ADVISORY COMMITTEE

UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE: PUBLIC HEARING

NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY

INSPECTION MEETING

Hearing held on the 5th day of November

at 8:30 a.m.

Washington Plaza Hotel
#10 Thomas Circle, N.W.
Washington, DC 20005

TRANSCRIPT OF PROCEEDINGS

BEFORE: DR. GARRY McKEE

INDEX

P R O C E E D I N G S

November 5, 2003

MR. TYNAN: I want to welcome everybody to the fall 2003 meeting of the National Advisory Committee for Meat and Poultry Inspection. I want to thank you all for coming. As the last time, I know some of you have come pretty good distances, and I think in Jill Hollingsworth's case, she's not seated here, but she came in from the IFT meeting last night, and in driving up to the front door, apparently her car died, so the car is more tired than she is at this particular point. But I appreciate you all coming.

On behalf of the Agency, I welcome you to Washington, DC. Unfortunately, you missed the good weather. We had some nice days on Monday and Tuesday, but Kevin Elfering ensured me that it's better than what he was having in Minnesota when he left yesterday, so I guess there is a silver lining to the dark clouds.

Before we get started, there are a couple of logistical things. I shouldn't say a couple, actually a quite a few logistical things. I'm sure everybody has already seen the coffee and the pastries outside. Please avail yourself of that. Keep the sugar content

up and that should help us through the meeting. There are phones, if you are not cell phone adapted yet, as I tend not to be. My sons tell me I'm technologically illiterate. There are pay phones going out this door into what I call the sub-lobby and to the left. There should be some pay phones down there. There are -- set in -- going again through the -- into the sub-lobby, there are double doors going back into the main lobby, and you're -- men's and ladies' rooms are on the left-hand side, if you haven't seen those already. For those of you who will be getting phone messages, and I suspect that all of you will probably be doing that, again, if your cell phones are off, and hopefully they will be during the meeting, if somebody needs to get in touch with you, the number to call is (202) 842-1300. And I've been assured that the front desk will bring messages back, and we'll try and do that as quickly as we can so that you're still in touch with problems and issues back at your office.

Sonya is probably outside, but she asked me to be sure to make sure that each of you keeps track of travel expenses and sundry things for the meeting. She has a form that she will be sending out to you or faxing out

to you immediately after the meeting. So if you could, if you could either touch base with Sonya before you leave to give her your fax number or perhaps e-mail it to us, that would be terrific.

The microphones are a little bit tricky this time. They are not all on, and there is a reason for that. We are trying to control who says what to whom. No, just kidding. Just kidding. The microphones are -- have buttons on them, and so to speak, you must press the button. When we have four or more -- four on, then the fifth person will not be able to use their microphone, so we'll have to try and remember during the meeting, and I am assured by Terrence and Chris, this is Terrence here and Chris has gone someplace else, that they will reach over and hit me on the back of the head to remind you to cut the microphones off and things. It is a better system than the last time, so I hope it works very well for everybody.

We also have a meeting transcriber, and that is Tim. And Tim is over here, and he is taking a verbatim record of the meeting, and that will be put -- we will receive copies of that. We will do some editing, and hopefully we will have that on our website before our

next meeting. We are still in the process, actually, of editing the last set of transcripts, so if you're looking for that for any reason, it's not up quite yet.

Anyone that wants to speak from the public, if at the end of the meeting we have time for that or if you want to make particular comments on anything that is lengthy, then we'd ask you maybe to sign up outside with our -- the ladies outside and let us know that you're going to do that. We're also going to ask the speakers from the Agency that will be presenting issues and briefing papers to come up here to the lectern and do their presentations from here, make it a little more formal, and I think it will allow you to see everybody a little bit better.

I should also mention to you that I was -- it was called to my attention this morning that there is a small error in the agenda. And it relates to the chairpersons of the Committees, the Subcommittees that will be meeting this evening. And the Committee list I think that's in tab three is the correct one. So I apologize. We printed the agenda a few days ago. We found out that Charles Link would not be here, and we

had to make some adjustments in the Committees. Being prudent stewards of your tax dollars, we decided not to reprint the agenda to make that one switch, and I appreciate Dr. Carpenter calling that to our attention. There is also one last thing I will mention to you. There is a topic list, probably under the agenda, in the front of your notebooks. And Ms. Eskin, who is not here yet, asked for a listing of the topics that were submitted both by the members and by the Agency in creating the agenda that we have today. So that kind of gives you just sort of an idea of what kind of topics we started out with and where we came to in the agenda. So we can discuss that at some point during the meeting if there are any concerns that you may have about that.

I'd like to take just a minute before we get into the substance of the meeting to actually walk through the agenda with you, if we could. The agenda, again, is in the front tab of the notebook -- or I shouldn't say the front tab -- the front pocket of the cover of the notebook. So this morning, we're going to have some opening remarks by Dr. Merle Pierson, who is our Deputy Under Secretary for Food Safety. And Dr. McKee will be

making some opening remarks as well. Then about 9:15, and we'll probably be a little bit ahead of schedule, we're going to talk about operating procedures for the Advisory Committee meetings. And this is a function of my first time in June to kind of try to find ways to make it a little bit more efficient and effective how we do the various sundry discussions that we have during the session. At 10 o'clock, we'll be talking about increasing industry awareness of food security. That will be a briefing, and Dr. D. W. Chen, who is Acting Director of that office, will be here to talk about that. We'll take a break at 10:30, and at 10:45, we'll be talking about procedures for conducting inspection in Talmadge-Aiken plants. And Dr. Barbara Masters will be here to open that up and, I think, Cheryl Hicks of the Office of Field Operations at our Agency will be doing the presentation. That will be an issue, and that will have some further discussion this evening in one of the Subcommittee sessions. At 11:15, we're going to be talking about how can FSIS better associate food safety activities with public health surveillance data. And Dr. David Goldman, who is sitting at the table, of the Office of Public Health and Science, will be presenting

that topic. It, too, is an issue, and that will be discussed further tonight in a Subcommittee session. So we'll break for lunch, and I'm sure that's a moment that you will all be looking forward to. At one o'clock, we'll come back for a briefing related to FSIS recall readiness and response. And Dr. Ken Petersen, of our Office of Field Operations, will be presenting that. At 1:30, we'll be doing another issue: what is the best use of data to support risk-based inspection? And Mr. Phil Derfler, of the Office of Policy and Program Development, will be presenting that issue. And again, that will be the subject of a Subcommittee meeting this evening. At 2:30, we'll have an overview on the FSIS laboratory system. Dr. Patrick McCaskey will be presenting that. At three o'clock, we'll be talking a little bit about poultry standards of identity. And Dr. Robert Post, of the Office of Policy and Program Development, will be here to talk about that. And that will take us through today. So we will have a moment of public comments and adjourn at 3:30 to four o'clock.

And on Thursday, we will talk a little bit about that now and perhaps maybe go through it again tomorrow morning. We'll do a little bit of a recap with Dr.

McKee, and then we'll have Subcommittee reports, and I won't take you through each of those, but we'll have Subcommittee reports in the morning. That will take us through lunchtime. After lunch, we'll be talking about the consumer complaint monitoring system. And Kimberly Elenberg from the Office of Public Health and Science will be here to present that. We'll have a briefing, an update, on the *Listeria monocytogenes*. And Dr. Dan Engeljohn will do that from the Office of Policy and Program Development. In the afternoon, again, at 2:45, we'll have a legislative update from Mr. Rob Larew, who is in our Office of Public Affairs, Education, and Outreach. And he is the gentleman that did the -- a similar briefing for you the last time. He'll kind of give you an update on where we are with legislative issues and so on. And then we'll finish up the day for briefings with Ms. Gerri Ransom of the Office of Public Health and Science. And she'll be doing an update on the National Advisory Committee for Microbiological Criteria for Foods. And then we'll have a little bit of time to talk about remaining issues, plans for the next meeting, perhaps some public comments at 3:30 to four o'clock. And then we'll adjourn and hopefully whisk you

on your way back to -- safely to your homes and offices.

And with that, we'll open up, perhaps, for a few questions, if there are any, regarding the agenda.

There being no questions, what I'd like to do at this particular point in time is introduce Dr. Merle Pierson, who is our Deputy Under Secretary for Food Safety, and have him give us some opening remarks. Dr. Pierson?

DR. PIERSON: Good morning. I'd like to welcome you to Washington, DC for those of you who had to drive here, fly here, or whatever here, and those that normally come in to Washington, DC for their daily work, I welcome you to this meeting, also. You know, it's the Committees that are advisory to FSIS and I very much appreciate you being here.

I, myself, have served for seven years in the National Advisory Committee for Microbiological Criteria for Foods, and currently I serve as the Chair of that Committee. That particular Committee includes representation for not only FSIS but FDA, Department of Defense, and Department of Commerce so it's a, you know, government-wide Committee. But what I very much

appreciate is the time and effort that's put forth by Committee members. You know, the fruit of your work and the importance of that work, and believe me, I understand now that I'm, you know, a part of the USDA team, how we are able to look at the results of these meetings or your deliberations and the importance that such deliberations are to our decision-making process.

What you do is not something that we just take and put on a shelf and say, "Hmmm, that looks nice." We do use your work as a valuable input to our overall process. You know, all of us are very vitally interested in food safety. We're very interested in advancing public health. And we have an unyielding commitment to that. I believe we are seeing very positive results in that regard. You know, all of the stakeholders have made very definite contributions to moving our public health mission forward.

As an indication of this, we recently announced, you know, that we saw -- we've seen a 25 percent drop within one year in terms of the *Listeria monocytogenes*. Now I'm having trouble saying that word now, Garry. It's too early in the morning. *Listeria monocytogenes*. I'm a professor of food microbiology, too. Anyway, we

are seeing great progress in *Listeria monocytogenes* (LM) control, and we've seen a 25 percent drop LM positive regulatory compliance samples for ready-to-eat products. And we have seen a 70 percent decline overall in the years since we've -- since it's been implemented. So we've seen very positive progress there.

Also, over the past year or year-plus, we have seen very significant changes, too, in the -- in *E. coli* O157:H7. We have seen great dividends in that regard in terms of the measures it's been implemented. For instance, on September -- as of September 30 of this year, we found 0.3 percent positive regulatory compliance samples compared to 0.8 percent overall for 2002. That's a 67 -- or excuse me, a 60 percent reduction in incidents and a very definite improvement. So again, there are two examples of very positive results that we've recently announced.

Progresses such as this is only made, again, through the collaborative efforts of all stakeholders, including the input and guidance that we receive from Committees such as this one. For the past 32 years, this Committee has helped USDA transform its meat and poultry inspection program into one that has a more

solid science base to it. This, in turn, has helped make the U.S. meat, poultry, and egg product supply the safest in the world.

Despite all of these successes, we're just not going to sit back and say, "Good enough." We need to push forward and do better. We still see periodic outbreaks, periodic problems. We want to be able to anticipate how we can address those challenges and how we can prevent further outbreaks. And in this regard, in March of this year, Secretary Veneman challenged us to take food safety to a higher level. And we've answered this challenge with the release of our food safety vision document in July, which outlined our commitment to and the progress that's been made to date on five goals that Dr. Murano had established when she was named Under Secretary for Food Safety. The document entitled, "Enhancing Public Health Strategies for the Future," is a comprehensive blueprint for building a stronger food safety system in the United States. And each of you have a copy of that in front of you.

Now, let me briefly go over the five goals and a couple of issues brought forth in the vision paper and point out the ones that you will be focusing on today

and tomorrow. Our first goal is to ensure policy decisions are based on science. And you know, with Dr. Murano's background in science, my background in science having spent 32 years at the university, and Dr. McKee and his scientific background and experience in public health, as you can imagine, we are very, very committed to applying science in the best way possible to address these public health issues.

Our second goal is to prevent intentional contamination of meat, poultry, and egg products. And in the aftermath, of course, of September 11, 2001, we know the threats to our Nation's supply can come in the form of terrorist attacks and even, potentially, contamination of food. We must do everything possible to protect our food supply from such threats, and this morning, Dr. D. W. Chen from FSIS' Office of Food Security and Emergency Preparedness will give you an overview of what we have done to date in this area.

The third goal is to improve the management and effectiveness of regulatory programs. One of the issues this Committee will be working on are the procedures for conducting inspection in Talmadge-Aiken plants. Currently, there are nine states working under the

federal/state cooperative inspection programs whereby state employees provide inspection to federal establishments. The role of this program may need to be re-examined in light of the advances we are making to integrate inspection and enforcement more closely and in the re-tooling of FSIS' front line workforce with the necessary skills they need. And the input this Committee gives on defining the role of Talmadge-Aiken plants, needless to say, is very important for how we proceed in this program.

Our fourth goal is to coordinate food safety activities with other public health agencies. This coordination includes working with all federal, and state, and other food safety agencies as well as those of other countries. Our activities and programs should be complementary to realize the maximum benefit and to avoid duplication of effort.

The fifth goal is to enhance food safety education along the farm to table continuum. And as a professor of food microbiology and safety at Virginia Tech, this goal certainly hits home with me. Everyone has a responsibility for food safety; therefore, our efforts must be broad enough that no segment of the public is

uninformed about food safety handling practices. If we look at it this way: education equals protection and education saves lives.

We are still furthering our progress to meet these five goals, and certainly there are a number of progress indicators that I could go through for each one of those, and I have just, you know, given a couple of statements for each goal, but you can read more in terms of progress within that report. You know, we are still, though, looking at new initiatives, and you will see those in the vision document. Two of the new initiatives you will be discussing at this meeting, the first one is to anticipate or predict risk through enhanced data integration. To further anticipate risks involving meat and poultry products, we must have available data to clearly identify the extent and nature of these risks in order to determine an effective response. These data consist of regulatory samples as well as samples collected by food processing establishments. And we need to improve access to and analysis of food safety data from all reliable sources. And as you can imagine, FSIS alone generates a tremendous amount of data. And, you know, handling all

of that data is a major undertaking.

The question we are asking for your input on is: What is the best use of data to support risk-based inspection? When evaluating this question, you'll need to look at the types of data that FSIS can and should collect, the sources of data to which the Agency should gain access to, and the ways to analyze the data that is made available to FSIS. And your guidance on this issue will help us to maximize the efficiency and effectiveness of our efforts to ensure the safety of meat, poultry, and egg products.

Another issue we identified is that there is a need to better associate program outcomes to public health surveillance data. And Dr. David Goldman will be discussing that with you further. Now in order to achieve this goal, we must be able to link food-borne illness with the consumption of specific foods. This data would provide the necessary means for measuring success of regulatory policies.

We are seeking advice from you on how to address the challenges that public health agencies have encountered in attempts to characterize the burden the food-borne illness by food commodity. We are interested

in your ideas on the use of existing FSIS microbiological monitoring data from product samples to better illustrate the risk to human health arising from the presence of pathogens on meat and poultry products. In addition, we are interested in how data linking food products to food-borne illnesses might be used to suggest changes in regulatory policies. This whole area of, you know, identifying cause and effect is -- can be challenging. And it's linking, you know, our regulatory compliance area and all we do on the regulatory side with public health outcomes. And it's a very, very important area, you know, when you look at it from overall policy and also when you try to address this on a scientific basis. And it's one that we want to address and address more effectively so we can better implement policy and policy decisions to have even a more positive outcome on public health.

There are very critical issues for you to work on today and tomorrow. And the Committee's input, again, is very, very important to us. It's very important to us to help us progress on our vision statement, our vision document, and again, in improving public health. You'll hear today from many FSIS representatives about

these issues. We urge you to ask many questions, challenging questions, and questions that'll help us move forward.

And again, I thank you for your time, your dedication, your commitment, you know, to the work of this Committee. I look very much forward to a two days of very productive discussions. And I would like to thank you very much for, again, your participation, and at this point, I'll turn the podium over to Dr. Garry McKee.

DR. McKEE: Good morning. It's certainly nice to see many familiar faces again this morning.

I think before I get into my opening remarks, if we could, let's go around the table and we'll introduce ourselves. And if you would, state the organization that you represent. We'll start with you, Ms. Baldwin.

MS. BALDWIN: Susanna Baldwin with Maryland Department of Agriculture.

DR. JAN: I'm Lee Jan, Texas Department of Agriculture -- Texas Department of Health.

DR. JOHNSON: Alice Johnson, National Turkey Federation.

MR. GOVRO: Mike Govro with the Oregon Department of Agriculture.

MR. SCHAD: Mark Schad, Schad Meats.

MR. HARRIS: Joe Harris with Southwest Meat Association.

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute.

DR. CARPENTER: David Carpenter, Southern Illinois University School of Medicine.

DR. LOGUE: Catherine Logue, North Dakota State University.

MR. ELFERING: Kevin Elfering with the Minnesota Department of Agriculture and the University of Minnesota, the Center for Animal Health.

DR. GOLDMAN: I'm David Goldman with the Human Health Sciences division of FSIS.

MR. TYNAN: I'm Robert Tynan with the Food Safety Inspection Service.

DR. PIERSON: Merle Pierson, Office of Food Safety, USDA.

DR. McKEE: Okay. Thank you very much. We will have others joining us later today, and I think there's a couple of our Advisory Committee members that will be arriving late as well.

Well, as it's always good to remind ourselves of the diversity that we have on the Advisory Committee. I think that's what really is the strength of the Advisory Committee is to bring different views about specific issues to the table. And so we look forward to that in the next couple of days, as Dr. Pierson mentioned.

As many of you know, my primary goal when I came to Washington was to make FSIS a world-class public health Agency that would be a model for all other public health institutions. This is a challenge that I've embarked on

to fulfill on an organizational level, but it is one in which we have already made considerable progress.

What does it mean to become a world-class public health Agency? Quite frankly, we need to be experts in improving the safety of meat, poultry, and egg products for the American people. And it is to this end that we gather here twice a year to solicit recommendations from you as stakeholders.

Before we get started, I want to draw attention to a vacancy we have here on the Advisory Committee. We are still seeking nominations for a consumer representative to fill that vacancy. We expect to have it filled by our next meeting, and the nominations will be accepted up through November the 19th. So we'll have an additional Committee member next time.

This is an important meeting for us. I am confident that FSIS will walk away with invaluable information to help us as we currently face the challenges that we have. At our last meeting in June, we discussed training and education, food security measures, and our state inspection review process. We made great strides in these areas since discussing them with the Advisory Committee.

Let me give you a quick update. Since the last Advisory Committee meeting, we have focused many resources on revamping our training and education program. We are updating all of our training programs to incorporate a strong public health focus. The program will integrate scientific and technical principles, including HACCP validation. We developed the Food Safety Regulatory Essentials Program, which includes HACCP training that is tailored to our inspectors and in-plant supervisors. In June, we trained 300 people in what we call the FSRE program. Now FSRE training has reached more than -- over 800 of our employees, and we have plans to train even more in the coming fiscal year. And that’s a basic food HACCP course with many of the basic principles. It’s been really well received among our employees.

FSIS is always moving to a system of delivering training that is close to the employee’s work site as possible. This is a new approach that I've mentioned the last time and we discussed. After discussing this issue in June, we established regional training centers in Atlanta, Dallas, Philadelphia, Des Moines, and Boulder to make training even more assessable to our

field employees. Our new regional training system will improve training at our regional centers as well as interactive sessions near the employee's work site and on-site training programs.

We have also developed a food security training program, and the training focus of that program is on prevention of terrorist activities rather than particularly focusing on response to an event. It advocates a multi-dimensional team approach to homeland security, encouraging local, state, federal, and private sector interaction and reinforcing reporting lines for suspicious activity. Since we initiated this training, we have had nearly ten district training sessions where we have invited our local partners from that district to participate, including state, FDA, and APHIS representatives.

And training is not the only initiative we have undertaken to ensure that our Nation's food supply is secure. We recently developed security guidelines to target the vulnerable transportation and distribution sectors of the food safety chain. These guidelines address points in the process where potential contaminants could be introduced as well as suggestions

for lessening the likelihood of that induction. We encourage shippers, transporters, and distributors, and receivers to develop and implement controls to prevent contamination of products through all phases of distribution. We also encourage them to have plans in place in the event of accidental or deliberate contamination.

FSIS has also strengthened its workforce by signing an MOA, Memorandum of Agreement, with the U.S. Public Health Service, which we completed last April. The agreement allows the detailing of public health service commissioned corps officers to FSIS. These officers help us to prevent food-borne illness, respond to any food-borne outbreak, and aid us in our homeland security efforts as well. Because commissioned corps officers are available 24 hours a day, 7 days a week, they allow us a greater flexibility to respond instantly during heightened security alerts or to be on duty in the instance of an actual threat to the food supply.

Finally, we have upgraded security at each of our four laboratories and are continuing to work on improving day sharing and communication with other laboratories. In close collaboration with FDA, we have

taken a leading role in the Food Emergency Response Network, known as FERN. And this is a system that will integrate the Nation's laboratory infrastructure for the detection of agents in food at the local, state, and federal levels. We believe that cooperation between all of those with an interest in food safety is absolutely essential. This includes industry, consumers, and all levels of government. As you know, we have worked very hard to strengthen our partnerships with other federal agencies, such as FDA, CDC, but also with state agriculture and public health departments.

In June, this Committee examined and provided recommendations about how FSIS reviews should be conducted on state meat and poultry inspection programs. After the meeting, we worked closely with representatives from state meat and poultry inspection programs and developed a manual for performing state reviews. We are currently performing comprehensive on-site reviews in Wisconsin, Missouri, Mississippi, and Kansas with more to come in the months ahead. The work we have undertaken since our last meeting to improve training, security, and cooperation have been instrumental in the progress we are now making. I

believe we are beginning to see certain successes that indicate our food safety efforts are moving in the right direction.

The Center for Disease Control and Prevention has reported a significant decline in the incidents of food-borne illness over the past six years. And FSIS is also reporting declines in positive sample results for several major pathogens, as Dr. Pierson shared with you earlier.

While I'm proud of our hard work and impressed with our recent successes, I fully realize that now is not the time to rest. Now is the time to focus on bringing and beginning work on new initiatives that will ensure our continued progress. These Advisory Committee meetings are essential to our success. We must be able to discuss and address emerging problems if we are to continue to improve public health. So while I am extremely proud of our progress that we've made over the last year, the food safety arena is not in a position to go on hold. We must forge ahead. At this meeting, we have an opportunity to address new issues with the same vigor that we have addressed training and food security in the last meeting.

We welcome the recommendations on inspection at Talmadge-Aiken plants, gathering data to support risk-based inspection, and how we can make a strong connection between our programs and their effects on public health. I want to thank you in advance for your hard work today and tomorrow. We greatly appreciate all discussion that will occur. And I know, as Dr. Pierson mentioned, that it's important that committed public health and food safety individuals like yourself have taken time out of your busy schedules to come and serve on this Committee and be part of the focus on how we can improve both public health and food safety.

So with that, I certainly thank you and look forward to working with you the next couple of days. Thanks.

MR. TYNAN: We got right back on time. That's -- you can't ask for anything better than that, I guess. Dr. McKee and Dr. Pierson must have worked on their script to make me look good.

But the item on the agenda that I mentioned to you earlier that we were going to talk about at 9:15 relates to operating procedures for the Advisory Committee. And I think it's under tab four in your notebook. Last

June, as you recall, was my very first meeting with the Advisory Committee. And there was just a lot going on. Sonya was not in the office. She had been out for quite a while, so myself and Loraine Cannon were pretty much doing everything by ourselves. That didn't give too much time to reflect on the process or the procedures for the meeting in advance, but we did spend some time after the meeting to talk a little bit about how we conduct the meetings.

And the question I asked was simply, how do -- what kinds of rules of order do we have for the meeting itself. And there aren't any. Now we have specified some rules -- or some roles and responsibilities for, certainly, the Administrator and the Subcommittees, but actually having how we conduct the meeting was a little bit vague in my mind. Perhaps I'm an organization freak, but I do like to have some parameters for how we do the meeting. So I put together the material that you see as "Meeting Rules of Order". And somebody kidded me the other day that that's "Robert's Rules of Order". This is the dumbed-down version for me. But I put some things together that I thought would be helpful to us in terms of the conduct of the meeting. I was going to go

up to as many as ten, but I thought then I'd get kidded that it was “The Ten Commandments”. So I decided to keep it short and keep it sweet. And what I thought I would do is maybe just walk through these now. We have left 45 minutes, because I do want to have some discussion. Obviously, this is a meeting that we all participate in, and there should be a dialogue back and forth. So this isn’t something that we want to impose on the Committee. But we would like to have a dialogue and come to some consensus on the conduct of the meeting.

What I thought I would do at this particular point is read through the various points. If there is some discussion right now that you want to have, questions that we want to talk about, that’s perfectly fine. The alternative is we can loop back and allow you today and tomorrow, perhaps over coffee and as we’re chatting, to talk a little bit more about them and perhaps finalize them at the end of the agenda when we talk a little bit more about the next meeting and some of the other issues. So if I can impose on you that I'm going to read through, we’ll see what my “Robert’s Rules” come out to look like.

I think the first one is -- some of these are, I should also mention, pretty self-evident, but since we don't have them anyplace, it's probably a good idea to just kind of put them down on paper. Certainly, the first rule of order is the Chair, that's Dr. McKee in this case, the FSIS Administrator, conducts the meeting. And that's pretty straightforward. He'll be opening the meeting, recognizing those wanting to speak, and impose limits on the time and the number of speakers. I think, in some of the meetings, I think the last one, we had a fair amount of time, so the limitations can be longer. I think in this particular case, though, Dr. McKee has to have the latitude if the conversation is going -- becoming pretty voluminous to at least limit it so that we can keep reasonably close to the time schedule. So that, in June, wasn't necessarily a problem, but certainly, depending on the level or the degree of conversation about some of these topics, it could be. So we let that sort of open-ended, but there are some constraints that Dr. McKee, as the Chair, would be able to impose.

The second one is all questions or requests to speak will be addressed to the Chair. People must be

recognized by the Chair before speaking. And again, I don't recall at the June meeting that that was a serious problem. Again, we'll be a little bit flexible on that.

I think number three, the presentation of issues and briefing papers are going to be followed by a short question and answer period. And the operative word there, perhaps, is short. Some of the briefings will go a little bit longer than others. There's going to be a short question and answer period, and in the interest of time, questions and comments should be limited in length and to those asking for clarification on the presentation. So the Chair will exercise, again, some discretion on the time allotted. I think when we're talking about clarification of the presentation, again, we're trying to focus on the issues at hand. All of us have different viewpoints. It's pretty easy for us to go off in directions that are good conversation but not necessarily at the heart of whatever the topic is. So I think that's what number three is getting to.

Number four, speeches or statements of opinion by the audience or by the Committee should be made during Subcommittee discussions or during the time set aside for public comments. So what we're saying there is

basically the longer kinds of comments we need to hold for other venues. I lost my place here. Committee members and members of the public will be recognized by the Chair during the public comment periods of the meeting and requests to speak may be presented to the Chair in advance. And as I mentioned earlier, we have a notebook outside for anyone that wants to do a longer presentation or has a specific issue that may not be quite on point. Again, this is a keep on task kind of a thing.

The fifth, the Chair approves in advance materials to be distributed by the Agency, Committee members, or the public at the meeting. Now as you noticed outside, the fine ladies that are taking care of me and keeping me on track have put a large number of handouts outside. I think that those are all focused on the topics at hand. And what we'd like to do is if there are any materials to be distributed, other than the ones that we're generating as part of the meeting, they should also be focused on the meeting as well. So if your organization has some material on something that's of a different topic or our Agency has something on a different topic, unless it's germane to the specific

meeting, but we'd ask that that not be distributed unless Dr. McKee, or the Chair, whoever that happens to be, approves.

Number six, the Committee members are expected to attend the preliminary sessions of the meetings and the evening Subcommittee meetings to which they're assigned. Committee members who do not attend the presentation of the issue or participate in the Subcommittee meeting for their assigned issues are to be restricted in participating in the final session consideration of the issue. My thinking here was, and I need to clarify that. As I'm reading it, it probably doesn't resonate real well, so we may have to wordsmith that one. But I think essentially, the people that take the opportunity to Chair at the Subcommittee, when we assign the members, we do try to take into consideration the interests. Dr. Jan mentioned the other day he had a specific interest in Talmadge-Aiken, and we tried to put him on that Committee so that he could address that. We try and look at your background and try and fit them as best we can with the topics that we're presenting for the issues. It seems, to me, if I were a Subcommittee Chairperson, I would like to be able to rely on people

that are assigned to the Committee and that they don't hike off and decide that they want to do another topic of their own choosing. What happens then is the following morning we're going to report out on that specific issue. So if you've left your Subcommittee to participate in another one, it seems unfair to me that you're able to weigh in on Thursday morning and make the comments that you, perhaps, should've been making Wednesday night during the Subcommittee session. So that was my thinking. It's an issue of fairness, an issue of helping the Subcommittee Chairpeople sort of manage their issues, because we don't have a lot of time. So it's only two, maybe two and a half hours, that you have on a Wednesday evening, and that all has to be done so that you're prepared for Thursday morning. So that was my thinking there.

Number seven, the Subcommittee Chair is designated by the Chair and controls the Subcommittee sessions. So we're saying here that the members of the public may attend the sessions and, at the discretion of the Subcommittee Chair, they may ask questions. And we're leaving the Subcommittee Chairs to make some decisions on how much participation they want from outside

participants.

And last, but not least, the rules of order are subject to review at each Advisory Committee meeting at the discretion of the Chairperson. So if there are some things that come up at this meeting that we don't have included here and you're thinking about it over -- I'm sure you're always thinking about these meetings and how they should play out, if there are things we need to add in at subsequent meetings, we certainly can do that as well. So those are sort of the rules of order. My thinking, try to make it very simple and straightforward. I see Jill.

DR. HOLLINGSWORTH: Thank you, Robert.

I have two quick questions and comments. One, on the materials that are provided, I was traveling the better part -- in fact, all of yesterday, and I saw an e-mail that there were additional materials provided to the Committee yesterday.

MR. TYNAN: Yes.

DR. HOLLINGSWORTH: Being on a plane, I wasn't able to download them. I have asked others here. They haven't seen them, either. My concern is that the materials are provided to the Committee the day before.

We don’t have a chance to see them. I don’t know what they were even. I haven’t been able to download them. I just feel that there might be something I should’ve been more prepared for and I didn’t, because of the time frame. So I'd like to ask that as soon as we could get materials, that would help us to be better prepared. I don’t know. Were those materials provided to us today, the ones that were sent out yesterday?

MR. TYNAN: They’re -- all of the materials are in your notebook. So all of the materials that were generated and were sent to you by e-mail are in the notebooks. I should have said early on when we were talking about the logistical things, I should’ve apologized to all that they are so late. Dr. McKee and I have had a conversation about that, and we had talked a little bit about trying to improve that process so that we are not at the last minute. I think Sandra Eskin sent me a note about a week ago and was asking for the material. At that particular time, we were only able to send out about half. That's a problem in the process that I apparently am using, and I apologize for that, but I've already gotten Dr. McKee to not fire me, and -- but he is committed, as I am, to try and do a

better job so that when you come in June, you have the materials further in advance. Admittedly, the material is only a -- is not a huge volume of material, but still it's reasonable to allow you enough time to read the material, think about it, and pose your questions. So I apologize, and we will do a better job for that. Now if you like, we can build that right into the rules right now.

DR. HOLLINGSWORTH: Robert, well, no, that's fine.

MR. TYNAN: Okay.

DR. HOLLINGSWORTH: And I don't want you fired, Robert. It's just, you know -- it's nice if we can have the chance to read them.

MR. TYNAN: Yes, I understand.

DR. HOLLINGSWORTH: And I know there's always going to be some that come last minute. That's understandable.

My second question, this may be something that, in previous years, this Committee discussed, but I'm still fairly new to the Committee. I'm curious about the decisions about who goes on what Subcommittees. And I know they're divided into three Subcommittees, but do

the members switch around and change based on the topics, or is there any advanced discussion on the expertise of each member and how they can bring the best expert advice to each Committee? I understand the need to sort of break them up so you have different representation. On the other hand, even looking at the ones for this session, it seems to me there's some expertise that may be better utilized in a different Committee, and I didn't know how you went about deciding that or if it was possible that the members could even provide feedback to you on the areas where they feel they have the greatest expertise in making those decisions.

MR. TYNAN: I'm not sure I can give you a good, detailed process on how we put people on the Committees. As I mentioned earlier, we try and look at the backgrounds that you bring to the various topics and try and select, certainly first and foremost, that way. And we also try and bring a balance to the industry, representation, and consumer representation, the academic representation. So we try and balance it that way as well and try and balance, again, with regional kinds of things as well, men and women kind of thing.

So it's quite a balancing act. We've talked a little bit about establishing standing Committees, and so that -- you know, in other words, we'll just set up a standing Committee and it will be that way forever. The experience, though, that we've had this week is a couple of folks that we expected to be here are not able to be here. So as a result, sort of at the last minute, and that's what prompted the change in our agenda that there was a little error in terms of who was going to be chairing. As a result of the changes, we had to modify the Committee and move around. And of course, as you know, one of our consumer representatives left the Committee, and we haven't been able to fill that position yet. So we're sort of -- the bottom line is that it's sort of a dynamic process. But certainly, if you have some -- if the Committee has some way that they would like to approach that, we'd certainly be glad to talk about it and see if we can't do a better job with the assignments. But again, we're doing it based on what we think your expertise is in looking at the resumes and materials you send in and then try and get that balance built in as well. Does that sound reasonable?

DR. HOLLINGSWORTH: It sounds reasonable, but I also wonder if there -- and again, it might be something the Committee wants to discuss. There might be a mechanism where we could even prioritize. If we know there are three issues and what they are, we could prioritize which ones we think we can provide the most input. Not everyone's going to get -- I mean, everybody may want to be on the same one, but...

MR. TYNAN: Right.

DR. HOLLINGSWORTH: ...maybe we can at least get our second choice. Certainly it would be up to Dr. McKee's discretion on who goes where, but I think that Committee members themselves might be able to provide you information on where they think they can make the greatest contribution for each issue.

MR. TYNAN: Well, let's think about that. Perhaps some of the rest of you also have comments in that regard in terms of how you're assigned to the Subcommittees. I'd be glad to talk about that.

What I -- before we conclude it, why don't we hold that until, maybe, tomorrow afternoon and kind of finish these up then and let's see what kind of processes maybe in the discussions you'll have over lunch and over

coffee that might come up from that.

Dr. Jan?

DR. JAN: Thank you. I've got a question more about the role of the Committee rather than the rules of the Committee.

MR. TYNAN: Okay.

DR. JAN: But I also want to lay out a little background before, so it may qualify under four as a speech. And if you prefer, I can wait and follow your rule and do it this afternoon.

MR. TYNAN: No, sir. That’s -- no, that’s the purpose of this particular exercise. Go for it.

DR. JAN: Okay. Well, let me lay out the background, first. Last November, FSIS brought to this Committee an issue related to the oversight of state inspection programs. This issue was whether a document that was created after a year or so of work by an Agency in collaboration with interested parties, a document for oversight. The Committee, in its Subcommittee, reviewed it and recommended that FSIS take this document and move forward with the document. Within four months, the Agency discarded that document and said, “No, we’re not going to do this document.” And they appointed two

people that have never been in a plant, and they developed a new, exhaustive, comprehensive tool for reviewing state programs. They did it with the guise or under the guise that the Farm Bill said the Secretary needed a new review process to do the report. The Farm Bill only said that the Secretary needed to make a report to Congress about the status of the state programs, where they are, and what they need to do to change -- or what might be -- need to be done to change in those programs so that the product can go to interstate commerce.

FSIS created a new document by people with little experience, in my opinion, about the process. They did it hastily, met, and Dr. McKee mentioned that earlier in his talk, and -- that he met and worked with the states. But actually, they brought the states together after hearing lots of comments and questions from the states just before this last meeting that we met as a group. The state directors met and had a lot of questions and put a lot of input, but before any of that input was able to even be included, it was brought to this Committee again. And also, at that Committee, one of the questions was what is equal to. So they asked the

Committee to identify that, but also asked about using this new tool. This Committee again recommended to FSIS to use the data that's available. All states have been reviewed in the last -- since the implementation of HACCP and for 30 years prior to that, since the implementation of the program, they have been reviewed, so there's adequate data in the Secretary's hands by people that were at least perceived to be competent in reviewing programs. The data was there. That was recommended by this Committee that the Secretary use that, slow down the change, make sure that the document is a useable document, make sure that document and the review process, if it needs to be changed, has the time to develop into a useful tool. I would emphasize again, they ignored that recommendation of the Committee and moved forward with their review process, asked each state to do a -- complete a long, exhaustive assessment, gave very little time to do it. The states could not do a very good job or could have done a better job, I'm sure, if they had been given a little bit of time. And then after that, they proceeded with no notice to the states, or essentially no notice to the states that were being reviewed that they were going to have a review and

people are going to show up at their front door.

So my question is is there a reason to continue to use taxpayers' dollars to pay for us to come here and give advice if FSIS and the Secretary are not going to use that advice?

MR. TYNAN: Dr. McKee, I'm going to allow you to respond to that one.

DR. McKEE: Thank you. Dr. Jan, you know, we have wrestled with this issue quite a bit, and let me just start back with the purpose of advisory councils, and that is the topics that you're asked to look at and give your expert opinion and recommendations are those that we have to take an advisement on how we manage the Agency. And I could go into a lot of detail about the process that Dr. Jan just mentioned regarding how we make decisions as to what we were -- going to have to do as far as review of the states. And the previous inspections were almost -- very superficial, two-page or so document. This is more comprehensive. I think that's the key is comprehensive. So even though the Committee may make some recommendations, the recommendations have to be also brought into the big picture of the management of the Agency. And the

Advisory Committee will make recommendations that will be helpful to either direction but not necessarily change in a 90-degree manner. And so even though some of the things that are brought forward may or may not be able to be implemented as they are presented by the Advisory Committee.

But again, the advice and the suggestions that are made will tweak what we do and in a way that will be sometimes not identified by the Agency and our staff. And that's the purpose of this. And we -- you know, we could -- it's required that we set the agenda. We could not bring those issues if we thought that we would get an answer that we didn't like, but if we get an answer that has several parts to it that we can't necessarily implement all of those issues as recommended is something that we have to take responsibility in the Agency to do.

So in answer to your question, basically, we're in a position that we can not implement everything, in some cases, that the Advisory Committee brings forward, but they bring forward concerns that we need to address in the future. And we certainly value that component of it.

Yes, Kevin?

MR. ELFERING: Maybe this is a follow-up to Dr. Jan's comments. If there's a report that's written on the proceedings, is there something included where the Agency is identifying issues that were brought up as recommendations by the Committee that they're not accepting or not using? So would that be appropriate to put in your final report of suggestions from the Advisory Committee that have not been accepted by the Agency?

DR. McKEE: Well, clearly, as we manage the Agency, some suggestions from the Advisory Committee may take over time to implement. And we wouldn't necessarily give a yes or no answer based upon a report that came in, because two years from now it might be appropriate or the timing might be as such that we could implement some of those suggestions. So we can't really give, I don't believe, a yes or no answer to the individual recommendations.

MR. TYNAN: Any other comments on the rules directly in terms of -- I think Dr. Jan's comment was a good one, and it relates, certainly, to this. In terms of the rules themselves? Yes, Joe?

DR. HARRIS: I only had one very brief comment. And on number four, on the statements of opinions should be done only during the Subcommittee meetings or during the opportunity for public comment...

MR. TYNAN: Um-hum.

DR. HARRIS: ...it would seem that during that time when the reports from the Subcommittees are presented to the full Committee that that might be an appropriate time for Committee members to express their input into those reports, because, just thinking back to past meetings, those are usually presented and then tweaked to some degree based on the input from the full Committee. So I'm a little concerned there that it's almost like Committee members should not express their views on those Subcommittee reports at that time. So I just wanted to kind of bring...

MR. TYNAN: Okay.

DR. HARRIS: ...that to your attention.

MR. TYNAN: That isn't the intent of that. I think what we're trying to do is kind of focus the conversation. And as we sometimes do, and I certainly am guilty of it as well, is you start talking and you kind of go in different directions. I'm just trying to

manage the time. So it wasn't our intent to cut off comments or opinion. Obviously some of the stuff that we're going to be talking about will generate opinions. So we'll work on that statement.

Anything else at this particular point? Yes, Dr. Pierson?

DR. PIERSON: Your point is under -- is that under number four?

MR. TYNAN: Number four, yes.

DR. PIERSON: So your question was [inaudible], because normally many members...

MR. TYNAN: Right. Have their discussions. Right. No, that -- right. Well, I think that there were longer discussions on other types of issues or things that, perhaps, are not particularly right on topic. I think we were encouraging perhaps that later time to be the best time for the longer things. But we'll work on that one a little bit, maybe come up with an alternative language. And I think your point is you need an opportunity to express opinions, right?

DR. McKEE: In terms of the output of the Subcommittees and then the discussion and adoption by the full Committee, do you have a protocol for that, you

know, how this output is then finally adopted -- discussed and adopted by the full Committee?

MR. TYNAN: You're talking about the Subcommittee reports?

DR. McKEE: Right, and then adoption by the full Committee.

MR. TYNAN: We don't have that here in the rules, but I think normally how we've handled it is there's a discussion and then there's a consensus that we...

DR. McKEE: And you adopt by consensus?

MR. TYNAN: Yes.

DR. McKEE: Okay.

MR. TYNAN: We can, perhaps, build that in as well.

DR. McKEE: Yeah, you'd want to -- probably want to put that in here, wouldn't you, how that's discussed.

MR. TYNAN: Okay. Anything else at this point? Yes, Dr. Johnson?

DR. JOHNSON: I think -- Gladys and I were just sitting here talking. I don't know that we always reach a consensus, but if we don't, then it's usually

noted on the recommendation.

MR. TYNAN: Yes, Dr. Bayse?

DR. BAYSE: Yeah, Robert, I have a little concern about, I guess, rule number five. Maybe it just needs to be expanded. But I guess how will -- perhaps Dr. McKee can speak to that. How will those decisions be made on approval, particularly from the public? I have the concern that, you know, we need to have the public feel they can express themselves here, and I can understand it’s inappropriate not being accepted, but maybe Dr. McKee could give us a little direction on the spot, you know, the criteria here for...

MR. TYNAN: Well, what we were thinking, and then I'll let Dr. McKee talk, is that the materials that we have here for -- and we have quite a few of them outside, as you can imagine, the topics that we’d like to have here for materials, this isn’t a place for distribution of pamphlets and literature from any organization, public or otherwise...

DR. BAYSE: Sure.

MR. TYNAN: ...just because it’s food-related.

DR. BAYSE: Sure, but...

MR. TYNAN: What we were trying to focus here

is that any of the materials, Dr. McKee would have an opportunity to see those before they were put down on that table. And certainly, I think the criteria that I was thinking we would use it would have something germane to this particular meeting and the topics that we're addressing on the meeting.

DR. BAYSE: Right.

MR. TYNAN: So I think that's...

DR. BAYSE: It would have to be included.

MR. TYNAN: Right.

DR. BAYSE: Perhaps I would feel more comfortable...

MR. TYNAN: Dr. McKee, did you want to elaborate on that?

DR. McKEE: Yes. The intent of that was, you know, sometimes the stuff that's passed out at any meeting that we have could be construed as an endorsement, so we just wanted to have an opportunity to review anything that, especially that a special interest group might want to bring and distribute at the Advisory Committee would be inappropriate. That's where we were coming from on that.

MR. TYNAN: Any other comments? Yes, sir, Dr.

Carpenter?

DR. CARPENTER: Robert, as I look at the material in tab 14, it appears to be an expansion of some -- of parts the meeting moves forward. Is that true? It's operating procedures and charter. It seems to give great detail and responsibilities of the full Committee and the Subcommittees.

MR. TYNAN: Right. But it's the roles -- mostly the roles and responsibilities as opposed to the conduct of the meeting, and that's what we were trying to focus on here, just the two days that we have here, specifically how we're going to manage issues and discussion as we go along. And I think 14 is a little bit more in terms of Committee Chair does this, Subcommittee does that kind of a thing. So this is, in answer to your question, a little bit of an expansion.

Did we beat this one to death? What I'd like to do is maybe table the issue, not trying to come to any agreement at this particular point. I want you all to think a little bit more about it, and perhaps on our agenda on Thursday, I think it will be during that 3:15 to 3:30 time frame where we talk about remaining issues and plans for the next meeting, perhaps at that

particular point in time, if there's any modification that we need to make, we can do it then. And that will give you an opportunity to think about it and see what other items might come to mind. Is that agreeable? No one has thrown anything up this way, so I'm assuming that means it's agreeable. Okay.

Maybe we could jump back into the discussion of the agenda itself. We're again, a little bit -- have a little bit ahead of time, so that might allow us to take a little bit longer break. Dr. Chen is here from the Office of Food Security and Emergency Preparedness. And he has a briefing that he's going to do on increasing industry awareness of food security. And Dr. Chen, if I could ask you to come out into the podium with your material.

DR. CHEN: Good morning, everyone. This morning, I'm going to spend some time with you reviewing some of the activities of our Office of Food Security and Emergency Preparedness. Now this is a briefing. I think last time Jesse Majkowski had a chance to visit with all of you earlier this year, and I think it was more of the issues or opportunity.

As probably Jesse mentioned to you when he visited with you earlier this year, our office was recently established back last year in 2002, in August and September. And I think he walked through with you sort of organizationally how our office is constructed and organized and some of our missions and responsibilities. And today, what I would like to do is just to walk through with you some of the more recent events since he had a chance to visit with you. Jesse actually was the first Assistant Administrator for Food Security and Emergency Preparedness at FSIS. And I served when the office was first established as one of his deputies. And he retired very recently in September, and I was asked to serve in the interim as the Acting Assistant Administrator for Food Security.

And I think you guys -- you folks have a handout

that kind of went around, and I -- you can stick it in your book. And you could also stick it in tab number five where there's actually a list of accomplishments in the homeland security area.

Okay. I don't know if I'm controlling the slides, so -- one of the -- these past couple of months have been fairly fast moving in terms of homeland security in general in the country, but also very much so for those of us working in the food and agricultural area. And I think one of the things that Jesse didn't have an opportunity to share with you a couple months ago and I want to spend some time talking a little bit about critical infrastructure protection. These are fairly recent developments in terms of the homeland security portfolio of our country. And I'll start out by just talking very briefly about a directive, a presidential directive that was actually signed during the Clinton Administration, PDD, that's Presidential Decision Directive, number 63, which basically established the Critical Infrastructure Protection Program in the United States, and this was in light of both domestic and overseas operatives and how critical it was to protect the critical infrastructure. And so that was first put

on the map, I guess, or established back during the Clinton Administration.

Very notably earlier this calendar year back in January and February, President Bush unveiled his new national strategy for the Administration in terms of physical protection of critical infrastructure and key assets. And of course, this was done, obviously, in light of 9/11 attacks but also the Anthrax evolution in the mail, a whole bunch of different things. There you see approximately -- there are about 11 critical infrastructures that were actually identified and then key assets as well.

You will notice that food and agriculture is the first one listed, and it is the first one listed in the national strategy. It's actually agriculture and food. I think there was a recognition on -- after 9/11 and certainly during the months and the year to follow that food and agriculture, and specifically food, represented an opportunity for those who wish to do our Nation harm using food as a weapon, both in terms of the effect on human health but also the economic and psychological panic and other issues.

This is very seminal and very important that food

and agriculture was added or is a critical infrastructure, because that means that a lot of work and activity has been going on across the federal family and now working with the states and with our private partners in industry and elsewhere in enhancing security posture and hardening our assets and hardening the target, much in the way as we did, as you notice number three, energy transportation as we do with a bridge or a dam.

Obviously food and agriculture are much more complex than a fixed facility like a bridge or a dam or a power grid. Food, obviously, is a very complex system from farm to table, but a lot of activity and work has been going on in the last year and within the last half of year, actually, with what is called organizing the sector.

A lot of that activity has received direction from the White House. And most of you know, the Department of Homeland Security was created and stood up back in March of this year, the Homeland Security Act of 2002 having created that new department within the Federal Government. That particular piece of legislation also created the White House Homeland Security Council, the

HSC. The HSC is the companion to the National Security Council, the NSC, which deals mostly with overseas and international issues. The HSC deals primarily with domestic counter-terrorism and homeland security. They have taken a keen interest, obviously, in terms of implementing, as everyone else has, the President's National Strategy and Critical Infrastructure Protection.

And we have been working in our Agency, in our department, very closely with the White House HSC. They direct a lot of the traffic in terms of departments and agencies playing a very, very high-level coordination role in terms of homeland security. And again, a lot of attention has been paid to the food and agricultural sector on getting that stuff pretty much together. Work has been after 9/11/2001, but the pace of activity has increased appreciably.

I put down there that the HSC issues Homeland Security Presidential Directives. That's a new terms. It used to be the President can issue executive orders or PDDs, Presidential Decision Directives. An HSPD, as we'll see later, is a Homeland Security Presidential Directive.

The second item of note, I'm not sure if Jesse had briefly mentioned this with you a couple months ago, is that the HSC established the interAgency food working group. There were a number of activities that actually were organized after 9/11 whereby many different departments and agencies realized, at least in the food area, that we needed to get together and coordinate things and share information and provide a much more seamless and integrated approach to a potential attack on our food supply. And things like the Food Threat Preparedness Network was one of those entities that was created not long after 9/11 where many different federal agencies got together and met regularly to pull together strategies and share information on food. And in fact, that organization was co-Chaired by Dr. McKee, our Administrator, and a Director over at FDA, the Center for Food Safety and Plant Nutrition.

This InterAgency Food Working Group, the IFWG, has since kind of taken over in terms of the main federal interAgency body dealing with food at this time. This food working group may not continue infinitely, but at least certainly in the last half a year, three-quarters of a year, the IFWG has looked at a number of very

important issues and has brought together many parts of the federal family in looking at how best to provide food shields to protect our food.

Most notably, the IFWG had three working groups, and they're still working right now. The first one was dealing with vulnerability assessments and food shields. We'll talk about that in a moment. And each of these subgroups, by the way, was co-chaired by someone from the FSIS and someone from FDA. The second work group had to do with laboratory issues and FERN, FERN being, of course, the Food Emergency Response Network, which is a laboratory-centric activity. And the last group dealt with incident management or Incident Command System, which I will discuss very briefly at the end here.

The first subgroup, the food shield and vulnerability assessment, many of you have known and Jesse might have mentioned to you the last time we visited with you that after 9/11 both FDA and FSIS both conducted vulnerability assessments of the food commodities that we respectively regulate. And the results of those vulnerability assessments which actually identified high-risk commodities and high-risk threat agents, threat agents being chemical or

biological or radiological agents that may be introduced into the food supply as a contaminant were identified. And the FDA did a similar exercise. And we had gotten together with FDA to sort of, you know, share methods and talk about what the InterAgency Food Working Group says, okay, take those vulnerability assessments that you've done and we'd like you to further enhance those. And in the last couple of months, we've been working with the Department of Defense and their special operations folks and looking at offensive targeting. We took our original vulnerability assessments and thought about the farm to table continuum and said, you know, where in that farm to table continuum are we most vulnerable physically. And using a method that, again, an offensive targeting tool that I think an enemy might use both was a way to sort of think about that in a very different way.

So what we were able to generate now, and they're all classified, is a -- using this thing called cover analysis. We're able to now identify actual nodes that we consider to be critical in the farm to table continuum. So now we have a list of high-risk commodities, high-risk threat agents, and now actual

nodes or critical nodes, infrastructural places. And that work is important, because the White House wanted us to also create these things called food shields, which is once you've identified these critical nodes, how can you contemplate developing countermeasures to protect those assets, to protect those very critical areas, whether it's a processing plant or even more specifically a particular operation with their processing. Is it in distribution? Is it the supermarket or retail or service site? Is it at a feed lot? Where in the farm to table are we most vulnerable?

The second part of the IFWG was the laboratory issue. I'll just quickly tell you that a lot of activity has been going on through a new entity called FERN that I mentioned, the Food Emergency Response Network. FERN is a federal/state partnership whereby -- it's a realization if we actually got attacked on the food, our surge capacity, our methods that we use, the standardization of those methods. I mean, all of those things we have to go beyond the federal family and look at also states in other areas to help us in the laboratory and testing and screening area. And FERN was

developed in a way to engage and pull in state -- primarily state labs, both food, public health, animal, plant diagnostic labs, veterinary diagnostics. And that's getting off the ground right now in terms of getting a steering committee together and pulling that together. A very big journey to get that together, but it's being worked on.

And the last thing I mentioned, number three, the incident command. I'll go over that in one of the slides here. I mentioned DHS. The only reason I put the slide here is that they are getting things off the ground as we speak. And we, here at FSIS, and we, at the Department, have been working very closely with a number of different directorates that were created in DHS. We work with the science and technology directorate on scientific and technological issues. We work with the transportation security border directorate on our import and ports of entry surveillance and protection. We work very much with the information analysis and infrastructure protection directorate in taking a lot of the work I mentioned with our vulnerability assessments and as DHS now tries to help coordinate organizing that food and agricultural sector.

Just to let you know, there has been a lot more experience dealing with some of the other sectors, whether it's energy or transportation. Food and agriculture is a little bit more complex, admittedly, and we've been working with DHS closely on that. And of course, we work with Customs and other -- FEMA and other agencies that have now been enfolded into the new DHS that were either separate agencies or located elsewhere.

I think Jesse mentioned to you last time a little bit about the HAS, the Homeland Security Advisory System. What we've done is under the orange and red threats, we are required by DHS now to have specific roles and responsibilities and assignments outlined and enumerated that this Agency undertakes whenever the threat level changes, the color code changes up to either orange or red and not only orange or red general, but there may be a sector specific alert. For example, it's conceivable, for example, that we may go to an orange with a food agricultural sector specific warning. What we do as an Agency when we have a general versus a potentially food and agricultural sector specific warning, you can imagine that some of the assignments we have are a little bit more rigorous and aggressive as

you go up the chain.

Here is a slide that just lets you know that we have been attempting to formalize and codify, if you will, some of the many things that we do across all program areas in the Agency whenever we go to orange or red. And these will find themselves in the way of directives, FSIS Directives 5420 Series. The first one that actually was published was 5420.1. 5420.1 was actually published right around the time that Liberty Shield was stood up back in March or April of this year. There's about, I think, going to be about six or seven 5420.1 all the way up to 5420.7 that talk about all of the different program areas and their specific roles, responsibilities, and assignments whenever we go to an orange or a red. 5420.2 hasn't been published yet, but that has to do with, like, handling of laboratory samples or something about surveillance or something about inputs. I mean, there's something about distribution. All of those will find themselves in these directives, which are going to be coming out fairly soon, the entire series. And the 5420.1 is being revised and updated since we first published that.

Very quickly, with Operation Liberty Shield, we

actually had a lot of practice in terms of the Homeland Security Advisory System. We actually went to orange, as you all know, four times since the HSAS was established. Operation Liberty Shield was stood up, obviously, during the hostilities with Iraq from March to April of this past year. That really wasn't exactly an orange or a red, but sort of like a burnt orange, if you will. What it -- what we did was we were asked, and we did it very quickly and it was classified before it was actually put in place once hostilities were initiated with Iraq, was a way to protect our homeland during hostilities with Iraq. And a lot of the protective that different departments and agencies took were directed at that threat, that is an Iraqi threat in our homeland. And of course, USDA at its many missions, APHIS, for example, FSIS all had assignments during Operation Liberty Shield.

We coordinated very closely at FSIS with FDA and CDC and what Operation Liberty Shield entailed was enhanced inspection activities in our plants, enhanced surveillance of in-distribution and import facilities both at our industries, facilities, and our import areas. We actually did random sampling of high-risk

commodities for threat agents. And we actually used our vulnerability assessments to help guide us in terms of what are the kinds of commodities and what are the kinds of chemical, biological, and radiological agents we ought to be testing for.

This was a very big decision to make, because, as you know, our laboratory enterprise at FSIS has a long history of just stellar and exceptional work. But the agents that they dealt with were the ones we deal with in a sort of an unintentional or accidentally, whether it's salmonella, O157:H7 or a chemical residue or an antibiotic and so on. When we talk about weapons of mass destruction and chemical, biological, and radiological agents, as you know, we're talking, in many instances, about completely different kinds of agents. And the things that are used and the screening tests and the confirmation, handling, special equipment, you name it, it's all different. And you can also imagine some of the challenges that our laboratory folks have to deal with is a lot of the tests that are used don't necessarily have confirmation types -- the sensitivity and specificity. Some of these things are not completely known.

And how do you -- a lot of the questions arise: how do you guide policy decisions on presumptive tests and so on? These are fairly challenging questions that have to be contemplated and answered as we move forward. So we actually did random testing of a harvest commodity. And I'll mention to all of you, one of the great spin-offs of putting a lot of investment and effort in homeland security or food security is that food safety also benefits. It’s true for homeland security at large in how we -- in terms of regular safety of our country.

We had actually tested liquid eggs as part of our screening program as part of Liberty Shield. And low and behold, we did -- we got hits from that, and we actually now realize that that was not -- in that instance, we got positive hits introduced intentionally, but something that occurs with liquid egg products and now we are attending and addressing that as part of our regular regulatory sampling.

And enhanced surveillance of human illness. We all know that the -- one of the end products of a food terrorist attack is people actually getting sick or dying. And during Liberty Shield, we had our folks working very closely with CDC and FDA and the states

that we had a daily conference call to see if there were any unusual reports of clusters of illness. We looked at our consumer complaint monitoring system. I think Dr. Goldman and his staff going to talk a little bit more about that as well to see if there are any unusual incidents from the consumer complaint area, so that's just to enhance the surveillance.

And the last two slides, I think, it's just mentioning that we have been very, very busily engaged in simulations since 9/11. As you all know, practice makes perfect. You have to exercise your muscles, and you have to exercise your muscles and do simulations to also find out where you are weak and where the gaps are so that you can find ways to fill them and address them. And there have been a series of tabletop exercises, some at the national level. Many of you have heard of Top-off 1 and Top-off 2. The last, Top-off 2, happened very recently in Seattle and Chicago simulating a very large event. The Department of Agriculture was involved.

Or how about Crimson Winter and Crimson Spring in -- a series of exercises conducted by the Deputy Secretaries of USDA, HHS, and DHS? Just to let you know

that we have been working on practicing and drilling to find out where we're weak. We plan to continue those kinds of drills and practices within our agencies, with our federal partners. And Crimson Spring was an FSIS tabletop exercise that occurred this past January. We involved many of the federal agencies. We had states involved, and many in the industry were invited as observers. In the future, there's no way that we can not be -- there is -- it is inevitable that in the future, tabletop and simulations will have to involve more substantively state governments and also industry. So stay tuned on this, because we're all in this together. And the initial tabletop is just to get the federal kind of family's house in order, and I think we're recognizing now they're going to get ready to sort of engage the many other parties and partners and stakeholders out there.

You know about -- I was mentioning about we have been -- have issued a number of publications in the food security area. The first one was the Food Security Guidelines for Food Processors that was published last year. These are voluntary. And I know that we discussed that with you folks at the Advisory Committee

recently about the voluntary versus mandating issue. Very importantly, back in August, we published a brand new, I think it's on your desk in an orange or a salmon colored booklet, called FSIS Safety and Security Guidelines for the Transportation and In-distribution. This is the companion to the food processing that discusses security in transportation and in-distribution. I will add equally important critical notes of vulnerability in the farm to table continuum. And I commend these to you to review to look at. We have -- you'll see in the list of accomplishments, and I'll let you look at those on your own, that we will be -- the last two of the four publications are going to be coming out very soon. We have guidelines for -- security guidelines for consumers coming up very soon and one for employees, FSIS employees. So those are the four sets of guidelines that our office has been working with, the rest of the Agency and our Office of Public Affairs and Education and Outreach.

This is a term I -- you may not know. Surety points is a new term in the lingo. We all know about HACCP, the critical control points, the safety points. Surety points is a term that is used when something is

uniquely related to a security point rather than a safety issue. Some of the critical control points obviously serve both functions, both safety and security. There are others, though, that may just be purely security related, and those -- there's a new coin that's been termed in the Homeland Security Department. It's called surety, s-u-r-e-t-y. I just wanted to share that with all of you to be familiar with that term.

And the last thing here is our office also, in addition to homeland security activities, does deal with emergency preparedness and response. I think Jesse mentioned to you -- let me just go back for it here -- about COOP last time, continuity of operations. We, as a department, we, as an Agency, have to have, by Presidential Decision Directive, PDD 67, a method or a vehicle or a means by which we ensure adequate succession of leadership and decision-making authority and the continuing -- continuance of mission-critical functions in the event that headquarters is no longer functioning and able to do that. We have a COOP plan in place, and we've had a number of drills and -- with COOP. And I wanted to also let you know that we had a

little sort of Mother Nature-related COOP event with Isabel recently and the blackouts. And I want to just mention that we were able to get through those things very well due to a lot of other great work by some of my colleagues in the Agency and making sure that we were up and running in a continuing function despite losses of certain things.

And I'm going to go backwards here just to you tell you about this last thing here, and that is I mentioned to you that the Homeland Security Council and the President can issue Homeland Security Presidential Directives, HSPDs. Well, the President has already signed off on a number of HSPDs governing a number of different issues. Number five dealt with the whole issue of national response. And I just have a quick word about this directive, because it is germane, very much in a big way, to our Agency and our department.

Currently, a number of federal emergency response plans govern how our Agency, how our department, how the Federal Government responds in the event that the President, through the Stafford Act, declares a state of emergency whether it’s a hurricane or if it’s a terrorist attack. There are a number of plans out

there. FEMA manages the Federal Response Plan. The Department of Energy manages the Federal Radiological Emergency Response Plan. That particular plan, for example, was first written in light of accidental release by a fixed nuclear facility, i.e. Three Mile Island. There's a con plan for domestic terrorism attack that the FBI and the Department of Justice take the lead in in the event of a domestic terrorist attack, and so on and so forth.

There's a contingency plan for hazardous material that EPA is responsible for. And each of these plans outlines specific roles and responsibilities of a lead federal Agency and supporting federal agencies and how assets and resources and roles and responsibilities play out during a national emergency. A number of these plans were written, obviously, before 9/11/2001. And a lot of these plans were obviously written before the Department of Homeland Security existed. Remember, FEMA, for example, was a freestanding Agency, and now it's part of DHS. So this Homeland Security Directive basically says that we take all of these existing plans and we fold them together into one big, new plan called the NRP, the National Response Plan.

And activity is being done feverishly now to meet a number of deadlines established in this HSPD in getting this new NRP on the table. That has implications, of course, for our department. It has implications for our Agency, because food and agriculture are big parts of all of these plans and of any new NRP. The other part of HSPD is, in addition to the NRP, the National Response Plan for this HSPD, lots of acronyms here, is that the Homeland Security Directive, Presidential Directive, says that the Incident Command Systems, or the NIMS, the National Incident Management Structure, will be the approach that all government agencies, federal government agencies, use in responding, preparing for, responding to, recovering from a large-scale catastrophe or incident.

This is the model, by the way, that the U.S. Forest Service has used for years in fighting fires. It is now the model that is to be used by all federal agencies as they think through their emergency response. And as we speak, we are looking at our own Agency's response and how we do things to make it dovetail and consistent with the different features of ICS.

Just to share with you, we can discuss a little bit

more with you at a future meeting about ICS, one of the key features of ICS is that it -- the reason why ICS is good is that it establishes an on-scene commander. There is no issue on who is in charge. And if you can imagine, in many different instances, whether it's at a local level, a state level, or at a federal level, who is in charge becomes a big issue. This says that there will be a person in charge, and that person will be an on-scene commander. There will always be one single person who is in charge, whether it's an on-scene commander initially or a long-term. And that on-scene commander, whether it's in a local or a national level, has access to the assets and resources of those underneath him, which has implications for our Agency, because we have a lot of human resource workforce assets available. For example, we have a large workforce of veterinarians, for example, that work in our plants and establishments. And we also, during the END, Exotic New Castle Disease outbreak out in, kind of, the West Coast primarily, that a number of veterinarians from FSIS and other federal agencies assisted APHIS in trying to address that outbreak. So ICS is kind of coming over the horizon here and does have some implications for us

as well as the NRP.

And with that, you do have a list of accomplishments there. Some of the things I mentioned already. There are some other items, and I would just ask you to review some of those when you have some free time, and maybe Bob, if I could entertain any questions from the group?

MR. TYNAN: Yes.

DR. CHEN: Okay. Great.

MR. ELFERING: I'm not sure if I heard what you had said correctly, but did you -- do you believe that there's a correlation as we increase food security that we have had an increase in food safety?

DR. CHEN: I think what the -- what I said was that the investments that are placed in food security-related activities have not only the direct effect of the security issues, but in many instances have spin-offs that benefit food safety as well. That's what I was trying to say. So the extent to which we have put in place a number of countermeasures to ensure security are going to help.

Let me give you another example. If we -- I'm not saying we do or don't do this, but let's just

arbitrarily say that we have tanker trucks that take liquid eggs, okay, from the plant to another food processing or bakery plant -- a baked good plant. Well, testing the product certainly for potential contamination is going to occur, and hopefully, if we have inspections of those tanker trucks, we will, hopefully, uncover not only things that have been deliberately introduced but potentially things that have been unintentionally introduced. I mean, I just mentioned the liquid eggs, and that's a very good example of how we did some things for food security purposes and found out -- well, we're finding that some of our liquid egg products, due to a variety of reasons, are breakdowns in the system. But nevertheless, it's something that we hadn't addressed in more recent years and more recent history, and we ought to do that. Because we -- after looking at that whole thing, we determined that it wasn't introduced intentionally, but it uncovered something else. So it's more of a spin-off issue.

And I think that's one way to also recognize that homeland security is expensive. And I will share with you that in the budgetary arena, getting resources for

food and agriculture security is still -- is a competitive thing. And you need money to get -- to buy the agents, to get laboratory systems up to place, for example. That's just one example. And this is going to be a challenging year ahead of us, because the, you know, $87 billion was just approved to cover Afghanistan and Iraq activities, and that's money. And when we develop our budget requests through our department and that goes all the way to OMB and the White House, they have to weigh these things against other things.

So in part, homeland security -- or food security is a challenge, because we do need the investment of additional monies. We need monies, for example -- we need monies to get out to states, because a lot of the state governments, whether it's health -- a public health Agency, the agricultural agencies, or the food and drug agencies, quite frankly, food and Ag has been a little bit short shifted. CDC, for example, gives a lot of money for bioterrorism. It's gone out through grants to do other food and agricultural related issues. So it's a really -- an area that needs a lot of resources and attention. And getting those things, I think, is we have to kind of wait and see.

So I don't know if that answered your question, but...

MR. ELFERING: Perhaps just one follow-up, though, on the -- this was done prior to pasteurization. Were you able to -- did you do any testing at all on product that -- after pasteurization, because it certainly would survive pasteurization?

DR. CHEN: I'm going to ask that Barb -- maybe can you say a few things just about it since I...

DR. MASTERS: Yeah, thanks, D. W.

Actually, in this situation, it was pasteurized egg product, and it was the toxin that we were finding, not the organism. So the toxin was not killed through the pasteurization process. The organism was killed, but the toxin remained.

MR. ELFERING: Exactly. So was there recall of product or anything?

DR. MASTERS: Fortunately, the product was all on hold, and we were able to get our arms around the product. Some of it had moved in commerce but to sister plants for further processing, so none of the products were actually in -- out in distribution at that time.

DR. CARPENTER: I want to specifically address

the slide on Operation Liberty Shield and the challenge you had indicated about the laboratory testing for threat agents. The Laboratory Response Network, which is, I believe, put together by CDC, issued protocols for certain organisms and chemicals. And we certainly appreciate that food is a very difficult to analyze for any of these things, but have any of those protocols been a value in augmenting FSIS laboratory efforts?

DR. CHEN: Dr. Carpenter, thank you for that question. It's a very good one.

After 9/11, and actually in light of the Anthrax issues in the mail, the LRN, which is primarily a public health clinical laboratory enterprise, really -- there's a lot of attention at getting that whole constellation of laboratories to get up and running and being able to do screenings for some of the bioterrorism agents, for example. But you put your finger on it. The LRN and the public health laboratories aren't necessarily equipped to do food matrixes. The only different -- very, very different matrixes than urine or blood or so on. And in fact, in getting together this FERN, the Food Emergency Response Network, which is primarily food-centric, okay, there are a number of state food

laboratories, okay, that do food testing. There are the federal family laboratories, of course. But there are some public health or clinical laboratories, and I said veterinary and plant diagnostic labs, because -- and there's been very close coordination between FERN and LRN, okay. In fact, someone from -- Richard Kellogg of CDC, who helps to oversee a lot of the LRN activities at CDC, sits on the FERN steering committee to make sure there's adequate connections to LRN and the public health laboratories, because to some extent, I mean, there are similar lab methods, but far less so than there are differences. Part of that is making sure that we can engage some of those public health laboratories that are so inclined and have the interest and capability of adding on to their portfolio of screening food matrixes as well.

So there is close connection and coordination between LRN and FERN. But I think there is a recognition, too, that LRN was not stood up or established to be able to handle the food and agricultural issues. And the same thing rests -- and the same issue is germane as well to the animal diagnostic -- veterinary diagnostic laboratories, too.

And a lot of this has to do with search capacity, making sure that in the event that we have a large-scale testing, now do we have adequate laboratory facilities and capabilities. And the challenge again is a lot of the methods -- a lot of methods haven't been validated for a lot of the threat agents in foods.

So what we did during Liberty Shield, to go back to your question, we were able to pick a menu of those agents that we felt were -- based on overall ability assessments, the highest risk, highest consequence for food. And we were able to purchase agents and so on to do some of that screening. But it -- the laboratory part of this, as I mentioned, and as you also cited, is a very challenging on.

But was I able to answer your question, Dr. Carpenter? Thank you for that question.

DR. HOLLINGSWORTH: I have a question about the National Response Plan that you mentioned under DHS. If I understood correctly, there will be a subset, if you will, of National Response Plans for different commodities or different infrastructures. And so with that in mind, I'm assuming there will be a National Response Plan for food and agriculture. My question is

who is leading that charge? Who is involved in it? Will it be -- given that it's a National Response Plan, I would assume it will cover all foods, all agriculture, how is that evolving or who is in charge of that? Is there industry participation in it?

DR. CHEN: Dr. Hollingsworth, thank you very much for that very good question. The politics behind getting and pulling together the NRP are very complex. And in a sense, USDA and our Agency are active observers that way, because the action is occurring within DHS, Department of Homeland Security. And they are responsible. Secretary Ridge is responsible. He is actually specifically stated in the HSPD number five of getting an NRP on the table.

Now all of the existing response plans I mentioned to you, for example, let's just take the FRP, the Federal Response Plan. Food and agriculture -- not food -- okay, the Federal Response Plan is split up into emergency support functions, one through whatever, and there are a number of support functions, ESF, that address food. The only one that actually has food in its title is ESF 11, I'm just, you know, giving an example, which deals with scarcity of food, not the

safety or the security of the food. Okay. Just making sure there's an adequate supply.

As these new -- all of these existing plans are being revisited and revised and pulled into one National Response Plan, there have been a number of working groups that have been established to address some of those very critical infrastructure errors or critical errors. As we mentioned, food and agriculture is a new one. When these original response plans were written, years ago in some instances, food and agriculture were not on the map as much. The one that's a little bit more on the map is the Federal Radiological Emergency Response Plan. But there are working groups that have been established now to examine the very issue that you cited, and that is as the NRP is structured, and it's not clear exactly what the exact, final template will be. Is it going to be annexes? Is it going to be emergency support functions? Or is it going to be something completely different. What is the approach that's going to be taken?

But rest assured that food and agriculture will invariably be a very prominent, visible item in that plan. Okay. So that's -- in the end of the day,

that’s good news. Okay. And then the responsibilities of federal agencies will be listed underneath that. Who’s in charge of developing the NRP within the DHS is a really difficult thing. And I don’t work at DHS, but I know that FEMA has charge of the FRP, but FEMA was not asked as an Agency to take a lead on developing the NRP. Actually, Admiral Roy, who is the Administrator of the Transportation Security Administration, now he is acting Deputy Secretary of the Department of Homeland Security, was given charge of developing that NRP piece.

So even within DHS, those many agencies are trying to figure out, you know, how are we going to approach this in a way that makes sense to everybody. Meanwhile, back at the ranch, all of the rest of the federal agencies and departments have to kind of play into all of this. And it is difficult, at best, to cobble all of these things into one thing and then, you know, take the lead of -- so I'll just say that DHS is in charge of pulling that together for now, but within DHS, actually, it’s a huge department, and they’re working on it. Governor -- Secretary Ridge actually released, very recently, an initial template for the NRP. It’s actually a very basic document. It was -- he had a

deadline that was established in the HSPD number five of getting something out. It is out on the street, and we can get you a copy of that, if you will. But it's very basic. It doesn't really talk about very much. It just says, well, here are some of the key assignments and roles and we're going to just roll or get something together.

Did that answer your question? Did I miss anything?

MR. TYNAN: Okay. We have Dr. Bayse. We're going to have two more -- I think Mr. Govro came up. We'll take Dr. Bayse. Then Dr. Johnson will have a two short answers. And then we're going to ask Dr. Chen to stay with us.

Dr. Bayse?

DR. BAYSE: Yes. Dr. Chen, I wanted to go back, and in fact it's already been alluded to by Dr. Carpenter, under Operation Liberty Shield. You mentioned the difficulty of the lab tests in terms of sensitivity, particularly in the food matrixes. And you also mentioned the coordination that's come about between state and federal. And then you also mentioned public health laboratories. I did not ever hear

involvement of the academic arena here. I hope it has been called upon wherever appropriate, and I realize there are security clearance issues, but I would like to think that the appropriate academic laboratories were being involved as well.

DR. CHEN: Right. Thank you very much for your question. You are absolutely right. I -- the academic laboratories represent a huge resource in this area. There are a number of issues that are sort of at play in more fully engaging the academic community. I think there's a more mature involvement of academia at some of the animal and plant diagnostic -- in fact, a number of the laboratories are actually located in academic centers. Some of those issues have to do with, I guess, regulatory issues, you know, regulatory-related issues.

But I think in food security, a lot of the regulatory issues kind of fly out of the window a bit. So I'll just say that the academic laboratories have been considerate. And I think at a certain point -- I mean, we've even -- there's been conversation, too, about research capacity, and we get really hit hard of industry. I mean, there are a lot of other resources

out there that we may need to tap into. And so I would just say that academia is certainly in our area, and I thank you for bringing that up.

MR. TYNAN: Dr. Johnson?

DR. JOHNSON: A quick comment first. You mentioned the interaction with APHIS and FSIS during the New Castle outbreak. Speaking for the poultry industry, we all certainly appreciate -- it was done very well and very effective, and we appreciate the activity. I understand those teams worked long and hard hours, and we appreciate the interaction there.

I do have a question on your vulnerability assessments that are being done. I know that's all classified information, but as you said, it all can kind of spill over to work toward the betterment of food safety security within industry as well. Is there any thought on how you share that with industry, how you get that information out? Is it already being done?

DR. CHEN: Very good. That's a great question. One of the difficulties in critical infrastructure protection and organizing sector is the extent to which we are able to share classified and sensitive information with non-federal entities. That

includes state governments and industry and so on. In fact, DHS is developing and further refining right now methods to share classified, sensitive information with the owners and operators of the sector, i.e. in this instance the food and agricultural industry. There is an information sharing and analysis organization that the DHS is actually looking at further refining and being able to get sensitive information out to, say, a select group of cleared owners and operators. They've done it in other sectors. They want to try to do it in food, and that's being worked through. Although that whole issue of security clearance is just -- is a tough one.

Now in terms of vulnerability assessments, the -- a lot of the initial work that we did at FSIS in terms of vulnerability and then with the DOD methodologies, we did in house. And now we have begun to engage state, industry, and others. We actually pulled together, a couple weeks ago, Dr. Carol Maczka in our Agency who is one of the leads in pulling together these vulnerability assessments and analyses, we brought together a select group of people from industry like the trade association from the state government to help us review some of our

work. And at this point, what we were trying to do initially is to sort of look at the unclassified aspects, methods, and stuff, and kind of say, you know, “What do you guys think? Are we on the right track here? Did we miss something?” Something like that. But we envision, at some point, trying to get security clearances for this group and others to help us further review and get feedback and insight from industry and state governments.

Down the road, we have to and we must engage state governments and our industry and other constituents in reviewing these materials, getting the information to them, and having them help us address this, because we’re all -- I mean, and I think right now what work is being done to slowly do that but to do that. And the security issues, I think, are trying to be worked out. That is an issue that DHS is really trying to take the lead on trying to grapple it, getting a large number of clearances for people. I think it can be done. It’s just a matter of trying to find the best way to do that. And we’re just itching to get this information out to others, because they have to help us think about this themselves. And at the end of the day, no matter what

we do in the federal side or even the state side, if -- the owners and operators have to do a lot on their own as well to get things together. So we recognize that. And it's an area that I think we're going to get more -- you'll see more and more and more and more and more and more.

Thank you for a good question.

MR. TYNAN: I'm sorry that Dr. Chen doesn't have a little bit of interest in his topical area for you. He has no short answers, I think, for any questions.

We're just slightly over time, but on my agenda, and I hope on yours, too, we're ready for a break. I know I am. And so maybe we could take 15 minutes. That would bring us back, according to my watch, about five minutes to. And then we'll start back into the agenda.

And I'd ask, again, Dr. Chen, to stay around for a little while in case there are other questions that need to be asked and answered.

***

[Off the record]

[On the record]

***

MR. TYNAN: I'm adding a new rule that responses have to be under half an hour for each question. D. W. knows the topic so well that he can't help but proceed a little bit further.

On our agenda, we're going to take at -- we're supposed to start at 10:45. We're a little bit behind. We're going to talk a little bit about the procedures for conducting inspection in Talmadge-Aiken plants. And we have Dr. Barbara Masters from the Office of Field Operations. And she's going to start it off. And I think Ms. Cheryl Hicks and Dr. Bill Leese are here to help out.

Could I ask one other favor? I was reminded that we do have transcribers. And so as you're introducing yourself when you're asking questions, if you could identify yourself, I think that will help the transcribers identify the people correctly who are asking the questions. Okay. Thank you. Sorry.

DR. MASTERS: Thank you, Robert.

Before we get started on our next topic, I would propose that perhaps I have the wrong title, and I would propose that because we recognize there's concerns today

in how the Agency is working with our federal/state inspection program, and that is not the purpose of this topic. We recognize those concerns exist, and we welcome input on that during the public comment period or also through chains in the Agency. But what we are really challenging and looking for from this work group is information that will suit us one or two years out from now so that doesn't take away that we have -- know there are concerns today, but we really need to use Robert's rule number three to stay focused on task, because the Agency's in a situation that our budget process takes us two years out as we start to make any changes.

And Dr. McKee has really challenged our Agency to put in the appropriate framework to become a premier public health regulatory Agency. The Office of Field Operations, to achieve that ultimate goal, has had to make some infrastructure changes to our workforce. As we make those changes, we have to do them incrementally along with the budget process. And Ms. Hicks is going to walk you through some of our goals and charges that we have for our own selves one to two years out for the budget process. And what we want to hear from this

Subcommittee is how we can ensure that our relationship and our work with the federal/state cooperative program parallels the changes that we're making so that we don't go one direction and leave where we're at today where we already have some concerns that we're aware of and get further apart. We want to be able to track those two things together.

So I want to challenge the group to not focus on the concerns that we know are surfacing today and to save those for the public comment period or for other times through the Agency. But we really do need and value the input on how we can move together to the ultimate structural changes that we're going to be making within the Office of Field Operations.

So with that, I'm going to ask Ms. Cheryl Hicks from our program area to walk through the paper and the questions that we have for this Subcommittee that we really do have some interest in getting some input on.

Thank you.

MS. HICKS: Good morning.

As Dr. Masters said, I'll be walking you through the paper that you have and the questions that we'll be putting before the Subcommittee this evening. I wanted

to also mention that the reason that I'm here presenting this paper is that I'm -- have been very much involved in OFO's workforce transition initiatives, but we have here Dr. William Leese who is the Director of our federal/state relations staff. And he is the expert on our state programs on Talmadge-Aiken.

As Dr. Pierson mentioned in his opening remarks, one of Dr. Murano's goals is to make -- emphasize the model of management effectiveness and efficiency. And of course, the Administrator, again, put forth his vision about us being a premier public health regulatory Agency, and that's kind of the framework under which we're presenting this topic.

As Dr. Masters mentioned, consistent with that vision and Dr. Murano's goals, we're retooling our workforce and infrastructure, particularly in the field. And one aspect that I wanted to highlight specifically is we want to move towards a more team approach in inspection in the field under which we'd have less of the situation we have today which is where our resources are tied to specific plants. We want more flexibility in how we deploy those resources to handle the food safety and public health and enforcement

responsibilities.

The -- getting specifically to the Talmadge-Aiken, the Federal/State Cooperative Inspection Program is a cooperative agreement under which state employees can provide inspection at federal plants. There are nine states under which -- that are operating with these agreements in place, and it covers about 350 plants. And where we are today, which Dr. Masters alluded to, is we need to examine the role of this cooperative arrangement in light of the fact that we're retooling our workforce and our approach to inspection and enforcement.

The authority for the cooperative arrangement is from the Talmadge-Aiken Act of 1962. And under these arrangements, FSIS has made decisions on a plant by plant basis in consultation with the state programs. And you know, the bottom line is there what is the best use of its federal resources and the situations under which it has worked and been used primarily is where the economics of the situation make it effective in that -- in -- particularly in remote locations, rather than assigning a federal inspector to that remote location if the state has resources in that area and is willing and

able to provide coverage, the arrangements have been put in place.

The funding for these cooperative arrangements has been consistent with state program funding, which is 50 percent. And again, this issue has been brought to light for a number of reasons, not only our desire to move to an integrated team approach to inspection and enforcement which called into question how that would square with these TA arrangements, at least in some cases, but also states encountering budget difficulties have led some of the states to consider dropping these TA arrangements.

Some of the difficulties and -- or issues involved in having state resources carrying out federal -- inspection of a federal plant are that there's two management structures involved. And that means at times in dealing with compliance or employee issues, it becomes complex and burdensome because you're dealing with the federal system and then the state system as oversight of those employees and those plants. So that can result in undue time delays and inefficiencies in dealing with the issues. And therefore, the cost of that, you may, in some cases, offset the benefits.

And then, as I mentioned earlier, we're seeking advice about how a Talmadge-Aiken arrangement would -- and our future team approach to inspection, whether that would be compatible.

So the questions that we're putting before the Subcommittee this evening are: how would you define a role for Talmadge-Aiken in today's public health regulatory environment, or as Dr. Masters says, the team approach we're talking about a year or two out? This isn't something that's going to happen tomorrow. And under what conditions would Talmadge-Aiken be appropriate in this environment? And then what measures of effectiveness should FSIS use to determine the value of a given Talmadge-Aiken arrangement?

And with that, I'll open it up to questions to clarify the information that's been presented.

Dr. Jan?

DR. JAN: Thank you.

Lee Jan, Texas Department of Health. I want to first mention that on your, about, third or fourth slide, you mentioned about the funding being 50 percent, but actually there's also another part of this, and I think it operates under Talmadge-Aiken agreement, and

that’s cost utilization where FSIS funds 100 percent. So there’s some discrepancy there.

But my question -- or what I'd like to do for clarification, you talk about the TA and team approach may be incompatible. Can you describe or tell us what the vision or the idea of the team approach is?

MS. HICKS: Yes. And some of you may be more familiar with the agencies than others, so I'll go into a little bit of detail, but you know, the structure we have in place now is we have circuit supervisors and a number of plants and the inspection resources that are assigned to those plants report to that supervisor. What we are in the process of doing is transitioning that position to what we’re calling a front-line supervisor, and the vision is that when we eventually get to a point where not only in-plant resources can be used more flexibly, as I said earlier, not necessarily assigned to a specific plant, you know, for an extended period of time, but also resources that we have currently that report to the district office, like our consumer safety officers and compliance officers, would also be assigned to these front-line supervisors. So they would have the full complement of our front line

workforce, and that front line supervisor would have the authority and responsibility for deploying those resources in a way he or she sees fit for that collection of plants in his or her area.

MR. SCHAD: Dr. Jan stole my question.

MS. HICKS: Okay. Ms. Eskin?

MS. ESKIN: Yes. Sandra Eskin. Could you tell me what was the intent in 1962 behind the passage of the Talmadge-Aiken Act, because that would obviously be relevant to the issue of how it fits in today's environment?

MS. HICKS: Okay. Dr. Leese, can you address that, please?

DR. LEESE: I guess my stereotype is that I was around, and this one is a parallelogram or something.

Well, the Talmadge-Aiken Act is a general document. It doesn’t make reference to food safety inspection service. It makes reference to the Department of Agriculture and the Secretary and gives the Secretary, at his, and it says his, authority to utilize resources from state programs when it would be mutually compatible and effective to do that sort of thing to avoid

duplication of functions, facilities, and personnel and contain closer coordination and greater effectiveness and the economy and the administration of federal and state laws and regulations. It's a very small law. It's only one paragraph.

MS. ESKIN: And again, over the last 40-some odd years, has -- we're up now, you said, to nine states and 350 plants. Has it been a pretty steady growth? Again, you say it's done on a plant by plant basis, or is it something that's being utilized more recently?

DR. LEESE: I think it started out -- maybe someone else has some comments or -- but it was something that began, in my understanding, primarily back in the late '60s when the whole transition under the modifications of the Beef/Poultry Inspection Acts came into place and the requirements as we know them now came into place for the states. That -- this program flourished. I don't know how many states were in the program, but I've been working with this for about seven years, and it's been consistent during that entire time.

DR. McKEE: As Ms. Hicks indicated, it was viewed initially to look at the opportunity to provide coverage for hard to fill or remote kinds of areas. And

that was the initial, as my understanding. And it was -- and that criteria has pretty much continued today.

MS. HICKS: Okay. Mr. Govro?

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. You've mentioned that there are nine states participating, covering 350 plants. And I'm wondering if you could characterize a little more completely the -- what this means to the Agency in terms of dollars and cents. Are there -- does this represent savings to the Agency? What is the cost involved in running the program? Is this something that makes sense, dollars and cents wise, to the Agency?

DR. McKEE: Well, as Ms. Hicks indicated, as we strategize on how to do team inspection and provide more expertise in the plants, the question comes up as to whether it is still feasible to maintain certain levels where you've got the inspectors in the area as well. And so I think that's the question that's on the table here is that what are the plusses or pros and cons of that continuing? In other words, the approach in the past has been it's 50 percent, and I know there may be some issues on cross-utilization. I'm not that familiar with that, but I think that's the issue of the TA plants

as to what -- how that will fit into a team approach inspection program.

MS. HICKS: Were you asking more about figures and stuff like that?

MR. GOVRO: Yeah, really about the cost, and I'm just kind of wondering if you scrap the whole program as not compatible with your future goals, would it represent then an increasing expenditure that you -- to the Agency to put USDA employees in areas where you currently have state employees, or have you determined that?

MS. HICKS: I don’t know that we’ve done that analysis as yet, but yeah, that would be a factor.

Okay. Dr. Hollingsworth?

DR. HOLLINGSWORTH: I’m not sure that I’m totally following this team approach concept in that my understanding is states have to have equivalent programs to FSIS anyway. So whether it’s a state program or a Talmadge-Aiken plant, my understanding is they’re going to have to have a compatible or equivalent system to FSIS regardless of whether the employees are state employees or federal employees. It’s the system that would be changing. So I would -- I'm not sure exactly

how the team approach would change a Talmadge-Aiken plant versus the entire state inspection program in those states where they have them.

And my other concern would be if there is a Talmadge-Aiken plant that currently is allowed to ship interstate and they choose to keep the state employees -- reporting to the state chain of command, then does that mean they would no longer be able to ship interstate, like a state plant? How would that impact the difference between interstate and intrastate shipment of product?

MS. HICKS: Well, I'm -- the issue that we're talking about here is not just state -- it's just the Talmadge-Aiken plants where state resources are in federal plants. And the reason we think that it's something to question the usefulness of that arrangement in view of where we're going through this team approach is because of the two management structures. We have the employee -- state employee under the oversight of the state and we'll have our front line supervisor deploying resources to that plant and other plants in that geographic area, and it's dealing with two management structures and having the flexibility to move

resources around is really that issue.

And then what your second question was about...

DR. HOLLINGSWORTH: Interstate shipment.

DR. MASTERS: A little bit more on the first question, just to make sure that people are clear on that, is for example, if there are ten people that make up a team, the front line supervisor is going to use information provided by the Agency data to assign those resources. And so if there is an individual assigned that is a state employee, they're going to have a different supervisor, and so the front line supervisor is either going to have to go through that supervisor to deploy that inspector or maybe the group can suggest other means that we could do that. But that's the issue there is there's another supervisor that that state employee reports to. But yes, they are equivalent systems. So it's not the system that we're concerned about, it's how our front line supervisor would deploy a state employee under team inspection since they already report to a state supervisor. So that's the question we're looking for some insight on.

As far as whether or not if the state decided to keep that, it's the plant's decision as to whether or

not they have state inspectors or federal inspection. So if they are choosing to have a federal grant of inspection for which they applied, then the Agency would provide the resources there, and so the interstate/intrastate would not be an issue. The grant of inspection is what would drive that, and the plant is the one that would fill out whether they wanted a state grant of inspection or a federal grant of inspection.

MS. HICKS: Dr. Jan? Oh, I'm sorry.

DR. JAN: Lee Jan, Texas Department of Health. I've got -- I wanted to respond just a little bit to Ms. Eskin's question about -- regarding the TA activity and stuff and clarify or expand a little bit on what -- as Dr. Leese said, but then Dr. Masters brought in something that I want to respond to as well. And that issue is that Dr. Masters' point first where a state employee in a federal plant needing to respond -- answer to his supervisor or her supervisor before dealing with the federal. The current set up is that those nine state programs, all of the TA plants form a circuit, and that circuit functions like any other circuit and the inspectors respond to the state program coordinator. And the state program coordinator then has a

relationship with the district manager. So there's not a supervisor interconnectivity currently.

Now if you're talking about changing that where state programs will not be able to function as front line supervisors of their own teams because states can't have CSOs, states -- you know, finally, after much pleading by the states, are allowed to send people, their staffing, to the CSO training, so they get the same training by the same people, so there's no reason that state, if the TA system is intended to continue or be utilized to finally be efficient that the state couldn't use that same team approach and would not have those issues about dealing with two supervisors, because we'd still answer to the same Agency -- the same person, which would be the district manager.

In responding to the -- or expanding a little bit on Dr. Leese's response about -- you know about the TA and it began in the '60s and all, from the state perspective, I just wanted to point out that -- or at least in my -- our state, for many years, it was pretty status -- the number of plants that didn't grow had stayed the same. It was those plants that had grown and were needing to ship in interstate commerce, but that

number stayed about the same until HACCP was implemented, until it was fully implemented and about the same time the use of the Internet opened up markets. And I think the two things together, the relative new -- relatively easy, new way of getting their products distributed across state lines for a lot of the smaller companies. And the costs associated with implementing some of these processes in plants made some of the plants -- more of the plants to go and request federal inspection. And at least in Texas, we more than doubled our load from what's been going on for years. And at that point, we've doubled from about 23 to 60.

So there are a lot of reasons. And those having that TA opportunity, I believe, helped FSIS pick up these plants and provide, because most of these are state plants operating an interstate system identical or equal to USDA's, so there's really no change for the plant. They just changed their market inspection and were able to move on. And had they -- had the TA system not been in place, it's likely that FSIS would have to say, "We can't take you on right now. We have to hire on new people." And everyone knows, I think, that FSIS has had a long-standing history of vacancies unable to

fill. So I think there's a purpose. The TA system works, and it provides a good resource for FSIS.

But anyway, I just wanted to point out that there has been an increase in the TA plants over, say, the last four years or so.

MS. HICKS: Mr. Kowalcyk?

MR. KOWALCYK: Michael Kowalcyk from Safe Tables our Priority.

On slide five, a couple of points disturbed me -- or actually slide six. Due to compliance issues becoming complex and burdensome as well as undue time delays. If you can expand a little bit on what problems you have seen with the Talmadge-Aiken plants with respect to compliance issues as well as time delays and what the Agency's -- what steps the Agency's looking into taking to address those issues.

MS. HICKS: First I'd just like to say that that was an example of, and there may be some instances that Dr. Leese or Dr. Masters can mention, but that was mainly an example of having to deal with the two management structures. More time is taken because they have to go through another chain of command rather than -- you don't have complete control over the resources,

so that's what that was about. And we're, you know, under this future approach than I think that what we're dealing with today. I don't think we have a specific incident in mind.

MR. TYNAN: Mr. Kowalcyk, did you have a policy -- a question? It looked as though you were -- okay.

MS. HICKS: Okay. I think Mr. Schad was next.

MR. SCHAD: Yeah. Mark Schad, Schad Meats. I'm a state plant, but not a TA plant, so I need a little bit of clarification on this. Is this strictly a budgetary issue with FSIS or not? It's not strictly that?

MS. HICKS: No, it's not.

MR. SCHAD: Dr. Masters, you were talking about that, and that's where I got confused on what determines what's a TA plant and not a TA plant.

DR. MASTERS: Okay. Let me clarify, Mr. Schad. When I was saying budgetary, it's budgetary only from the perspective that if we made drastic changes, as an Agency, we have to make those changes to our budget two years in advance.

MR. SCHAD: Okay.

DR. MASTERS: It's clearly not a budgetary issue for us, and that's why we want input from the Subcommittee is we -- and it feeds back to what Dr. Jan was saying. There may be approaches and we're not opposed to those approaches. What we're looking for is the best way to utilize our resources so we don't have duplication. If the front line supervisor is in the field and the TA plants are spread across, for example, the State of Texas, which is very large, that state inspector may be pulled into a team that is led by an Agency front line supervisor. And so what we're looking for from the Subcommittee is will that work. If it will work, how? And if it's not going to work in every case, the Agency may have to adjust their budget request for two years out. But it's not because it's a budget issue with TA plants. What we're looking for is the best and most efficient utilization of that agreement.

MR. SCHAD: So a state plant interested in interstate shipment, do they have that option whether, you know, I'm going to apply for federal or I'm going to apply for TA? Is that -- who decides that?

DR. MASTERS: The plant would -- could apply for federal inspection, and it would be an agreement

between the Agency and the state programs as to the best way to cover that facility. It would not be at the request of the plant.

MR. SCHAD: Okay. Thank you.

MS. HICKS: Okay. I think Mr. Govro was next.

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. Could you just elaborate a little bit on the first two questions there? They seem a little bit vague to me, and I would just appreciate a definition there.

MS. HICKS: Yeah, I -- the first one is, you're right, it is stated kind of broadly, but really it should be -- what we are doing with our front line workforce is in the context of our public health regulatory environment. And so when you're addressing that question, it's really what we've been talking about this morning is, you know, what do you see as the role for a Talmadge-Aiken cooperative agreement, keeping in mind where we're going with our workforce to fit into our public health regulatory environment.

And then it -- the second one is just kind of an extension on the first question which is under what conditions would it be appropriate in that environment.

So what role would it play and under what conditions, because as I think we have stated in both the presentation and some of the discussion here, it doesn't have to be an all or nothing, and it could be that in some situations it's appropriate and some it wouldn't be.

Dr. Hollingsworth?

DR. HOLLINGSWORTH: In addressing this issue, then, is there anything else that the Committee would need to know? Like, is there any legal reason or -- other than just the supervisory chain of command, is there any reason why a state inspector can not be part of a federal team in coverable federal and TA plants or would there be -- I guess what I'm not sure of is is that even an option? And we don't know if we can consider that. Can a state inspector be assigned, if their supervisor -- if their state supervisor is okay with the idea, can a state inspector be assigned to a federal plant that is not a TA plant? Is there any reason why that just couldn't work if that state employee becomes part of the federal team or is there a problem there that we're not aware of and that's why you're challenged with this issue?

MS. HICKS: I think that the Talmadge-Aiken Act is what allowed the Agency or the USDA to assign state inspectors to federally inspected plants. I don't think -- I mean, it doesn't go -- it's not specific at all. As Dr. Leese pointed out, it's a paragraph. So I don't think there's any impediment to -- legal impediment to -- that agreement working under team inspection. It's more of a -- this is an efficient way to go, because it would be effective.

DR. McKEE: I might just answer your question. If I understand it, in the state of -- state employees usually can not engage in any kind of activity with the federal mission, regardless of what area of food, or any other area, without a formal relationship, in other words an MOU or some kind of a contract, in order -- because of the responsibilities being delegated and reimbursement issues and supervision issues. So that has to be a formal arrangement. I don't know if that was part of your question or not.

DR. HOLLINGSWORTH: I think it does so long as what I'm understanding is that that's exactly what the Talmadge-Aiken is is it's that formal arrangement to allow state employees to work in a federal facility or a

federally inspected facility.

DR. McKEE: I think that’s fair to -- yeah. You’re right.

MS. HICKS: Ms. Eskin?

MS. ESKIN: Two questions. First, again in the slide and in the discussion, you've talked about the complexities of having, sort of, overlapping authorities, and I guess the question is have complaints reached you from the field saying that there are -- it’s very hard or there are certain obstacles in implementing and having these Talmadge-Aiken plants? That's question number one.

And number is I know you say it’s not necessarily going to mean all or nothing. There may -- the program may be retooled in some way, but again, if these state inspectors are doing what federal inspectors would otherwise be doing to govern all of them, then there is a budgetary impact. You would have to have more inspectors to take the place of these -- more federal inspectors to take the place of these state inspectors? I know it may not be that extreme, but that’s what we’re talking about here.

DR. MASTERS: And I think it would -- we would

have to look at it and see. In some cases, it would not, under a team approach, may require additional inspectors, depending on the remote area of the plant, whether it's remote or whether it's closely associated with other federal plants. And I think that's -- so it may or may not have budgetary implications. And at this point, what we're saying is at this point the Talmadge-Aiken, the federal/state cooperative program is working. It's not that we don't believe it's working. It's just that as we move forward to a team approach, if we're going to continue with the TA arrangement, we want to parallel that approach as opposed to staying where we're at today and us moving forward with our infrastructure changes and approaches to inspection and not bringing that TA program along with us to be compatible to that in those cases where that would work. Because today, as Dr. Jan said, that state inspector would report to the TA coordinator. They would not report to our front line supervisor. So what we're looking for is are there ways to bring that TA coordinator into the fold. Are there ways to bring that state inspector into a front line supervisor fold? We're looking for the group to share with us how we can be parallel and move forward as

opposed to an arrangement that works today that may very well not work two years from now if we leave it at the status quo.

DR. McKEE: I might just add to that that my experience in the state is that it would be unacceptable, for instance, somebody from one state that was an inspector to be on a team that would be inspecting in another state. And that would be an issue, I think, from the state level unless that is -- have a dialogue about that and is overcome, because clearly that becomes an issue for state governments.

MR. TYNAN: Are there any other questions on the topic? It's -- we're running just a little bit over again, so perhaps it would be good to pass on to the next topic. Any burning questions? Okay, then. Thank you, Cheryl. Thank you, Dr. Masters. And thank you, Dr. Leese.

I think the next topic on our agenda relates to Dr. David Goldman, and he's going to do an issue related to how can FSIS better associate food safety activities with public health surveillance data? Dr. Goldman?

DR. GOLDMAN: Good morning and thank you. Just to reiterate the point that both Dr. Pierson and

Dr. McKee made earlier, this issue that we're bringing before the Committee today is directly related to an issue that's contained in the vision paper that was referred to earlier. In fact, it's on the very last page. It's issue number three, so you could take a look at that later and see how Dr. Murano has characterized needs that need -- issues that need to be addressed with respect to associating our program outcomes with public health surveillance data.

As was also mentioned, FSIS is very keenly interested in linking the outcomes of its regulatory program with human health data. As Dr. McKee said earlier, one of his goals or his overriding goal in coming to the Agency is to make FSIS into a first-class public health Agency. In fact, FSIS is a public health regulatory Agency. And I've listed here the -- what I've -- my characterization of our public health issue, which is to reduce food-borne illnesses that are associated with the products that we regulate. Our regulatory mission might be characterized as our efforts to ensure safe and wholesome food production through our regulatory programs.

If you look at both of those missions, you realize

pretty quickly that they are really the same mission. The problem that we are bringing to the Committee today is how best to assess how we are doing in meeting those missions, that is how to link our food safety efforts with changes in food-borne illness rates. And let me give you an example to illustrate the problem that we have. Again, this will reiterate something that was mentioned earlier, but over the last six months, FSIS has announced publicly that there have been declines in the rates of salmonella contamination in raw products, decreases in the rates of listeria contamination in ready-to-eat products and decreases in the rates of *E. coli* O157:H7 in ground beef.

Now on the human health side, Food Net, in its most recent data, which actually is from 2002, has shown a significant decline in listeriosis cases and also a decline in salmonella type [inaudible]. If you were to look at the Morbidity and Mortality Weekly Report, which is the CDC's weekly update on public health surveillance, the provisional cases, year-to-date of salmonellosis, listeriosis, and *E. coli* O157:H7 infections are down this year compared to last year for the same time periods. Now these are provisional cases.

They haven't been absolutely confirmed, but if you put these two sets of facts together, there is good news here, and we all have a shared interest in trying to link those two sets of data.

And that's, again, the issue that we bring before you today. Linking those two sets of facts is not a simple matter, however, and the complication is in our incomplete knowledge of what we, in the public health community, call attribution. In this context, attribution refers to the determination of the fraction of food-borne illness that are caused by specific food vehicles. Let me illustrate one of the problems we have in attribution with another example. *E. coli* O157:H7 has historically been associated with ground beef ever since the outbreak about ten years ago that was associated with fast food hamburgers. However, in the public health community, since that time, we have learned a great deal more about this pathogen. It has been associated with illnesses that have been caused by produce, from unpasteurized juice, from recreational water contact, from contact with farm animals. So what is not precisely known now is the proportion of illnesses or in any given outbreak the number of

illnesses in that outbreak that are related to ground beef or to beef or to any other exposure. And that, again, is an illustration of the problem that we have.

Now in an ideal system, we would be able to track a pathogen from its food, animal reservoir, through production, to the consumer's table and then into human illness when those illnesses occur. We don't have such a system right now, and it would be a very costly system to build. Food histories are a very essential key to our getting to the bottom of this attribution issue. Food histories are necessary, although they're not always sufficient in our attempt to describe attribution more precisely. For example, if all persons who presented to a position or for medical care with a gastrointestinal illness were to immediately give a complete food history, we would be better off than we are now. But as any of you who have had such illnesses can recall, first of all, you don't always go to the physician or to a -- to seek medical care, but even when you do, if you go to an emergency room, you're not always questioned in a very detailed way about your exposures. Certainly prompt investigations of those cases that are recognized, and especially those cases

that are lab confirmed, an investigation of outbreaks are critical to our knowledge of attribution.

Finally, there is another method that is being employed more and more called molecular epidemiology. And that typically involves subtyping of pathogens, and it helps to provide the link, in some instances, between human illness and the food vehicle that led to that illness. I'll just mention here that FSIS is a full member of an entity called Pulse Net, which is a lab network that’s based and housed at CDC and has participation from the 50 state labs, typically the public health labs, as well as the regulatory labs. And it contains a data warehouse of pulsed field gel electro patterns from clinical specimens and from food specimens. This tool has been used extensively in recent years, really in the last two or three years especially, to help us identify outbreaks and sometimes in cases where the epidemiology, or that is the food histories, haven’t yet linked those cases together.

Now Food Net is another entity, a public health arrangement that was created in 1995 to help describe the burden of food-borne illness in the population and, more specifically, to better describe the relative

contributions of the various food products to that burden of illness. FSIS was one of the founding partners in this arrangement, which originally consisted of five partner sites and now includes ten partner sites. And you can see the three federal partners listed there. Food Net provides annual estimates of the burden of illness through its active surveillance of lab-confirmed cases.

Within Food Net, there are specific kinds of studies that are done that help us, that is at FSIS and the public health community at large, to learn more about attribution. There is an epidemiology study called a case control study, and I won't go into great detail, but these case control studies have been used to generate what are called population attributable fractions. That is, they are able, in some cases, to determine, based on an analysis of the risk factors that led to illness with a particular pathogen and the proportion of the population that has been exposed to that risk factor to give us a fraction of a particular illness that might be attributable to a certain exposure. There are a group of case control studies that Food Net is -- has completed and are about to be

published early next year, so I will just let you know that there will be a special edition of the Journal of Clinical Infectious Diseases early next year, which will have a good number of these case control studies in it.

There is a separate and another effort within Food Net and within the attribution work at Food Net that is housed in what has been formed this year and called the Attribution Work Group in which there will be comparisons of food product microbiologic data, food consumption data, human illness data and put into a mathematical model and employ a method to help us better understand the exposures that have led to illness. Let me just provide another brief example. There has been some recent work as part of listeria risk assessments in which there was an analysis of the different exposures that might lead to listeriosis. Pasteurized milk is not commonly thought of as a risk factor for listeriosis, and yet there are some people who have gotten sick from pasteurized milk. Smoked seafood, on the other hand, has been shown to be quite a significant risk factor. But on a population basis, because there are so many more servings of pasteurized milk across the country than there are exposures to smoked seafood, the

population attributable fraction is different than you might expect.

Let me elaborate a little bit on the Attribution Work Group. The Attribution Work Group was established at this past year's Food Net vision meeting as one of the top priorities. And it has remained a top priority for our Agency, and I indicate here that we have eight staff members at least working on this issue representing all four divisions within the Office of Public Health and Science in addition to the Human Health Sciences Division. And I want to acknowledge now that we have three of the eight members in the audience today: Dr. Jane Harmon back in the corner, Dr. Kristin Holt, Dr. Alecia Naugle are all three members of the Attribution Work Group and are actively engaged in the efforts of that group. And also, Dr. Sean Altekruse is from the Office of Policy and is also actively engaged in our Agency's efforts in this issue.

Let me explain a little bit more about the model, the attribution model that this work group is working on. I mentioned earlier that it is a -- as I said, it will also incorporate whatever data is available regarding food-borne infections and whether it be data

from food animal infections, that is in live animals whether it be their microbiological contamination data that is collected either at retail sites or that is collected by our own Agency, it will incorporate food illness data, and again, will provide a model for explaining, better than we can at present, the exposures of interest to FSIS in particular but in fact for all foods that have led to human illness.

There are some other attribution methods I just want to mention to you. Outbreaks are another way of looking at attribution. Unfortunately, the etiology and the vehicle, meaning the food vehicle, are not known for the majority of the outbreaks that are reported. And although when outbreaks are investigated and do determine a particular etiologic agent and the food vehicle, they are -- they do provide good information about attribution, again, that represents only a minority of the reported outbreaks.

I will also mention here that FSIS has used information and data from outbreak investigations to examine and re-examine its regulatory program, so the use of outbreak data and investigations has yielded an opportunity for FSIS to address particular pathogens,

particular processes in its plant and the implementation of its policies. I'll mention briefly here, and no offense to any risk assessors in the group, this is just my characterization of risk assessment, but risk assessment really is a method for predicting risk from particular food vehicles or exposures through -- again, through a use of mathematical models, so it tends to come at attribution from a predictive perspective.

I want to end up by really just listing some of the barriers to our better understanding of attribution. This is not even an exhaustive list, but it does list some of the issues that are core to the problems we have had as a public health community in determining food-borne attribution. As I mentioned or eluded to earlier, not only do people not present to physicians or for medical care in every instance of food-borne illness or gastrointestinal illness, but in fact, when they do present for care, there is not always a culture taken or requested, and there’s not always a culture confirmation of a particular pathogen. As I also mentioned a minute ago, there are often incomplete investigation of food-borne illness cases, and very prominently among sporadic cases. And what I mean by that is it’s the isolated

case that comes to the local health department on any given day and a nurse or an environmental health officer will get a lab report that says salmonella. It may or may not have the species there. And that public health investigator will do some follow up on that sporadic case, but a recent survey of public health departments by a national organization found that the primary reason for not investigating cases of food-borne illness is a lack of staff. So public health resources are simply not available to investigate, again, mostly sporadic cases. We do a better job, generally, with outbreaks.

Another key barrier is an inability to locate and test suspect foods. Again, in that same survey of local and state public health departments, it was found that typically either the wrong food was identified or was -- or the food that might have been appropriate to test was simply not available. A lot of that has to do with the timing of the effort to find that food. Another barrier is this lack of specificity in food pathogen pairs. And I, again, alluded to that earlier when I mentioned the illustration of *E. coli* O157:H7, which historically has been associated with ground beef. And as I said, we are learning more to the extent that we can no longer assume

that an illness is caused by even a meat product when we see *E. coli* O157:H7.

The last bullet refers to the fact that there is -- remains incomplete knowledge about the variance of pathogens, and an example here is that FSIS monitoring data frequently -- or one of the most commonly recovered salmonella pathogens is *Salmonella kentucky*. However, in the CDC's surveillance of salmonella illnesses, *Salmonella Kentucky* does not show up on their top 20 list. So again, we do not fully understand why some species are pathogenic and some are not. Again, this is a continuation of a list of some of the barriers that we face.

The second bullet, there is not an ongoing program of continuous microbiological testing of food in all commodities. One of the issues that's raised in the vision paper is a commitment to ongoing baseline studies, and that is something that FSIS is considering how to implement right now.

And again, on the last bullet, there is a lack of complete data on human illness, and probably one of the most critical factors is timing. And back to that example of the public health nurse who gets a report of

an illness, especially if it happens to come in on a Friday, there are a couple of extra days built in to her ability -- his or her ability to follow up on that case. And timing is a critical factor in obtaining a good food history. And *Listeria monocytogenes* is a special case which presents special problems, because it has -- or can have such a long incubation period. Public health authorities now have endorsed the use of a standardized questionnaire for all cases of listeriosis, which may help us in our ability to get at the risk factors that caused that illness.

I'll end by just calling your attention to the three questions. I don’t have them on the screen here, but the three questions that are in your packet on tab seven: how might data linking food products to food-borne illness cases be used to suggest changes in FSIS regulatory policy? How do or can we get human illness data or other data that’s linked to food? And what other types of data should be considered in the development of regulatory policies, for example, the data that FSIS currently collects in its plants?

I'll stop and see if there are any questions now. Mr. Elfering?

MR. ELFERING: I guess one of the questions I would have is are you -- presently, are you getting any information at all from veterinary diagnostic laboratories? And I'll just give an example. In Minnesota, human health practitioners are submitting their slips to the state health department. Our food samples, positive -- any food positive samples go to the health deportment for testing. The same with -- from the veterinary diagnostic lab. We also have a poultry laboratory. All of those are molecular subtyped right now. Are you receiving any of that information, for example, from Minnesota?

DR. GOLDMAN: I don’t know whether we get that information directly from Minnesota. We -- there is a new initiative within OPHS to look at linking animal health data and food product data more closely, and it’s housed in another division so I don’t know the details of that. But I do know that we have a great interest in linking that. And if I failed to list that as one of the barriers, that is one of the barriers is to bring in animal health, live animal health, data to complete the picture from the farm all the way to the consumer.

MR. ELFERING: And I think one of the things

that we're finding is that there are so many food-borne illnesses that are animal health and food safety related.

Another thing is are you looking at -- there are some concerns with, maybe -- toxin producing *E. colis* that may also cause HUS. Are you looking at other than the 157 as far as *E. colis*?

DR. GOLDMAN: If anyone can help here. I'm not sure -- if your question is are we looking for non-0157 in our labs, I'm not absolutely sure. Lauren, do you...

MR. LANGE: We test for 0157s.

DR. GOLDMAN: Okay. We are certainly aware that that is an issue that there are non-0157s that are causing human illness and that it is something we probably will need to address in the future, but I guess we're not testing for it presently.

Dr. Logue?

DR. LOGUE: Hi. This is more -- mainly just a comment rather than anything. And I know you're gathering data, as you say, from your version or your view, but I just realized that as you're saying this that you're trying to find this link. One of the things

that you might want to consider, and I'm going to speak from an academic point of view, is the academics will have a completely different kind of way of approaching some of this. To me, it would seem like a perfect opportunity to go for -- to link the whole lot. And you know, as I say, from an academic or a research point of view, especially on a -- you know, like a university or a line grant institution, we would probably have -- I don't know if the right word is to say an easier time of doing some of this, but I think we could make the links easier. And surely this is something that you guys need to explore in more detail.

DR. GOLDMAN: Thank you. Dr. Carpenter?

DR. CARPENTER: Yes, I'd like to address barriers to one of the points of precise attribution, and that is the data on pathogen food pairs. I know that on a local level the Pulse Net methodology has been very valuable at tying food pathogens to an outbreak that's -- and from humans. I mean, is that something that you can expand and use in being able to overcome that barrier at FSIS?

DR. GOLDMAN: If I understand your question, we do routinely use this in outbreak investigations, as

you point out. We also submit all of our *E. coli* O157 and our listeriosis for analysis. So they are posted to Pulse Net, to the database. And so even if -- I mean, these are our regulatory samples, so that those that have not been associated with illness or have not been recognized as associated with illness are posted there so that there is -- and one of the things that Pulse Net staff does is to regularly scan all of the postings to Pulse Net so that they can find linkages that might not be evident to the public health community. So yes, we are very much engaged in that process right now.

DR. CARPENTER: Okay. Do you feel that methodology is a top priority to overcoming this barrier to pairing pathogen with isolates?

DR. GOLDMAN: I think it is one of the methods that has been used successfully, so it has a good track record, and will continue to expand. I mean, Pulse Net is continuing not only its certification of labs to participate but also its list of pathogens that will be standardized with -- by this method. So yes, I think it is an important tool.

Dr. Harris?

DR. HARRIS: This is Joe Harris. Just, if you

could -- I'd like to try to get you to elaborate a little bit more on the questions that it -- that you've posed here, the three questions. Specifically, number three comes to mind. The question implies that the Agency currently is not using data collected in plants and development of regulatory policy. Could you elaborate a little bit more on what you're asking there? It says: What other types of data should be considered in the development of regulatory policy? And then for example, data FSIS currently collects in plants. I would assume that those data are already being used.

DR. GOLDMAN: Yes.

DR. HARRIS: I need a little more detail than what you're looking for there.

DR. GOLDMAN: I think maybe part of the problem is the way the question is worded. Yes, we are using data that we currently collect in plants. I think the question is are there other kinds of data that we might be able to use other than the data that we collect in the plants. So yeah, that would be the question to the Committee. Thank you for clarifying that.

Mr. Govro?

MR. GOVRO: It seems that in crafting --

Michael Govro, Department of Agriculture. It seems that in crafting regulatory policy, it would be important for you to know the point of contamination of a food. I'm just wondering of the data you get back separates that which can be attributed to contamination in the plant versus that which happens down the chain.

DR. GOLDMAN: I'll start the answer, and then I'll throw it out to any of my colleagues who might want to contribute to the answer.

Certainly in outbreak investigations those that our Agency participates in, there are very thorough investigations of a point in the process, if, in fact, the process has failed, the point in the process where contamination was introduced into the pathogen. I'm not sure whether the other methods that I've outlined will always be able to account for the point in the process. Certainly, if we have more data along the continuum, we'll be able to narrow down the point in the process at which contamination has taken place, but I don't think we'll always know or maybe even frequently know the particular point, now again, accepting the outbreak investigations in which I think we often can find a point, a weak point in the process.

And Dr. Harmon, please?

DR. HARMON: Yes, I am Jane Harmon. I sit on the Attribution Work Group. And to address two of these issues, I want to address the veterinary diagnostic lab point as well.

I'll start with your question about at what point in the continuum are we going to try to focus on. We're going to try focus on wherever we have sufficient data. And our first thrust is looking at salmonella, because we are using the pattern of serotypes in different reservoirs. It's not the same in swine as it is in cattle as it is in chickens as it is in eggs -- egg products. We are using that to compare to the pattern we see in humans. This is the plan for this fancy modeling, and it's not magic. It uses the comparison of these patterns to go back and try to pin a certain proportion of the cases on ultimately having come from a certain reservoir.

And our best data at present looks like it comes from the products that come out of FSIS plants. It comes at that level, ready-to-eat products in the supermarket, perhaps. We don't have very good data on the salad bars. And this -- for salmonella serotype

patterns. We would love to have more data like that. FDA has done some testing of a very few commodities, but unless we have a pattern just for this one project, salmonella attribution, we need the serotype patterns. If we had money to go out and look at all of the salad bars and test salad bars in restaurants or salad products in the grocery store and give us some sort of a pattern for serotypes of salmonella that they find there, that would be wonderful. We would put that right into our effort. So we are going -- we are at the beginning of this modeling effort, and we are looking at where we have our best data on salmonella serotypes.

To go to the veterinary diagnostic lab, that is, of course, one of the places we, as vets, three of us on this Committee are veterinarians, we thought immediately of veterinary diagnostic labs. A problem with that data is that these are, for the most part, data from sick animals submitted by clinicians, submitted by, you know, the private practitioners or clinicians. And a lot of the human case data is also sick people. For the animal data, we prefer prevalence data from healthy animals or a general population of animals. There are some limited sources out there, APHIS, USDA has done some

surveillance of healthy animals. I know that in some of the universities, some of the vet schools in line grant universities there is some, too. And we are hoping to try to gather as much of that as we can and make it into sort of a national estimate the best way we can do. So those of you who know of these data sources, there's David's e-mail and he'll get it to us.

I would also ask private industry if they have their own proprietary data. We have a university working with us, the School of Public Health. This data doesn't have to come to us, a regulatory Agency. It can be completely anonymous and used by our partners at the School of Public Health. And we have sensed that there is some good data out there in the proprietary system, so the better data we have, the better these models will be. We ask help from all of you.

Thank you.

DR. HOLLINGSWORTH: Thank you. Have you looked at other countries and how they're dealing with this issue? My understanding is that Denmark has a system that's able to integrate all of this data. Have you found that helpful in either ways you hope to learn more from these other systems?

DR. GOLDMAN: Yes, as a matter of fact one of the things that this Attribution Work Group that we were just discussing has done is to get a lot of input from Denmark. So yes, we are aware of that. And we have learned that England does attribution in a completely different way. They use outbreak data, and they extrapolate from the information they get from outbreak data. So yes, we are aware of the systems of at least a couple of other countries.

DR. HOLLINGSWORTH: Two questions. The mention of the School of Public Health, what school is that that you're collaborating with?

DR. GOLDMAN: It's the University of Minnesota who are collaborating as a partner to Food Net.

DR. HOLLINGSWORTH: Okay. And then my other question, in mentioning things like salmonella in salad bars, in this effort here at the Subcommittee, do you want them to be looking at food products beyond the regulatory scope of FSIS? And if so, you might want to incorporate expertise from FDA because there are things that they are doing similar on non-meat and poultry products. And I wasn't sure if we were going to go beyond the scope of poultry and eggs.

DR. GOLDMAN: Well, I think I at least alluded to the fact that food attribution is a big issue, and it does extend beyond the parts that we regulate. Our original course is in our better understanding of the attribution -- to our products. Yes, we are certainly aware of the efforts and the methods of other agencies, and there is some overlapping in the ways that we can go about getting a better understanding of attribution for our respective food commodities, but we're particularly interested in your ideas about data that we might employ for attribution related to our food products.

MR. TYNAN: Are there any other questions? Thank you, Dr. Goldman.

It's a little bit after 12 o'clock, and according to my agenda, I think it's time for a lunch break. We'll break away for about an hour. We'll come back at about five after 1:00, and we'll continue with the agenda.

***

[Off the record]

[On the record]

***

MR. TYNAN: If any of you came back, we will

now hear from Dr. Kenneth Petersen.

DR. PETERSEN: Okay. Good afternoon. I see some familiar faces, and I see some new faces. I am hopefully on the back end of a cold, so if I start getting a little crackly, please bear with me.

We wanted to give you a briefing on some of the activities we are doing in recall and we believe helps us manage the recall information more proactively. We manage it both on the front end of a recall as well as from the back end to ensure that no product is distributed inappropriately.

First I wanted to just briefly go through a couple of slides so that we're speaking the same language. This is our definition of a recall, which is a voluntary removal of distributed products when there is reason to believe that they are adulterated or misbranded under one of our statutes. And we essentially have three classes of recalls. Class one is reasonable probability. That's -- the operative word, reasonable probability of serious or adverse health events, problems, or even death. Class two, the operative word is remote probability. And then class three are typically economic issues, misbranding, that kind of

thing. So class one and two are exclusively those that are related to public health. Class threes are other adulterations, misbranding, under the statute.

This is what happened and the emphasized recall realm in the fiscal year that just ended September 30. Roughly 77 recalls occurred during that fiscal year, going back to October of 2002. That's an approximately 30 percent decrease from fiscal year 2002. And the relative distribution you see here is typical of what occurs from year to year. That is most of what we do is class one. And then from year to year, class twos and threes will kind of interchange on which is second and which is third. But the relative percentages you see here is typical of what we see from year to year. So we went down in this past year.

Now getting to topics and initiatives that we're doing that we think helps us get in front of the recall information. We -- for every recall now, we will have one District Recall Officer. That individual is the Deputy District Manager. That is the number two official in any of our 15 districts. That's the management level we want for field management of a recall. So the District Recall Officer is the Deputy

District Manager in the district where the recalling firm is located. That individual coordinates a variety of field activity. They initially will assign an Enforcement Investigations and Analysis Officer (EIA). Perhaps you've heard of that already today. If not, that is what many of you would consider to be a CSO. This is the new CSO with some expanded duties largely on the compliance side. So EIA Officer is the person who gets assigned to do the hands-on activity.

The District Recall Officer interacts with the recalling firm. He or she interacts with their peers and other districts and they coordinate with Recall Management Division here in Washington, DC. The District Recall Officer also will develop a new effectiveness check strategy.

Then a couple terms we need to make sure we're clear on. FSIS for our pathogen monitoring, pathogen verification program, we report out pathogen results in a couple different ways here. Potential positives are the initial screening result. And our Office of Public Health and Science will report those out for potential positives for largely *E. coli* O157:H7. About -- only about 15 percent of the potentials will subsequently

confirm positive. So it basically puts it on the map that we have something that may be of interest, so it's a screening test. Where we start to now manage off of is at the presumptive positive stage. And these are various chemical microbial analyses that progress through the confirmation process.

So at the presumptive positive stage, OPHS will report out presumptives for 0157, for salmonella or listeria in ready-to-eat, or for salmonella in egg product. And at least 90 percent of those will subsequently confirm. And as I said, we'll start to manage at that point. And the confirmed positive stage is when product is, in fact, adulterated because it contained one of the contaminants.

The -- several things that we have done on the accountability side of -- is for -- is at the district office level where in the last several months since recall, the recall activity in the last year or so when the reorganization came back to the Office of Field Operations. That helps us manage our field resources a little more directly. The -- we have clarified 24/7 availability for recall activities in each of our 15 districts. Each district weekly will post the name of

the individual who will be on call should there be a need for a recall. And that's the distribution list and we all know who is available. And then, for example, if Ron and I have a question on a particular district, I know who to call. Those individuals need to review our lab results routinely, which, in my mind, means at least daily, routinely for lab results in their respective districts.

As I indicated for all presumptives, we expect the District Recall Officer to verify the hold status of that product. When one of our inspectors pulls a sample, they tell the plant, "We're pulling a sample." And they recommend that the sample be retained pending those lab results. Plants are not required to retain it, but many of them do. But we want to confirm it at the presumptive stage, again, because 90 percent of those will subsequently confirm. If the product is, indeed, held, then no recall will be necessary. There may be some activities at the in-plant level regarding that particular -- there will be no recall.

If the product is not held, meaning the product is in commerce, then we begin the pre-recall process. Again, it has not confirmed, but we have a higher

likelihood that it will confirm. So the District Recall Officer will assign one of the EIA officers I mentioned if product is not held. The product not being held, we're particularly interested in getting that understanding when we get late in the week, Thursdays, Fridays, before holidays. We want to have the right people available in preparing at the presumptive stage, so that if we get into the weekend and the product confirms, we're ready to go with the right folks.

At the -- every recall basically begins with problem identification. And these are in relative frequency of how a recall comes about, with the most frequent being a result of FSIS verification sampling, typically microbial sampling, but it can also be chemical sampling and some other sampling that we do. But quite frankly, quickly right behind that is the plant itself. It is not at all unusual for the plant to notify the Agency that either there's been a processed deviation or they have a positive in one of their products, so they will tell us. And that will engage the process. And then in-plant inspectors, outbreak investigations, and the Consumer Complaint Monitoring System also can come into play. You'll hear about CCMS

a little bit more tomorrow.

So we have a presumptive. My District Recall Officer has assigned one of his EIA officers, and this is what I would expect them to do. First, contact the establishment. Typically, the establishment will also receive that presumptive information, if not, then we inform them at that point that you have a sample that's a presumptive. It doesn't mean it's positive, but in all likelihood, 90 percent or more, it will confirm. And so they discuss what that means.

Then we want to make sure the firm has the recall worksheets, which is a variety of information that this is the product involved, these are the production patterns for that particular product, basically just a preparatory measure and -- in walking through those worksheets.

Then, in the case of an *E. coli* O157:H7 presumptive, we want to begin collecting supplier information, suppliers that may have given rise to that presumptive. And again, we get it at this stage.

Continuing with the example of a microbial recall, for example, a couple -- a day or so later, the sample does, in fact, confirm. Then the recall committee will

convene to begin their discussion, their deliberations on the scope of the recall, the classification of the recall, and what have you. In addition to field operations having 24/7 accountability, other program areas also have 24/7 accountability. Should a recall be coming down on a Saturday or Sunday, people in the Office of Policy, people in Congressional Public Affairs, Office of Public Health and Science are designated to be available so we don't have to wait to find people. They know who they are and they should be prepared.

Then the committee, if they do, in fact, recommend a recall, they recommend it to one of the executives in field operations who can concur or not concur with the recall. Typically, of course, they usually concur, but not all of them. Then the company conducts a voluntary recall. The Recall Management Division issues a recall notification report for all recalls. The Congressional Public Affairs Office posts a press release, and all of those are posted on our website.

Then the EIA officer begins verifying the distribution information, where specifically did the specific products go. That is information we need so

that we can begin doing our effectiveness checks. Effectiveness checks are where we verify that the plant has notified their customers of the recall, they have notified them of the class of the recall, and they have told them what to do with the product if they have it. That's the back end of a recall.

If product is distributed in other states, then my District Recall Officer will notify his or her peers requesting assistance and the recall effectiveness process and will share the distribution lists and discussions about the products and what have you. Those other districts will conduct their recall effectiveness checks and report the results of those back to the District Recall Officer, the person with the authority over the firm that actually did the recall. The effectiveness checks can take, depending on the scope of the recall, from days to weeks. It also depends on the classification of the recall. If we have an MOU with states, this was discussed at the recall public meeting last December, MOUs with states to share distribution information. Then we are looking to our state partners to facilitate and help with those recall effectiveness checks that helps them be more responsive to their

constituency and it also facilitates the effectiveness check process.

And then, after a period of time, the District Recall Officer will recommend closing out the recall. And when we've done everything that we think we can do, we close out the recall.

I mentioned some new strategies for recall effectiveness checks. And again this is where the recall has occurred, and we want to make sure the right folks know about it, and we want to make sure they're doing what they're supposed to do with the products being recalled.

Historically, we have done a fixed percentage of notification or verification checks to the consignees. Consignees are the customers of the recalling firm or secondary customers. Historically, we have done roughly 20 percent of the primary customers, 10 percent of the secondary customers. That worked well for quite a period of time. It was convenient, but it no longer really helps us say how effective a recall was or was not. So we are, within the next, I would say, two months or so going to be coming out with a new effectiveness check process that is risk-based, risk-

based meaning we will do our effectiveness checks based on the hazard. In this context, the hazard is the class of the recall, whether it be class one, two, or three. A class one I would expect to be doing much more intensive verifications of effectiveness checks than I would for, say, a class three, so the risk-based and the hazard end.

We'll also be risk-based on the exposure side. Consignees in this context will be considered to be those at the point of purchase or the point of consumption, not just the distribution level. So we will be pushing the number of verifications down to where the product may have, in fact, ended up. That will help us more effectively verify the status of the recall and we'll have sampling strategies that are based on various sampling plans to help us decide which ones, which of these consignees, we need to verify.

We also want to verify product disposition. You have a recall of a product, what did you do with it? Did you return it to the firm? Did you send it to somebody else to cook it? Did you landfill it? Those are some of your options. I want to verify that you did, in fact, do that. And so that would be part of the

effectiveness check strategy.

And then we'll be looking at enforcement activities related to those who did not correctly handle their product or firms that did not effectively or appropriately implement their recall strategy. We're looking at avenues.

Earlier, I alluded to suppliers, specifically for *E. coli* O157:H7. Since the spring, we have a database of plants that supply production that gave rise to an Agency positive for 0157. This is the -- where various trim, if you will, gave rise to the positive. We notify those firms that they supplied product that gave rise to an Agency positive. That doesn't mean they were the ones who actually had the O57:H7, but we want them to have this information so that they can look at their production practices and do any reassessments and decide what, if anything, happened to that particular production.

So the districts enter the supplier information that they received from the plant. The Recall Management Division maintains the database, and our tech center does analysis on the suppliers. We also -- the database serves to notify supplier plants. You gave --

you produced this trim. It was part and parcel to an Agency positive, and we're putting you on notice that you supplied the product.

For repeat suppliers, we do have repeat suppliers in the database. And at a minimum, repeat suppliers, in my mind, meaning more than one, the Agency will look -- do specific verification procedures on that particular production lot. That will be done by our in-plant inspection folks so we know what production was supplied. We will be doing -- have some verification procedures on that. We may do separate EIA officer food safety assessments depending on the complexity, depending on the repeat nature of a particular plant. We will do a food safety assessment with one of our EIA officers. There has been occasion where, for example, somebody may be a repeat supplier and we simply are uncertain why. We've been in the plant. Things may or may not be on track, and so we may send in a multi-disciplinary team to assess what's happening in that plant.

We think all of this helps us get in front of a plant that, for whatever reason, it could be as simply as them producing and shipping a lot, but for some

reason they may keep showing up in our database. We want to have a look at those and decide if there's something in their process that can be adjusted so that they are not repeat suppliers. So this is essentially a public health surveillance tool that helps us get in front and hopefully prevent a potential recall.

So essentially FSIS has a more, I think, coherent clear strategy on what we're doing on the recall front. Of course, we do recall management. We think it's more proactive now for some of the reasons I gave. We clarified lines of accountability. I have one District Recall Officer per recall. That individual is responsible for the field activities. We also have accountability headquarters as far as availability 24/7. We, as I indicated, react at the presumptive positive stage. We start managing off the information as we get it. The effectiveness checks we will be able to more objectively describe the success and failure of a particular recall. We manage the supplier database, and as you will hear tomorrow more about the Consumer Complaint Monitoring System, that's also a surveillance activity.

And with that, I would take any questions.

MR. SCHAD: In regards -- you were talking about going back to the suppliers if there was more than one instance, and say, for example, that supplier was just a bone plant, is there -- and you found some positives there or something that wasn't on track, as you said, is there any action by the Agency or any thought of going back even one step farther to the slaughter plant?

DR. PETERSEN: Yes. I mean, it depends on what we find at the supplier. And we may go to the supplier and look at their records and find they have not positive results on their own testing. Most likely, at some point, the Agency has done some testing there. We may not have a positive there, but there's a -- something may be going on, so we want to more critically look at the design and execution of their compliance and see if there are avenues for improvement. But through that process, that may lead us back to a separate firm. And so yeah, we would have no objection to doing that.

MR. SCHAD: Okay. Thank you.

MS. ESKIN: I have a number of questions. First, in your list of effectiveness checks, you talk about, I think -- well, first of all, do you include any

consideration of the amount or percentage of product that's actually returned? I know that's only one piece of it. It may be disposed by the consumer. Is that something that's taken into consideration?

DR. PETERSEN: That is, as I understand it, something we're looking at as a fallout from the public meeting, not so much on the effectiveness check, per se. The effectiveness check is based on the criteria I gave. The product retrieval, as you know, can be based on a variety of -- the nature of the product and that kind of thing. That would not necessarily be a driver of my effectiveness check.

MS. ESKIN: But it's something you're trying to -- but you're saying is initially that obviously is out there and...

DR. PETERSEN: Yes, it's an issue that was out there. It was certainly put on the table at the public meeting, and fallout Agency analysis of the public meeting is ongoing and at a minimum we'll be updating our recall directive to incorporate many of the things that happened at that meeting.

MS. ESKIN: I -- that was my next question, actually. You referenced in the two-page memo that the

recall directive has been revised?

DR. PETERSEN: I said has. I should have -- it's been revised over time, but the last revision was a couple of years ago.

MS. ESKIN: Okay. So it -- I'm just -- it's -- revised it to reflect public input, so it will be. It's in the process of being revised?

DR. PETERSEN: It will be. Yes. Yes.

MS. ESKIN: And my last question is after you do an effectiveness check or review and it's determined that the recall was not effective, what's the next step? How does -- again, it's not an authority that the Agency that the department has to mandate a recall, I understand, but the issue is for practical purposes, if you determined that, through this check, it just wasn't handled properly, what happens?

DR. PETERSEN: Well, we have some immediate authorities, and that, of course, would be detention and potential seizure. And if a recalled product was still offered for sale, I would expect it to be removed, if not, we would take it.

MS. ESKIN: Has that happened in any recent experience?

DR. PETERSEN: Yes, at some point it has happened.

MS. ESKIN: Right.

DR. PETERSEN: And then they have a period of time to decide how they're going to deal with it. When I said we're looking at other authorities could say -- could knowingly sell and recall product be considered a prohibited act under the sanction. That's being looked at, that type of thing.

MS. ESKIN: Thank you.

MR. TYNAN: Okay. We'll go to Mr. Govro, and then we'll go back around this way.

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. I have some questions about the use of states in conducting your effectiveness checks. You mentioned that you will use the states if you have MOU -- an MOU with them. I'm wondering how many states you use for that purpose where you have MOUs and if not all of the states, why not? Do you actively pursue those MOUs and what do you do in states where you don't have a state to participate in this effectiveness check process?

DR. PETERSEN: Okay. There was an extensive

discussion of the state MOUs at the public meeting, so that transcript is available for those who want that kind of detail. Currently, we have nine MOUs with states. The real driver of the MOU is do states have the legislative authority to protect the confidentiality of the distribution organization, which is proprietary information. Some states apparently do not. They have sunshine laws. They get the information they have to ship. But if the states do have it, we are encouraging and we had some discussion with the -- to try and get more of the MOUs. If there's any real or perceived barriers to the MOUs, we want to discuss them, because the -- particularly the way I outlined our new thinking on effectiveness checks, we want to partner more with the states to do the effectiveness checks from both the resource side as well as from their side, because they are more closely linked to those constituencies. So we have nine, and we'd like to see more, but we intend to engage them more fully. The ones that we have the MOUs with, we have done it already with few recalls.

MR. GOVRO: I'm a little bit unclear on the nature of the confidentiality concerns. It seems that in an -- if you're in a recall situation, all of that

information should be very public. And so what part is it that needs to be confidential?

DR. PETERSEN: A recalling firm has a customer distribution list. That's of value to them. That's of value to their competitors, and so it -- under the statutes, that's considered proprietary information, and it can not be made publicly -- it can't be publicly disclosed. That -- again, there was some discussion on that at the recall meeting. The regulatory citation I gave on the MOUs will give you a sense of the type of confidentiality we're looking for. That was all part of the regulatory initiative that played out about a year and a half ago.

MR. TYNAN: All right. Dr. Hollingsworth?

DR. HOLLINGSWORTH: I know in previous public meetings that FSIS has held, particularly on this issue, there have been a number of suggestions and recommendations, and I'm wondering if you can give us a status report or an update on any of those. The two, in particular, that I can recall was the issue of press releases and whether they should be issued for all recalls even if the client is not in distribution. The other one was the issue of allowing the industry to

participate in reviewing the press release for accuracy before it went out. And I know there were several other recommendations that came from those public meetings. Are those still on the drawing board? Are they being considered? Have there been any changes in regards to those?

DR. PETERSEN: There have been no changes implemented, but those, as I indicated, are discussions. Those were comments recently put out at the public meeting. And as I understand more on the execution end of the recalls, that would be more on the policy development side, but those are being actively entertained as well as a variety of other things that were put on the table, entertained for should that be the type of thing we should implement with the revised directive.

DR. CARPENTER: I'd like to direct my question to the district office recall responsibilities, in particular, responsible to review lab results routinely, I think you mentioned daily. How comprehensive is that review? I mean, are those results from all labs or just labs that are in a -- I mean, an agreement with FSIS?

DR. PETERSEN: These would be Agency lab

reports. And you'll get a sense of that later this afternoon from Dr. McCaskey, but the -- any lay Agency lab result, say, if we're talking on the micro end, a potential presumptive confirm, those get reported out through both an e-mail system called Bytes. That's in the briefing paper you have. And a variety of officials, both here in headquarters and as well as in the districts, get that information. The districts would get the notification just relating to the plants under their -- here, we would get them nationwide. That's the e-mail system. That's instantaneous. That comes in and I get them everyday of the week, including holidays and what have you.

Then there's LEARN, which you'll hear about this afternoon, which is a laboratory reporting system that our inspectors can access online. They pull up a particular plant. They may pull up a district. It tells them the status of various samples that have been submitted, and they should be looking at that to know where things are at. So we use that for both notification of what's happening with the lab results, and we also can use that to track the sample submissions and that type of thing. But it's really for reporting

results. So yes, they should be accessing that data.

DR. CARPENTER: So potential to -- potential...

DR. PETERSEN: Presumptive.

DR. CARPENTER: ...to confirm is all done within the FSIS lab system?

DR. PETERSEN: Yeah. We're talking about Agency lab results. Now we will get -- occasionally we get information from our state partners or perhaps CDC. Those are some of the outbreak things that I mentioned under the recall process. Those come in through a different mechanism. Typically they come in either through the recall side and they come into the districts, or frequently they'll come in through Dr. Goldman's staff that you've heard about earlier. So we can get them through that avenue, but those are not reported out electronically, because they're not our results.

MR. ELFERING: I'm Kevin Elfering with the Minnesota Department of Agriculture. One question that I have is on the MOUs. You said that the recall committee will notify first the district where the recall initiated, other district offices, and then also

states that have MOUs. Who actually notify the state? Does that come from the district office or from the recall committee? And then, as kind of a follow up to that, if a state would be involved in an effectiveness check, where are those requests coming from?

DR. PETERSEN: The answer to both of them would be at the district level. The district would have the distribution information and they would have it locally. They would also know which of the distributed product is in your particular state, and so they would provide you with Minnesota. They wouldn't provide you with South Dakota. They would provide you with the information that you need. And that's also the way the relationships are, typically. And so that's where the information sharing should come from.

MR. ELFERING: Okay.

DR. PETERSEN: Any other questions? Thank you.

MR. TYNAN: Thank you, Dr. Petersen. The next agenda item I have is Mr. Philip Derfler from the Office of Policy and Program Development. And he's going to talk to us a bit about what is the best use of data to support risk-based inspection.

MR. DERFLER: We don’t mess around with title pages. We go right into it. My issue, like, I think, one of the issues this morning, comes out of this document, Enhancing Public Health Strategies for the Future. And in that document, the -- Dr. Murano in the Agency talked about the need to achieve the next level of food safety and the need to develop better tools to prevent food safety problems. And the paper says that one key to achieving that next level of food safety is to have better tools to prevent food safety problems. In particular, the paper cites the need for tools that help the Agency predict or to anticipate problems arising within inspected plants or with product as it moves through the distribution chain to the consumer. And one of the keys to developing such tools is data. And it’s about data that I need your help, and we’re going to ask your help today. I'm sorry, that’s my job. Data is important because, if properly used, it can provide the Agency with insights into an understanding of how food safety problems develop. This fact has been illustrated numerous times, for example, by studying the data that had to do with ready-to-eat products and how ready-to-eat products were processed. People learned

that -- were a site for harborages of *Listeria monocytogenes* and there's been a significant redesign of a lot of ready-to-eat plants in response to that. Similarly with *E. coli* O157:H7, data has shown us that there was a lot heavier load of pathogen on product when it came into the slaughter -- on animals when they came into the slaughter plants, and as a result of that, last October we issued a -- directing plants to reassess their plant to see whether *E. coli* O157:H7 is a hazard reasonably likely to occur in their operation.

In each of these instances and in numerous others, analysis by FSIS, other governmental agencies, industry, academia, and consumers have produced an understanding of the circumstances that made hazards reasonably likely to occur. And so going back to the *E. coli* O157:H7 example, the available data supported that the prevalence of the pathogen begins to rise in spring and goes on through the end of the year. Since that coincides with the portion of the year that a lot of consumers increase their consumption of ground beef, it led us to intensify our inspections during that part of the year.

So while there has been significant advances by the

Agency with regards to its reliance on data to it as a means of adjusting its inspection activity, the need for more and better ways to anticipate problems persist. For example, some of the outbreaks associated with meat and poultry have been the result of misuse or nonuse of data that, if properly viewed, should have led to steps that could have prevented such events. So our goal is to use data to develop tools to anticipate problems and to do a more effective job with this data that we get.

So where do we get the data that we're talking about and that we rely on? One of the major sources of data is through a close evaluation of the results of the Agency's own verification testing and of our enforcement activities. For an example -- for example, when a plant has failed two consecutive salmonella tests, FSIS will do a food safety assessment at that plant. And as -- we've been analyzing the results of the food safety assessments that we've done, and as a result, we're starting to develop a sense of the kind of practices that do not lend themselves to effective process control. When an establishment is employing these practices, there is a basis for a concern as to what's going to be going on.

FSIS sampling for a range of pathogens has also been extremely important for the Agency in developing an understanding of these pathogens as well as for ensuring compliance. FSIS has announced its intention to conduct new baselines, and it's our belief that these baselines will only deepen our understanding.

Another source of data for us is research that FSIS supports or that is conducted by other USDA agencies. For example, some of the data that FSIS relied on in its listeria risk assessment were generated by a study of hot-dogs that FSIS contracted with ARS to conduct. ARS develops other data for the Agency in response to research needs that FSIS identifies in a meeting that we hold with ARS each year. CSRAS, another USDA research Agency, has funded research that has been important to FSIS and the Economic Research Service also provides us with important data. I'm sorry.

Okay. The third source of data is industry of the regulated industry itself. Industry generates data for -- as a means of -- for a number of reasons. It develops data in monitoring, verifying, and validating its processes. Establishments develop data to satisfy their customers on the conditions of their product. For

example, many beef slaughter establishments are now testing their trim for a variety of pathogens and non-pathogens on an ongoing basis to satisfy the companies that they supply.

Establishments also develop data to support safety and efficacy of new technologies. These data are submitted to FSIS with notifications of the use of new technologies or for a request for a waiver or regulatory provision or with petitions to amend the Agency regulations. And in addition, companies and more frequently trade associations support research on a range of issues. The results of this research are regularly made available to the Agency. Companies and trade associations have submitted results of research on a range of hazards, including *E. coli* O157:H7, listeria, and salmonella.

The Agency also relies on academic and peer review journals. FSIS scientists carefully review the studies that are produced, and this reliance can be seen by a number of our compliance guides and some of the other materials that we put out in conjunction with our rule-making documents as well as from our risk assessments.

And finally, another source is consumer groups.

Even though consumer groups often lack the resources to fund research, they will often compile data and present that data to us in the form of petitions asking us to take certain courses of action.

So how does FSIS currently analyze data? FSIS -- one of the key ways that FSIS analyzes data is by the -- its use of risk assessment. Risk assessment helps us to understand the likelihood, that is the risk, that a hazard will occur and the effective various factors on the likelihood of that occurrence. Obviously, risk assessment is a way for us to learn how to anticipate hazards and how to prevent them. To date, our focus -- our risk assessments have focused on one pathogen being modeled and have not addressed non-pathogen indicators. But the risk assessment was really key in the development of our listeria final rule.

Other ways that FSIS uses data to learn how to anticipate problems include the fact that both the technical Service Center and my office, the Office of Policy and Program Development, now have data analysis units. These staffs are looking at enforcement and other data to try and identify establishments that are likely to have problems and thus to direct our

inspectional resources to those establishments before problems actually develop there. They also are looking at the data in a more macro sense to see whether there are any trends that are developing across establishments so that we can address those trends in a notice or a directive or a rule-making before they develop into a major problem.

We're also looking at data to see what's working. If we can, through compliance guides or the use of incentives, induce establishments to employ best practices, then we have effectively helped establishments to anticipate problems and thereby to avoid them.

But this actually points up another important use of data, and that is evaluation of programs. We need to do a better job of using data to evaluate whether the programs that we've put in place are actually working. And the best example of that is the fact that we didn't evaluate the way the directive on *E. coli* O157:H7was working. We left that directive in place for four years, but what it did was to provide an incentive -- before HACCP was in place, to provide an incentive for plants to do either their own testing or to put in

interventions for -- against *E. coli* O157:H7. We said that we would not test in those plants if they did either of those things, but we never really went back to look and see how it was working. And as a result came the Con Agra recall in the early summer of 2002.

FSIS believes that if we had modified our directive in a more timely manner, we could've better ensured that the establishment was effectively responding to its own data and feedback it was receiving from its customers.

The Agency has established the Office of Program Evaluation, Enforcement, and Review to ensure that this type of evaluation does, in fact, occur. Furthermore, FSIS is looking to providing guidance to industry regarding the design, verification, and testing program to better ensure that sufficient numbers of samples are taken and that laboratory analysis is sufficiently specific and sensitive to detect low levels of pathogens.

All of this brings us to what we have for you, and that is I talked about our goal and the need for data and the sources of data that we use and how we're using that data that we collect. Now we would like advice from you on how we can do a better job of gathering,

assessing, and using data to reach our goal. FSIS needs to improve its access to and analysis of data, food safety data, from all reliable sources. We need suggestions on how FSIS can do more with -- to help more -- to develop tools to anticipate problems with meat, poultry, and egg products and thereby to better protect public health.

So at the back of the issue paper are three questions. The first is: What reliable source of data should FSIS be tapping into to develop tools that will help it better anticipate problems? What I tried to do is review the general types of data that FSIS currently considers as it develops policy and verification programs. The question we'd like you to consider is whether there are other sources of data that the Agency is not relying on or of which the Agency is not aware of that would help it to achieve its goal of developing better tools to predict problems. For example, you may be aware of an organization with which FSIS does not regularly interact that collects relevant data. Or you may be aware that data that establishments collect that have not previously seemed relevant to what FSIS does, but that would be relevant for our efforts to anticipate

problems is available that we should be looking for. These are the types and sources of data that we would like you to make us aware of.

There are a couple other aspects of this issue that I'd like you to consider. One source of data that FSIS has not tapped into very much is the willingness of industry, and particularly industry organizations, to conduct studies or to coordinate the aggregation of multiple plant data and to share that data with the Agency without fear of having the data used against the industry.

FSIS is aware that there is a perception that the sharing of data might lead to enforcement action. FSIS is interested in having timely and meaningful data that is sufficiently detailed to provide the context in which it was collected and assembled and is not interested in creating unnecessary barriers to receiving such data.

So what kind of incentives or allowances do you think the Agency should be offering to industry to encouraging to support research? For example, industry groups sometimes conduct studies on meat and poultry without publishing the names of the establishments or tested facilities. However, there is some question as

to the ethical steps to follow whenever an adulterant or pathogen is found. FSIS is interested in how it should be involved in such studies and what should be the outcome of a study where an adulterant or a pathogen is found. What factors do you think FSIS should consider in deciding whether to provide incentives to industry to do research? Do you think the nature of the data gaps and the significance of the health problem that's to be addressed by the research should be factors in the Agency's consideration of whether to provide incentives and what those incentives should be?

One related -- last related question. One source of data that I did not mention is the states. I think this is a very significant omission. FSIS recently surveyed the states that -- meat and poultry programs on ready-to-eat data, and that was very useful and helpful to us. The question that we would be interested in is how can FSIS make better -- coordinate better with the states so that we can take advantage of the data that they're collecting?

The second question is whether there are data that the Agency is collecting or that it could be collecting that we're not taking appropriate advantage of. I tried

to give you some insights into the data collection activities in which the Agency currently engages. All of you have some general familiarity with these Agency efforts. Are there types of data that you know that the Agency collects that you never hear about the Agency using that you think could be helpful to the Agency in developing the kind of tools that we want tools to anticipate problems? We ask that you highlight these types of data. Similarly, if you think that there are other useful data that the Agency could be collecting and is in a position to collect but is not, again, we would appreciate it if you point those out to us.

And finally, are there methods of analysis that FSIS may not be using but that it should be using to enhance its ability to anticipate hazards? To answer this question, we ask that you draw on any familiarity with data analysis that you have to suggest analytical tools that the Agency should consider using. Are you aware of any analysis that are being employed by experts in food safety that the Agency may not be aware of but that are proved or have the potential to be particularly useful in hazard analysis?

We recognize that this issue that I've laid before

you is a general issue and the type that you don't usually get, but we think this group is particularly well situated and very knowledgeable, and we hope that you'll be able to help us.

Thank you for your attention, and if there's any questions, I'd be happy to answer them. We look forward to your input, believe me.

MR. ELFERING: I just have one question on your last line. How inventive does the Agency want to go? There's some technology out there right now using bioluminescence that is specific for *Listeria monocytogenes* that would give you an instant result. Is that something that the Agency would consider looking at? It's not necessarily anything that's been validated, but the technology is there.

MR. DERFLER: Validation would obviously be important to our ability to use the data. I mean, I think what we'd be interested in is the ideas so that we can -- I mean, we're looking for ideas. We're looking for things that we might be able to use to enhance our ability to anticipate problems, and then we'll review those and consider those as we do policy development.

MR. ELFERING: And does the Agency have any

interest in funding some of that validation?

MR. DERFLER: Well, not right now. I mean, the problem is we're on a budgetary process that puts us that the -- our budget proposal for 2005 is still being reviewed and is not within the administration. The next time we get a chance to come through with ideas is for 2006. But obviously, if we don't have the ideas, if we don't get the input and the proposals, there are things that we could not get to or we would not think to consider when the time comes.

Dr. Logue?

DR. LOGUE: Hi. Dr. Logue. Do you ever tap into any of the stuff that's already there, like USDA, you know, challenge grants or research grants that are given to individuals or institutions or groups? Do you ever try mining that or tapping that?

MR. DERFLER: What we do is we have communication with ARS particularly and with CSRES.

DR. LOGUE: So have you been able to access them?

MR. DERFLER: Well, their agenda is often influenced by us. As for specific studies in what we're doing, as we become aware of it, yeah, we look at the

data that they're developing, yeah.

DR. LOGUE: Okay. I have one more question.

MR. DERFLER: Sure.

DR. LOGUE: You mentioned that you're looking for data. Do you have any specific areas that you're looking for right now, or are there some gaps out there that you can tell us that we really are desperate and we'd like to know about? Can you list any?

MR. DERFLER: Other than what's in the vision paper that we're looking for tools to help us anticipate problems. That's the focus. We're trying to make our tools as effective as we can.

DR. LOGUE: All right. Thanks.

MR. DERFLER: Okay. Thank you. Mr. Schad?

MR. SCHAD: Mark Schad, Schad Meats. Just a comment as far as sharing data, as an industry person, you know, we generate data a lot in just determining a hazard or during our hazard analysis. And at least from my business, I'm more than willing to share that data. And I guess the only thing that this -- what I'd be asking for, and I think most industry people would be asking for, is just the credit for saying yeah, your data is good and you have determined a hazard analysis

when you've done a good hazard analysis. And if not, the guidelines are the parameters to make this data at least believable to the Agency.

MR. DERFLER: Okay. Well, I mean, I think in our directive, we sort of discuss hazard analysis and...

MR. SCHAD: Okay.

MR. DERFLER: ...I mean, if you're not getting an NR, I think you're doing fine. I mean, I think one of the things about individual plant data, I mean, it would be interested, perhaps -- interesting, perhaps, if trade associations, as I suggested, you know, aggregated data and looked at various quests in doing that.

MR. SCHAD: Okay. Thank you.

MR. DERFLER: Mr. Govro?

MR. GOVRO: This is Mike Govro, Oregon Department of Agriculture. Does the Agency have a method of communicating its interests in research to the academic community, people that might be writing papers on this sort of thing and then possibly making money available to those people?

MR. DERFLER: Yeah. We're not allowed to fund research directly, but we do do it through the Agriculture Research Service and through CSRES, both of

whom do fund academic researchers.

MR. GOVRO: And with regard to communicating your interests?

MR. DERFLER: When we talk to them about our food safety needs and as a result they develop a research agenda, and some of that translates into money and into research that's done. I mean, I can't cite any specifically right now but certainly there's been some.

I was doing okay, and then I just saw Dr. Johnson perk up. Dr. Johnson?

DR. JOHNSON: Okay. I have to say something about trade associations and data...

MR. DERFLER: I wasn't knocking it.

DR. JOHNSON: I know. I know. And kind of to back up something that Mark said. I know that we have, in the past, worked with not just the Turkey Federation but all of the trade groups in town and in California and elsewhere have worked to compile some data. And I think that all of the groups are willing to continue to do that. And I think it's very useful, however there has been some disappointment with the fact that the Agency has chosen not to use that data in certain --

some of the risk assessments as well as there's always the problem with -- that we confront, well, it's industry data so does that mean it's credible. And I think that would be something interesting for the group. I'm not in this work group, but it would be interesting to hear some thoughts on that as well.

MR. DERFLER: Okay. Thank you. Ms. Eskin?

MS. ESKIN: Yes. Sandra Eskin. Phil, can you comment when you said at the very end of the presentation again that you don't use state-generated data right now. What are the barriers there? Is it just -- well, what are the reasons for that currently?

MR. DERFLER: I'm not sure. I mean, I think -- I mean, there are issues that we have developing now, some of the listeria issues at retail and different things like that, that we would be very interested in the state data. I -- we have reached out to them, as I said, in this recent survey that we did of the state programs. The answer is I don't know. I mean, it occurred to me as I was writing my talk that I got to the end of my list of things that I knew that I had done and I didn't have states on it, and I thought that was a major omission. That's why I particularly wanted to

raise it, and I would be interested in hearing -- or we would be interested in hearing from the state people how we can work together better to ensure that we can get the advantage of what they're doing.

MS. ESKIN: Okay. Another quick question. Of all the data sources you list, obviously you started with the Agency-generated data. And again, in this morning's presentation that dealt with data but within a different context, there was a note that there is a lack of ongoing microbiological testing programs and therefore data. Again, that is a source of data. Is -- it's a question of resources. It's also a question of authority. I mean, currently it's the view that FSIS collects all of the data that it can. Is there a thought or consideration to expand that data collection? Is that one of the things being considered? You're looking at other sources, but my point is focused on if you've exhausted all of your possible...

MR. DERFLER: Well, I don't know whether we have, and it's -- I think that's one of the questions, not to turn it around, but I think that's one of the questions that I posed to the group. I mean, if you think we're not taking adequate advantage of something,

we'd like to know.

MS. ESKIN: Okay.

MR. DERFLER: Thank you.

DR. McKEE: Just before we get ready to go to break, this -- these presentations this morning were the last of those presentations that will be used in your Subcommittees this evening. And I do want to mention that the questions that are asked, three or so in each one of the Subcommittee groups, are questions that we don't expect a definitive answer, but we -- what we would like to have is the thoughts about what criteria might be used to find a solution for these questions and what might be the pros and cons of those criteria that you come up with. So you don't need to feel that you have to come back with an answer of here's what the Agency needs to do, but here are the issues surrounding this question that needs to be looked at by the Agency and the advantages and disadvantages that the Agency might encounter if they pursued some of the criteria specifically associated with those questions.

So I just -- I noticed from some of the questions that we had, there may be a thought that we were looking for something more definitive, but as we look at issues,

it’s important that we look from all angles. And I think that’s the advantage and the power of the Advisory Committee is to say, you know, the federal Agency may want to look from this way and here are the issues associated with that.

MR. TYNAN: And I have the pleasure of announcing we’re going to take a break for about 15 minutes, please, so if we could get back at 2:30.

***

[Off the record]

[On the record]

***

MR. TYNAN: Next on the agenda is a discussion of an overview of the FSIS laboratory system. And I have Dr. Patrick McCaskey from the Office of Public Health and Science who is going to give us an update on the laboratory system. Dr. McCaskey?

DR. McCASKEY: Thank you, Robert. We’re going to enter the homestretch here. Thanks for sticking with us late in the afternoon like this. I kind of want to give you an overview of the FSIS labs. And unlike Phil Derfler, I actually have two title slides.

I'll basically give you a laboratory overview. I

know we have some folks in here who are probably very interested in the laboratories. A couple folks are probably from laboratories, but many of the people here probably really are not that familiar with laboratories in general and, for sure, with the FSIS labs. So I want to cover a lot of the information in kind of a short period of time and not too much detail. So at the end of the meeting, or later today, we can have a chance to have more of a discussion of the specific issues, if you want.

These are the kind of things we're going to kind of cover this afternoon. We'll basically talk about where our labs are, our organization, our functions, capabilities of the labs, and then get into accreditation and then some of the software programs we're using to run our labs and run our daily reporting as well as kind of briefly discuss some of the issues associated with food security and with the Food Emergency Response Network.

So where are the FSIS labs? FSIS has four different laboratories: three regulatory laboratories and one special projects laboratory. They are located in Alameda, California where our western lab is. Our

Midwest lab is in St. Louis. And our Eastern lab and our special projects labs are both located in Athens, Georgia.

And this is our overall structure of our laboratories, the FSIS regulatory laboratories, again located in the St. Louis, Alameda, and Athens. Each of our laboratories has chemistry and microbiology sections. In addition to that, our Athens laboratory has a veterinary pathology section.

I'll just kind of show you what these laboratories look like, I mean just to give you a picture of our different locations. Our western laboratory is 50 or 60 years old. It’s an old military building that was converted into a laboratory. And it’s a nice little facility actually right in downtown Alameda right in the bay area. And you know, it’s a nice little laboratory. We’ve got about 50 or 55 people who work out of this facility. And this is our office building where our headquarters is for that laboratory in Alameda.

Our Midwestern laboratory is located in St. Louis, and that’s on a military complex. It’s an old building that’s probably about 40 or 50 years old. It was a warehouse that was renovated into a laboratory space

about 20 years ago. And we've got about 60 employees that work in our St. Louis laboratory.

And our eastern laboratory in Athens is located in the Russell Research Center, which is an ARS USDA building. Many of you folks probably have seen this building or have seen a picture of this. We have about a third of this building. The rest is owned and operated by ARS or the USDA. And my office is down in the lower part down here. Let me see if I can figure this. My office sits right -- oops, I guess that's not going to work. So right down in the lower part of the corner there, so go back. And then we have the entire sixth and seventh floor where we do our chemistry and microbiology, plus we have a large area in the back of this building. I'm not sure we have a few minutes here.

One of the other things in that building is, again, our special projects laboratory. And basically, these folks, as a routine, do not do regular regulatory samples. They do our special projects samples. They do our method validation work, and they do samples associated with outbreaks. And we've got about -- I guess around ten people who work in that laboratory.

Also in the same building in Athens, we have a

fourth function. That's our quality assurance division. And this division has microbiology and chemistry branches, and their job is to oversee the whole quality system for all four of our FSIS laboratories, so they play a major function in making sure that we're following our policies and procedures and are doing things correctly.

This is -- if you look in the top corner, and again I can't make this laser work. There you go. This right here is the back of the building that I showed you a minute ago. And in the back, we have a large what they used to call a pilot plant. And back here, in this area, our special projects laboratory would be over on this side of this floor. This right here is our new BSL-3 lab that we're building, and it's going to be in this area. Our quality assurance branch or division sits back here. Down here is our big sample receiving area that I'm going to show you in a few minutes as well.

This is a -- what's a regular day in the FSIS laboratory? Everyday, about nine o'clock or so, we get a large Fed-Ex drop that comes with several hundred packages. And basically, what we do is we take people

from our laboratories who are told the truck is there, and we have about 15 or 20 people who rapidly go down and help unload that truck and log in samples. And when these employees get enough samples to start working up in the laboratory, they take it up in the laboratory, because we're trying our best to start running these samples as soon as we can. Our focus is trying to turn these samples around, get the results back out to industry, to -- you know, to the public to make sure that we can be on top of things and again provide the services that we can. So we have about 15 or 20 people who come up -- come down there and help take boxes off.

This is the back of the big Fed-Ex truck. And sometimes that truck will be actually full of boxes. We can get up to 300 and some boxes in that truck. And there are days we actually get two deliveries sent to our laboratories. And we have a very nice system where people take it off. It's organized. We know which boxes go where. Our boxes are labeled as to what kinds of samples are in them.

Again, we are into throughput and into efficiency at our laboratories. Our samples are taken. They're

logged in to make sure that they meet the criteria. We have very tight discard criteria in our laboratory, so if there's anything wrong with that sample, with a form, with the data that we -- if we have to go to court on the situation and there's something wrong with that sample, we don't want to go to court. We don't want to analyze that sample. We're going to discard that sample and say send another one in. So we try to have very tight discard criteria.

And this is Mike Glass who is one of our employees who is actually logging in samples to make sure that they're not leaking and the temperatures is right and everything is properly filled out, logging in some of our *E. coli* samples, again just kind of showing what we do on a daily basis in our lab system. And then, of course, they go up into our laboratories, and in our laboratories, we have a variety of different functions. This happens to be one of our robots. We have multiple robots in our lab system doing a variety of chemical analysis. So the robot sits right here, and this arm actually rotates back and forth and goes to all of these different workstations and overnight can handle about 40 samples that we don't have to be handling.

Again, just showing some of our other instrumentation. We have a well-equipped system of laboratories with the latest of technologies. This is our Athens laboratory. These are two of our veterinary pathologists actually cutting in tissues that came from animals with various types of disease. And here's our special projects lab where one of our analysts is working on the system I assume for salmonella or listeria.

And of course, there's a lot of data entry. There's a lot of -- you know, we get all kinds of forms into our laboratories, and we need to be, obviously, staying on top of these things so there's a major data-entry portion of this. I'm going to talk in a few minutes about how we're going to get away from some of that data entry.

Our laboratory is -- you know, years ago, when Jill was around over at the labs, basically we used to have our laboratories doing pretty much the same thing at all of the laboratories. But over the last decade or decade and a half, we have kind of rotated it and gone to the point where we're not -- all laboratories are not the same. We have different functions at different

laboratories, which allows us to improve our efficiencies. And of course, most of our laboratories, again, have chemistry and microbiology. And then we have certain things, such as antibiotics, which are primarily done at our Midwestern laboratory in St. Louis and pathology, of course, which is done in our eastern lab in Athens.

So that just kind of tells you basically what our laboratories kind of do for a living. And again, all of our laboratories do our microbiology testing for listeria, salmonella, and E. coli. That's one of the major functions of our laboratories.

Our laboratories have been very busy over the last several years, and we've accomplished an awful lot, and I think we have basically cutting-edge laboratories as far as being on top of things.

Two years ago, our laboratories, all four of our laboratories, became accredited to ISO Standard 17025, which is renowned as the gold standard for testing laboratories. It's internationally recognized as the accreditation body or program for food testing and other testing laboratories. And this was really a -- took us about three years of intense work to get there. We

probably have 20,000 hours of work to actually get our laboratories accredited, but it's really been a fantastic system for us. It makes us document everything we do. It has improved employee morale. It allows us to again have complete documents and data packages of all samples. Everything we put through our laboratory now we can actually go on back and know who did what and when and where and how with those samples. So it's been a fantastic system for us.

And as part of putting that together, we have one quality system for all of our laboratories. We don't have four separate laboratories each kind of doing their own thing. And every laboratory has the same lab-wise standard operating procedures, and then they have separate, in many laboratories, work instructions where they do certain specific analyses. But our laboratories right now have something like 800 work instructions that are written and documented and approved and 600 forms. So it's a major process trying to stay on top of those things and track all of that information.

And one of the things that we've also been doing over the last few years is we have actually been playing a major role in trying to encourage other laboratories

to seek ISO accreditation. About five years ago, we brought in a bunch of upstate laboratories and trained them on what ISO Guide 25 was at that time. And we've worked closely with many of the state laboratories and other federal systems and some local laboratories to again try to train them to encourage them to work towards getting ISO accreditation. We hired a consultant to work with some of these laboratories. And we have also made our complete quality system, which is about this much data, available on CD-ROMs to any laboratory that wants to look at our system, any laboratory that's interested in going to ISO accreditation. We're willing to share that and say use whatever you want out of this, you know, if you're working on working towards ISO accreditation.

Another thing we've done is again we have put hundreds of samples through our laboratories everyday. And as of this moment, everything is handled in a paper fashion. We do not have a laboratory information management system, but we're in the process over about the next three or four months of putting in a single expansive Laboratory Information and Management System, or LIMS, in all of our laboratories. So we are having

one LIMS system so all of our data from all four of our laboratories will go in this system and be available to laboratorians, to management folks, as well as to inspection personnel in the field, so they're going to actually be able to look at a system and find out where in a laboratory a sample is, who has it, and what's going on with that sample. So that's going to be available to our inspection force.

Okay. The next thing I want to talk about, and I think this may have been mentioned a little before, was what's known as our LEARN, our Laboratory Electronic Application for Results Notification. Our LEARN system for reporting results. And LEARN is the official name of it, but I call this the Bernie Scheider [ph] project. Okay. Bernie is the one who stimulated this about three or four years ago.

We had a meeting with -- giving some concerns about us not giving the proper turnaround times and providing the service to industry. So Bernie called a meeting, and we came in, and in our lab, we developed the LEARN process. And this went into play about a year and a half or two years ago. And basically, it's a system that allows us to rapidly get information out to our

inspection force.

Our inspectors, as Ken mentioned, everyday can go on to a web-based system and find out everything that's going on with the samples they send into the laboratory. And here's -- this information goes out to a whole wide variety of folks, to inspection personnel, enforcement personnel, circuit supervisors, district offices, tech service center, headquarters personnel, and also the establishment management can get the results. They don't get it through LEARN, but they get it through an e-mail system. So if management has given FSIS an e-mail address, we can actually report that result out to management right away when we send it off through LEARN to our inspection force. So again, our results are reported out very rapidly to the field, which again, allows, you know, management and inspection to do what they need to do with those products. There's also a mechanism for notifying state officials of the results of these different analyses.

This is one of the screens for the LEARN system looks like. An inspector can go in here and find out -- if he has two or three different plants, he can go in and find out which plant it is, when sample was

submitted, you know, what it was analyzed for, what the results are, whether it's been discarded or not. Those are the kinds of things he can rapidly stay on top of.

There's also a system that we're developing that should go into effect some time in 2004 called e-sample. And right now, every year, FSIS prints about 150,000 to 200,000 paper forms. And these go out through operations to the district office all the way out to 6,000 or 7,000 plants telling inspectors what kind of samples to collect and when to collect them and where to send them. And these things get lost or they don't get printed on time or there's an error in them or whatever else, and it causes a lot of problems with discards. And it causes a lot of problems with the laboratories not getting the appropriate samples.

So we're putting together a system called e-sample, which basically takes a whole wide variety of different databases FSIS has. Right now, FSIS has multiple different databases that don't talk to each other. They all kind of collect different information. Sometimes the information doesn't jive. Sometimes inspectors have to enter the information into two or three different systems. We're taking this and trying to move it into

one system that actually works through a corporate database so that once you enter stuff in there, that -- then other databases can actually tap into that information and make that available. So e-sample is a system that's really going to take all of our stuff on our plant profiles and our sample collection data and our laboratory information and those kinds of things to make it available through one large system to people who have access to that information. So it's really a nice way to make that available to our inspection personnel.

This right here happens to be one of the draft screens of our e-sample system. And basically, what will happen is an inspector will get an electronic notification on his computer that says over this month you have to collect this many samples. And it will tell you what kind of samples you're supposed to collect, what product it is, what tissues to collect, and where to send it, and what date to send it. And each one of these fields needs to be filled in. There will be a bunch of pop-up menu type stuff so it's pretty easy to point and click and fill these things in. And then once an inspector does a lot of these things, they'll be in there permanently so he won't have to change it. Every

time he does another sample, he's not going to have to go back and fill the address and all of those kinds of things, so it's going to really simplify the process and make it so these things come into the laboratory right.

And also one of the things we do is we throw a lot of samples out right now, because things are improperly filled out. And these fields are going to require that they be properly filled out, in other words, if they try to leave a blank or if they put something in or try to put something in that doesn't make sense, or they try to put in that they're sampling a product that doesn't -- that the profile says that does not -- is not produced in their plant, they'll have to go on back and correct things. So it's really going to reduce the number of discards that come into our FSIS lab system.

Going on into another huge area that I think maybe was briefly mentioned earlier today, FSIS is -- our lab system has really had to get into the food security area. We have done a bunch of things over the last two years now trying to get our labs physically ready to respond to emergencies but also ready to protect our laboratory resources. We put in video cameras and fences and key card accesses and those kinds of things

to make sure that our actual facilities are protected. Obviously, we have a much better system for inventory control. We've gotten rid of things we don't need to have around the laboratories, and everything else is properly maintained and controlled.

We have built BSL-3 laboratories. We have a small BSL-3 in our special projects lab in Athens, but I showed you where our new, big, state-of-the-art BSL-3 is going to be in Athens. And that really is going to be a top-notch facility that's going to give us a lot of capability to handle large numbers of high-consequence pathogens.

We have also entered, through our special projects laboratory, the Laboratory Response Network, which is the CDC based system that many of the public health labs are participating in, and we're participating in that as well. We have obtained select agent registration and now are re-registering, which, I guess, is due by November 12. There are new regs out on that, and that's been our -- a huge ordeal trying to go through and meet the requirements of that. I guess everybody -- all laboratories are having the same problems trying to meet those requirements.

And again, as I've mentioned, we've done the security enhancements in our laboratories. But also, we have gotten, or are in the process, of obtaining the security clearances. And there's a difference between a security clearance, which I, and other folks, have to be able to have access to the information that's secret, and also there's a lot of work that we have to do in the laboratories to actually do the personnel suitability stuff. So any person in the laboratory who is going to be working on any of the select agents or high-consequence pathogens has to go through an evaluation, a background check, and those kinds of things to make sure that they can actually work and handle agents that may be of interests to folks who shouldn't have those agents.

There are also some things, you know, obviously back in March or April when we went into Liberty Shield in the war against Iraq. FSIS, up until that time, had not done a lot of stuff to truly prepare to respond to terrorism related to food. And as part of that process, there were additional requirements placed upon the FSIS laboratories, and other laboratory systems, to make sure we had some capability to test for a variety of things

in food products. And nationwide, there was very limited capability to test for various agents in food. And we kind of led the effort in, obviously, meat, poultry, and egg products to start doing things to find out whether there are methods, to validate those methods to make sure that they do work on our products, to have things so we can do screening and confirmation so that if we do find something we know what it is and can verify that it's there. And we also -- as part of our process, we see our role as being high throughput screening laboratories so that if there is a threat to a food product that we have the capability to run a lot of samples for a variety of different -- in those samples, and we have spent a lot of time in the last six months improving our efficiencies and capabilities to actually, you know, provide some protection for the Nation's food supply.

Along those same lines, you know, the Administration now is identifying food as one of the basic infrastructures that need protecting. And as part of that process, there has been an Interagency Food Working Group put together run by the White House Homeland Security Council. And they have put together a

variety of different sub-work groups, one of which is laboratories. And I have been on the laboratory one basically trying to figure out how we're going to protect the food supply from attack and what we're going to do in case the food supply is attacked. And so what we're doing is we're putting together what's known as the Food Emergency Response Network, or FERN, which is a large network that is being co-chaired and run by FDA and FSIS. And we have put together an organization in our -- building this system. And I'll talk about the structure in a second.

There are also a couple of other networks that I'm sure many of you are aware, one of which is the Laboratory Response Network, which is more the -- mostly the public health laboratories. I think there are 100 and some laboratories in there. Again, we're -- our special project laboratory is part of that process. There's also a new National Animal Health Laboratory Network, which is the vet diagnostic labs from states as well as APHIS laboratories. So there are basically three different networks that are out there that are going to be testing different commodities.

And all three of these networks are kind of using

the same laboratories. And, you know, many of the ag labs, state Ag labs and the food testing laboratories are part of the LRN. Many of the -- some of the vet diagnostic labs are part of the LRN. But these laboratories are also joining the FERN and some of these labs will actually join the Animal Health Network. And what we're doing is coordinating very closely with our steering committees with the three different organizations to make sure we're doing things the same way, we're using the same policies and procedures, when possible, and the same due diligence reports and really trying to make sure this is a coordinated effort. And again, there's a meeting coming up next week at CDC of the LRN partnership. And we will be there as the firm representative talking about what we're going to do and how we can coordinate and what we're going to do to actually build this process and this system.

As part of this, you know, in our organization for our FERN, you know, we basically have set this up. And we have a FERN steering committee, which we've had a couple of meetings now. We -- this consists of all of the federal agencies who want to play a role or think they need to play a role in food safety or food testing

for biosecurity and, of course, the FBI, Homeland Security, and other folks are there. But we've also invited the public health -- the state public health labs to be there, the state Ag labs, the veterinary and diagnostic labs. So we've got all of the players, and there are about 15 or 20 different people or organizations that are part of the steering committee.

And then we have a FERN operational unit, which is actually going to be the group -- small group that actually runs the day-in/day-out operation of this. And this will be, again, chaired by FSIS and the FDA. And then we're setting up five different regional coordination centers or hubs throughout the country. And we're in the process of setting up two of those right now, because we don't have the resources, and we're trying to get our act together, so we set up a hub in Athens, Georgia and one in Rockville. And that's kind of where we have our human resources place right now. Those things may change down the line as we get further in the process, but basically, these hubs are going to consist of all of the different testing laboratories in those regions. And again, they'll be the federal labs, the state agriculture, the state

veterinary diagnostic, and public health laboratories will all be working in tandem to determine who has what kind of capabilities to again work on putting together systems to be able to handle large numbers of samples during an emergency.

And also, there is a thing such as our FERN support programs. As you're building a huge network like this, which we envisioned probably down the line will consist of about 100 or so laboratories, there's all kinds of requirements on training and proficiency sampling and method of validation and development and data reporting. And there are countless items that are going to have to be put together and agreed upon amongst these different organizations who are participating in the FERN process here. So this is a huge effort that we're now just starting on and we're trying to obtain resources. We've gotten the buy-in. I think there's a lot of enthusiasm by all of the different laboratories who are now working in the hubs. And I think this is going to be a process over the next couple of years that's really going to take a lot of effort, but I think it's going to really bear some dividends down the line for us here.

So I've just gone through a whole bunch of things

very rapidly, and I'm sure I could answer some questions, or I'll try to answer some questions, if people have things they want to ask. Yes, Dr. Jan?

DR. JAN: Lee Jan, Texas Department of Health. I just had little questions about the e-sample, which sounds like a pretty good deal. Is it -- does the e-sample computerized request form, is that generated automatically by the PBIS system or a separate system? And does that come from the plant profile? And then does it also tell them -- or how do they know whether they're taking a ready-to-eat or, you know, salmonella...

DR. McCASKEY: It will come from a plant profile that basically says this plant produces this kind of products. And there will be a mechanism that actually determines which plants we want samples from, and it will tell them to take a ready-to-eat this kind of sample within this window of days, and it goes to this laboratory. So that will be all planned and designed ahead of time. There will also be a mechanism for a plant out there that if this is not a sample that's scheduled but they could also bring up one of these things. If they say I think I've seen this in

this plant. I want to take a sample because I suspect something, they could also do that electronically. And once they fill out this form electronically, at this stage of the game, we're printing off a paper form that will actually go with the sample, but down the line, we want to get away from the paper altogether. But when they enter this into the computer, they'll hit the button and that'll go back to the central database, and then the laboratory will know that sample's coming tomorrow, so we're going to be able to plan how many samples we have coming on a certain day and be able to kind of make more efficient use of our resources, knowing which samples are coming in and how to orchestrate our daily work.

DR. JAN: Where -- by what mechanism? You said that it will tell the inspector what to collect. Now is that in, like, an e-mail message or -- the form doesn't look like it's...

DR. McCASKEY: It will go -- you didn't see the one form. They'll get a form, an electronic message of all plants, each plant, once a week, once every two weeks, whatever it is, I'm not sure what that schedule will be, that will actually say over this period of

time, here are the samples. Here are the six or eight or ten or one sample that you're taking. And it will say, you know, do a HACCP sample of chickens on this date. Do a -- you know, a residue on this date. You know. So it will actually define what samples that they should collect. And then this plant will also know that if they're doing chicken and they're supposed to do 52 or 53, whatever it is, if that sample goes in, it'll reduce that number by one, but then it'll -- if the lab, for some reason, discards the sample if it came in too late or it was leaking or whatever else, that will go on back into the system, and it will bump it back up to 52. So there's going to be a mechanism to really keep on top of where this plant is and how many samples they need to be sending in. And it's going to be a very efficient system on tracking that information without having to have humans get involved to fix things that are out of whack.

DR. JAN: Yeah. One more question related to that. Currently, I know that a big problem is that they get a paper request and either they didn't get it or they forgot they got it or for whatever reason, I know this will fix a big part of that. But if they get a

message to collect this sample and, you know, in 30 days collect these samples, does that keep popping up until they get them filled? Or does it tell them one time and then if they forget then they can have the same problem?

DR. McCASKEY: I believe this will keep popping up until they either send that sample or, for some reason, correct the frame that says we don't produce this product. But and then also, this is going to go back to management, so management is going to be able to say I've got this plant out here that's got ten requests over the last month, and they haven't done anything. Let me actually go out and make sure that -- you know, that this guy knows what he's doing or that, you know, maybe there is a problem and this plant doesn't produce this product or something. But it will give management a much more rapid update than -- and idea that there could be a problem with that plant. So I think we're going to get much better compliance with the submission of samples into the labs.

Yes, Sandra?

MS. ESKIN: How much money, in the most recent budget, has it taken to run this laboratory system? And has that increased significantly over the last five

years or ten years? Obviously the biosecurity piece of it is relatively new. I just want to get some sort of sense of what kind of resources are devoted to this system.

DR. McCASKEY: I think our budget went up probably the most in about ’96 or ’97 when HACCP came on line and we started doing additional HACCP sampling. And since that time, it’s been relatively flat, you know, maybe with an inflation bump. But that’s kind of where we got our additional bulk to do additional sampling. We did get some BT money that was kind of a one-shot thing to, again, built our BSL-3 and do some of the security things, but we haven’t gotten a budget influx to actually continue some of the things we want to do to further prepare and do surveillance sampling and the kind of things we really need to do to have those things in place. There are many methods and things that we need to do to -- that -- to be sure we have methods for some of these agents that could be used in food. And there are things where we’re trying to find mechanisms that we’re trying to seek additional monies, but you know, some of those things are in the works, but we have not obtained those yet.

DR. HARRIS: This is Joe Harris. The e-sample thing looks great. You -- and you may have said this and it may have went right by me. What is the timeline for having that implemented?

DR. McCASKEY: There -- up there, last week in Omaha, we were in Nashville when they had the talk, it's -- we're looking at implementing certain portions of it some time early in 2004. And it's going to take a while to get the various different forms on there, but they want to start this in 2004. And in fact, we kind of told them a year ago that they were -- we hoped to start in 2003. It didn't make that time frame.

DR. HARRIS: That's all I have.

DR. McCASKEY: This is going to save all kinds of time. I mean, right now, we have -- for example, we have plants out there that do a couple hundred thousand antibiotic tests on a plant. And these guys all fill out a paper form, and those forms all go to Des Moines to the -- to be keypunched into a system. That's not going to happen anymore. He's going to enter this into the same -- push a button, and we're not going to have to do all of this manual paper handling that we are right now.

Lauren?

MR. LANGE: Yeah, this is Lauren Lange of DHS. The system is actually, you know, developed and running right now. And we're in the phase. This week there are former field people that are at the tech center running the system, logging on, getting the alert that they're supposed to take a sample, you know, trying to fill it out, test the instructions and stuff. And then we expect to pick a circuit in the field in February or early March and introduce it as a prototype system in one circuit, iron out bugs then, and then over the -- in the remainder of 2004, plan to take it nationwide.

DR. McCASKEY: Also, as I showed you before, there are four or five or six different databases in FSIS that are all being worked upon. And they all have to kind of come together to make it work. And like LIMS is kind of waiting on our M2K database, the corporate database, all of these things need to know how they're going to intertwine. And so right now, they're trying to figure out how those pieces are locking together, and they've put a lot of effort into that. So again, all of those things over the next six months are going to fall into place. But it's been a hugely complex process

trying to take all of these different databases and merge all of these things into one comprehensive system.

David?

DR. CARPENTER: If you look to increase the -- David Carpenter. If you look to increase capacity capability in your whole lab system, think about state public health labs, state Ag labs, if they get ISO 17025 accreditation, would you deputize them to use those data?

DR. McCASKEY: Again, FSIS is looking at the possibility of using the laboratory data from state laboratories. And I'm -- you know, that's being discussed in policy and other folks as far as what can we do, what can't we do. You know. I think that -- I'm hopeful that there's going to be a major move by laboratories to get ISO accreditation, because I really think that 17025 makes you demonstrate competency. And if you -- if you're ISO accredited and have the annelids that you're reporting under the scope of your accreditation, that's a pretty good indication that you're doing a pretty good job. So I think that the move will be down the line to support, you know, recognizing those types of results. So I think we're

trying to form an integrated national system of laboratories, and as part of that, we need to be able to trust the results that are coming from different laboratories.

DR. LOGUE: Hi. I'm Catherine Logue. And I have just one quick question. What kind of rejection rate are you looking at right now, and when they get -- when samples get rejected, how long does the turnaround take before those come back in again? I know with the e-sample you're talking about they're pretty much -- will go back on the list of things to do, but how do you deal with that now?

DR. McCASKEY: Well, in the past, we have had a rejection rate or a discard rate of six or eight percent of times. And again, some of these may be a truck that's delayed. We have very tight requirements set up. We basically say in some of our samples, if they're not -- if they're collected today and they're not here tomorrow, we don't analyze them. Or if they're above a certain temperature or, obviously, if they're leaking or if they have a -- some key data on the form that's not there, we discard them. And right now, the -- it's not the fastest system to actually get that back

into the process to re-request those things, because we're, again, printing off forms and doing those kinds of things even though the plant now does -- the inspector does now get notification back through LRN that that sample has been discarded so they can release that product or do whatever else, because they don't wait for that result to come. But through the e-sample, they ought to get very rapid notification, and the system should be set, say, okay, let's send out another request or add that request back to that list. So the inspector ought to have rapid notification of that.

Any other questions? Okay.

MR. TYNAN: No other questions, then, thank you, Dr. McCaskey, for taking care of us on that one.

DR. McCASKEY: Thank you.

MR. TYNAN: And I think last, but not least, on the agenda, we have Dr. Robert Post, who is going to talk to us about poultry standards of identity.

DR. POST: Thank you. I think this afternoon's -- well, probably today's agenda shows a variety of things that the Agency gets involved in and has a responsibility for, and this is a slightly different issue, but it is important for us to present

to you, and I'll explain why.

We published in the Federal Register on September 29 a proposed rule. And it deals with classes of poultry or standards of identity for poultry. And I have -- I'm glad to have the opportunity this afternoon to talk to you about it, to brief you, on the proposal and the changes to amendments -- or amendments to the regulations that exist right now in the Federal Register in Title 9. I'm going to summarize the intent of our proposed rule as well as cover some of the major or central points in the proposed rule.

Well, as you know, the Poultry Products Inspection Act and the implementing regulations in 9 C.F.R. prohibit the distribution and commerce of poultry products that are adulterated or misbranded. The Act authorizes the Secretary to establish definitions and standards of identity for poultry and poultry products to ensure that consumers receive products that are truthfully labeled. And the Act also requires that the Agency consult with the appropriate Advisory Committee, and in this case, this Committee, before issuing standards of identity for poultry products, particularly to ensure that there is no inconsistency between federal

and state standards. And any changes to the revised standards that occur as a result of these consultations will be incorporated in the final rule.

Well, poultry classes were established by USDA almost 30 years ago to aid in the labeling of five kinds of poultry. And those kinds of poultry included: chickens, turkeys, ducks, geese, and guineas. The classes were based primarily on the age and sex of the birds, except that for Rock Cornish game type chickens, they were also defined by breed. And today, these definitions appear in 9 C.F.R., 9 Code of Federal Regulations, in Section 381.170. An example of a current poultry class definition and standard is for a boiler or fryer. And that's defined as a young chicken, usually under 13 weeks of age, of either sex that is tender-meated with soft, pliable, smooth-textured skin and a breast -- and breastbone cartilage.

Though FSIS uses these standards to ensure that poultry products are labeled truthfully in a non-misleading manner. For example, a product with labeling that declares broiler chicken would mean that the bird would be a young chicken that meets the criteria I just mentioned, in other words, usually less than 13 weeks of

age of either sex and according to the rest of the criteria in the standard. We would find a roaster chicken bearing that same label to be misbranded, because a roaster is defined as a bird that is usually three to five months of age. So that's an example of how we use these standards.

In addition to FSIS's use of the poultry class definitions, the Agricultural Marketing Service, AMS, uses these classes for their grading certification and commodity procurement specifications programs.

And I will -- before I forget, I will note that I did ask someone from AMS to join me today, and -- in case there are some questions about the AMS aspect of the use of these standards, and that's Dr. Craig Morris, and he's with the -- he's the Associate Deputy Administrator for Poultry Programs at AMS.

Well, through discussions with the poultry industry representatives and poultry breeders and looking at the scientific literature and marketing information, FSIS and AMS are aware of advances in poultry breeding and poultry production practices. And we determined after review that many poultry classes in 9 C.F.R. do not reflect today's poultry characteristics or industry

practices. Generally, advancements in breeding and poultry management techniques have shortened the time required to attain birds with market-ready weights.

But furthermore, the current age references in the regulations may be misleading to consumers, especially, because the ages associated with the regulatory classification do not reflect current industry norms. And when consumers purchase a bird labeled as a boiler, they are generally getting a bird that is -- that takes less than ten weeks to market at the typical 3.5 to 4.5 pounds, not one that's as old as 13 weeks, as suggested by the current boiler class definition. And that definition is about 30 years old.

We determined that the poultry class definitions need to be revised to be more accurately reflective of the poultry that's marketed today and to ensure that the labels for poultry products are truthful. And it's also anticipated that AMS will incorporate the updated poultry classes into their marketing programs as a convenience for those processors and marketers and consumers, using AMS's voluntary poultry grading services.

While the crux of the proposal is to make the age

criteria reflexive of today's practices, and so what I've done is list out the major changes that are in the proposal. We are proposing to lower the age definitions for six classes of poultry that exist now. And specifically the age criteria for Rock Cornish game hen, for example, would decrease from five to six weeks to less than five weeks, which is reflective of today's market. Boilers or fryers would go from under 13 weeks to less than 10 weeks. That would be the text in the regs. Roaster or roasting chicken would decrease from 3 to 5 months to less than 12 weeks. For fryer/roaster turkeys, the age requirement would go from under 16 weeks to less than 12 weeks. And young turkey would go from under eight months to less than six months. And these are all reflective of today's market.

In addition to the changes in age definitions, their proposal states that the Agency is considering revising the geese and guineas standards to include the age criteria to make these standards more consistent with the rest of the class definitions. And we are seeking comments on this issue.

The Agency's proposal is also to make the terms hen or tom optional on the labeling of old turkeys, because

the general physical characteristics of birds identified as mature or old turkeys are the same, regardless of gender. And related to old turkeys, in most of the poultry class definitions, the term mature refers to old adult birds. However, the term fully mature, in the yearling turkey class definition, is used to describe the breeding capability of the bird and at the size determined that the description of the age and physical characteristics provided in the proposed yearling turkey definition sufficiently characterizes the birds in this class. And therefore, for consistency, the Agency is also proposing to delete the term fully matured from this class definition.

The other salient points in the proposal are to define the Rock Cornish game hen or Cornish game hen category or classification in terms of age and weight, not breed, because it’s doubtful that any purebred Cornish or Rock lines exist in commercial production today.

Other aspects of the proposal include changing the broiler and fryer duckling designation to duckling. And currently, these birds are labeled as duckling without these prefixes, so it’s a matter of updating. And

another point is to change the roaster duckling class to ducks to reflect current industry practices.

There are other editorial changes to improve clarity and consistency and uniformity, and I won't go into the details there, but it's basically to make the standards less vague and make them more enforceable and true definitions.

At the suggestion of trade representatives, the Agency is considering the merits of including requirements for ready-to-cook carcass weight ranges by class standards, particularly for turkeys and roasters, because some interest has been elevated to us. It's not necessarily an industry-wide interest, and so therefore the Agency is considering these kinds of -- this kind of criteria, and we are seeking comments on ready-to-cook weights being part of these definitions.

The ultimate goal, in conclusion, is the intent of the proposal, and that is to ensure that poultry products are labeled accurately and reflect today's production practices. And that will enable the Agency to enforce truthful labeling. Because all poultry marketed today have attributes that conform to the proposed class definitions, entirely new standards are

not needed, only the modifications that I highlighted.

And as with all proposals, there's always a comment period. And the comments on the proposal must be received on or before November 28, 2003, so obviously we are in the midst of rule making.

And as a final comment, I'd like to say that the comments of the Committee are welcome and desired. And as I said earlier, we will incorporate the Committee's comments in the final rule. Thank you.

MR. TYNAN: Dr. Hollingsworth?

DR. HOLLINGSWORTH: Bob, when you were looking at current poultry production practices, did you also look at practices for, perhaps, non-traditional raising of poultry, such as organic, natural, free-range, those animals that, in fact, may not be raised under the same conditions or with the same kinds of controls and feeding regimens that you see in commercial poultry production? My only concern is to be sure that we're not excluding on sector of the marketplace because they use different production practices. Can they also meet these standards?

DR. POST: The issue had come up. I would say that our proposal reflects the majority or the typical

production that's out there, not necessarily organic or anything related to organic where animal production claims are involved. But your point is well taken. I think it's something that we need to address in our final rule, and if, in fact, they -- make sure that they don't apply to make that information available. I'm not going to -- I don't want to, but I will put Dr. Morris on the spot, perhaps, and he can add more to that since he's from AMS and, of course, the dealing with organic and other issues.

DR. MORRIS: The surveys that we started about four years ago were based mainly on commercial production. We did not survey the organic industry, however we did provide a copy of the proposed rule to Rick Matthews [ph] who is the National Organic Program Manager. I don't know if he's shared that with the NOSB, but I will check on that, actually, when I get back today. I'll set something -- we will make sure that gets done, that Rick makes sure that that gets before the NOSB.

DR. HOLLINGSWORTH: Okay. My only concern would be, like, under an organic system, it may take 11 weeks to get a bird to market, and then it would no

longer be eligible to be called a broiler. It would be moved into the roaster class.

DR. POST: Right. And that's why I think that is a very worthwhile comment, and we'll address it.

DR. HOLLINGSWORTH: Thank you.

MR. TYNAN: Could I ask Dr. Morris to, perhaps, identify himself for the purpose of the transcript?

DR. MORRIS: Sorry. Craig Morris, Acting Deputy Administrator of the Agriculture Marketing Service Poultry Programs, currently Associate Deputy Administrator.

MR. TYNAN: Okay. Thank you, Dr. Morris. Further questions? Mr. Schad?

MR. SCHAD: Yeah. One is just a comment to really just kind of back up what you said, Dr. Hollingsworth. I was thinking about free-range turkeys that, I think, take longer than what may be typical of other turkey production. And I was thinking about how that might fall in under your proposal. And that may or may not be the same as organic. I'm -- I really don't know.

DR. POST: Okay. Actually, I can address

that. And free-range, as a claim, would apply to any kind of poultry that meets the definition. And at this point, the definition is access to the outdoors for a significant portion of the bird's life.

MR. SCHAD: Okay.

DR. POST: It -- I don't know if that would be a case where we'd think about differences in bringing to market a 3.5 to 4.5 pound boiler, for example, and that -- but we will consider that. We will consider other raising issues or raising or production issues as far as the development of a final rule.

MR. SCHAD: Okay. And then I have a question under the -- under chickens there just to maybe clarify for me in the proposal. I'm looking boiler or fryer from -- your proposal is to make it less than 10 weeks, and a roasting chicken to less than 12 weeks. Say you've got a chicken that's produced in nine weeks. How do you -- under your proposal, is it a fryer or is it a roaster?

DR. POST: Well, we would think there's a benefit in marketing it as a broiler if those birds are viewed as tender, more tender, somehow beneficial for all...

MR. SCHAD: So it could go either way, then?

DR. POST: Exactly. Yeah.

MR. SCHAD: Okay.

DR. POST: There wouldn't be a requirement.

MR. SCHAD: Yeah. Okay. Thank you.

MR. TYNAN: Dr. Jan, you had a question before?

DR. JAN: Yeah, just one quick question. Once these rules are in effect, and I don't know if we're getting any of these -- this type of product imported, but would that affect foreign markets coming this way? Would they have to qualify for this, or do they have their own standard, and who would know the ages on those?

DR. POST: Well, as with all labeling requirements, domestic requirements hold. I mean, all imported products need to meet domestic requirements, so we would expect the same definitions to apply to imported product.

DR. JAN: But since it's not -- there are no inspectors there, I mean, you just have to take their word that they're adopting these? Because their practices may be different. They may not get that size, and I don't know. And it...

DR. POST: The -- as with -- well, all other labeling and food standards requirements to our expectation is through the system we have of assuring equivalent systems in other countries in order to be eligible to export meat or poultry to the U.S. We would cover that. We would see in their -- in a review of labeling as well as standards regulations in a foreign country that that system is the same or would result in assurance that these products are accurately labeled in accordance with domestic requirements. So I think we have a check in the system, and if that's -- if necessary, we'll also deal with that as a comment in our final rule.

DR. MORRIS: Craig Morris with AMS again. I could add that in terms of a trade perspective, the amount of product which we would market under these standards of identity are very small in terms of imported product to the United States.

MR. TYNAN: Do we have any other questions on the poultry standards? Mr. Schad, are you -- okay. That's okay. You'll be punished for that. If there are no other questions, then we'll let Dr. Post off of the hook. And thank you very much for doing that for us.

DR. POST: Yes, sir.

MR. TYNAN: And I think we're to the last segment of the afternoon's agenda for the public comment period. And I'm going to turn that over to Dr. McKee to take care of that for us.

DR. McKEE: Okay. Thank you. We have some time now for public comment before we adjourn. There will also be time for public comment tomorrow as well after we've heard the report from the Subcommittees in their work that will occur tonight. And as usual, we want to try to focus on the issues at hand and the public comments then should be focused in one of the areas that we have had an opportunity to visit with and discuss all day today. Do we have anybody -- there was nobody that signed up requesting specifically to address the Advisory Committee, but I would like to open it up to our audience, if there happens to be anybody that would like to address the Advisory Committee on any of the issues today. What I'd like to do is if you could, limit your comments to about three minutes, and then if there are others that want to go in and talk, and then if you still have additional comments, I'll let you have a second turn.

MR. CORBO: Tony Corbo from the consumer group, Public Citizen. I just have a couple of comments about the proposed operating procedures for the Committee, especially in terms of material that public members may bring to the Committee meetings. And I wanted to thank Dr. Bayse for, at least, sticking up for us earlier today. I know that during the deliberations of the Micro Committee in August, they had set up a table about 20 feet away from where the material was being used for the meeting, the official documents that were being used for the meeting. The table was set aside for any other material that groups wanted to distribute. I think that that is something that I think needs to be explored. Whether there are reports or studies that public -- groups that are not part of the Committee deliberations may want to bring to the Committee members for consideration, I think that should be encouraged.

The same with the Subcommittee meetings. Now I've attended these meetings now for three years. I've attended the Subcommittee meetings. And for the most part, the Chairs of those Subcommittees have been very solicitous of the folks sitting in the audience who are

not part of the formal Subcommittee deliberations and have encouraged folks in the audience to participate in the Subcommittee's work. Your agendas deal with very weighty issues. You're working under a compressed time frame, and sometimes folks in the audience may bring a different perspective than the small Subcommittee. So I would really encourage that the public attending these meetings, making the effort to come here, get the full opportunity to participate.

DR. McKEE: Thank you for that comment. Our direction in the past to the Committee Chairs has been that the Chair actually has the purview of engaging visitors or audience within their Subcommittee meeting to make a decision as to the appropriateness and the productivity of comments. Like you mentioned, there is a lot of work that's going to go on in a short period of time, and so in order to have the Committee stay focused, that is a responsibility of the Chair to decide what would be appropriate for that particular person's Subcommittee how much outside the Committee dialogue would be necessary and be brought to the table.

Any other comments? Okay. Hearing none, we will adjourn. Do you have a meeting with the Committee

Chairs or...

MR. TYNAN: Yes. If I could just mention that...

DR. McKEE: Okay.

MR. TYNAN: ...very briefly. Let me finish up with one logistical issue. Perhaps if the Committee Chairs, the Subcommittee Chairs, any of the facilitators or typists could come back just a little bit early from dinner so that we could spend just a couple of minutes to make sure that we're all on the same page in terms of what needs to be done this evening. I know some of you have been through the drill before, but it would be helpful just to be sure that we're all going in the same direction for the Subcommittee activities. So if we could maybe meet back here at quarter to 6:00, that would be very helpful.

Yes?

DR. HOLLINGSWORTH: Do you have our assignments?

MR. TYNAN: Yes, I was just going to mention that to you. The TA group, the Talmadge-Aiken group will be meeting in the Senate Room. And these rooms are, as you go out the door, it's almost like taking a

U-turn. So instead of going back out toward the main lobby, there's a hallway to the left. So it's just going back out through the double doors and hanging around to your left-hand side. The first room is the Senate Room. That'll be the Talmadge-Aiken group. The Cabinet Room, which will be the next one down, will be the group that's doing risk-based. And I think the last room down, the Congress Room, we're going to make the surveillance group walk the furthest. And that'll be the Congress Room. So the participants on the Subcommittees could just meet back there, I think, if that's okay with the Subcommittee Chairs.

Okay. So we'll see you at quarter to 6:00, and enjoy your dinner. We'll meet back here in a couple of hours.

CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

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

HELD AT: Washington, DC

DATE: November 5, 2003

We, the undersigned, do hereby certify that the foregoing pages, numbered 1 through 220, inclusive, are the true, accurate and complete transcript prepared from the reporting by the reporter in attendance at the above identified hearing, in accordance with applicable provisions of the current USDA contract, and have verified the accuracy of the transcript by (1) comparing the typewritten transcript against the reporting or recording accomplished at the hearings, and (2) comparing the final proofed typewritten transcript against the reporting or recording accomplished at the hearing.

Date:

_____
Shelley Kohr, Transcriber
York Stenographic Services, Inc.

Date:

_____
Christine Forrest, Proofreader
York Stenographic Services, Inc.

Date:

_____
Tim Wagner, Reporter
York Stenographic Services, Inc.