is considered whether or not we can afford to do that from a state -- that remains to be seen. But at least, we ought to have the option to be able to do that, because I do believe we need to think about those businesses, because they are not -- most of them are not going to just go home and say, okay, I am not going to make a living anymore. They are going to make some kind of living, and if it is pushing them to retail where there is a whole lot less inspection, no SSOP's, is that the way we want to go?

MR. TYNAN: Dr. Jan, if I might interrupt you and allow -- maybe we can come back to you again and see if there are some modifications to report. Mr. Schad, if you wanted to pose your question?

MR. SCHAD: Yeah. I just wanted to ask Mike, could you expand upon this second bullet under mixed teams -- tell me exactly what your Subcommittee was

talking about? Were you talking about state inspectors in the state plant, and then federal people coming in periodically -- or when you say the federal employees in the area -- I am trying to figure out exactly -- I think I know what you meant, but I just want to make sure.

MR. GOVRO: I am going to ask Lee to answer that for us.

DR. JAN: Well, I think to get the answer you need, maybe Dr. Masters can give a summary of the team concept. I think if everybody understood what FSIS's idea of the team concept is, it would give you a better idea how we would intermingle and have these mixed teams and straight teams. I think that would be better.

DR. MASTERS: Okay. And I won't draw on the napkin again today. This is Barb Masters, and basically, we talked about team inspection and help better define it for the group, in that we are looking at, for example, a cluster of six plants might be in the area, and they may be covered by -- we said twenty plants with six inspectors in the area. And they may currently have specific assignments, that they have two or three on their assignment. And what we are saying is

the frontline supervisor could take those six employees, and when we define what risk-based inspection is, allocate the time to each establishment, and then rotate those six employees between those twenty plants. You wouldn't automatically have one person going to X plants. They could be used within any of those 20 plants, so that you can get away from that "my plant" concept. And so when we talked about mixed teams, what we were saying is that if there is a situation that there are federal plants and state plants in close proximity, which is really the smaller percentage of the time. Usually, with TA we are talking about the state plants, and the federal plant aberrantly showing up there. But we have recognized that we have moved to the point that there are some situations that there are a good conglomerate of state and federal plants together. And in those cases, the agency and the state determine it most efficient to use a state employee in some of those federal plants. So in that concept, when we were saying that plants were together that had both state and federal employees, we were looking at the state employees working in federal plants, which would now be the TA concept. But to get a team together to draw a

line around a group of plants to get a team together, you would be sweeping in both state employees and federal employees, all covering federal plants. And so the question that we had put to the group was, in that scenario, some of the folks would report to a state supervisor and some to a federal supervisor. And we were asking how we could do that in the context of the purpose of the Act, which is efficiency and nonduplication. And so they said in that case, it may be easier to have those state employees working in federal plants to also report to a federal supervisor to get that stovepipe out of the way, that in some cases that may be more efficient than the traditional TA concept.

MR. TYNAN: Dr. Hollingsworth.

DR. HOLLINGSWORTH: Going back to Dr. Jan's comments, last night this issue did come up about the idea of small businesses and how states might be able to actually support and assist those companies because they have a closer working connection with them. But we were afraid, I think, that in the wording of it, it might come out sounding like we were saying they should be given a break or they should have less inspection. I

think our general concern was that we didn't want that message to come across. But actually, rethinking it through as Dr. Jan has, I wonder if it might not be useful if under the list of what were the outcomes that we hope to achieve by using these two different options for a T/A facility, if we included a bullet that would say something like one of the outcomes would be to support small business startup and growth opportunities.

MR. TYNAN: That would be under mixed teams?

DR. MASTERS: It would be under outcomes, as one of the things that we want to achieve in addition to good use of resources, and meeting federal requirements, and all those other good things, would be to support small business startup and growth opportunities. Dr. Jan, does that sort of address it, because I know we were worried about sending the wrong message, that we thought they should be given a break, and that wasn't the point.

DR. JAN: Even allow may be a better word than support -- allow small business startup and growth.

UNKNOWN: A true diplomat.

MR. TYNAN: Dr. Harris, did you have a question or a comment?

DR. HARRIS: Yes. Joe Harris of Southwest Meat Association, and I just kind of wanted to very briefly follow up with what Dr. Jan's comments were, and I think we almost kind of went down that road of implying that somehow small plants deserved, or needed, or wanted a break from regulatory requirements, and I don't think, you know -- I don't know of anyone that would suggest that, that small plants are committed and dedicated to meeting all regulatory requirements. I think -- and I don't want to put words in his mouth, but from my perception, small plants, especially, the very small ones, react much better to assistance because, in general, when they are not meeting regulatory requirements, it is usually not an unwillingness; it is a lack of understanding of what those requirements are and what their duties are. And assistance in that scenario works an awful lot better than a real big hammer. I know with a lot of large companies, the bigger the hammer, the better the response. But with small companies, I think Dr. Jan is right, you just drive them away from being under inspection, and I just wanted to kind of add to that and sort of second some of what he said.

MR. TYNAN: Ms. Eskin, did you have a comment?

MS. ESKIN: Yeah. Actually, my question goes back to Dr. Master's brief discussion of the team approach. Is this team approach laid out anywhere? Is it in Dr. Murano's vision paper? Because I know it has been discussed and sort of bandied about a lot, but I don't think -- maybe you had a conversation, as apparently, you did, with the Subcommittee, but we really haven't flushed the idea out here as a full Committee.

DR. MASTERS: It is not yet laid out as a specific document. It is something that we briefly discussed two years ago at our national supervisory conference. There has been spent much more time last week at a supervisory conference as a vision for the Office of Field Operations to move to a situation where we can better utilize our resources and move away from the "my plant" concept, and have a current circuit supervisor, which is kind of the mid level supervisor, focus on everything from ante mortem to administrative enforcement actions without having ownership to X number of plants, and having folks rotate between the plants so that they can move away from trying to protect the plant

and look more objectively. We hear too often -- we hear of some trying to protect the plant and we hear of the others trying to go after the plant, and so either are equally inappropriate, and we are hopeful that by moving to this team approach, people will be able to look at things more objectively rather than subjectively. So we do not yet have it laid out.

MS. ESKIN: And obviously, as it is laid out, it evolves and develops, one issue that will be addressed is the view that this approach is consistent with the underlying statute.

DR. MASTERS: Absolutely. That is the intent of doing this. When we say that team inspection, one of the caveats that we talked about with the group last night -- we had a couple of assumptions we had the group work under, and one was that state employees and federal employees would be considered equal under our scenario. We recognize there is bad players on both sides, but we took the approach they are both equal, that we would meet the intent of our statutes, which is daily inspection of every facility, and ante mortem and post mortem inspection in a continuous fashion, and the team approach looked at by our agency would also be

consistent with that approach.

MR. TYNAN: Mr. Schad.

MR. SCHAD: Yeah, Mark Schad. I just need to make a comment along the line of what Dr. Jan and Joe Harris was saying here. As a small plant, I am definitely not looking for any breaks or anything. What I need more than anything else is information, what are the expectations. Sometimes that is unclear. Sometimes they seem to change from day to day. And I just want to make one comment. I went to Raleigh for the Listeria Monocytogenes Workshop, and to be frank, I did not feel like that was towards small or very small plants. I thought there was a lot of Con-Agra people there, a lot of Uni-Lever people there. I appreciate that it was done, but just to be frank, I did not feel like it was catered to small or very small plants. I just wanted to get that comment in.

MR. TYNAN: Dr. Jan, did you have a follow-up comment or -- okay. You decided -- you have tired yourself out.

DR. JAN: I think I made my point.

MR. TYNAN: I am sorry. Dr. Elfering.

MR. ELFERING: Yes, Kevin Elfering with

Minnesota. One question on the team approach, and maybe a comment on inspection. Whether it be federal inspection or state inspection, I really think we do need to be looking at doing more education with small plants, because a lot of these plants, a lot of times, the person who is working on the slaughter floor is working on the processing floor the next day, and also doing the record keeping. They don't have the expertise or the ability to have quality control staff, and I think that is something that all of us have to do, because we all have an interest in food safety, is doing more education in all of these operations. The other thing with the team approach, I know everybody has heard of Chicago, and Minneapolis, and Dallas, but I don't know if you have ever heard of Warroad, or Gonvick, or Hallock. Those are towns in Minnesota that we say they are not the end of the world, but you can see it from there. How is the team approach going to work on some of those remote locations where, for example, in Healey, there is a federally inspected plant, and they don't have another plant for another about 250 miles. So is there a way that perhaps in some of these circumstances that even a state inspector or a federal inspector could

work with a state team?

DR. MASTERS: Just to comment back to Kevin, I think that is what we were focusing on when we were saying there could be separate teams, and the agency recognizes that even if there were no state plants in that area, that there is going to be some remote locations which is just not conceivable to pull into the fold of a team. And what you are describing, if you have next to the end of the world, and state plants in that area, and a federal plant there, that is what we were pulling into our concept of separate teams, that that federal employee may well be – T/A employee may well become part of that state team as opposed to a federal team, that that would be headed up by the state program.

MR. ELFERING: I guess my question is would you consider having a federal inspector as part of a state team that would be supervised by a state inspector, rather than a federal supervisor?

DR. MASTERS: We have not considered that but, certainly, it is something we could take a look at.

MR. TYNAN: Mr. Govro, any other comments from your group or any modifications you want to make to the

report?

MR. GOVRO: No. It appears that we are done. I did have one more comment on teams, however, myself. FDA used a team approach back in the early years of reinventing government, and at least the Seattle District of FDA did, and they have since then abandoned that approach as problematic. And I would recommend that you talk to FDA about their experiences with the team approach and see what sort of difficulties they encountered and see if you can avoid some of those on your way in. And with that, I think we are finished.

MR. TYNAN: Okay. thank you. Are we accepting the report? Can I hit save? Do I have consensus? Okay. All right. I think where we are in the agenda right now, I would suggest we take our break now and then perhaps start Group 3 immediately after the break. And since we are a little bit ahead of time, I have called a couple of the presenters for this afternoon to try and move the schedule up. One of the presenters may have a little difficulty and we will have to decide how we want to adjust the schedule, but nevertheless, we are moving forward, so we will try to keep the agenda going. So at any rate, let us take a

break, 15 minutes on the break. Mike, the watch says 9:30; if we could get back together at 9:45?
[Recess]

MR. TYNAN: As I mentioned earlier, I know everybody has some travel commitments, and not that we want to slight the topics at all, but we would like to address them and still get you where you need to be and move on. What we are hoping to do -- we are a little off target already. I was thinking that from -- this is how I propose to do the agenda, if you are agreeable to doing it. From 10:45 to -- or 9:45, rather, to 10:15, we would be finishing up with Subcommittee Number 3 and their report. We have Dan Engeljohn here who can do a Listeria update for us from 10:15 to 10:45. From 10:45 to 11:15, we have Gerri Ransom, who will give you an update on the Micro Committee, and they had a meeting so she will bring you up to date on what they found. We are hoping at 11:15 to 11:45 we will have Mr. Rob Larew, and perhaps Mr. Larew will be able to give you a legislative update. We are trying to get in touch with him. I think he has a meeting on Capitol Hill, of all places, so he will have the most hot news to provide.

So hopefully, he will be able to get in here at 11:15. And then we have Kim Elenberg, who is with our Office of Public Health and Science. She is with the Public Health Service, and she was going to do the Consumer Complaint Monitoring System, so she would be from 11:45 to 12:15. You have a choice at that particular point in time to take a break for lunch and come back and do remaining issues and other things, or we can press on and do the remaining issues around 12:15 and be done, and I know some of the folks have airplanes to catch. So if that is agreeable to you, then we will continue in that way. Suggestions/comments? Okay. Let us -- there being no opposing viewpoints there, then we will proceed with the agenda in that way. And if I could impose on the Subcommittee Chairperson for Number 3 to come on up, or I guess we have set the precedent that you can probably do it right there, Alice, if you like.

DR. JOHNSON: I think we will just talk from the table here, if that is okay. First of all, a couple of words of thanks to everyone in our subgroup, Kevin,

Gladys, Mark, and Michael. I think we had fun, and we certainly covered a lot of ground. A special thanks to Dr. David Goldman, Dr. Kristin Holt, Dr. Sean Altekruse, and the star was Alecia Marie Naugle, who attempted to capture what we were saying on the computer in spite of the fact that we were redoing and going over and over things and the fact that the computer froze up on her several times. So we really do appreciate her efforts in trying to capture what we were saying. And we certainly appreciate the information sharing that the USDA folks provided us. We were asked to look at how FSIS can better associate food safety activity with public health surveillance data, and our first question was how might data linking food products to foodborne illness cases be used to suggest changes in regulatory policy. When we considered this question, we originally looked at it in two components. One was how would we look at that based on current policy and how would we look at that based on future policy needs. And one of the things we soon found out as we went further along in our discussions, that we probably could put both of those questions together because the way you would -- the data that was available and the way we would look at

the data probably could serve for both evaluating current policy as well as looking at policy needs in the future. We also made just a blanket statement to talk about the utilization of outside experts. It is imperative to achieve unbiased sampling design and data analysis, and we did talk a little bit about the agency's efforts already through the National Advisory Committee, the Microbiological Criteria for Foods, as well as the National Academy of Science work that has been done to review the data and look at the sampling methodology. And we would definitely encourage the agency to continue along that line as they develop new information. We understand they are working on an ongoing baseline and that we would encourage the outset experts do reviews of this information as well as the methodology sample design. FSIS should review available data trends and determine statistical significance, and this is to look at intervals that are appropriate round point estimates relative to specific policies. This would include, again, design and development, statistically sound methodology and sampling, and to gain consensus among the FSIS experts on the sample design and the methodology used. In extrapolating data,

scientifically sound processes should be used. Any future policy should be based on statistically significant results and the use of risk assessment. We talked about the agency's work with risk assessment with regard to the ready-to-eat rule and think that is appropriate means to work through policy development, and we support the agency and continuing baseline studies using scientifically sound sampling methodology. And with that, I will ask my Committee, Subcommittee, if there was any other thing that we left out based on the first question -- Michael, Mark, Gladys, Kevin -- it is imperative that you speak up. The second question was how do or can we get data that is linked to food. In our discussions on this question, we talked about looking at current data, particularly, the data that is ongoing with CDC and the current case studies, case control studies, looking at both the outbreak and the sporadic cases, and to try to identify risk factors from that information. We had heard a little bit yesterday about the attribution project that FSIS was embarking on, and I think Dr. Holt gave us a good update on that last night and that we would encourage FSIS to move forward with that and to include all concepts such as

Baysian modeling, risk ranking, case control study, and review of all pertinent work by other federal agencies, think tanks, academia, state and local agency, as well as industry and some of the consumer group information that had been put out. We encouraged FSIS to look at the salmonella serotypes that they have collected from the FSIS HACCP regulatory verification sampling data and look at those that are most frequently associated with the foodborne illness that CDC has identified and that the agency might want to consider further subtyping of that information. Subtyping, we got into a discussion, PFGE Ribotype, PFGE typing of selected isolates may want to be considered. We went a little bit beyond what we understand to be the scope of FSIS -- imagine that -- and started talking about efforts to enhance the public health infrastructure, providing more information quicker. One of the investigations in the time lag between getting folks out to conduct the investigations, trying to decrease the time span once an illness is identified and when the patients were interviewed, as well as providing education to help care providers, consumers, and health agencies to try to increase the disease reporting incidents. I know we had -- Kevin

mentioned that some states had very good reporting mechanisms in place and that other states might be lacking. So we felt like education on getting this information out would help increase the reportability of the diseases, of the outbreaks. Mark -- thank you.

MR. SCHAD: Yeah. Alice, at least according to my notes under the second question, first bullet, I think we also discussed that these case control studies should include other types of food other than just meat and poultry, and we don't have that in the report here. Is my recollection correct -- are my notes correct on that?

MR. ELFERING: This is Kevin Elfering. I think -- yeah, we did discuss, you know, there are so many of the case control studies that are going to cross different food products, and I think there was some discussion on that, perhaps at least be able to disseminate that information out.

DR. BAYSE: Under the second bullet, Alice, did you want to include industry and consumer groups? I don't think it is on the typed form. And I believe in the next bullet -- isn't it PFGE?

DR. JOHNSON: Yes. Thank you, Gladys.

Robert, did you catch all that?

MR. TYNAN: I didn't catch the edits, where we need to fill them in.

DR. JOHNSON: Okay. I think continuously review case control studies, outbreaks and sporadic cases as they become available, to identify risk factors, this should include food types other than meat and poultry. Mark, does that address -- foods other than. Thanks. And then on our second bullet, just put a comma, industry and consumer. Could we go up on the first bullet and put, "This should also include" -- to be sure that meat and poultry -- we understand meat and poultry should be there.

UNKNOWN: In the second bullet, consumer is misspelled at the end.

DR. JOHNSON: And then on the next bullet, let us be sure we have PFGE right. Thank you. Any other comments from the Subcommittee? They were a lot more talkative last night. Question Number 3, What other types of data should be considered in development of regulatory policy, data FSIS currently collects and plants. And in this discussions, we started talking about the need for FSIS to look beyond. Most of our

discussions seemed to be on regulatory data that the agency is collecting, but we went a little bit beyond and said, you know, the agency should look at all types of data collection, be it inspectional data, chemical analysis that the agency does. And we thought it might be appropriate with the agency's move toward more of a public health regulatory mission to review regulations, policies, and procedures, to ensure consistency and relevance to the FSIS public health mission. This process would both eliminate unnecessary activities and free up FSIS resources for public health focus. This would include interpretation of data from PBIS as well as from micro, biological, and chemical testing. And we had a discussion about the performance based inspection system, PBIS, and the fact that these compliance data to those tasks had been being collected since probably 1990-something. And you know, has there been a review and how has that changed with regard to the agency's public health mission. I know that the task weighting was changed in the mid '90s to represent more of a food safety concern, but are there a lot of those tasks in there that could be reviewed to determine consistency with the public health mission. We talked about

reexamining the existing data the agency has and determining additional usefulness for public health purposes and investigating different uses and approaches for analyzing data, and that this might apply to data that the agency currently has as well as in future data collections. Subcommittee?

MR. ELFERING: This is Kevin Elfering. One thing I might want to add is just having the agency look, for over the years there have been different directives and different additions and things of looking at food safety. But maybe you have to take a step back and see some things that have been done for years that really aren't necessary anymore. An example would be even like generic *E.coli* testing in slaughter plants. Is there a good correlation to generic *E.coli* testing and foodborne illness outbreaks? And if there is not, maybe it is something that could be considered that wouldn't even be valid anymore to be doing that analysis, just looking at some of those things. And with PBIS data, looking at more food safety issues rather than economic.

DR. JOHNSON: I think Kevin and Mark brought up a good point with something like generic *E.coli*

testing, requirements for the smaller plants. Is that really a good use of their resource if there is no true public health benefit in collecting that data and should maybe there be a revisit to focus those resources on the part of the plant to something that would serve more benefit from a public health standpoint.

MR. TYNAN: Dr. Johnson or Dr. Elfering, did you want to include something in the -- as part of the bullets or...

MR. ELFERING: We certainly could, but I think one of the things -- I don't think we want to necessarily specify any one particular program. I just think that as you evolve, you need to be able to not only look at the things that are put in place today, but is there a way that you can eliminate some things that were done yesterday by what you have done today. So I don't know if we want to get as specific as -- maybe that is what should be done all of the time. Anytime that there is something new that is put in place, maybe the whole system needs to be reviewed to see if there is something that can be eliminated. Unless the Committee thinks that we should have something more specific.

MR. KOWALCYK: This is Michael Kowalcyk. I

think based on the question and the information we had to go with, I think I would be hesitant to get more specific with that recommendation.

MR. TYNAN: Okay. Dr. Johnson -- oh, I am sorry.

DR. JOHNSON: I think we will leave it, Robert. Thank you.

MR. TYNAN: Okay. I had one question for you. In that first bullet under Number 3, FSIS should -- when you were reading in that last sentence, it said, this would include -- and it originally said inspection of data, and I think when you read it, you said interpretation of data? I don't know if that is a big deal, but I thought maybe you just had missed an edit on the disk or something.

DR. JOHNSON: I don't know -- I will leave that up to Kevin. Should we change that wording?

DR. JAN: This is Lee Jan, Texas Department of Health. I don't have a problem with what you presented there, but I did -- this Number 2 stimulates a thought process that maybe was considered, maybe not, but the question is how do we get data that is linked to food, and epidemiology, and reporting outbreaks is mentioned

as one way. But there probably is a lot of resource information out there that is not being tapped because epidemiology for the most part is passive, and a physician reports only if he reports. I mean, certain diseases are required, but a lot of them are not, but there is a lot of useful information. But almost every physician gets paid through an insurance company, and insurance companies have ICD-9 codes that they use that are standard. And if the agency could somehow cooperatively tap into that code, or into that database, not people specific but only disease specific, to see trends that may not otherwise be reported. They would be syndromic, but there are certain syndromes that may say this could be foodborne outbreak and that might stimulate the epidemiology group to go and look deeper and see is that something that might be related to meat and poultry. And that is just an idea, and that could even extend to Homeland Security if -- the Homeland Security people are not here, but if they would think about that as well as identifying spikes that are unusual that may not be reported because they are being seen at so many different physicians that may only see one or two cases. But put them together, you may see a

spike in an area that otherwise would go unrecognized. But I just think that we all have made insurance companies successful because we all have to have insurance. Then why not ask them to give something back and see if they would be able to -- or be willing to work with -- provide access to the disease portion of that database. That is just some thoughts. It may be a long way from getting there, and it may even be a paradigm shift. I don't know. Thank you.

DR. JOHNSON: Subcommittee, would we want to put a bullet in that said work with physicians and insurance companies to recognize disease spikes that might assist the agency in linking food data?

DR. BAYSE: I think it is worth a try if the agency is willing to be involved.

MR. TYNAN: Okay. Where would you like me to put that?

DR. JOHNSON: Under Number 2. Michael, are you okay with that?

MR. KOWALCYK: Yes. I think that would be a reasonable addition, at least something worth looking into because of the nature of data, if you can get more accurate data -- if there are ways to get more accurate

data, that should certainly be investigated.

MR. ELFERING: I think something should be included, too -- and I always look at some of these things as the story about the blind men who are looking at the elephant, and one was holding a leg and was trying to describe the elephant, and one had a hold of the tail, and another one had a hold of the trunk, but nobody saw the entire elephant. And I think that are some of the things we have to look at in public health, is we have to look at things that are sometimes obvious to us, and sometimes we close our eyes to what is obvious and look at all of these different areas. I think there is a lot of things that we don't think about. That has never even come to my mind of thinking of insurance companies that are going to have this data, and I think that is good information. And I think anywhere that we can find additional data relating to foodborne illness outbreaks is going to be helpful.

MR. TYNAN: Dr. Johnson, did you want to suggest some language?

DR. JOHNSON: Work with physicians and insurance companies to recognize disease spikes that might assist the agency in links to foodborne illness.

Dr. Jan, does that reflect what you were saying?

DR. JAN: Yeah. I would even -- you might just say work with the insurance companies, because physicians already are supposed to be reporting some of these things.

DR. JOHNSON: Okay.

MR. TYNAN: Work with physicians and insurance companies to identify spikes in...

DR. JAN: I would say insurance companies and HMO's.

DR. JOHNSON: Take physicians out.

DR. JAN: Because physicians are doing it as a matter of getting credit and they will report that quickly, or their staff will.

DR. JOHNSON: Okay. Dr. Holt?

DR. HOLT: Kristin Holt, FSIS. I just want to make a comment that FSIS doesn't normally do human health surveillance directly, that we usually rely on CDC or State Public Health departments to actually do the human health surveillance. So I don't know if that might suggest -- you know, the words, slightly.

DR. JOHNSON: Maybe that would be another one that we would want to say may go beyond the scope?

DR. ALTEKRUSE: Sean Altekruse. It might be worthwhile considering -- this seems to be getting at early warning so that outbreak investigations can be done quickly, and CDC has developed an electronic system of receiving data from the State Public Health laboratories called PHLIS, Public Health Laboratory Information System. And what they have done is used data from previous years to create a baseline of the expected number of *Salmonella typhimurium* or *Salmonella enteritidis*, or Heidelberg infections that are suspected. and when that number exceeds the threshold that is considered normal for that same timeframe, it creates a flag. And perhaps one thing that could be done is to encourage timely follow-up of those flags as a way of getting at early reporting, because that already exists. That infrastructure already exists and it is more specific to the pathogens that are of concern to us. My concern about HMO's is both that there could be a lag time in that and that more than 50 percent of gastroenteritis is going to relate to unknown etiologies, viral gastroenteritis, and that sort of thing.

DR. HOLT: This is Kristin Holt, FSIS. There

is activity, I guess related to Homeland Security actions, to look at syndromic surveillance, so the human health community is working in that area, so great minds think alike.

DR. JOHNSON: Well, it might be good to keep that bullet and then maybe add something else about the early warning. And Dr. Holt, maybe we should put work with insurance companies, HMO, and maybe in parenthesis put what is the initial -- Department of Homeland Security. If they are, in fact, doing that review, the agency may want to just pull that in as well, and that might be more within the scope of what the agency could do. Subcommittee? Dr. Jan, does that -- and that may -- and then we want to put another bullet in about, you know, early detection and the CDC Public Health Laboratory Information Services -- I am sorry -- it is -- maybe we should say...

DR. ALTEKRUSE: It is Public Health Laboratory Information Systems.

MR. TYNAN: So the acronym is PHLIS, Public Health Laboratory Information Systems?

DR. JOHNSON: And Robert, maybe we should put review early detection and -- move the parenthesis away

from Department of Homeland Security. Jill?

DR. HOLLINGSWORTH: Maybe -- I think perhaps putting Department of Homeland Defense will -- Department of Homeland Security will cover this, but there is a whole series of activities going on that I guess are being more driven by security, but they overlap with safety, and the other one that comes to mind is there is an initiative right now where retail sales of over-the-counter medications like anti-diarrheal, cold and flu medications are being tracked to see, again, if there is any spike which would indicate within a community that something has changed as far as the health status within that community. Because most people will medicate themselves until they are like at the brink of death before they go see their doctor. And so I think if there is a way we can capture the whole idea that initiatives, be they safety or security, that are capturing other data sets related to public health, is FSIS could start utilizing or collaborating with those other data sets. And I am not sure if having Department of Homeland Security covers that, but because there are so many new initiatives that are being funded and can be accomplished under the security banner, there

is this whole new set of data available to us.

DR. JOHNSON: Maybe we should -- we are adding to this thing like crazy here, but maybe we should either put a bullet or a sub-bullet that says FSIS should review, you know, Department of Homeland Security initiatives to see if available data could be used, or something similar to what we talked about. Let us see do we know exactly what the Department of Homeland Security is all about and what they are doing, and are there other initiatives that they are undertaking that might be useful. Michael, Mark, Gladys...

MR. TYNAN: I am sorry. Could you finish that statement for me, Dr. Johnson? I got the first part and didn't catch the end.

DR. JOHNSON: FSIS should review Department of Homeland Security initiatives to determine relationship to foodborne illness and public health protection. Beautiful.

MR. TYNAN: And can I impose on you to go back up to two bullets to the one that said work with insurance companies, that we just added, and it says to identify spikes in -- and I inferred from the conversation there was something else to go there, but I

didn’t quite catch it.

DR. JOHNSON: We talked about spikes in illness...

DR. JAN: Spikes in human health illness syndromes related to foodborne.

MR. ELFERING: If I might interrupt, I do have a little bit of something that I wrote up here, to identify spikes in human health cases of foodborne illness that may be associated with meat and poultry products.

DR. JOHNSON: Robert, thank you. You are doing a good job of catching all our discussions, too. Any other discussion from the Subcommittee? Full Committee? Yes, ma’am.

DR. LOGUE: I have a quick question for you -- Catherine Logue. On the PFGE data and stuff like that, do you want to make it kind of a recommendation or a consideration that it might be nice to put some of that on Post Net or something that may be of advantage to the CDC or somebody else who is trying to trace an illness, and if FSIS has profiles and they can link them?

DR. JOHNSON: Well, we did talk a little bit about that. In fact, that exact comment was made, but

we decided we weren't going to recommend where it went because most of the information, it is my understanding, is in more of the ready-to-eat direct link, and the information that FSIS is gathering here is the raw product, and there is some other way the agency or CDC would want to capture that. That was the discussion. Any other comments from the Subcommittee?

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. In reading the issue here, it was presented as how can FSIS better associate food safety activities with public health surveillance data. And the three questions that were asked of the Subcommittee were very much focused on data regarding foodborne illness, data that is collected at the plant level, and I would like to suggest that -- and I don't think this is going to be a part of the document here, but just sort of to go on record, that FSIS consider this in a broader context and think about other things that it does do or should do to promote public health. For instance, I think education and outreach are an important part of what the agency does and can do to protect the public health. In reading the recently

released Listeria risk assessment, it suggested that if the public were to uniformly turn their refrigerators down to 40 degrees, it would reduce listeria or listeriosis by 98 percent. That would be -- I believe I have that number right. That would be a significant reduction in illness. And if we looked at some of the agency's efforts to educate the public and change the public's behavior with how they handle food, and analyze the effectiveness of those outreach programs in the same way we analyze data collected at the plant, we might learn quite a bit about affecting the public's behavior. The same thing could be said for improving the effectiveness -- or FSIS management. This Committee, several sessions ago, discussed FSIS directives and how well they were understood and followed. And again, that would be something if the agency looked as closely at determining whether or not its management policies were effective as they do at analyzing data on microbiology of the product that is produced, you also might learn some interesting things and discover some better ways to be more effective and ultimately achieve your goal.

DR. JOHNSON: Thank you. Anything else from the Subcommittee or the full Committee on this group's

work?

MR. TYNAN: Shall I hit save?

DR. JOHNSON: Save. Thank you.

MR. TYNAN: Okay. Thank you. I want to thank the committees for all the hard work, hanging around last night. I was tired watching you, never mind having to actually do it, so I am very grateful for all the hard work that everybody put in. I think the reports are very good. We will -- what I would like to do now is maybe shift back to the briefing portions of the agenda. And as I mentioned earlier, we have Dan Engeljohn, who probably doesn't need to be introduced. He has probably been here so many times now we should make him an honorary member of the Committee. But he is going to do a little *Listeria monocytogenes* update for you.

DR. ENGELJOHN: Good morning, everyone. I am going to give you an overview of the activities FSIS has underway with regard to control for *Listeria monocytogenes*. I don't have a presentation in the book for you. I am just going to give you an overview of where we stand with our activities. Many of you may know, and I have presented to this Committee information in the past about our activities, but beginning back in May of 2000, FSIS, along with FDA, began stepping up our efforts at addressing *Listeria monocytogenes* in the products that we regulate with the specific goal of reducing the incidents of foodborne illness related to this particular pathogen. Also, in the year 2000, FSIS instructed establishments producing ready-to-eat products that they needed to reassess their HACCP plans in order to address new data available about listeria in ready-to-eat meat and poultry products. An FDA FSIS risk ranking was issued in January of 2001 that identified the relative risk with regard to a host of foods at retail that presented increased risk with regard to listeria. Many of the meat and poultry products that we regulate were at the top of that list. Following that January release of the risk ranking

information, FSIS issued a proposed rule that specifically dealt with mandatory controls that needed to be in place for meat and poultry products. We finalized that regulation in June of this year, June 6, in which we issued an interim final rule and provided an 18-month period in which we would evaluate the effectiveness of this particular rule. That rule went into effect on October of this year, and to my knowledge, we have had great success with implementing that regulation. I will point out that, uniquely, with this particular regulation, we issued instructions to our employees that their first activity upon the effective date of this regulation would be to sit with plant management and ask them to identify how the plant was going to control listeria in the post-lethality exposed ready-to-eat products that the plant produced. My understanding is that that has generally gone over very well. I have not received a great number of concerns about the implementation or the role. We continue to monitor the effectiveness of the implementation. We do have updated guidance with over 100 questions and answers that have been provided through a series of workshops that the agency hosted in

which we are providing clarity to establishments on how to comply with the regulation. In particular, the agency hosted five workshops prior to the implementation of the regulation to get information out about what specifically had to be done in order for the establishment to come into compliance on the effective date of the regulation. The regulation on listeria control includes three alternative control measures which the establishment needs to address. We believe that the most effective means for maintaining control of listeria in a post-lethality exposed ready-to-eat product is through the use of an effective post-lethality treatment that actually causes a reduction in the level of listeria that may be there if there is post-process contamination, and the inclusion of effective levels of antimicrobial agents that would suppress the growth of the organism if immeasurable numbers of cells were present but had the opportunity to grow to harmful levels throughout the shelf life of the product. The second means of control that the plants could choose from would be to use one or the other with regard to post-lethality treatment or growth inhibition. We believe this provided additional protection against

the risk of listeria surviving and growing in the products, but that it does not include both the post-lethality treatment and growth suppression. It would include one or the other. The third means of control, which many of the small establishments do, in fact, fall within, as well as many of the uncured products today, fall within the alternative three, which is strictly use of sanitation to ensure that the organism is not present in the environment, on the food contact services that the exposed ready-to-eat product would come into contact with, and that there is no effective use of post-lethality treatment or post-lethality suppression of the organism in those particular products. The establishments need to identify how they are going to control listeria in their operation, have identified the rationale behind how they will demonstrate the effectiveness of their control procedures, and then maintain that information for FSIS to have access to. There is a mandatory requirement with all three of these control measures that the establishment has to have in place, verification activities that demonstrate that the ongoing control measure is, in fact, working. The directive for this regulation also issued prior to the

regulation becoming effective, it was designed to provide very specifically the inspection tasks that the inspectors would conduct on a day-to-day basis. The agency provided compliance guidelines to industry for how they can meet all the requirements of the individual components to the regulation, and then provided information about the latest scientific research that is available so the small businesses, in particular, would have an understanding of how the research applies to their particular products and how they could use it to help with the validation of their ongoing control measures rather than having to invest resources to demonstrate it themselves if, in fact, the validating material is directly related to their particular product and process. I will say that the agency is now stepping back and taking a look at how well this regulation is being implemented throughout the country. We have an ongoing period, 18 months, in which we are going to study this effectiveness. We committed to having an assessment done by December 2004. Within the period of time in which we are assessing the effectiveness of this regulation in post-lethality exposed products in the retail -- I mean, in the federal establishments, the

agency will begin collecting information from industry as to what products they are producing, the volume of production of the various products, and the alternative control measures that the establishments are using, and an identification of how effective those control measures are. We made that data collection document available in the compliance guidelines that we issued with the implementation of the regulation, and we hope to have that documented. It would be in electronic form that establishments can fill out, available on our web page prior to the beginning of the new year, and establishments can begin providing that information to us. We would use that information, particularly, to design a risk based verification testing program, in which the agency would, in fact, make some determination about how effective the control measures are in the various establishments relative to the risk posed by the products and the control measures that are there, and then make some determination as to where it will invest its resources in terms of providing greater attention to follow-up testing to ensure that the production operation is, in fact, appropriately controlling for this particular pathogen. One other activities that the

agency is intending to step up this coming year will be its educational efforts related to consumer handling of ready-to-eat post-lethality exposed products, and in particular, vulnerable populations that, in fact, today are given the message that rather than eat the products we regulate, if they choose to, they should fully cook them. That happens to be a message that the agency is intending to change the approach in which the consumer is given guidance about the products we regulate. To do that, the agency is looking at the educational materials that are received and used as part of the training materials in the public health institutions, particularly, with physicians. And then to focus on the consumer handling so that, in fact, consumers have in place the appropriate information about how to adequately control in their own homes to reduce the risk of listeria being on the products that they consume. We did identify in this particular regulation in terms of the cost benefit that we recognize that less than 50 percent of the ready-to-eat meat and poultry products that are consumed are actually produced in the federal establishments or the state inspected establishments, and that we estimated that greater than 50 percent of

the ready-to-eat products that are consumed as deli items are actually sliced at deli counters. This regulation does not specifically address retail operations with regard to listeria control. We did include within the directive that we issued in terms of giving a decision type of approach for the inspector of what products to pull for the FSIS verification testing, but if, in fact, there were no post-lethality exposed products within the establishment, but they did produce products that likely would be sliced at retail, we did tell the inspectors to select a product that was not formulated with a gross pressing agent, believing that the inclusion of growth inhibition agents will, in fact, have some effect at retail in terms of reducing the potential risk of these products at that level. So throughout this coming year, we intend to step up our focus on consumer handling practices and the activities that occur at retail, which this regulation does not specifically address, but we first want to ensure that the regulation itself is effective, is it being implemented as intended, and that we have accurate information being supplied to us from industry about the products that they produce so that we can, in fact,

design a risk based verification program. I will add that the record keeping documentation of the products that are produced, that are applicable to this regulation, is, in fact, a regulatory requirement. We believe that there is a definite need to have better information about how much product is produced by the various establishments and how effective their control measures were in order to determine how we should establish our verification program, and so we made that part of a mandatory component to this regulation. So that is all I have to present on the activities to date. We do expect to be issuing updated compliance guide materials within the next few weeks, and that information -- the first round of information, the agency recognized that the inspectors don't have the ability to pull up large volumes of information on their Government computers, because they don't have access to high speed internet hookups, and so we put all the material on CD's and mailed out CD's, 5,000 CD's, to all the inspectors around the country will all the resource documentation that we had at the time to help them understand why the regulation was developed as it was and information about how effective programs could, in

fact, be designed. So thank you. Are you entertaining questions?

MR. TYNAN: Yes, certainly. Well, I am not entertaining them.

DR. ENGELJOHN: Yes, Mark.

MR. SCHAD: Dr. Engeljohn, on the subject of data collection in regards to state plants, are you wanting to get that information directly from the state plants, the FSIS, or is it going to go to the safe programs into FSIS, or are you wanting the data from the state plants?

DR. ENGELJOHN: Well, I think you raise a very good point about what happens at state plants. The data collection effort, of course, being a mandatory requirement for the federal plants, is one that we would expect the state plants to also have to deal with. Our issues would be that we would be working with the states to figure out how best to access that information and then how best to give you guidance on how you should use that information as well. Presently, the agency is not intending to do verification testing at state inspected facilities, although, we are interested in ensuring that the programs are equal to, and that one way to do that

is to ensure that you are at least doing a program similar to ours. So we have not yet worked out that information. It will be something we certainly will be doing with each state. Dr. Hollingsworth.

DR. HOLLINGSWORTH: Dan, thank you for the update. One of the things you did not include in your comments was the issue of labeling these products. And at retail, we have a lot of questions about the labeling provision, and I am wondering if you could provide some information. Our concern about that is what products can have the label and what happens if the product comes into retail with the label but then we further handle the product? Is there different labeling for products produced under option 1 versus option 2? And what kind of focus groups or anything were performed to determine what were the messages? Because our concern is at retail, consumers are going to see those labels and those messages, and we have no idea how to explain what they mean or why one product now appears to be safer -- more safe or less safe than another, and how we are going to address that.

DR. ENGELJOHN: Yes. When we issued the regulation in June, in the preamble to explain why we

designed the regulation that we did, we had a section in there that dealt with incentive labeling that we believe would be one way to address the issue of how consumers, particularly, vulnerable groups within the population, could select ready-to-eat meat and poultry products that, in fact, have been treated to have enhanced safety. And one way to do that was to look at the labeling that could be placed on that product, so there is a claim of some sort that identifies if the product has been specially handled or meets minimum performance criteria to maintain that label throughout its shelf life. The other component to that would be considerations of maybe needing new packaging, so that particularly for vulnerable groups, rather than buying family sized pre-sliced products, or sliced products, is that they buy individual servings so that once it is opened, the integrity of that product is not maintained once you have opened that container and put it back in the refrigerator. All of those things were designed to put in place a mechanism for which we would have a dialogue with industry, with consumer groups, and with public health professionals to collectively come up with an approach that would work. We did not make it a

mandatory component of the regulation because we didn't have the exact performance criteria or the wording that we wanted to use at that time. So the intention was to start the process of getting in place a type of educational training type program that we can effectively put out there in which we could better ensure that the ready-to-eat products, particularly for vulnerable groups, are, in fact, safe throughout their expected shelf life.

DR. HOLLINGSWORTH: So can we assume then that none of those labeling requests will be entertained at this time -- in other words, there will be no labeling of this nature on product until all this other work is completed?

DR. ENGELJOHN: I can't say that there will be no labeling. I can say that we have received some of those types of labels. We have not, to my knowledge, received validating information to demonstrate how that label would be maintained and so forth. So at the moment, those are the issues that we are working with. We are aware of efforts within the industry to look at some focus group information, and we are certainly willing to look at that information to make some

decisions how best to go forward. We do see value, though, however, in directing consumers to products that have, in fact, been formulated or handled in a way to provide enhanced protection against growth of this organism.

DR. HOLLINGSWORTH: Okay. I would just request that there be considerable thought given to educating not only the consumer, but the people who are going to have to explain to the consumers what that means, because right now we don't know how to explain those labels.

DR. ENGELJOHN: Okay.

DR. HOLLINGSWORTH: In fact, we are running into a negative effect, and that is people think that labels that might say something about antimicrobials, in fact, indicate the product is less safe because of antimicrobial resistance. I mean, we have trained them on that, or tried to educate people to that degree, and now they are getting confused by the messages. So we would like to work with you on framing the messages in the labeling.

DR. ENGELJOHN: Yes. We, certainly, were not willing to step back and say we need more time to

provide added protection to the vulnerable groups, and that we needed to move the ball forward with making available some of the options that could be considered and hoped to get the stakeholders to the table to begin dealing with this issue in a constructive manner. Yes, Dr. Harris.

DR. HARRIS: Joe Harris with Southwest Meat Association. Dr. Engeljohn, I wanted to kind of explore a little further, or get you to explain a little further, how the agency plans to evaluate the success of this final ruling. You indicated that there will be an 18-month window where you will be looking at -- not you, but the agency will be looking at this rule to evaluate its success. That will be coupled with a very -- it sounds like an active and aggressive public education component, and so I guess I am interested in sort of what are the specific criteria that will be used to determine whether or not this was an effective rule, and will there be provisions in place if, for example, one of the criteria to be considered is a reduction in number of illnesses associated with *Listeria monocytogenes*, how would you separate the effectiveness of the rule from the effectiveness of your public

education component?

DR. ENGELJOHN: I think the issues related to how we are going to evaluate the effectiveness of the rule are ongoing, and we certainly will make them more known as we walk through the individual pieces. At the moment, the initial focus is to ensure that everyone producing a post-lethality exposed product is, in fact, complying with the regulation. One thing that we have noted over the years in terms of implementation of the HACCP regulations is that there is a big difference between having a written program that meets the letter of the law in terms of the components that have to be there versus the substance of what is there in terms of the quality of the information, and in particular, the validating data for the ongoing effectiveness. One of our first steps, I can tell you, will be to make some assessment of the effectiveness of the individual plants' control programs, and part of that is to ensure that there is some rationale in place within the design of the programs with how the individual plants verified its ongoing effectiveness. I know the sampling frequency and the design of the testing programs for listeria species and *Listeria monocytogenes* is of

particular interest to us in that the rationale behind that sample size, the type of laboratory testing, the frequency at which the food contact surfaces are tested are all issues which play into how effective the establishment itself judged the effectiveness of its program. It is one of the questions that we will be getting back in terms of the documentation that the plants will have to provide us. So I think the first step will be to get the form available to industry so that they can, in fact, provide that information to us within the first -- sometime within the first quarter of this fiscal year so that we can begin then targeting our verification programs at those operations that don't appear to know or have in place effective measures. So we will be looking at the various aspects, but the first issue is to ensure that the regulations are being complied with and that there is definitive information within those plans for the rationale. Thank you.

MR. TYNAN: Thank you, Dr. Engeljohn. On our speedy agenda, I think the next person that we have is Ms. Gerri Ransom. Hi, Gerri.

MS. RANSOM: Hi.

MR. TYNAN: She is going to give us an update

on the Micro Committee, or sister or brother committee, depending on what your preference is.

MS. RANSOM: Okay. Good morning. I have got some slides here, and I guess I need to get them up, and I don't know how to do that. I was anticipating being here at the end of the day, so I made sure to have slides for you. Okay. I am going to be providing an update on the other advisory committee, the National Advisory Committee on Microbiological Criteria for Foods, or NACMCF. We recently had a week of meetings this past August. We included two full committee meetings and numerous subcommittee meetings. As far as new work that went on that week, we had the review of the FSIS baseline study protocols, and I will be talking a little bit more this with you. As far as ongoing work, our three active subcommittees met that week. The

criteria for refrigerated shelf life based on safety, the scientific criteria for redefining pasteurization, and also, the microbiological performance standards for raw meat and poultry group met. As far as the review of the raw ground beef component baseline study protocols, we had asked the subcommittee on performance standards to undertake this work, so they were quite busy that week because they also had some performance standards work. The FSIS had given NACMCF a charge during that week of August to review our baseline protocols, and by the end of week, we were successful in having NACMCF produce an adopted report. This was quite a priority issue for the agency, and it was unusual that we ask the same week a review be completed, but as I say, this was a high priority for us. Before I continue talking about the baseline review, just to cover some background, it was in keeping with the 1996 pathogen reduction HACCP rule, and also with previous NACMCF recommendations, those in particular out of the 2002 performance standards report with particular reference to ground beef, that FSIS plans to update microbiological profiles of raw meat and poultry products through ongoing nationwide baseline studies. And it sounded like you

had heard a little bit about this already this week. As far as phase one of this baseline initiative to update our data, the agency is, as you heard, going to determine the microbiological profile of raw ground beef components. We started out by examining raw ground beef manufacture, and the agency identified various raw ground beef components as being starting materials for ground beef. And these raw ground beef components were grouped into five proposed baseline studies, and it is the protocols of these studies that we asked NACMCF to review in August. Now, as far as the goals of the baseline studies, we wanted to identify the components contributing to the prevalence of foodborne pathogens, the data for these baselines will be to inform risk assessments and also to support science based risk management programs, such as performance standards and evaluation criteria. And of course, the overall goal of these baseline studies is to help us reduce pathogens in raw ground beef. Now, to give you some specifics of the baseline charge, in particular, FSIS was looking for feedback in these four main areas. We wanted NACMCF to look at the priority and grouping of the raw ground beef components into the five baselines. We wanted feedback

on protocols for sample collection, feedback on sample plan design, and also on the test organism selected. Just to give you some highlights of the NACMCF report, these are some of the general recommendations. NACMCF points out for us that there is additional information on samples that we ought to be collecting, such as geographic location, origin of livestock, the age of ht animal, antimicrobial interventions used, line speeds, estimated 24-hour production volume. These are some important things that are going to help us assess the data. Some other things NACMCF brought out was that the agency should consider linking of samples, and this is, in looking at the various raw ground beef components which I am going to give you in the next slide, taking these components from the same lot of animals, it is felt that this could help us in planning future baseline studies. NACMCF also pointed out that the agency should seek funding for collecting data out of state inspected establishments for both raw ground beef components and raw ground beef. And NACMCF also suggested we assess the importance of retail produced ground beef. Okay. As far as one of the first points we wanted feedback on, the priority and grouping of raw ground beef components,

the categories you see up here are the five baselines that FSIS proposed. Domestic trim and subprimals was one baseline. Advanced meet recovery products was another. Low temperature rendered products, imported beef, and weasand, head, and cheek meat; weasand being the muscle surrounding the esophagus. Now, as far as what you see here as far as priority of the baselines, this is the priority that NACMCF recommends to us at this time. One of the reasons we needed to prioritize is because we could not run all of these baselines at once so we had to pick which might be the more important baselines to start out with. Domestic trim and subprimals came up on top. This is largely based on the fact that this is the largest volume component going into raw ground beef. But some other considerations were the perceived public health risk, processing variable, and expert opinion. And NACMCF also did point out to us that under domestic trim and subprimals, we may want to do pilot studies to really fine tune the priorities. As far as protocols for sample collection, some of the things NACMCF said was to sample proportionately by volume for each component, and I mentioned the pilot studies to fine tune, stratify

samples by region and month, use animal age as a stratifying factor, sample greater than 12 months from each region, and also in the report there was specific advice on the five components. As far as sampling plan design, NACMCF points out that the agency should use the statistical estimation procedures based on a previous raw ground beef survey that was done. This will provide a good measure of prevalence and standard error measurements. And NACMCF also pointed out to us that we should use probability sampling techniques, particularly, stratified random sampling by month and region to obtain representative samples. Okay. As far as the test organisms, these are the organisms FSIS was planning to test and NACMCF agreed that these were a good choice. We are planning on collecting quantitative data for all of the organisms. NACMCF did point out to us that we should consider investigating the prevalence of other serogroups in producing *E.coli*. Okay. As far as where we are going with these baselines, FSIS is evaluating the NACMCF report. We anticipate making protocol revisions based on the NACMCF recommendations, and this baseline work is going to be done by contract laboratory, and this work is on the front burner. So we

do expect to be moving forward with this. Okay. As I mentioned, during this week in August, other subcommittees were also working. The performance standards subcommittee, as I mentioned, were quite busy. They are working through performance standard evaluations for various commodities. They also were able to cover the commodities they are working on now, which is broilers, ground chicken, ground turkey. They are at a work in progress stage on a draft document and I am hearing they do not need too many more meetings before we see them release a draft document. So this project is moving along. The subcommittee on criteria for refrigerated shelf life based on safety also met. This project is an action item for the HHS USDA Listeria Monocytogenes Action Plan that was released in January of 2001, and this was for FDA and FSIS to have a scientific advisory committee working on this issue. This is also a work in progress. This group is focusing on the scientific parameters for safety based use by dates for refrigerated foods, but they are studying psychotrophic pathogens and looking at the increased risk as you move through the refrigerated storage period time. Some of the organisms they are focusing on are

Listeria monocytogenes, Yersinia enterocolitica, and non-proteolytic *Clostridium botulinum*. Okay. The subcommittee on the scientific criteria for redefining pasteurization also did work in August. This is our newest subcommittee that began work in June. This is an FDA work charge to define pasteurization within the scope of the 2002 Farm Bill. This group is working on the most resistant organisms of public health concern and looking at the parameters to take care of these organisms. This project has quite a large scope because they are reviewing alternative treatments to traditional heat pasteurization. And also, there is a variety of foods and treatments involved, all the way from surrey meat, to juices, to pasteurized egg products, looking at things like irradiation and high pressure, so there is quite a large scope to this project. The group is looking at validation issues with all of these treatments. One of the overall goals of the project is that when pasteurization claims are made, that we have enough information to determine whether or not the food is, indeed, safe. So this will be quite an interesting project, and as I mentioned, this is just starting out so I don’t have an end point for you at this point.

Okay. As far as future meetings, our next full committee meeting will be the week of February 8. We will also have subcommittees that week. The active subcommittees I mentioned will be working, the performance standards, the shelf life, and the redefining pasteurization. We also anticipate that between now and February, the subcommittees may also meet. Okay. And finally, I just wanted to leave you with how to get NACMCF information on line. We do have a web page that you can get to off the Food Safety Inspection Service website, where you can get updates, meeting information, and reports. Okay. And I wanted to thank you for your attention, and I can try to answer questions if anybody has got any.

MR. TYNAN: Are there any questions regarding the Advisory Committee? There being none, we are going to let -- oh, I am sorry. I apologize. Dr. Carpenter.

DR. CARPENTER: The slide that talked about tested organisms, I noticed that one criteria they are going to pursue is APC.

MS. RANSOM: Right.

DR. CARPENTER: I mean, is aerobic plate count?

MS. RANSOM: Right.

DR. CARPENTER: And so within all those organisms, you then look specifically at the four that are listed above that, or five?

MS. RANSOM: I can't get back to it. Let me see.

DR. CARPENTER: My point is being that you use a test to look at all the aerobic bugs, and then you are going to look at the five specifics that are listed?

MS. RANSOM: Right, to get that overall measurement. Okay. Thank you.

MR. TYNAN: Next up, I think, when we revised our agenda was Mr. Rob Larew, and I mentioned to you that he was perhaps at a meeting up on Capital Hill, and he is, and is going to be unable to attend. So instead of delegating down, we delegated up, and we have Mr. Larew's boss, Mr. Bryce Quick, and before he reminds me, he is also my boss, so Mr. Quick.

MR. QUICK: And if this doesn't get out by noon, you are fired. It is good to be with you. As Robert said, there is a lot going on on Capitol Hill right now, and we thought it better to send Rob up there. There is a number of amendments that may come up

on the Senate appropriations side, so he is up there monitoring those to see what damage the Congress is going to inflict upon us. But what I am here to do is give you a quick legislative update on the bill that is the most important to us as an agency, and that is the appropriations bill. And we have been waiting -- it has been a long, long process this year, as it was last year. We have gone through our second CR now, and they are threatening to go into another CR, possibly, up to January 15 if this bill doesn't pass today and if they don't convene a conference sometime this week. So I am going to quickly run through our budget request, the funding that we got, the new initiatives that we asked for, the 2004 appropriations, what happened in the House, what happened in the Senate. If you have any questions, please stop me, or you can ask at the end, and I would be happy to answer those. We, initially, asked for $797 million from the Department, for a total of $899 million after you factor in the existing user fee money. It represents an increase of about $42 million, and I will cover some of those costs. Basically, what we are going to do, I am just going

to -- I have captured some of the initiatives, they key initiatives that we have asked for -- $5.7 million to expand our training programs. There is a very high level of interest on both sides of the aisle and both sides of the Congress to improve our training, and the $5.7 million that we are asking for this year, we are hoping we get this. This is a start, and Congress is aware that this is only a start and that the number will have to increase in the out years, the next three years. We anticipate this being a larger number, but it will incorporate our public health focus and allow us to make the changes within the plants that we want to as an agency to get us to a public health focus and integrating the scientific principles that Elsa Murano, our Undersecretary, and Dr. McKee have outlined for us as a food safety agency. $1.7 million to establish a continuous baseline program. $4.5 million to provide additional microbiologists, chemists, laboratory technicians to increase our ability to identify adulterants in meat, poultry, and egg products. Additionally, we have asked for $4.3 million to increase

the size of our workforce to take into consideration the growth of industry. This represents 80 new positions. $1.8 million to help us in our audits overseas. We will be able to go from 33 to 40, I believe is the number, with the $1.8 million that would go into our foreign -- our international programs office. $1.5 million to help us in our education efforts. This is one of -- Dr. Murano, when she first came on board, one of her key goals, one of her five goals, was to improve the education and outreach efforts we do to consumers from farm to table. So we are hopeful that we get this -- $1.5 million is a drop in the bucket. We could spend that in a day on education, so we will -- and the Congress knows that we will be asking for additional funding for this. The House, on the 14th of July, this is the first action we had on our appropriation bill, passed the bill, giving us $785.3 million. Depending on whose accountant you talk to, this represents a $30.4 million increase. Really, if you look at the way the numbers are juggled, it really gives us our $42 million. But they are paying for, in this bill, increases on the pay raise. All the federal employees get a number of other accounting gimmicks that will have to be worked

out in conference. The Senate Appropriations Committee on July 17 approved its version in Committee, and that is what has now moved to the Floor yesterday. Like I said, you see a little bit of difference there. Really, after you look at the numbers, there is about $1.5 that is not accounted for that will have to be accounted for in conference. During consideration of the House bill on the House Floor, the House rejected an amendment that would have actually struck the section of the bill; it would have stopped the implementation of COOL. This is a very controversial issue that, as many of you know, has halted the action, and it was a very spirited debate, and it will go into the conference as well, and it generates some major fireworks, and we are expecting the same. They rejected an amendment by one vote, introduced by Gary Ackerman of New York, that would have prohibited us from spending funds on the human consumption if it comes from nonambulatory livestock. And for us as an agency, it is a very difficult issue. And AFIS, we are in agreement with AFIS that if this bill were to survive the conference, it would make our efforts to do surveillance for BSE and other diseases within livestock very difficult. And so I assume that

Congressman Stenholm and others that led the fight on the House side to defeat it will be very active when it goes to conference, because yesterday it did pass by voice vote in the Senate. And what this means is it is a weak vote, but it is still in conference, and they still have to iron out the differences, and they are going to have to fight it out, so we will just hold our breath on that one. Let me see. This is basic language from the House bill. I have explained this. This is the differential. The second bill is the differential between the House and the Senate that they are going to have to iron out. The Senate has different accountants than the House, and it usually works out and we are hopeful that it will work out. Humane methods of slaughter is something I think most of you are very familiar with. We received $5 million in the last appropriation bill last year, and we were to hire 50 FTE's for the sole purpose of doing humane methods of slaughter enforcement. And we as an agency take this very, very seriously, and it has become a key priority for the agency, and we think that we are well ahead of the number required by Senator Byrd and others on humane methods of slaughter. As I said, that would allow us in

the Senate bill as well to hire 80 additional inspectors for the growth -- taking into consideration the growth of the industry. The $1.77, we rounded up, so it is about $1.8 million on the foreign equivalencies. We went through that. Like I said, it is supposed to pass today. If it doesn't pass today, if the 30 amendments do come up that are anticipated, Senator Frist has let the Chairman of the Appropriations Committee know that he will pass the bill, he will uphold the bill, and we will be stuck in a continuous cycle of CR's, so we are keeping our fingers crossed and hope that some of the senators wait until conference to introduce their amendments if they want to do so. But who knows what is going to happen over there. Any questions? Thank you.

MR. TYNAN: Well, that was easy. Okay. There are no questions at all? I am going to check -- I didn't see Kimberly come in. Is Kimberly here? I will leave it to you. We can do issues and things of that nature, or if you like, we can take a quick break. I think we have been going pretty strong.

DR. MCKEE: Let us take a short break and give her a chance to get...

MR. TYNAN: Why don't we take a short break,

maybe ten minutes.

[Recess]

MR. TYNAN: ...Lieutenant Commander Kimberly Elenberg and Lieutenant Commander Jenny Doan, and they are going to be here for the Consumer Complaint Monitoring System. And Kimberly just assured me that she had a white knuckle ride in a cab getting here to help us out, so she has probably lost about ten years on her life, but I will turn it over to Kimberly.

MS. ELENBERG: Thank you. I am really excited to be here. Last year, we presented this to the Committee. We had set up this Consumer Complaint Monitoring System. We had set up operating procedures to take the tool that the Consumer Complaint Monitoring System -- and use the tool in a very effective manner. And we have had a year with great growth, and so I am just really happy to be here and really grateful for you all to be here. Okay. So I am going to give a little background. There are some new faces I see. And I want

to start out by telling you that this is an electronic database. This electronic database was created so that all of the complaints coming in from consumers across the country could be centralized and looked at in a manner that can take in the entire country. So in other words, if you have an establishment X but it distributes to multiple states, and some of those states exist outside of a district, we can still see the implications nationally. So in other words, each district isn't just looking at what is happening in their district. Some person in headquarters is looking at what is happening in all of the districts and putting the big picture together, and working with each district then to effectively manage and investigate different complaints. The electronic database is used to record and triage all consumer complaints. There are multiple ports of entry. We get complaints from the states, we get complaints from FDA, health departments, AG departments, and from consumers themselves that come in, sometimes through the districts and sometimes through the 1-800 hotline. We implemented it in November 2001, and by last fall it was in all 15 districts. The goals of the CCMS are to collect this data and use it to protect the

public health by identifying different food hazards that have reached commerce that are related to FSIS regulated product. It also supports and augments Homeland Security, and we do this because traditional surveillance systems take in traditional data, things like lab confirmed foodborne illnesses. But in order to get a lab confirmed foodborne illness, a person first has to go to the doctor. The doctor has to agree to take the lab, and there is not much incentive to do that from HMO's because you can support a person who is sick with IV fluids without having to pay for a lab to test it. And then we have to hope that the information gets to us or to CDC. And in the literature, only 30 percent, apparently, of these cases actually get reported. There is a lot of -- I thought the doctor sent it, and the doctor thinks the nurse sent it -- things like that. So by giving consumers a voice, we are giving them an opportunity to give us information that we might not otherwise capture. When we have an outbreak that might be related to something that is intentionally introduced, it might be a pathogen we are not used to seeing so there might not be a traditional culture test for it. And the database that we are

building, or enhancing at this point, will have that ability to identify by geography, space, and time, new things that are happening, and therefore, has the possibility of identifying emerging pathogens that are either occurring naturally or intentionally. Okay. CCMS is housed -- the Consumer Complaint Monitoring System is housed in the Health and Human Sciences Division here in the Office of Public Health and Science. We have algorithms that were created by representatives from Public Health, representatives from biology, chemistry, toxicology, and field to identify, come up with an algorithm that helps us identify the potential food hazards, and to identify when we need to initiate an investigation. We don't initiate an investigation, necessarily, on every single complaint coming in. Sometimes we gather more information for clarification and sometimes we do initiate an investigation if we have two or more like coded complaints, then the intensity in the investigation accelerates. So in other words, if we have someone who says I have a tooth -- I found a human tooth in my soup, we might look and say, well, there is no other complaints like this. It is not necessarily a public

health threat and we may not initiate an investigation. We may, instead, choose to seek clarifying information. And in this particular case -- with that particular case, it was a real case, the wife had lost her tooth and didn't tell her husband. However, if we get two complaints in and the people have -- it is amusing at times. But if we get two complaints in and there are two people who live in geographically different areas but it is a complaint related to a product from the same establishment, and it is the same product, and the onset time of their symptoms are the same, and the types of symptoms they have are the same, then we are definitely going to initiate an investigation because it is possible that there may be a public health hazard there. The Office of Field Operations works -- we work collaboratively with them. They are wonderful. All communication regarding consumer complaints goes through the CCMS. Once the complaint reaches CCMS and we triage it to see if we are going to initiate an investigation, we then shoot off into the case notes and write the Field Ops a little note, kind of like, we are initiating an investigation, this is why, could you please collect this sample, we would like it sent to this lab, and we

would like it tested for this. And could you go ahead and take a look in the plant and see what is going on there. And I have some case studies where I can go more thoroughly into how that actually works. We get feedback through those case notes and then we move on into another analytical phase where we decide what our next step will be. Sometimes something turns out to be nothing and we can go ahead and close the case. Sometimes it turns out to be something that warrants an 02 procedure in the plant. In other words, a closer look at the HACCP procedures. And sometimes it leads to recall. We also work in conjunction with the technical center. One of the things that they are doing is looking at the data we are collecting and linking trends to establishments to improve programs. Right now, it is a little bit difficult for them to do with the type of -- the way that we collect data, so we are working

with them on improving -- not improving, but manipulating data so it is data that they can use, and trying to make it as agency-wide as possible for support. Okay. In addition to OPHS, and in addition to the field, and in addition to the tech center, we are also working with the School Lunch Program. So all complaints involving FSIS regulated product are now getting entered into the CCMS and we are working in conjunction with the outbreak branch and the state and county health officials when we are getting school complaints that involve illness. Furthermore, right now I have a bullet up there that says provide service to F&S and AMS. That is the school lunch program, in specific, that I am trying to address here. And I do introduce that into a case study. So I am going to jump down there now to talking about the analysis of these elements between F&S and AMS and our need to establish this bi-directional communication with them. So the tech center that I said we worked with has only one direction of information. They can read only into this information. They cannot write into our case notes. They don't have anything to do with the individual cases. However, the school -- and the same thing with

the School Lunch Program. We get the information from them, we do the investigation and provide it back to them. However, with the field, that is bi-directional flow of investigation. Now, when I talk about needing to increase this bi-directional flow of investigation, what it means is right now for the School Lunch Program, we get pieces of paper from their database and we have to manually enter it into our database. And as I said, our data elements don't exactly match, and so what we want to do is automate that procedure so that it happens in a more timely manner. Okay. As I said, data enters the Consumer Complaint Monitoring System primarily through the OFO, the Field Operations and hotline, and it is the compliance officer and the EIAOs who are responsible for clarifying that data and carrying out the investigation. The SOP's, the operating procedures for that, are located on the CCMS toolbar so that any person who is coming into the program and is new has the obligation and opportunity to review those standard operating procedures. We are working with the field officers to have a QA program so we can identify who in the field has read those SOP's and come up with a means for testing them, and that is a web based design that we

have initiated on those education modules and that test their understanding of those operating procedures, and that is a current project underway. We control -- the Health and Human Science Division now controls access to the CCMS, which is different from last year, and that also increases our security. We know who each user is, and why they are using it, and what type of data they can get out. Because as I said before, not every user needs to have the same use ability with the database. The tech center doesn't need to write in it. We don't wan to accidentally enter case notes that would be erroneous. We don't want anybody to accidentally delete a case note. So capabilities within the database are defined by the person's job. Okay. The Consumer Complaint Monitoring System has been a very successful tool in coordinating the case investigations throughout the United States and its territories over the past year. Right now, our current search capabilities are pretty simple. They are by product brand and product name and by establishment number. That is something we are working on right now. We are enhancing the database so that search capabilities, as I said, take into consideration geography, time, and space; take into

consideration matching different elements of symptoms. Right now, all of that analysis is done by hand. It is very time consuming. So it is not that that analysis isn't being done; it is just that our capabilities within the database are limited and are not able to do that right now. However, as I said, we are completing a statement of work that architects the ability to do that through the database, and we anticipate in December making an award on that. Okay. One of our case studies, I told you I was going to -- we are very happy with our success. The primary success of the Consumer Complaint Monitoring System is that it allows us to see how a HACCP in a plant is working -- is the HACCP procedure in a plant effective or is it not. If I am getting in complaints that regard wood or I am getting in complaints that regard metal, then that critical control point for wood or metal in that particular plant probably needs to be tweaked. And this gives us this information. It allows the inspectors to go in there, to do the 02 procedure, to look at the HACCP, and say, okay, we need to fix this. So that is the everyday meat and potatoes of the CCMS is that it allows HACCP assessment. Now, sometimes we have bigger implications

from the cases we find. This is an example. Earlier this summer, we identified two boys. We got two reports of lab confirmed *E.coli*, 0157:H7. At that point, we had not heard -- the information did not come directly from the state to us, so we immediately contacted our outbreak branch, and they work directly with the Department of Public Health and Environment of that particular state, and conducted an epidemiological outbreak assessment. And in the end, what ended up happening was a recall of 194,700 pounds of ground beef that had been potentially contaminated with *E.coli*. A second example of the effectiveness of this tool has been a case where we received complaints of a student having his esophagus lacerated by bone in product and needing surgical intervention. It happened at school and there was a profuse amount of bleeding. Now, bone isn't inherently considered a foreign object in a product like chicken, and that is what this product was, but this is a very vulnerable population, and this was not the first injury we had received on this, and we also had complaints from commerce, people in commerce, on this particular product. So what we decided to do was take this product, send it to the lab, let us

measure and see what size bones are really showing up in this product, what does the specification say, the contract specification say, between AMS and the producer who was making the product, and let us see what we can find in this. and what we found was the bones were -- they were not as large as what was allowed in the specifications, and yet, we were having injuries. So we were able to go back to them with medical literature and objective information and work with AMS to change the contract specs to what would be considered a safer size bone, if bone should get into the product. It did result in a change to the AMS specs. It also led to a recall of the product from the schools. And since that date, I have not received any injury, whether it was from commerce or whether it was from the School Lunch Program on this product anymore. So that was pretty significant. So in general, going back to CCMS and looking at its potential for future, what have we learned when it comes to epidemics? When you look at the SARS epidemic, that is our most recent epidemic, we saw that time was very valuable. Had we known about this outbreak in Hong Kong, maybe we could have prevented it from spreading. Okay? We are a very

globalized world. Agriculture and its distribution is very globalized. If we are intentionally attacked using a number of biological agents or chemical agents, the amount of time it takes to detect the presence of those agents affects morbidity and mortality. So as I said, under the first bullet, I can't emphasize it more. Under the right circumstances, epidemics can spread very quickly. The world is smaller as we become global, and the traditional surveillance depends on knowing what the pathogen is and having a test that can already identify it. It also takes time to develop a culture, and you need someone to go to the doctor to have the culture drawn, and the doctor willing to draw it. This is a slide from DARPA. It is a very good graphical representation of what time can do. You see over on the left-hand side, zero, and over here, time and hours. So this 144, or time in actually gain of days. So you can see that with traditional disease detection, the red line, that the incubation period and the time to identify this illness can take a number of days. I am sorry -- the bottom line is hours. The lines there represent, between the blue and the red, a gain in days of two times. The blue reflecting early detection

through nontraditional data collection and the red reflecting traditional disease detection. This early detection can allow for an effective treatment period that might be lost, and that happened with the anthrax outbreaks a couple of years ago, where there was no early detection of anthrax. We weren't anticipating it. It was actually traditional detection through a clinician, not through a lab culture, though. And unfortunately, we lost a few lives to that.

MS. ESKIN: What is DARPA?

MS. ELENBERG: DARPA is a group that has a military base that looks at the different scientific problems. This was -- now I am having a brain cramp. I don't have my notes in front of me and I apologize. Go ahead.

DR. LOGUE: Catherine Logue. As far as I know, it has something to do with DOD, Department of Defense. I think it is advanced research projects.

MS. ELENBERG: Right, but there was a group, in particular, who came up with this that was just disbanded. So they were -- I can't believe I am cramping up, but anyway, the point is that early detection saves time and can mitigate morbidity and mortality. Okay. So do we have the legal mandate to do this type of surveillance? Yeah, we do. We have the mandate to collect information for public health purposes, for the purpose of mitigating an outbreak sooner than later. We know that September 11 changed the way that we look at the world around us. This Consumer Complaint Monitoring System will support Title 3 of President Bush's Bioterrorism Act which specifically identifies agriculture as being vulnerable to a bioterrorism attack. However, as I said, as effective as the Consumer Complaint Monitoring System has been in helping us assess HACCP, in helping us identify outbreaks, it is all done by hand. All the analytics are done by hand. We have multiple databases that contain information that is important to us. We have the recall database. We have the labs with their data. We have state health departments with their data. And then we have our data as well. And we need to get

them to communicate together. The receipt of data from states and laboratories is not timely. It is still hand faxed. As I said, that is a lot of -- I thought this person does it, I thought that person does it -- so we are not necessarily receiving all the data. It is cumbersome to navigate within the database. It is a lot of going in and out of screens. And it is not using state of the art technology, and that would the computational and detection algorithms that can help with this analysis. So our goals are to increase the ability to harness relevant information. We want to provide a graphical picture of the analysis and the data so it is easier to interpret. When we go to Code 2 or Code 3 with Homeland Security, we need to issue reports daily to them on the status of the database, and a picture can give you a very quick -- a picture can illustrate very quickly what is going on. We want to increase our support to the local district offices, since they are our responders, and we want to be able to disseminate information very quickly between the agencies that need it, which would be us, the state health departments, the centers for disease control, because outbreaks are their responsibility, and the tech

center. And we also want to have collaboration with each initiative. We would like to have a portal of entry for the database through the worldwide web. Okay. Basically, what this slide is illustrating is that we also need a method for rapid alerting. When we get the information in, if it is identified, we need to be able to do this 24 hours-a-day, 7 days-a-week. So in order to do that, we need to have a rapid alert system; in other words, rules. If three complaints come in like this from the same establishment, my Blackberry goes off. You know, so that the database can be covered on weekends, as well as evenings, as well as holidays. We also need to have information sharing. Okay. The system platform is built on the NED system platform. NED is the National Electronic Disease surveillance system, and that will give us interoperability with the states. States can no longer get funding from CDC and their public health departments for IT initiatives unless they meet these standards, so I believe these are the technical standards that will be the national standard. It is also nice to know that this is the standard that seems to be -- it is being adopted by the vet community; in other words, a state of messaging. So

if you have two databases, but they are separate fields, in order for them to communicate, traditionally, you have to have the same fields. But imagine, if we want our database to communicate with all the different veterinary health, and all the different human health, there is no way we can match our fields to them. And so when I talk about standards, what I mean is that you will use a messaging standard, like health level 7 is a set of standards that says when your information leaves your database, it will look like this. It will go into a repository and your receipt end on this -- will be able to accept the information looking like that. So in other words, like when you -- each of these plugs along the wall looks the same, and each of the wires at the end of them has a two-prong, and it goes right into the plug. So in other words, it is kind of like that, so that they can communicate no matter how many systems are integrating with each other. And it will also -- the other thing that NED allows us to do, the National Electronic Disease surveillance system standards allows us to be compliant with HIPAA. And what HIPAA is, is the Health Insurance Portability and Accountability Act of 1996, and it requires that information that is

exchanged electronically maintain certain safety standards so that people's information can remain private, your healthcare information can remain private. We do not necessarily have to comply with HIPAA according to the definition in the law. We do not provide healthcare. However, state health departments do provide healthcare. They provide mental health, they provide other different types of healthcare, and they have to comply. And so in order for them to feel comfortable exchanging information with us, we need to be compliant and assure them we will protect information contained within those lab results that we get from them. Okay. Once we do collect the data, what are we going to do with it? We are going to try and detect abnormalities. We want to gain actionable intelligence from it. There are different models to do this. We already talked about looking at things not just linearly, but in a multidimensional way, time, space, geography, symptoms, things like that. There is going to be noise. The type of data we collect is not traditional data. It is consumer complaints. Some of it is traditional; that is a small percentage. That would be the lab confirmed illnesses. The part that is

not traditional are the ones that call up and say, I don't feel well and these are my symptoms. The tooth example was provided as kind of some of that noise. Okay. We recently had an outbreak in a state, a woman got ill, the state pulled all the product off of the shelves. I couldn't understand why. We went and we talked. We had the epidemiologist talk to the state to find out what happened. They just did it. We ended up getting two more complaints from that area, from that county, but when we really looked at it, it was different product, it was different production lots, different production times, and so it was noise, and we know we are going to have that. So we are going to have to look at how we are going to handle that within the database. Some of the ways we can deal with that is we are going to train field officers on trying to collect the best data as possible, not just I had a stomach ache and the doctor said I have food poisoning -- you know, what does food poisoning mean -- is it a lab confirmed foodborne illness. We also want to look at using different filters. Filters are just things that say, you know, it is the tooth, it is not really a public health hazard, so we don't need to maybe necessarily

investigate that. And we want to try and identify -- I think there is going to be confounders and other noise that we are not aware of right now, things like seasonal increases in complaints. Also, if you hear that there is an outbreak, and then all of a sudden everybody else gets sick, it is kind of like the elementary schools, they are a little challenging. Well, not just the elementary schools; all the schools. If one kid gets sick and throws up, all of a sudden 50 kids are throwing up, but most of them, maybe ten of them ate the hamburger, but the rest didn't, but you know, they were next to the person who threw up, so they threw up, and you know, that sort of stuff. Okay. So in conclusion, the Consumer Complaint Monitoring System is going to adopt and implement standard based technology. It will be integrated with other databases and with other HHS agencies that wish to be integrated with it. It will have interoperability within the agency, with the tech center, with R&D, you know, that would be recall -- with jut different parts of the agency. The computational and the detection algorithms will contribute to the intelligence, will help us with the analysis. It won't remove the human element, but this way, I don't have to

print out 30 cases and wit with a highlighter and try and match all the codes and everything like that. It will help me do that. And it will result in progress towards identifying any food hazards in commerce. So currently, the red line demonstrates the current CCMS. And you can see from its implementation in 2001, our ability to identify any acts of bioterrorism has gone up because we went from nothing to having complaints come in from 15 different districts, to having a central database, and having nurses triage every complaint that comes in, to going down after 2002, and that is because as we increase the number of cases we get, our ability to analyze each of those complaints for relationships by hand is getting more difficult. And so it will lose its effectiveness if we don't get some help, some computational help from the database itself. With the computational help, I think that our ability to increase bioterrorism capabilities will just continue to increase. Okay. I am sure you probably have lots of questions.

MS. ESKIN: Sandra Eskin. This system went into effect almost two years ago, approximately?

MS. ELENBERG: Yes.

MS. ESKIN: Do you have the actual number of the number of complaints -- I am just curious -- that have been submitted, and maybe broken down this many in the first year, this many in the second year?

MS. ELENBERG: The number of complaints has not significantly increased. We got close to 1,000 in each year. It is not really well publicized out there, I don't think. If I ask my neighbors if they know about it, they don't yet. We know we need to increase the denominator, and we know we need to increase the number of cases. We have been working with our congressional and public affairs group, and we have developed a communication plan, both for internally and externally. We needed an opportunity to develop the operating procedures and we have done that. And we feel now that we have operating procedures in place that can support this tool. We feel that we have an effective tool for looking at it, and so we are moving in that direction of really making sure people know about it.

MS. ESKIN: Can you share with us maybe some aspects of that plan to better publicize and disseminate information about the system -- is it like public education or -- I mean, you are gearing it to various

audiences, I assume.

MS. ELENBERG: Exactly. Gearing it to various audiences, yes. It includes public education. We are looking at hiring an additional person specifically to make contact with each of the states and really let each state know that this is there and we are available to them. We don't feel that the states necessarily know that we are there for them. They know FSIS is there for them, but the mechanism for getting this. So they are getting us information and we are collaborating. We want to enhance that and enhance that knowledge. What we want is -- the states know. We want the local guys to know. We want people to know. If there are consumer complaints, we want people to know. We have a bus that has gone out. We are going to work with the school bus -- what is the name of that bus that goes out? It is a beautiful bus on our website -- yeah, the Food Safety Mobile. So we are working with them to get it out, and that means we are looking at putting out announcements in the newspapers. We are looking at putting out announcements like through the morning talk shows, things like that. That is in its really rough draft, so I can't obligate what we are doing.

MS. ESKIN: I understand. There is the 1-800 number that is the hotline. That is the number that people can use to call?

MS. ELENBERG: Exactly. That is one means.

MS. ESKIN: Okay.

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. I am on a committee with the Association of Food and Drug Officials, the Food Committee, that is at this time examining the entire system of collection of foodborne illness complaints, and follow-up, and so forth, and we are trying to identify what weaknesses the system has, or systems have, and come up with some sort of recommendation for addressing those. And so I would like to talk to you maybe a little bit later and get your card.

MS. ELENBERG: Certainly.

MR. GOVRO: But to that end, I think part of the problem that exists is that there are so many different systems for collecting and evaluating that information and the lack of communication between them. And I would like to offer that I think it might be confusing for the agency to put this complaint system out there to the general public as a means of putting

that information into the system. I think most of the time foodborne illness complaints traditionally go to county health departments, local health departments, and I would think it would be more effective for the agency to solicit that information from the states and locals so that you get a lot of -- and focus your efforts on making sure that all of the state agencies and local agencies are aware of the system and that you would like to receive that information. I think it might be confusing for the consumer to have a number of different options as to where to call in a complaint. That is my opinion.

MS. ELENBERG: One of the things that the case study did demonstrate is that sometimes information doesn't get to go where it is supposed to go, and so this is kind of a back fall. The system doesn't collect just information on food illness, the Consumer Complain Monitoring System. It is all consumer complaints, so that includes metal or wood -- you know, any of the foreign objects. It includes potential economic adulteration, it includes illegal activity, which then would be vetted over to the Office of the Inspector General. So it just gives consumers a place to complain

and keep it generic like that. The amount of information we get on foodborne illness, a lot of times, like I said, it is not lab confirmed, and we do share the information back with the state and county health departments. When we feel that the information has come to us that is not our jurisdiction, we immediately send it to the state as well. States have often gotten complaints that are on FSIS regulated product, and they send it back to us. So you are right. We do need to enhance our relationship with the states, let them know we are there, and get a more bi-directional flow of information. However, as I said, the Consumer Complaint Monitoring System, it is actually relatively small; 25 percent of the complaints are related to illness; the rest are foreign object and others.

MR. GOVRO: Do you prefer to receive complaints that are forwarded to you from the states or local agencies through email, or telephone, or do you have some contact numbers that you could give us?

MS. ELENBERG: Right now, the way we receive them, sometimes the states go straight to our district offices, and that seems to be a good way to go because then each district office can enter it, and we analyze

the information. But that is part of the problem, is that you have that duplicate data, that duplicate entry, you can make mistakes. That is why we want to automate the ability to communicate with the states. But yeah, I think going through the district offices is the best approach.

MR. TYNAN: Other questions for Lieutenant Commander Elenberg? If I remember my military days, I don't remember any lieutenant commanders looking like that, but I think you are done.

MS. ELENBERG: Okay. Thank you. And can I just say one thing then?

MR. TYNAN: Absolutely.

MS. ELENBERG: Okay. I just really wanted to emphasize that it is exciting to see when something is very effective. It has really helped -- this database has really helped us cut across all the different parts of our agency and work collaboratively together. It has been very effective in really doing that HACCP assessment, and it is exciting. It is really exciting to see how this is working out and playing out. Thank you.

MR. TYNAN: We have two items left on the

agenda, one to talk about next meeting and remaining issues from this meeting. And then we have a short public comment period. So I am going to perhaps turn it over to Dr. McKee to do the remaining issues and follow-up items. Before I do that, however, I do have some dates. Sonya was good enough to identify some dates for our next two meetings. So we have tentatively scheduled June 1, 2, and 3, so we have those blocked out. If you could confirm for me, we will plan on doing it on the 1st and 2nd of June, but we have the 3rd sort of as a slip date if Wednesday and Thursday, as it did this time, Wednesday and Thursday works better, we will use those two dates. But for now, we will plan on Tuesday and Wednesday of that week. So it will be June 1, 2, and 3. We also have -- and this, we don't have any slippage with. It would be November 3 and 4, which is Wednesday and Thursday. So that will be our meetings for 2004.

UNKNOWN: Is that election day? Is that the first Tuesday?

MR. TYNAN: I don't know. We will have to check on that.

UNKNOWN: Election Day is the 2nd.

MR. TYNAN: Okay. We will check on that and

be sure. But at least -- okay. For now, we will have June 1 and 2, and as I say, if you could confirm for me that that works on your schedules? And as I say, if you prefer Wednesday and Thursday, we will try and accommodate that as well. And we will check on November. And with that, I will turn it over to Dr. McKee.

DR. MCKEE: Okay. Thank you, Robert. Well, I think we have had a very successful two days. I think it is very informative to get your input on the process and we will certainly identify subcommittees and information that needs to go out to you in advance next time to make that work easier. Also, we had the list of recommended topics as well that we will be looking at in the agency to identify your desires to talk about some of those at the next couple of meetings for next year. Is there any -- I will just open it up before we go to public comment, if there is any other additional kinds of comment that you would like to make as far as any remaining issue or issues that you didn't get to bring to the Committee as to how you would like to see it handled differently or any of those comments. And of course, any time that you have anything beyond this

meeting, you can certainly send those to Robert, and they come to us. Any comments that the Committee would like to make? Mr. Govro.

MR. GOVRO: I think I said my peace earlier.

DR. MCKEE: Okay. Well, I think with that, we will move to public comment. We have -- we will go to the public comment sheet for those that signed up to make comments. Again, we want to focus on the issues and the items that have been discussed over the last two days, and if you would limit your comments to three minutes. We have one that has signed up, and then I will open it up after that to anybody in the audience that would be interested in making comments. If you would, when you comment, if you will state your name, who you represent, and then your comments. The first that I have on the list is Mr. Danny Hughes.

MR. HUGHES: Thank you, Dr. McKee. If you all can bear with me, I have got a touch of something going on here in my chest and voice, but I will limit my comments to things that has been said or discussed here. As it relates to cooperative agreements, memorandums of

understanding, I would just like to say that that is a two-way street, and I can't speak for all districts, the 15 districts. I can speak for one. When cooperative agreements become one-sided, it makes it very difficult on the state trying to maintain that cooperative agreement. Well, I will just tell you, we lost our cooperative agreement, September 30, on an egg products plant. I know very little about the State meat and poultry inspection. We don't do that in Arkansas. I guess I question something that has come up that sounds like the state inspector's integrity is questioned as it compares to a federal inspector, where a state employee or someone might give a small plant or any plant a break. I don't think, or I don't know of a state employee, and I have been in associations for 31 years as it relates to eggs and egg products. I don't know of any of us or any of our inspectors that has been in bed with the plants. And it does kind of hurt when you hear someone make a remark that would question the integrity of the state people. I think their efforts, their desire towards a good public health system is just as important from a state inspector's standpoint as a federal inspector. And I would just like to ask FSIS to

maybe work closer with particular districts to try to maintain good working relationship with the states in the various things you have asked for, the state's assistance in data collections, biosecurity, and I think all the states are very willing and want to do that. But at the same time, then we would like the opportunity to continue doing work for FSIS. It helps our programs, it is good for our programs, and I don't think all the problems that you feel like is related to the state inspection is totally the state inspector as it is FSIS supervision. And I think most state employees, especially, in the mandatory plants, 95 percent of their efforts is under total FSIS supervisory control. I don't think dual jurisdiction as it relates to a state supervisor or state administrator gets involved but very, very little. They want the FSIS supervisors to give instructions to their people and expect those people to do as they are told. The only time that there would be an involvement from a state administrator, I think, would be if they were contacted by FSIS District Office and told that we have a problem. In my case, that didn't happen. And I also think under a cooperative agreement, when you are canceled, you should

at least get a letter giving you some reason, and not just a three-sentence page telling you that effective a certain date you no longer have a cooperative agreement with us. So that is all I have to say. Thank you.

DR. MCKEE: Okay. Thank you. Do we have any other public comments from the audience? Bernie.

MR. SHIRE: Thank you. My name is Bernie Shire. I am with the American Association of Meat Processors. We are a trade association that represents mostly small and very small meat and poultry processors, slaughterers, and others. Our members include both federal and state plants. We also have about 30 affiliated state associations with us, and most of their members are small state inspected plants. I want to talk about, briefly, two issues that were raised during the past two days. The first has to do with risk-based inspection, and there has been a lot of talk in the agency lately about risk-based inspection. We want to encourage the agency to move forward with this idea. The whole idea of having inspection based on various

risks to the consumers is something that our association has supported for a long time. We think that the agency needs to look at several different areas when it is setting up and moving toward more risk-based inspection. First of all, not only the products themselves, there is a certain amount of risk there, depending on what they are but, also, the populations that consume those products. For example, elderly, immuno-compromised people, and the very young. Those things need to be taken into effect as well. I also wanted to mention, briefly, the whole idea that the agency is now moving toward, basically, a team approach and putting -- and using inspectors more effectively. We would also like to see that happen. Last night at one of the subcommittee meetings, Barb Masters used as an example, situations where you can have a plant that has an inspector there all the time, and the inspector is doing maybe 2, or 3, or even 400 percent of his or her job because he never goes anywhere else. Whereas, you have another setup where an inspector may go to three or four different plants. This is one of the things that we think needs to be evened out so that the inspectors are used in a more efficient manner, and we hope that

happens. The other thing I wanted to talk about just very briefly has been addressed by other people, but I would be remiss if I didn't say something about it myself. Over the past two weeks, I have been to three different meetings where there has been discussion about state inspection and state plants. And in those meetings that I have been at, three different times there have been comments made by USDA FSIS officials about concerns about whether in state plants and in state inspection programs that the same kind of inspection is going on or not. I think this is, really, totally uncalled for. One of my responsibilities at work is to deal with calls from various members of ours and other small plants who are having problems with inspection, and I can assure you that we get as many calls from people who are in state inspected plants or in TA plants as people in federal plants. These people don't get an easier row to hoe because they are in state inspection. Lee Jan mentioned this morning the fact that -- he mentioned the possibility that in some ways it is more helpful for small plants to be under state inspection, not because they get breaks -- that is not the situation. They don't get breaks, but sometimes

they get more advice from small -- from state inspectors than federal inspectors. I can tell you that when Jay Winthrow, who is here with me today and yesterday, and myself, and we handle -- we get calls from our members and from other small plants, they are not calling us to ask us for breaks or how to get around the regulation. They are asking us for help in how to comply with the regulation, and we try to give them help in that area. And I think that needs to be said, and I think everybody here needs to understand that, that small plants are not looking -- and state plants and small federal plants are not looking for breaks, but looking for ways to comply. Unfortunately, some of the rules that have been set up by the agency are, let us say, more large plant friendly than small plant friendly. An example of that would be the recently enacted ready-to-eat listeria rule, and that is unfortunate. There it was set up where you have three alternatives, and unfortunately, most of the very small plants are put in alternative 3, which is sanitation. And unfortunately, what can happen down the road after a certain period of time, a plant is going to have problems with sanitation. Some of our plants are trying to do the second alternative, alternative 2, but

they have difficulty with that because when they make changes and add things to their products, it changes the nature of the product in many instances, and it ruins the product, and that is a problem. So plants were put into this third category. Now, we are hoping we can work with the agency to come up with ways to make this easier -- not easier for the plants, but easier for them to carry out the regulation in a way that the agency has directed.

DR. MCKEE: Okay. Thank you, Bernie. I appreciate it. We have had a lot of dialogue about the state inspection system and the surveys that we are doing, and let me just be on the record as saying that FSIS views the state programs as equal, or we wouldn't by statute -- couldn't allow those operations to continue. The challenge that we have, directed by Congress, is to document in a comprehensive way that, indeed, that we have a standardized system within this country given the different structures within states. I spent 30 years of my career in the state system in Oklahoma and Wyoming, and I can assure you that I understand the challenges and I understand the issues

involved not only with budget, but political structures and others, and how helpful it is to be able to say, we have to do it this way because this is the national standard. And that is where we want to go with this, is to support the standardization that all plants -- and we have reached out as much as we can. States clearly play a part. They know who their customers are. At the same time, we have to develop strategies in order to make that system as effective and efficient as it can be, and we have had some dialogue about that. We will continue to have dialogue in the future about that. But clearly, when we talk about, especially, not just food safety, but Homeland Security in the food supply -- I was in the State of Wyoming when they had the anthrax outbreak, and I can tell you it is a local issue, and that that is where the first responders are, and you will see the same thing occur in food. I am very cognizant of that and how that is important to our being able to respond appropriately, and at the same time, know that we have got the connections there to provide the response that needs to happen. So I think one of the values of this Advisory Committee is it focuses on state issues. It is an opportunity for us to discuss from all different

levels, and backgrounds, and expertise, different ideas and approaches as to how we can better tweak the system, if you will, to make it go in the direction we are wanting to in order to improve the public health and the food safety of this country. So I think with that, if there is not any other comments, that we will close for today, and look forward to seeing you at the next Advisory Committee meeting. And we will change our process to get the information to you, and again, if you think about something that you feel that we should know, we are very welcome to get those comments in the next several weeks. Okay. Thank you.

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[End of proceeding]

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IN RE: NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION MEETING

HELD AT: Washington, D.C.

DATE: November 6, 2003

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