UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE THE SECRETARY OF AGRICULTURE

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COMMITTEE ON MEAT AND	X	1767 KING STREET
POULTRY INSPECTION	X	ALEXANDRIA, VIRGINIA
MEETING	X	

VOLUME I OF V
GENERAL SESSION

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DR. GLADYS BAYSE
Department of Chemistry
Spelman College

DR. JAMES DENTON
University of Arkansas

DR. JILL HOLLINGSWORTH, Vice President, Food Safety Food Marketing Institute

DR. ALICE JOHNSON
National Turkey Federation

MR. KEVIN ELFERING, Director
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Minnesota Department of Agriculture;

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ALSO PRESENT:

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Maryland Department of Agriculture

MR. MICHAEL GOVRO
Food Safety Division
Oregon Department of Agriculture

MR. MICHAEL KOWALCYK, Chapter President
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MR. MARK SCHAD
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Ohio

MR. CHARLES LINK
Cargill Meat Solutions
Cargill Value-Added Meats

MS. SANDRA ESKIN
American Association of Retired Persons
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MR. DARIN DETWILER, Educator
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P R O C E E D I N G S

8:30 a.m.

MR. TYNAN: As always, I want to welcome you to the June meeting of the National Advisory Committee for Meat and Poultry Inspection. It's a pleasure to have you all here. I know this is an important meeting from our standpoint and we appreciate sincerely the time that you take out of your schedules to come here and help us out.

Briefly what I'd like to do to start the meeting, before we have our keynote speakers, was to perhaps go around the room and have everybody introduce themselves again, it's been six months, just to be sure we remember who we are, and kind of give your name and affiliation, if you could do that.

However, I have one introduction that I would personally like to make. We have a new member on our Committee, Mr. Darin Detwiler. Mr. Detwiler is filling that consumer vacancy that we had back at last November's meeting.

So let me just read a little bit of Mr. Detwiler's bio, to introduce him. Mr. Detwiler is a decorated Gulf War veteran. He heads the math and science department at Best High School in Kirkland, Washington. So Mr. Detwiler and his wife, Vicki, endured a life-changing experience in 1993 when their 17-month-old son, Riley, died of E. coli 0157:H7, after being exposed to the pathogen by an infected day-care classmate. This personal tragedy motivated the Detwilers to become aggressive advocates for consumer food safety improvements and foodborne-pathogen education. Rather than embarking on a career in engineering, as he planned following

his honorable discharge from the Navy, Mr. Detwiler decided to dedicate his life to teaching and to food-safety education.

Mr. Detwiler began his drive to make the issue of food safety relevant to young people by weaving it into history and science lessons. Then, by working with the National Science Teachers Association, he developed ways to use food safety to meet national science standards for schools. His hands-on food-safety-education curriculum has been applied in high schools around the country, and currently Mr. Detwiler is also working to expand food-safety education through a program to teach instructors at the college level.

Mr. Detwiler's tireless efforts in the consumer food-safety-education arena have taken him to the White House, to the halls of Congress. He is a sought-after speaker and has appeared on CNN, National Public Radio, and that's my personal favorite, and Good Morning, America. He has written or consulted on food-safety articles that have appeared in the New York Times, the Seattle Post-Intelligencer, and the Bellingham Herald.

So Mr. Detwiler, welcome to the National Advisory Committee for Meat and Poultry Inspection, glad to have you.

Now if we could, if we could go around the room, and maybe I'll start at this end, and allow everybody to introduce themselves and to give their affiliation.

DR. PIERSON: I'm Merle Pierson, Deputy Under Secretary for Food Safety, USDA.

DR. MASTERS: Barb Masters, the Acting Administrator, FSIS.

MS. CUTSHALL: I'm Mary Cutshall, I'm the Director of Strategic Initiatives, Partnerships, and Outreach Staff at FSIS.

MR. SMITH: I'm Bill Smith, Assistant Administrator, Field Operations, FSIS.

DR. SIDRAK: Acting Director, Recall Management Staff, Office of Field Operations, FSIS.

DR. GOLDMAN: I'm David Goldman, the Director of Human Health Sciences Division of FSIS.

DR. RANSOM: Gerri Ransom, FSIS, Executive Secretary, with the National Advisory Committee for Microbiological Criteria for Foods.

DR. JOHNSON: Alice Johnson, National Turkey Federation.

DR. DENTON: James Denton, University of Arkansas.

MS. HOLLINGSWORTH: Jill Hollingsworth, Vice President of Food Safety for the Food Marketing Institute.

DR. JAN: Lee Jan, and I'm the Director of the Texas Meat and Poultry Inspection program, in the Texas Department of Health.

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

MR. LINK: Charles Link. I'm with Cargill Meat Solutions, actually, a division of that, Cargill Value-Added Meats. I'm currently responsible for technical services and regulatory compliance for a number of beef and poultry plants.

DR. BAYSE: Gladys Bayse, Department of Chemistry, Spelman College.

MR. ELFERING: I'm Kevin Elfering and I'm the Director of the Dairy Food and Meat Inspection program with the Minnesota Department of Agriculture and also an instructor at the University of Minnesota, Center for Animal Health and Food Safety.

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

MR. KOWALCYK: Good morning. I'm Michael Kowalcyk, Chapter President of the Dane County Chapter of Safe Tables Our Priority in Madison, Wisconsin.

DR. CARPENTER: David Carpenter, Associate Professor, Department of Medical Microbiology Immunology, Southern Illinois University School of Medicine.

MR. DETWILER: Darin Detwiler.

MS. BALDWIN: Deanna Baldwin, Maryland Department of Agriculture.

MR. SCHAD: Mark Schad, Schad Meats, Inc., Ohio.

MR. TYNAN: And last but not least, I'm Robert Tynan, with the Strategic Initiative staff. Mary and I

worked together to try to put this program on.

So I think we've got a good agenda for you this morning, and without further ado I'm going to introduce our first speaker. It's Dr. Merle Pierson.

Dr. Pierson is the Deputy Under Secretary for Food Safety in the U.S. Department of Agriculture. In that position he works with the Under Secretary for Food Safety, Dr. Elsa Murano, to oversee the policies and programs of the Food Safety and Inspection Service. Dr. Pierson is internationally recognized for his work with hazard-analysis critical control points and research on reduction and control of foodborne pathogens.

Prior to his appointment to USDA he served as a professor of food microbiology and safety at Virginia Polytechnic Institute and State University. He received his B.S. in biochemistry from Iowa State University and his M.S. and Ph.D. in food science from the University of Illinois.

So I take great pleasure in introducing Dr. Pierson.

DR. PIERSON: Thank you, and good morning, welcome to Washington, D.C., I'm glad we could bring this nice weather to you, we put it in order, it had been standing in place for quite some time, but we got it cleared out over the weekend and everything's nice. So I hope you have an enjoyable time.

In coming over here this morning, I was just

looking at the area, it's a beautiful area, and I hope you get out a little bit during the day, when you take a stretch, you know, from your deliberations, and I hope you enjoy your time here in D.C.

On behalf of USDA and the Office of Food Safety, I welcome you for joining us this morning, I extend my sincere appreciation to the members of this Committee, and, in particular, Darin, you know, welcome to the Committee and we look forward to your contributions.

I very much appreciate the dedication that you have to ensuring consumers with the safest possible food supply. I very much appreciate the work done by committees, I know, I work very closely with Gerri on the National Advisory Committee for Microbiological Criteria for Foods, another committee that addresses food-safety issues. In the deliberations, these committees are very, very important to us.

Many of you have made the cause for food safety your life's work, and because of collaborative efforts of government, industry, consumers, and academia alike, we all reap the benefits of a safer meat, poultry, and egg products supply.

I might say that we've made many significant accomplishments in food safety since the last meeting in November. One of the areas that has come to the forefront has been BSE. December 23rd was quite a life-changing event,

as you can imagine, I know, in USDA. Although we'd been already addressing the issues surrounding BSE, there was many, many more things to address, and that we have done.

Dr. Barbara Masters, Acting Administrator of FSIS, will be outlining some of the recent BSE-related initiatives in her presentation.

Another area is that we have improved the implementation and verification of SSOPs and HACCP plans, leading to a dramatic decline in the number of meat and poultry product recalls during 2003. The number of C lass I recalls was nearly cut in half from the total of the previous year -- that is, from 2002 -- and we trust that that trend will continue.

However, the real proof of whether our policies are working to protect the public is in determining whether they are impacting public health directly. That is why I'm thrilled by the recent report from the Centers for Disease Control and Prevention where they report on the incidence from foodborne pathogens and notice significant declines from 1996 to 2003 in illnesses caused by E. coli O157:H7, salmonella, campylobacter, and yersinia, specifically to the products we regulate.

Illnesses caused by salmonella typhimurium decreased by 38 percent. And, most significantly, between 2002 and 2003, illnesses caused by E. coli O157:H7 dropped by 36 percent. 36 percent, a very substantial reduction in one

year. And, again, we trust that that trend will continue.

The CDC in their report attributes the changes in the incidence of these infections to control measures implemented by government agencies and the food industry, enhanced food-safety-education efforts, and increased attention to the issue by consumer groups and the media.

So it's a collaborative process, it's just not one entity that makes that difference, but it requires a multi-disciplinary approach and one where we work together to address these issues.

Furthermore, the decrease in E. coli O157:H7 illnesses brings the United States very close to achieving the Healthy People 2010 goal of 1 case per 100,000 people. We are very hopeful that if we all continue to do our part, this reduction will not be for just one year but will continue from now on until we have achieved the greatest reduction in possible in illnesses caused by this pathogen.

This is very exciting news, and this data further validates our scientific approach to improving public health through safer food. As we all know, protecting public health by ensuring safe and wholesome food is not accomplished, again, by just one entity but it's through collaborative efforts. We all work together.

We need to challenge ourselves, challenge each other, and, above all, hold ourselves accountable for improving food safety. The health of all Americans relies on

our continued cooperation and success. All of us have to look at ourselves as public-health stewards and never rest in our mission to make the food supply even safer.

Over the next two days you will hear from many FSIS representatives, and I urge you to ask questions and think critically about the path we are taking. Your work will go a long way in helping FSIS develop and implement policies that will better serve consumers worldwide.

Again, I thank you for your time and continued commitment to this committee, and I look forward to a productive two days, and at this time I would like to turn the podium over to Dr. Masters, our Acting Administrator of FSIS. Thank you.

MR. TYNAN: Sounds like a plan.

(Applause.)

Before we go any further: Mike?

MR. KOWALCYK: Yes. Michael Kowalcyk, from STOP. Dr. Pierson, in reference to the CDC statistics, while it is encouraging news, there are some caveats in the CDC report, especially within the Editorial Note, that I think is important not only for us on the Committee to be aware of but also the general public, because these numbers do seem better, and they may indicate an improvement; there are some limitations to the data.

One, the Food.Net sites might not be generalizable to the entire United States because there are only nine

sites. Secondly, and even Dr. Tauxe at the CDC has mentioned this, in statements regarding these numbers, that year-to-year changes may be a natural variation and that further data is needed to discern trends.

Also, Food.Net data is limited to lab-diagnosed foodborne illnesses. Again, another source of variation could be resources at the state level in reporting foodborne illnesses. And finally, just anecdotal experience shows us that past declines in E. coli especially have been followed by increases.

So while these numbers seem better, it's by no means -- I don't want the public's perception to be a false sense of security, because a lot of work still needs to be done. I just wanted to get that on the record.

DR. PIERSON: If I could respond, you know, in my presentation, I talked about how I trust that these trends will continue, or I hope that it will, and, you know, the incidence of foodborne illness is not the only one indicator of, you know, what the success is of the initiatives that are being undertaken. You know, in our surveillance work, you know, we're seeing some changes.

So, you know, we're seeing indicators that progress is being made, and we're seeing indicators relative to -- you know, I know what the industry is doing in terms of intervention. So there's just a number of things to put together to show that, you know, the right things are being

done, you know, and, quite frankly, we're all after that "right thing" to be done, and we want to do that on a continued basis.

MR. TYNAN: Thanks, Mr. Kowalcyk, and let's allow Dr. Masters to do some opening remarks and perhaps we can continue that discussion during the Agenda.

DR. MASTERS: Good morning all, and I want to welcome all of you on behalf of FSIS. As the Acting Administrator of FSIS, this is the first meeting that I've had the opportunity to serve as a chairperson. I'll certainly have had the opportunity to attend the meeting as a representative of the Office of Field Operations, so I understand the importance of this Committee and the work that you do for our Agency.

So I look forward to hearing the discussions and the recommendations of this Committee as we work through the next two days. We have a very aggressive agenda that we'll be going through for the next couple of days, and in a moment Mr. Tynan is going to talk to you about some changes, some significant changes to the Agenda, some changes that I think that you'll like hearing about, as far as our format and changes in the approach that we're taking in this meeting and the approach to this meeting.

I briefly want to address the three areas that we're going to look at having this Committee bring us some recommendations on in the form of sub-committees. Their full

discussion is in your packets, the books that you got, but one area for which we're looking for some recommenda-tions is in the area of listeria monocytogenes.

As you're aware, we put out an Interim Final Rule on listeria October 6, 2003. It was unique in that when we put that out we said, We're going with our Final Rule, we're implementing this Final Rule, but we want to give ourselves the caveat that we're going to assess whether or not we're doing the right thing and whether or not we need to make any changes before we make it the final Final Rule.

That said, we are doing our own assessments to make that determination and we would like the sub-committee working on this to answer the questions: Are we asking the right questions of ourselves in this assessment? And: Are there any additional areas we need to be considering as we move towards a final Final Rule? So that's one area we have a sub-committee working for us at this meeting.

Another area is Applying the Mark of Inspection, we are asking whether or not FSIS should delay the application of Applying the Mark of Inspection to Product Tested for the Presence of an Adulterant until the Agency has received those test results.

This issue has naturally evolved as we've tried to improve our food safety programs. It's an issue that we have discussed at previous public meetings, and it's one that, after those discussions, evolved some naturally through the

BSE issue. With our Interim Final Rules on BSE, the Agency made the determination that any animal carcass that is tested for BSE, that we would not apply the marks of inspection until we receive the test results for that animal.

So the question we're asking for the sub-committee to provide some recommendations to us is: should we consider expanding that policy to other products for which we are testing for adulterants.

At the previous meeting for which we had this discussion there were a lot of conversations on whether or not this type of policy would be useful and the impact it might have on small and very small establishments. So that's the area that we're particularly interested in hearing from the sub-committee that's deliberating on this, on how we might be able to work through some of those issues if we were to implement this type of a policy.

The third area where we're looking for a sub-committee to bring us some recommendations is in the area of food security. Food security is of vital importance to all of us.

We have taken a number of significant steps in the area of food security and we'll be talking to you about some of the things that we have done related to food security, but we'll be asking a sub-committee to talk to us and provide us some recommendations on whether or not we should require an establishment to implement a food-security plan, and if the

answer is yes, what that food-security plan should contain.

I think those three topics will keep the sub-committees very busy, and there's certainly topics which are very relevant and pertinent to our Agency and for which we will value the advice and recommendations that we get from these sub-committees and from this Committee.

These three topics, as you can recognize, are longer-range type issues, things that we're working on a little further out, and that's kind of the approach we take in these meetings, that we need to get information from you for issues we're working on in the future, so that we can take that recommendation as we finalize our policies.

That said, I wanted to share very briefly with you on some very near-term recent information, as Dr. Pierson indicated, on BSE. As of yesterday -- since it's pertinent, I thought people might be interested in things that are happening.

Our Agency has one small piece in the Depart-ment's BSE surveillance program. The Department itself, in our overall expanded BSE surveillance program -- the BSE surveillance program basically has three big chunks, or chunks of different sizes I guess I should say.

The Department itself will be looking at testing, over the next 12 to 18 months, as many as they can, in excess of 200,000 high-risk cattle for BSE. Those animals will primarily be tested by renderers' 3D/4D operators by our

sister Agency, AFIS.

So that's the biggest chunk of the extent of the BSE surveillance program. Another piece of that expanded BSE surveillance program is another 20,000 animals that are 30 months or older, or, in essence, those animals that would have eaten feed so they were alive prior to the United States putting in place our ruminant-to-ruminant feed ban in 1997.

So, basically, 20,000 animals, that appear to be healthy, that will be going through slaughter plants, that will be randomly selected, will be part of our Department's surveillance program.

And in addition to that, FSIS has had some involvement in another piece of the surveillance program, that began yesterday, where our veterinarians are sampling all antemortem-condemned cattle at federally-inspected establishments, with the exception of CNS-condemned calves and those animals for which an establishment elects, through regulatory exclusion, to treat those animals, which is a very small population of animals.

So animals that are antemortem-condemned will be tested -- or sampled, the sample will be taken by an FSIS veterinarian and submitted to an AFIS-approved laboratory for sampling for BSE, and that began yesterday, and so I wanted to share that with you, that the Department's surveillance program has begun and FSIS began our piece of that role yesterday, and things are going smoothly, that we're aware

of, and so we wanted to share that with you, that that is going on and that the surveillance program is also going on.

The bigger part, the "in excess of 200,000," will take place over the next 12 to 18 months, the goal being that 200,000 need to be tested in 12 consecutive months, so it's kind of a rolling window for which we need to have those 200,000 tested in 12 consecutive months, so within the next 12 to 18 months, we will reach that capacity, reach our capacity of our BSE surveillance program.

I know BSE is of great interest to all of us, so I did want to share at least the latest information of what's going on in the area of BSE, but -- we could spend our whole day on BSE, but we've got a lot of important things on our agenda, so, that said, I'm going to turn it back to Mr. Tynan.

This meeting is very important to me, and I want to let you know I do intend to be here for both days. Unfortunately, I do have to leave for a brief few moments, my counterparts in the Russian government have a forum that I need to be at very briefly, to open this morning, through video teleconference, they were not willing to reschedule it, they're not quite as flexible as we are in the United States, trying to open up some trade barriers going on with our Russian counterparts on some poultry issues, I see some of my entry [phonetic] folks saying thank you, so I will go get that meeting opened.

I did everything I could to get it exchanged; I could not do that. But I will be back. This meeting is very, very important to me. I do appreciate the time all of you have given up to be here, I know that you don't have to be here, you're doing it willingly, and I thank you very much, and I look forward to the work that you're doing, and I will be back to spend the rest of -- this afternoon and tomorrow with you, so I thank you for the work that you're doing. Thank you.

(Applause.)

MR. TYNAN: Is it possible we're ahead of schedule? This is, I guess, the moderator's dream, to be ahead of schedule.

On the Agenda, at 9:00 we have an item on the Agenda called Charge of the Committee and Overview of the New Meeting Procedures, so I thought we'd take just a moment to kind of review the role and meeting format that we have.

I do want to welcome you again to the 2004 meeting of the National Advisory Committee for Meat and Poultry Inspection, I think we do have an excellent agenda planned, and a revised format that I think will be beneficial to each of you and beneficial to the Agency as well.

After our last meeting the Committee expressed some concerns about several areas and the way that the Committee operates. For my part, I appreciated those comments, I think they were well-thought-through, I think they helped us in

kind of formulating how we wanted to approach our meeting today.

It's a good time, though, to review the Advisory Committee procedures to sort of clarify the goals and expectations a little bit and the responsibilities of everybody involved.

It's our intent to try and create a meaningful and productive relationship between the Agency and the Advisory Committee. Let me say at the outset the Agency does place great value -- and I would reiterate what Dr. Masters just said -- in terms of getting your input, receiving your recommendations, and we do appreciate sincerely the time and effort you all devote to the Committee.

Briefly let's cover the role of meeting format and the procedures. As far as the Committee role is concerned, the purpose of the Advisory Committee is to provide comments and recommendations to the Agency on matters of regulatory concern, particularly those that are affecting federal and state inspection programs and food standards.

It's of critical importance that we receive your views on regulatory areas the Agency has in development, so we need to receive your ideas and your thoughts. At the same time, we also have solicited topics from the members, and in an effort to match those Committee interests with the Agency needs, sometimes we've been able to do that, other times we have not.

In either case, we seriously consider your suggestions for issues and briefings and we try to incorporate them into the Agenda whenever possible. It's important to remind the Committee that if a topic or a recommendation is not acted on as part of the committee process, should not imply to anyone that we did not give every consideration in creating the Agenda or in establishing whatever the Agency policy was that was under discussion.

It could very well be that the topic may be one that was recently addressed or where we're not sufficiently along in our thinking to make it worthwhile to make it either an issue or briefing for you. At the end of the day, however, the Agenda-setting process is an Agency responsibility to ensure that we get the specific information and the recommendations necessary to formulate those regulatory policies. So I think we're in great need of the input and the views that you all have to share with us.

In that regard, one of the suggestions, I think, that you made in your letter took us to looking at the format we have for the meeting. As you noticed in the briefing materials that we sent to you, the meeting format has changed, we've altered the meeting schedule, so we focused this meeting on the issue papers, as opposed to the briefing papers, and these are critical areas of concern to us, as an Agency, and they're the areas where we need your input and your expertise.

So let's quickly go through the Agenda and I'll try and highlight some of the changes that we're going to have for this meeting. They're pretty simple, they're pretty straightforward, just to be sure that we're all working off the same page.

At 9:20 -- and we may even be earlier. At 9:20 we've incorporated some time for an update on issues, so I think that was a request that you all made, so we have allowed some time for the presenters of issues at the previous meeting to give you a little bit of an update on where they are.

Now, you have to recognize that we're only six months from the last meeting, so progress will not be necessarily dramatic, but having said that, we'll do our best to give you an update on where we are and what's happening.

At 9:40 we'll have questions from the Committee members related to the briefing papers so -- we've sent to you, in the packets you received, and hopefully you received them in enough time so that you had an opportunity to look through them, we'll allow some time for questions on those briefing papers, so we'll not be doing the normal presentations.

So, as I mentioned, the focus of the meeting is the issues, the briefing papers, there should be five in your packet, and we can talk about those in a few minutes. We've allowed time on the Agenda for you to ask the questions, to

make any comments on those papers that you have. We will have Agency staff here, and probably most of them are here already, who will be -- who were in the development of those papers and will be able to respond to your comments and questions. So that could be the full 20 minutes or maybe something shorter, depending on how your questions go and what interests you have in those areas.

We will not have the five separate 30-minute presentations that we've had at past meetings. So we'll utilize that time to allow the members on the sub-committees to begin their deliberations relating to the issues for today's meeting.

So beginning at 11:15 we'll begin a discussion of the three issues of the meeting, that's listeria monocytogenes, Applying the Mark of Inspection, and last, but not least, Food Security. So that will begin at 11:15. And the sub-committees then can begin their deliberations at approximately 2:45 on the Agenda, so you'll be able to break into your groups and get started on discussing the issues and the questions that the Agency has posed for you.

So we're going to leave it up to the chairs of the sub-committees to determine whether or not you need to hold discussions this evening, so we've provided the rooms, they will be available after dinnertime if the sub-committee chairs would like to continue the discussions or there is so much activity in the work group that you can't get it done by

the 5:45 or 6:00 time frame. So you will have an opportunity to continue later on.

As in past meetings, the sub-committees are going to report out their findings and their recommendations to the full committee in the morning session of day 2, so that will -- there is really no change on day 2, other than we'll be focused, again, on the briefings.

And then, finally, on both days we've allowed some time for public comment for the meeting. We would ask that the people that have some interest in making public comment, if they could register outside at our registration desk, so we can get a sense of time and how much time we need to allot for questions.

One of the other things that we talked about at our November meeting, besides the format, was the meeting procedures, and we just discussed some simple rules concerning the conduct of the meetings, to make the most of the short time that we have. I think we were -- you were giving me a hard time, I think we were calling these Robert's Rules, as I recall, and they were intended to facilitate the accomplishment of the work of the Committee and guide the deliberations.

So I thought we might just take one moment to go through those. I think the Robert's Rules, if you will, are under Tab 12, if you want to just take a look at those real fast. I don't think there's any surprises there, I think we

were all in agreement with them at our last meeting. The very last part of Tab 12.

So there is -- on my sheet we have eight, so the chair, the FSIS administrator, Dr. Masters, will conduct the meeting, she'll open the meeting, recognize those wanting to speak, and impose some time limits and the number of speakers and adjourn the meeting, so that's all pretty straightforward and I think that's not as much of a change as it's just putting it down on a piece of paper the way we work in reality.

All questions and requests to speak are going to be addressed to the chair, people must be recognized by the chair before speaking. Presentation of issue papers will be followed by a short question-and-answer period, and in the interests of time, questions and comments should be limited in length and to those asking for clarification on the presentation, so the chair is going to exercise some discretion in terms of the time that's allotted for those. And, again, that's more to keep the Agenda on track than it is to try and inhibit anything that you have to say.

Speeches or statements of opinion by the audience -- or by the Committee, for that matter -- where it's a little bit lengthy and it's not necessarily related directly to the issue, should be made during the sub-committee discussions or during the time set aside for public comments.

The committee members and the members of the public

will be recognized by the chair during the public comment period at the meeting, so requests to speak again will be presented to the chair in advance, and that's why we asked if anyone wants to do something during the public comment period, if they could register at our registration desk with the ladies out there, they'd be glad to help.

The chair approves in advance any materials to be distributed by either the Agency, the Committee members, or the public at the meeting. There's a table outside where we have some handouts. If anyone has any material that they want to put out there, that needs to be approved by the chair.

Committee members are expected to the attend the plenary sessions. We've had some discussions about participating on the plenary sessions and who's participating on what sub-committees. We submitted a list to you, I think it's in your briefing packet, of how the committees would be structured. I think they're similar to the last meeting. We did not hear any comments or concerns about the way the sub-committees are structured, so I assume that that is okay.

We do want to make the point, however, that the Committee members are expected to attend the plenary sessions, this morning's sessions, to hear the issues themselves, the meetings and the sub-committee meetings to which they are assigned. So the Committee members who do not attend a presentation on an issue or participate in the

sub-committee meetings for their particular assigned issue, in our view, are restricted in terms of participating in the final plenary session on Thursday morning, in considering that issue. I think if you haven't participated in a discussion of the issue this morning, you're not participating on the sub-committee that you were assigned to, then weighing in the following day on that issue and making a lot of changes or bring up a lot of concerns at that point seems to me unfair to all of the members of the Advisory Committee as well as to the Agency.

So the sub-committee chair is designated by the chair and controls the sub-committee sessions. The members of the public may attend these sessions, and at the discretion of the sub-committee chair, they may ask questions, so the sub-committee chair has authority to determine how much involvement the public who attends the meeting may have.

And last, but not least, the rules of order are subject to review at each of the Advisory Committee meetings at the discretion of the chair. So you might say that's sort of an end-of-the-meeting discussion.

There's a couple of meeting logistics -- so do you have any questions up to this point, we okay?

(No response.)

MR. TYNAN: Okay. Meeting logistics. The meeting is being transcribed, and there is a record made, so during

the session, when you'd like to ask a question, if you could stand up your tent card -- and I think we've done this a thousand times, so I don't think this is anything new, if you could stand your tent card up, and when you're called upon, if you could identify yourself for the record so our good gentleman from the transcriber company can be sure they get it accurately.

Again, anyone from the public wishing to speak, if you could register outside at our table out there, we appreciate it very much.

As a final item, there's some basic but important information. Our rest rooms are located out the door and slightly to the left, there's a hallway over here. There are pay telephones there in case your cell phone battery has gone amiss. So they're all in the same location, just directly across the hall.

If someone needs to contact you, I understand the phone number at the front desk is 703-837-0440, so that number again is 703-837-0440, so if anybody needs to contact you and, for whatever reason, they can't get through again on the cell phone, that would be the number at the front desk. If you need faxes, the fax number is 703-837-0454. So that's the front desk and the fax number, so hopefully that will -- if anybody needs to contact you, there's an emergency situation, something like that, it will be available for that, and if there are some messages that come in, we'll make

sure that you get them as promptly as we can.

Are there any questions on our charge, our format, or how we're going to proceed for the day?

(No response.)

MR. TYNAN: Great. Okay, the next item on the Agenda has to do with an update on the issues from the previous meeting. We have some of our presenters from the last session here, Dr. Goldman, Bill Smith, we have -- is it Mr. -- Dr. --

MR. SIDRAK: Sidrak.

MR. TYNAN: Sidrak, okay. And you were sitting in for Ken Peterson?

MR. SIDRAK: Ken Peterson.

MR. TYNAN: Who did an issue related to consumers?

MR. SIDRAK: To the effectiveness checks with the recall issues.

MR. TYNAN: Okay, great. And with that, I'm going to turn it over to Dr. Goldman to perhaps start us off, and if he could -- David, if you'd like to sit at your seat, I don't think there's any reason -- unless the committee objects to that or would prefer we get real formal and come up here to the podium, I'm going to let Dr. Goldman relax a little bit and speak to you from there, and if you could introduce the topic that you discussed in November for us and then maybe kind of give us your update.

DR. GOLDMAN: Thank you, Robert. Good morning, and

thank you for the opportunity to very briefly update you on the issue that I helped the Committee address last November, which was: how can FSIS better associate food-safety activities with public health surveillance data, and you'll recall from the last meeting, and certainly Dr. Johnson's sub-committee will recall, that a good deal of the time in discussion at the full committee and in the sub-committee had to do with an issue that we call attribution, and very briefly, very simply, as an example: it is to try to determine for any given case of illness what was the exposure that led to that illness, so if you use E. coli O157:H7 as an example, obviously many people, when they hear of a case that's diagnosed, will -- first on the list will be exposure to ground beef, but we well know from our studies that swimming in farm ponds and rivers can be an exposure, attendance at a county fair, direct contact with farm animals, and person-to-person contacts are other means of exposure to E. coli O157:H7 that might result in illness, so we did spend some time at the last meeting talking about this issue of attribution, so I do want to update you a little bit on that particular issue. So I'll start there.

You'll recall also I explained to you our participation in Food.Net, which is a collaborative activity with FSIS, CDC, FDA, and, at this point, ten states, or at least parts of ten states. One of the three goals of Food.Net from its inception in 1996 was to determine, better

than we knew at the time and we still know, which exposures to foods lead to particular illnesses, so that issue of attribution was one of the three original goals of Food.Net. To that end, in 2003, at the Food.Net annual meeting, called the Vision Meeting, the attribution issue was fully engaged by the Food.Net steering committee, and since that time, so for about the past 18 months, there has been a considerable amount of work done on this attribution issue.

There is a work group that's been engaged for that period of time. FSIS in fact has in the past 18 months had ten different staff members involved in some aspect of the attribution effort at Food.Net. Particular issues that have been addressed by the attribution work group are an effort by the state sites to better exclude illnesses that are travel-associated, especially, in particular, foreign travel-associated illnesses.

You'll recall that Food.Net is an active surveillance system of lab-confirmed cases, so the information that is obtained from labs on particular cases is very limited to some basic demographic information, so Food.Net is attempting to include questions about foreign travel as a way of excluding those cases from -- or at least segregating those cases as a way of better explaining those cases that are relevant or have occurred as a result of exposure in the U.S.

Food.Net is also engaged in trying to segregate

those cases that are related to outbreaks as opposed to what we call sporadic cases, those cases, one and two single cases or few cases, that occur sporadically in the population, that are not associated with exposure to a common source.

And finally, in Food.Net's effort to get at attribution, FSIS has been particularly involved in development of a mathematical model, I think I may have mentioned this at the last meeting, in which the salmonella HACCP verification data is being used together with human illness data to help us understand better those products that have led to human illness.

So we are using -- we are providing the Food.Net modelers -- and in this case it is a model that's being developed at the University of Minnesota through a cooperative agreement with Minnesota and the CDC, to help us understand better those food vehicles which might have resulted in salmonella illness in this case.

There is a separate effort going on at CDC that's apart from Food.Net, which we are not participating directly in but which we are following quite closely, and that is: an analysis of the outbreak data from 1998 to 2002, the Foodborne and Diarrheal Diseases branch of the CDC is in the midst of analyzing the outbreaks of foodborne illness, and the specific goal of this study will be: to get a better understanding of the food vehicles that have resulted in those outbreak cases.

One of the very difficult issues in this analysis has been the issue of dealing with what you might call mixed foods, so if someone -- an outbreak is attributed to lasagna, as an example, someone has to make the determination about whether it is the meat, the cheese, the pasta, or any vegetable components in that lasagna which have been ultimately responsible for the illness.

We expect to hear -- or we hear from our colleagues at CDC that there should be a draft manuscript on this particular study in the fall of this year, so we are looking forward to that analysis.

I'll just give you one other example, in terms of attribution, an effort that's going on both in Food.Net and, actually, on the national scene, and that is the use of a standardized listeria case interview form. Many of you know that listeria is a particularly difficult pathogen because in humans it has a very long incubation period and the ability to get a good exposure history is quite limited because many times people are asked questions about their exposures that go back at least 30 days in the past, so one effort that's being piloted in Food.Net sites is to ask each of the listeria cases, once they're -- immediately after they're identified, a series of questions, and the draft questionnaire that I've seen runs to about 12 pages and covers every known exposure that has resulted in listeriosis, in our knowledge of this disease, so that we will be able to

capture, in as timely a way as possible, the possible exposures that have led to the illness.

I want to shift gears a little bit and I want to expound a little bit on the comments that Dr. Pierson made and Mr. Kowalcyk made regarding the E. coli data that was publicized just recently in the MMWR, and I do want to commend to your attention that MMWR, if you haven't already read it, but I want to very briefly describe what I think is a cycle in which you will be able to see that FSIS has taken human-illness data, has reacted to that data, in this case in a regulatory fashion, and the results of that action.

So FSIS published a Federal Register Notice in October of 2002 in which those facilities that produced ground beef were asked to reassess their HACCP plans. Very specifically, in the preamble to that Federal Register Notice was a reference to the fact that at that time E. coli O157 illness rates had not changed over the preceding several years, so that was cited as one of the factors for issuing this Notice.

As a result of that Notice, and as you heard earlier we are aware of some industry action which we believe resulted in less contamination, specifically the industry held a summit in January 2003, in which they discussed the significant problem of E. coli O157. We are aware that they've been engaging in more of what is called test-and-hold procedures, in which they test product and hold it pending

the results of that test for E. coli O157.

So as a result of both the FSIS action and the industry reaction to that Notice this past year, for the first time FSIS was able to demonstrate a significant -- statistically significant decline in the percent positives of E. coli O157:H7 from 2002 to 2003, so it was the first year in which we've been able to actually note that decline in E. coli O157 in our ground beef samples.

And then, as you heard earlier, just this year, in the April issue of the MMWR, which talks about preliminary data for 2003, Food.Net did cite the decline in E. coli O157 illnesses, and, as has been pointed out, this is a one-year change, one year does not make a trend, we do look quite hopefully to the future. We do also hear from our colleagues at Food.Net and CDC that there is continuing to a decline in the reports of E. coli O157:H7 illness this year, in 2004, so we hope to see that trend -- actually, that one-year change become a trend, with next year's data.

But I do think that this illustrates an instance over about a two-year period in which FSIS, as I said, issued a Federal Register Notice, there was the action by the industry, we found changes in our testing data, and then there were changes in human-illness data, and I think this is an illustration of FSIS' ability to use data, even though it's a historical example.

And I'll end by saying that you will hear discussed

just shortly the effort that FSIS has made regarding ready-to-eat products, and particularly the control of listeria monocytogenes. I think this is another example in which the Agency reacted to human illness, in this case at least in part to an outbreak situation, among other things, and put in place, in this case, an Interim Final Rule, and we are now earlier in that two-year cycle, or two- or three-year cycle, and will begin measuring its impact on human illness, and I look forward in future meetings to presenting hopefully good news there as well.

I think I'll stop, because I don't want to take the time from Mr. Smith and Mr. Derfler --

MR. TYNAN: We could perhaps take a couple of quick questions, we're a little bit ahead on our schedule. Any questions? Go ahead, Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk, from STOP, again. You mentioned earlier a drop in positives in the testing results. Was this the verification testing program (inaudible) last year?

DR. GOLDMAN: Yes, it was, and --

MR. KOWALCYK: I know -- with regard to the verification testing program, I know members of our organization has been in contact with FSIS as well as other areas of USDA. Even in the reports it does indicate that the testing, while they're regulatory in nature, are not designed to measure national prevalence. Again, I think that's an

important caveat to note. And yes, based on the 2002 Directive, it is -- there is a positive indication that what industry is doing is -- may be improving when you look at the verification testing. However, because of the way the verification testing is done, where different plants are sampled year to year, and there are questions about the sampling methodology as well, again, those -- I think those caveats need to be raised.

DR. GOLDMAN: Thank you for that comment. I'll use this as an opportunity to say that a manuscript which very much in detail describes the analysis of that data is in the clearance process and will be submitted to probably the Journal of Food Protection, so you can look forward to hopefully a peer-reviewed analysis of that testing, and it will acknowledge some of the limitations of the data. So I appreciate your comment.

MR. KOWALCYK: I look forward to that report.

DR. GOLDMAN: Pardon me?

MR. KOWALCYK: I look forward to seeing that report.

MR. TYNAN: Dr. Hollingsworth.

DR. HOLLINGSWORTH: David, I just need you -- if you would go back, on the analysis of the outbreak data, what were the years that will include?

DR. GOLDMAN: 1998 to 2002.

MR. TYNAN: Other questions regarding Dr. Goldman's

remarks?

(No response.)

MR. TYNAN: Okay. I'm going to let Mr. Smith, from the Office of Field Operations, talk a little bit about the next issue from November's meeting.

MR. SMITH: And I was asked just to give an update of where we are on the Talmadge Akin usage and authority. At present we have not changed how we presently apply that program, which is where we see a general benefit to the Agency and to the state program, usually in isolated locations, where it makes sense to utilize some state folks to help cover those operations, that we will enter into those agreements.

We will take the information from the last meeting and incorporate that into our thinking on our Federal/State Directive that we're now in the process of developing. I know all the State Directors are involved in development of that new Federal/State Relations Directive, and a key component of that will be: looking at cooperative agreements and Talmadge Akin provisions.

We also plan to have this as a topic of discussion at the upcoming State Directors' meeting, which will be two weeks in Washington.

So at present that's where we are with the Talmadge Akin issue.

MR. TYNAN: Dr. Jan.

DR. JAN: Lee Jan, Texas Department of Health. I'm going to surprise you, I'm not going to talk about how we fund TA plants, but I would like to know: what was the basis of the decision to not include TA plants in the recent Work Measure Assessment that was done for all FSIS districts. When we were here last time, there was talk of the new Work Measure Program, that would include all federal plants, including TA, in assigning work, but when the work was assigned, TA plants were not included, so I was wondering what was the basis of that decision.

MR. SMITH: That decision was based on -- we hadn't really had time to sit down and talk to state directors about that impact, and so instead of making a major change, based on that, we felt it was better to exclude those plants where we already had the agreements, because, again, to make a change in the middle of a fiscal year has an impact, certainly changes -- it impacted us in the middle of a fiscal year, impact us, and so we felt that would have the same impact upon the state, and so that's why we decided to leave that out for this year.

DR. JAN: For this year, is that what you said?

MR. SMITH: Well, again, once we decide, then, on how we're going to use Talmadge Akin in the future, to everybody's benefit, then, you know, this -- our regular assignment of personnel will fall in -- will take over those practices, because this -- the work assignment is only a one-

time reordering of the work force also.

MR. TYNAN: Other questions on Talmadge Akin? (No response.)

MR. TYNAN: The next presenter would be Mr. Phil Derfler. Phil.

MR. DERFLER: I've been asked to talk about what we've done in response to the Advisory Committee's recommendations from last time and I'm trying to get new sources of data, and we were looking for the sources of data to enable us to effect Dr. Murano's Vision, particularly the first issue at the end of her Vision statement, about being able to use data in order to predict public-health problems or predict problems as a way of anticipating problems, rather than being totally reactive to them.

As a result, we made some progress, although I really can't -- I don't want to overstate it. One topic that's been of particular concern to the Agency is listeria monocytogenes, and particularly the presence of this pathogen in product at retail. FDA did a risk assessment in which deli meats sliced at retail were a particularly high source of risk for listeria monocytogenes.

So since the Advisory Committee meeting, one of the things that the Advisory Committee suggested was that we work closely with the states to try and get data, and we've entered into an agreement with one state, in order to get their data on monitoring, monitoring that they've done at

retail of Lm in deli meats and other products at retail. We've entered into a contract with AFDO in order to get data from them that we can use in developing a baseline, and we've also made arrangements with Dr. Denton's group to get additional data on retail product and Lm in retail product.

So we've made significant process in that regard. Last week I spoke to the Committee on National Statistics, of the National Academy, at which I re-made this point, about our need for data for food safety, and tried to encourage them in the report that they're developing and the recommendations that they're making, to try and use that vehicle for us to get additional data and encourage other people either as sources of funding or sources of data, for data that we can use in this regard.

But the big -- the big issue when the Committee considered it last time, and the issue that remains, is industry data and how we would get access to industry data and the issues that are ancillary to that, about: what would be the consequences if the data were made available to the Agency and questions of that type.

We're planning to have a public process on the question that that issue raises. Unfortunately, I will take the blame, I dropped the ball, quite frankly, between BSE and E. coli O157:H7 and various other issues, I just have not had the resources to take on the issue of -- or take on the public process that we need to have, on how we get access to

industry data and how we work through the issues that are ancillary to that.

So while we remain very interested and fully intend to take on this issue, because it is a part of the Under Secretary's Vision and an issue that is important to us, unfortunately, we have not taken on that aspect, although we certainly intend to do so.

MR. TYNAN: Do we have any questions for Mr. Derfler? Mr. Schad.

MR. SCHAD: Mark Schad, Schad Meats. You said you'd made agreement with one state?

MR. DERFLER: Right.

MR. SCHAD: Is there a reason why there's only one, or do you expect more to (inaudible)?

MR. DERFLER: The part of the agreement with AFDO is that we will have a number of states and get the data from a number of states. One state just came forward as a result of some contacts we made and made their data available to us.

MR. SCHAD: So you do expect (inaudible)?

MR. DERFLER: Yes.

MR. TYNAN: Other questions?

(No response.)

MR. TYNAN: So we're done with the update for the issues. Yes, Ms. Eskin.

MS. ESKIN: Hi, Sandra Eskin. Just a general comment. I think it's great that we've gotten the update. I

just want to say that there's no need to limit it necessarily to the most recent meeting. Obviously, the committee is a two-year sort of cycle, so if it were appropriate to update us on something that happened in, you know, a meeting a year before, that would be great as well.

MR. TYNAN: Thank you for that comment, Ms. Eskin.

Okay, if there's no other comments or questions regarding the update on the issues, let's move on to the next item on the Agenda, which has to do with the briefing papers, and I think, as we've talked, we've changed the format, so we'll not be doing the normal presentation, so this is your opportunity, after having reviewed the five briefing papers, to offer any comments or concerns that you may have, questions that you may have, regarding those briefing papers.

We have five briefing papers. The first one is Administrative Enforcement Report, and Mr. Smith is here and can address that.

The recall effective checks, Dr. Sidrak is here and he can cover that one for us.

Bio-security readiness in the laboratories, Dr. Maczka is here and can answer questions related to that.

For the legislative update, Mr. Larue was not able to attend but Mr. Bryce Quick is in the audience, so if there's any questions related to the legislative update, we'll ask him to try and respond to those questions.

And then last, but not least, the National Advisory Committee for Microbiological Criteria for Foods, we have Dr. Ransom here, and she can talk a little bit about -- or Ms. Gerri Ransom, I apologize -- who can talk a little bit about that committee.

So with that I'll open it up to the Committee members, if you have any questions regarding the briefing papers, to offer them up. Dr. Hollingsworth.

MS. HOLLINGSWORTH: Jill Hollingsworth, with Food Marketing Institute. On the listeria paper, you identified the seven different groups that have been put together. Is there a list of the names --

MR. DERFLER: That's not a briefing paper, that's -- I'm going to talk about that.

MS. HOLLINGSWORTH: I'm sorry. I'll hold that question.

MR. TYNAN: Yes, hold that question. I know it's a good question, but hang onto it for just a minute.

MS. HOLLINGSWORTH: I'm sorry.

MR. TYNAN: Let's focus on the five briefing papers that are at issue, on the Tabs 7 through 11. Sounds like a gaming device, right, 7 become 11 or something like that, never played that. Mr. Schad.

MR. SCHAD: I may be going slightly out of order. I've got questions on Number 4 and Number 5.

MR. TYNAN: Start anywhere you like.

MR. SCHAD: On the legislative update, I would like a clarification on the last paragraph, it says "two other critical elements of FSIS' mission are to continue the enforcement of humane slaughter regulations and to provide for the full cost of front-line inspection, so on that last paragraph, is it -- I need a clarification. Is FSIS asking for more money to have more front-line inspection or more money to continue the front-line inspection it's doing now?

MR. TYNAN: You're referring to the last paragraph.

MR. SCHAD: Last paragraph.

MR. TYNAN: Last paragraph. Where it talks about "two other critical elements"?

MR. SCHAD: Yes.

MR. SMITH: Can you just state that one more time, your question.

MR. SCHAD: Yeah, okay. I really just need a clarification on that, Bill. It's asking -- FSIS is asking for more money for humane slaughter and to provide for the full cost of front-line inspection," so is that more money to continue the front-line inspection that you're doing now or is it more money to increase the amount of front-line inspection?

MR. SMITH: Two things. One is, the humane slaughter regulations, that has not been -- continually that's a year-to-year funding, so we're asking that the funding for the last two years that be provided -- continue

for the -- ongoing also, to fund, because we're hired people, and we've put people in place, and we've dedicated staff years to performing that function, so we're asking that to be continually funded.

And then, of course, to meet our antemortem, postmortem, and then verification responsibilities, that's to, again, fund our full costs for meeting dated carcass-by-carcass inspection and once-per-shift-per-day inspection requires in the processing environment.

MR. TYNAN: Dr. Carpenter, would you like to pose your question.

DR. CARPENTER: Yes. This question has to do with -- this is David Carpenter, SIU School of Medicine. On the administrative enforcement report, which is the first one, the last paragraph talks about establishing a case specialist position which will be assigned to every district office. I mean, how is that going to enhance the overall consolidation of information and of communication about the efforts that the Agency takes?

MR. TYNAN: Dr. Carpenter, that was in which paragraph were you referring to?

DR. CARPENTER: The very last paragraph, administrative enforcement report, it says "OFO recently established a case specialist position."

MR. TYNAN: Thank you.

MR. SMITH: We've established this position, and

this is not -- we are not asking for any new resources, we are using some of our previous either public health veterinary people that have been trained in the method or consumer safety officer, that would be where we'd select these people from.

Why we're establishing this position is to make sure that when we put a case file together, that all the evidence supports the violation. The administrative enforcement report is put together to support our documentation of violation of the statute, the law, and so these people make sure that the focal point -- that when we identify a violation of the Act, that the evidence that's accumulated in these files support that finding, and so that is their purpose. And there's one in each district that will be doing that.

DR. CARPENTER: So will each individual have a finite number of cases or all the cases in that district?

MR. SMITH: All the cases within that district will be -- this person will be doing the check on that. Now, they're not the only ones who build the cases, again, it's our enforcement investigation analysis officers, which were formerly our consumer safety officers, our public health veterinarians, who were trained in this method, they do the actual -- go out to the plant and do the actual assessment and then they accumulate the information, whether it be memorandums, interview, laboratory findings, in-plant

results, food safety assessment results. So they build that case.

What the district case specialist, again, determines is: does the evidence support the case that's been brought forward. So there's one for each district.

MR. TYNAN: Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk, from Safe Tables Our Priority. Again another question about the administrative enforcement report. I guess in the second paragraph, towards the middle of the paragraph, "exhibit documents, including non-compliance records and laboratory results." Would "laboratory results" also encompass testing that was done by the plant? -- because I know in reviewing the OIG report of the ConAgra recall, there was testing done at the plant that was outside of regulatory testing, that there was confusion as to whether or not inspectors had access to that, whereas the Agency said that yes, they did. Is this to be included in the administrative enforcement report?

MR. SMITH: The collection -- well, first of all, we have a Directive out, and I believe it's 5000.2, that makes very clear that Agency personnel have access to establishment laboratory analysis as they relate to support of their HACCP pathogen-reduction programs. So in this case the officer would document that those findings, laboratory findings, would document those in memorandum of interview,

and that would be what would become part of the case file. If we needed the actual laboratory result to make a case, then we can -- we can always have access to those records and use our subpoena authority. So they would be part of -- if we decide to take an action and we need that as documentation of evidence, those are the three ways we could collect that information.

MR. TYNAN: Mr. Govro.

MR. GOVRO: Yes, thank you. Michael Govro, Oregon Department of Agriculture. Another question about the administrative enforcement report. Was there a procedure in place prior to the current procedure that you've adopted; and if so, how does it differ from what you're doing now and what improvements do you expect to realize from the new procedure?

MR. SMITH: There was a procedure when we first started up, we had what we -- what our compliance personnel used to use, which was called a case file. Pretty much that process, though, was built on making a criminal case, not an administrative case, so we found that in many cases that worked for us but in many cases it didn't, so what we wanted was -- what we're teaching our people, the change we see here, that we are focused purely on administrative action, the Office of PEER does the criminal investigations within the Agency, and so we wanted a process that worked just for administrative actions.

And so, again, what we're teaching our folks is:

there has to be a violation of the statute, the Federal Meat Inspection Act, the Poultry Product Inspection Act, or Egg Products Inspection Act, and if you find a violation, then you must accumulate the evidence, which would be the HACCP plan records, SSOP, SPS, laboratory results, things of that nature.

And it also -- it is very important to follow the Administrative Procedures Act that the establishment is afforded all due process. In our sharing results, they're always noticed -- they are notified when we find something so they have a chance to respond, those type things.

So this whole process was built in order for us to, again, document violations and follow the Administrative Procedure Act requirements very closely. So the establishment is always provided due process every step of the way. So that's why we developed it, and that is a little different than developing a criminal case.

MR. TYNAN: Mr. Elfering.

MR. ELFERING: Yes. Kevin Elfering, with the Minnesota Department of Agriculture. Maybe not so much of a question but more of a comment. I just see so many opportunities, with all of these, to be able to do a little more collaboration with state and local agencies. There's so many things that we're already doing, we're inspecting grocery stores, we're able to do effectiveness checks for recalls.

This is an example, a couple of years ago, we have -- we have some of these slaughter operations that are also retail establishments, many of them being a large grocery store, where there was an FSIS inspector on the slaughter floor, one of our state inspectors happened to be inspecting the grocery store, and two compliance officers came in to do an effectiveness check on recalls.

And I think that there's many ways we can utilize each other's resources, even with laboratories, it just happens that one of -- our laboratory is now part of the FERN, so many of these emergency response analyses can be done in state laboratories as well as in a federal laboratory. Even in enforcement, where our compliance officers and investigators will assist compliance officers from FSIS to investigate even in criminal investigations. And even with the E. coli Directive that has just come out, where we have inspection personnel, again, in grocery stores, where we would be able to really see a benefit in maybe eliminating some of those duplication of efforts.

That's it.

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

DR. DENTON: Yes, sir. With regard to the briefing paper on bio-security readiness for FSIS labs, I have a question, more for clarification, I think. As I looked at the paper with regard to the Food Emergency-Response Network,

as well as the National Animal Health Lab Network, it was not clear to me whether or not incorporated into that state and federal network --

We have the land grant universities. Many of the labs that are located on these university campuses have very good laboratories, with very specific assays, both chemical and microbiological, and they're geographically dispersed. It would seem to me that if this resource were tapped would be an outstanding way to handle any incident that takes place anywhere in the country, that we have the capacity to do that.

DR. MACZKA: That's a very good point. I don't know the answer to your question, though. We could find that out. And if not, it's a good recommendation to put forth. I'll put that (inaudible).

DR. DENTON: Thank you.

MR. TYNAN: Dr. Johnson.

DR. JOHNSON: Alice Johnson, National Turkey Federation, and I'm behind Tab 8, on effectiveness checks, the Agency -- under the "Background" they talk about "all reasonable efforts to retrieve and appropriately dispose of recalled products," and in the past we've talked a little bit about the poundage that's used on the recall and the fact that it is all product produced, and in some cases you can see that the product that is produced between certain dates may very well have -- the shelf life is expired, you know,

you can expect that a lot of that product has been consumed. In looking at this, does the Agency ever consider, "Okay, maybe this is the amount of the pounds of product produced during the time frame in question," but do you look at any type of "Here's the reasonable amount that we can assume may still be around"? We're looking at a risk-based approach. Is there any type of formula that could be generated -- I know companies have a lot of data on turnover and how long you can expect someone to hold, and recognizing that some product may be frozen, but if you look at 2 billion pounds of product to be recalled, generally there's a certain percentage of that that's already gone, that will not be retrievable.

MR. TYNAN: Dr. Sidrak.

DR. SIDRAK: The Agency tried to address that, at least -- in the Directive, actually. If you would see that we put forward three questions in place for the Recall Committee to consider when evaluating a recall situation. One of them is the availability of product to the consumers, so if it is not available, then there is no need to recall, and it spells that in black and white.

I think there was a serious attempt to address the issue that you're bringing up. So it is an assessment of a particular situation, every recall is taken on a case-by-case basis, to obviously assess that in estimating whether or not the product still be available to consumers. So there is a

possibility, when you're evaluating a particular case, that a product has an expected shelf life or it has actually some indication on the particular product that the expiration or use-by date, so that's taken into consideration, and if it is expired, the decision usually is that there is no need to recall. So --

(Pause.)

DR. JOHNSON: Maybe I'm not understanding the Directive, that -- but it's my understanding that there will still be a poundage published that represents product to be recalled. Right?

DR. SIDRAK: That's correct.

DR. JOHNSON: But the Recall Committee will now allow for product that is out of date in some sort of percentage based on company data?

DR. SIDRAK: The percentage is really very hard to estimate, but the clear cut would be in a situation where the product is no longer available to consumers. In other words, we've tried to address this particular issue in something that can be applied across from one case to another, which, in my mind, it's difficult to address the situation where you have a recall with 1 billion pounds and some of that maybe has been used and some of it hasn't. We're assessing that, we look at it on a case-by-case basis, but it's hard to put it in black and white and include it in the Directive, to address that.

MR. TYNAN: Mr. Derfler.

MR. DERFLER: In drafting the comments, in response to the public meeting, along the line that you're suggesting, we considered if it were possible to have some kind of formula or some sort of way of trying to report how many pounds are likely in commerce or something like that when we announce the recall. Ultimately we just concluded that there wasn't a real credible way to be able to do that, on the basis of the information that's available now.

However, I mean, one of the things that we really tried to do in this Directive is made clear that we're judging the effectiveness of the recall on the communication aspect of it, rather than the amount of pounds of product that are -- because -- because we don't have any control over the amount of pounds, but what we do have control over is: everyone through the chain making sure that the communication occurs, that is necessary in order to get the product out of commerce, and if we find that people aren't communicating, then we made clear in the Directive that we will take action against them.

DR. JOHNSON: And I an appreciate that you're -- the communication is a big part of it. However, I think it's very misleading when you look at a recall notification and you have the pounds that are to be recalled and then you look at pounds actually retrieved, and there's definitely misperception on what that all means. Thank you.

MR. SMITH: One of the things that we're trying to do, though, we're having an investigations analysis officer go to each one of the establishments now and sit down with plant management and fill out the recall worksheet. It is automated, that's printed out, and the plant manager actually gets to see that, which is then forwarded to the Recall Committee.

So the establishment has numerous chances for input, to make sure that data on poundage is accurate as possible. So there is some give and take in that process, to accurately identify how much is in commerce. And then as Dr. Sidrak said, the other part is the commingling, once that starts occurring, trying to estimate poundage on that gets to be an adventure.

DR. SIDRAK: I just want to add that I agree with you that the retrieval of the recalled product is not necessarily the ultimate measurement of the success of the recall process. There are so many other ways that we can measure that, and we've tried to share that with JO and other folks that are looking into the process.

DR. JOHNSON: Well, I think public perception is to do a basic comparison, so anything you can do to try to communicate what is actually anticipated for retrieval I think really helps us all.

MR. DERFLER: And the more data that we can -- I mean, if people have any kind of data, people have any kind

of insights about how product is used, how product is consumed, what's a realistic number, realistic way to digest the number, we will consider that, but we just -- in doing the direction of -- given where we are now, we just felt that we couldn't credibly do that.

DR. JOHNSON: Thank you.

MR. TYNAN: I'm going to go to a couple people that haven't had an opportunity to ask a question, then I'll come back around to second questions from the other group. Ms. Eskin, would you like to --

MS. ESKIN: Sandra Eskin. My comments also go to the recall effectiveness paper. Actually, there's a question and a comment. The question: could you just clarify what the current procedure is regarding press releases, when they're actually -- if they're submitted -- if they are issued for all classes of recalls or just more high-risk recalls; and second, again, in the way you're describing it, I think this is a case by case for every single recall, someone's going out, you're taking a look at the procedure, at the communications for that recall, has there any thought been given to do some sort of an annual report?

Again, I appreciate the fact that circumstances vary from recall to recall, but maybe by looking at it over a period of time you can detect some weaknesses or some places where revisions to your procedures may need to be changed, by taking, again, a sort of more systemic look at it?

DR. SIDRAK: Thank you for your comment, and I want to say that the Agency had recognized, and you can see that reflected in the most recent Directive, again, published and effective May 26th, which was just last week, so the Class III recalls generally -- we will not issue a press release to Class III recalls, those are recalls that has no public health impact.

MS. ESKIN: Can you give an example?

DR. SIDRAK: For example --

MS. ESKIN: They don't meet the standard of identity or there's --

DR. SIDRAK: Yeah. If you have -- sometimes you have a mislabeling issue, where the automatic labeling, as it is the case now in most establishments, will print the word "turkey" instead of "roast beef," for example, you know. I think most packages will show the difference, I guess, between turkey and roast beef, but in a situation like that, you do have a technical violation and, you know, if an establishment is -- if we are in a recall mode, then there is no need, in our judgment, to issue a press release. That would be the generally accepted or, you know --.

Now, there are a very few exceptions to a Class III that can have an economical impact, let's say for example you have undeclared water percentage, of course that's something where the general public then will benefit from a press release to that effect. There may be other examples.

But, you know, hopefully that addressed partially what's the current procedure. So, of course, to arrive to that, there was quite a bit of looking into the data from previous years, as of -- and evaluating the reason and the public benefit of issuing press releases, but for press -- for Classes I and II, where there is a public health concern, we continue to issue a press release.

And also the press -- the new Directive does indicate that we will be sharing the draft with the recalling establishment so to ensure accuracy of information that's put forward.

MR. SMITH: We also -- as you know, we post the results of the recall on the Web, and we respond to Congress each year on the number of recalls and the types of recalls, and we can certainly make that information available in a summary form on some kind of basis, whether it be six months or a year, whatever your suggestions. I don't see anything preventing that.

MR. DERFLER: The other thing that the Directive does provide is that we will evaluate recalls after they're done, to see if there's things that we could have done better or things that we didn't -- that didn't go the way we wanted to, so we will do it -- and there is an explicit provision in there.

MS. ESKIN: Certainly. And, again, it's both the individual recall and then any sort of sense of how things

have -- if there's any sort of a trend or an obvious similarity or issue that to many recalls, that would be useful for your purposes. Thank you.

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

MR. LINK: I have a question, yes. On the legislative update, there's a comment in there or a statement that the Agency has announced new regional training centers, I guess five of them, across the country, and I assume this is in response to closing down the one in College Station and trying to take a little more training to the field, and I commend the Agency for doing that, I think it's got to be a big benefit to help get to all the inspection work force you guys have to deal with every day.

Is there -- for all these locations are there five different separate training staff now, or is there one group that kind of travels around the country; and is there an agenda for all these places -- all these training sessions, that we could see what's going on and know when industry might be able to participate in some of the sessions?

MR. DERFLER: I'll answer that.

MR. TYNAN: Go ahead.

MR. DERFLER: This is Phil Derfler. We filled four of the regional trainer jobs, and we have gotten the fifth -- we want to make sure that our regional trainers are really well-qualified, and so this is the third time we've tried for the fifth trainer, in the Denver District, or Boulder

District.

We have not shut down College Station. We have ended our contract with Texas A & M and we're now replacing it with a series of three contracts, but we have not closed down College Station. I mean, sort of our goal is, on the one hand, to have centralized training so that we maintain consistency among the training but at the same time bring the training as close as possible to the workplace, to minimize time that people are off the job and to minimize the expense of traveling.

We don't have an agenda, I don't think, posted as yet, I mean we're working on it. Right now the big issue that we're dealing with is training all of our consumer safety inspectors on food-safety regulatory essentially, which essentially is taking on training 3500 inspectors, and that is -- as well as state inspectors, and that's taken up, you know, the major bulk of what we can do.

We are also -- we are doing front -- I mean, there's just a whole series of new trainings. I think Karlease Kelly, last time you were here, and I don't remember when that was, but Karlease Kelly gave you a briefing on sort of some of the trainings that we're doing, and I'm happy to say that we've started training our public health veterinary officers, we started that training about three weeks ago, and we've got the first class in that.

We're going to start training every food inspector

when they come on the job, we're training our front-line supervisors, we're training our EIAOs. Now, we are very interested in working to try and see how we can do training with industry. Up to date, trying to get our work force trained has been a major commitment, but we're starting to look at how to do that.

We have made -- through the HACCP alliance we've made available a session in College Station on the FSRE training, as well as the training of then consumer safety officers, now EIAOs. And so we are exploring that issue, but it's been sort of a step-wise basis as we try and do a better and better job of making sure that our inspectors -- our inspection personnel are as well-trained as possible.

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

MR. SCHAD: On the paper regarding the National Advisory Committee on Microbiological Criteria for Foods, n the sub-committee on redefining pasteurization, has the sub-committee drafted a document yet, or if not, when's the time table for that?

DR. RANSOM: Okay, the sub-committee met in April and they made significant progress in getting a draft together. They are going to meet again in July, the week of July 15th, and we do hope to see them adopt that document at our meeting. We have a plenary session in August, the week of August 23rd, so we could see a final adopted document then on the redefining-pasteurization work.

MR. SCHAD: Okay. Thank you.

DR. RANSOM: While I've got the microphone, I also wanted to mention: in the briefing material, the document on broiler performance standards, that document has been released and is on our website.

MR. TYNAN: Dr. Carpenter.

DR. CARPENTER: Thank you. David Carpenter. The same paragraph that is marked, that refers to -- I've just got one more question. The very last paragraph talks about alterative processing technologies. Has the Committee decided on what those will be or is it till in the evaluation-of-all-available-technology stage?

DR. RANSOM: They have worked through and decided to cover some main alternative processing technologies. They do have a list. I don't have a full list with me. I believe irradiation was one of them, high pressure. So they're looking at some of the main technologies that there has been some work done on.

DR. CARPENTER: Okay. Thank you.

MR. TYNAN: Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk, from Safe Tables Our Priority. I had one question about the legislative update and then -- actually, when training was brought up, I actually have two questions regarding the legislative update. The first one is: the $1.65 million for the continuous baseline program of risk assessments and performance

measurement, if I recall correctly, this is significantly less than what the Agency originally asked for when they went to Congress; and also it's not -- because it's worded as "continuous," there's no mention of it for the 2005's initiatives. Is funding for that coming out of general monies for testing, if you can address that?

MR. QUICK: I know this is what we originally asked for. It's my understanding we got exactly what we requested, to do the baseline studies that we had planned to do, so it's -- I mean, they've given us everything that we've wanted, that we've asked for.

MR. KOWALCYK: Are there funds allocated in 2005 for continuing that?

MR. QUICK: No. I think that in discussions of OPHS, that -- when they finish the baselines that are currently in the pipeline and they intend to go forward with additional baseline studies.

MR. TYNAN: Mr. Govro.

MR. GOVRO: Michael Govro, Oregon Department of Agriculture. I have a comment on the subject of recalls and perhaps the broader subject of making recalls effective. It's my understanding that USDA does not distribute for media release the locations where product has been distributed for retail sale and that the requirement there for the retailer to comply is to post a notice in the grocery store that they were a seller of product that's been recalled.

If you were to do an effectiveness check, to check the compliance of the grocery store, you might find a hundred percent, you would not find that a hundred percent of the people who purchased the product were actually aware that the product was being recalled because they would not necessarily have gone to that store or seen the notice even if they were there.

Getting back to the BSE recall, I can assure you that the process of recall -- that particular process of recall was not effective. What I did for about three weeks was take calls from consumers and media representatives, asking "Where did the product go? Where did the product go," and of course most of that product was distributed in Oregon, and our answer, much to our chagrin, was "Well, gee, we don't know, USDA won't tell us," we had not signed a memorandum of understanding with USDA regarding recalls, and so we couldn't respond.

We didn't feel very good about that, and there were just dozens and dozens of calls that we took at our agency, and I'm sure there were other agencies as well, took calls, by very distraught consumers, wondering where the product had been distributed, and I would recommend that USDA look at the policy -- well, it's more than a policy, I think it's 9 CFR 390.1, with regard to distribution of that information, as to whether something could be changed to allow you to more effectively distribute the information about where product

has been distributed at retail, because the current system, in my opinion, doesn't work.

MR. TYNAN: Dr. Hollingsworth.

DR. HOLLINGSWORTH: I have a follow-up question for Gerri on -- I'm sorry. Jill Hollingsworth, Food Marketing Institute. Follow-up question for Gerri. Is the sub-committee -- the Micro. Sub-Committee on Refrigerated Shelf Life also meeting July -- the week of July 15th, prior to the August meeting?

DR. RANSOM: Okay, they will not be meeting prior to the August meeting.

DR. HOLLINGSWORTH: They're not going to have any other meetings. Okay, thank you.

MR. TYNAN: Mr. Detwiler.

MR. DETWILER: Darin Detwiler. Related to Mr. Govro's remarks, also with effectiveness analysis, changing market trends, I've recently come to find out that there are finer grocery stores that take previously-frozen, for example, lasagnas, as was mentioned earlier, that one could buy and prepare at home and they basically take that shelf item and prepare it at the grocery store and sell it in their deli counter as something that someone would purchase and then go home and reheat, but no one has indication of the fact that it was a -- "this name brand" item or any of the safe handling information along with that, because it was previously cooked at the grocery store and then sold at a

cold temperature.

So as we have change in markets and the way the consumers are buying their foods, again, it becomes harder and harder, on the issue of recalls, for someone to know that "this product" was actually sold by "this company," because they're not given that information in that instance.

MR. TYNAN: Thank you. Do we have other -- Dr. Bayse.

DR. BAYSE: Gladys Bayse, Spelman College. At Tab 9, under security readiness, I had a couple questions and comments. The second page, under -- sorry -- second paragraph, under "Main Points," that laboratories had validated multiple new analytical methods to detect agents, pathogens, and so forth, I think to echo something Dr. Denton said, and perhaps Mr. Elfering, I hope that the Agency is using expertise from the universities and from the state laboratories to develop or validate methodologies which may not be new for the Agency but which are perhaps established already, certainly not, perhaps, are established already in these other institutions.

And to follow up on that, the next to the last paragraph, the goal is to include all major food laboratories in the network. Again, I think some of these laboratories with very useful analytical methods may not be, quote, food laboratories.

DR. MACZKA: As far as the methods, they -- in

terms of the methods they're developing, they do look far and wide for methods that are not even -- for the matrices that we are most concerned about and then they try to modify them and they look throughout all the agencies and state labs and such for methods, so they are scanning wide for these methods.

And in terms of -- I'm sorry, your second question was --?

DR. BAYSE: -- that some of these might not be, quote, food laboratories.

DR. MACZKA: Right, and -- that's right, they do look at other laboratories. Like we've looked at some analytical methods from EPA and stuff like that, so it's not just food laboratories, but then we modify the method for our matrix.

MR. TYNAN: Do we have other questions from the Committee regarding any of the briefing papers?

(No response.)

MR. TYNAN: Funny how it -- yes, Dr. Logue.

DR. LOGUE: Catherine Logue, North Dakota State. One question. This data that you're gathering using your limb [phonetic] system, what do you propose to do with it? Is it in a format -- besides using it for your recalls and other information, is it in a format that will be useful for your trends and data and statistics and, I don't know, putting it up on Food.Net and places like that, is it worth

doing that?

DR. MACZKA: The information is recorded from the FERN network, will be recorded in ALEX.Net [phonetic], which will connect to MARKUS [phonetic], and even to the LRN database from the states, and yes, it will be used to look for -- not only as an early-warning system, it could be used as an early-warning system, but to look for possible trends, even the threat agents, so they are screening it that way, and then -- yeah, so --.

MR. TYNAN: Other questions or comments?

(No response.)

MR. TYNAN: This committee is a very good committee, because on my watch it says just about 10:15 and on the Agenda it says it's time for a break, so why don't we take a break real quick and come back at 10:30 and we'll begin a discussion of the issues.

(Off the record and reconvened.)

MR. TYNAN: Our first issue is listeria monocytogenes, and here this morning to discuss the issue is Mr. Phil Derfler and he's going to discuss the Interim Final Rule on listeria monocytogenes.

MR. DERFLER: Good morning. I don't know, I'm just going to jump into this. Apparently I told everybody who's presenting with me that I wasn't going to do Power Point, so it's a surprise to all of us, including myself.

(Laugher.)

The Interim Final Rule on listeria was published in June of 2003 and it became effective in October of 2003, and in a lot of ways this rule is innovative, or new, or different. In the Rule we said that listeria monocytogenes is a hazard, reasonably likely to occur in post-processing-exposed -- post-lethality-exposed product unless prevented by a pre-requisite program or the SSOP. So in other words, for the first time, we had actually by rulemaking established a pathogen that had to be addressed by an establishment, either through its HACCP plan, its SSOPs, or a prerequisite program.

On the basis of the risk assessment that we did, we provided for three alternative approaches. Again, this is different than most rules, where the Rule sort of sets out a particular approach to compliance, but the risk assessment showed that there was a reduction of risk through either of the three approaches, and so we thought it appropriate to include it in the Rule:

Either dealing with the pathogen through the HACCP plan and having a growth inhibitor, that was alternative 1; alternative 2 was: either in the HACCP plan or with a growth inhibitor; and alternative 3 was: through the SSOPs, keeping the environment free of listeria monocytogenes.

The Agency said that its verification would be risk-based, taking into effect such factors as the alternative that was chosen and the volume of the product that the establishment produced. It's an Interim Final Rule,

which meant that even though there was a Final Rule in place, and it's been in place and effective since October, we would take comments for an additional year, it was actually 18 months, from the date that we published the Final Rule.

This is normally all that an agency does, take comments, if it does an interim final rule at all, which is unusual; however, we decided -- in addition to taking comments, we decided that we would do our own review of the Rule. This is a groundbreaking sort of approach, it's something that agencies don't normally do, but our goal is to ensure that when the Rule becomes final, both the Rule and its implementation are as well-designed as they can be, for ensuring the public health against the hazard of listeria monocytogenes. We're interested in ensuring that the rules are as well-designated as they can possibly be.

We're now at a pivotal time and a pivotal point in the development of the Rule, where the Rule has been in effect for approximately eight months, so we're about in the mid point between the effective date and the close of the comment period, probably a little bit further in than not, and therefore we're seeking your input at this time.

Now, as I explained in the issue paper, that you all received, FSIS has established seven internal teams to review various aspects of the Interim Rule and the issues related to the Interim Final Rule, and the teams -- in addition to being sort of the midway point, the teams are

nearing completion of their interim reports.

It's our goal to make the findings of the teams publicly available and to get public comment on those findings, which we'll consider, along with the comments that we get from the public on the Rule itself, and so we'd like to ask the Committee to consider the Agency's process of reviewing the Interim Final Rule, the results of that process, which I'm going to present a little bit of today, and the Interim Final Rule itself, and to give us your comments, your suggestions, and your guidance.

The first question that we put in the issue paper was: What suggestions does the Committee have about the assessment? Are there different things -- well: What do you think about what we've done so far and what we're doing? Are there issues that the Agency is not considering in the assessment, that it should be considering, as part of its goals in trying to make sure that the rules that we ultimately wind up with are as well-designed and as effective as possible.

And then, finally, having functioned under the Rule for approximately eight months, since last October, does the Committee have any comments, suggestions, or ideas about how the Interim Final Rule -- about the Interim Final Rule itself that you would like the Agency to consider?

So those are the things that we'd like to hear from the Advisory Committee. Any questions about what I've said

so far?

(No response.)

MR. DERFLER: Okay. So now what I want to do is turn to the assessments that we're conducting. As I said, there's seven teams that are doing this. It's internal. In the briefing paper that I gave you, I talked about how the work of each team -- the work of each team and the questions that the teams are considering, and today what I'd like to do is talk a little bit about what the teams are finding so far, as we develop our review of the Rule.

Now, the public health team, the economic team, and the labeling and consumer education team are focusing on the impact of the Final Rule. In other words, these groups are focusing on what effect implementation of the Rule has had on the public health, on the economies of the ready-to-eat industry, and on the labeling of these products.

The public health team is focusing on whether it is possible to assess the effects of the Rule on the public health. Now, the group has recognized that it's probably still too early in the process to be able to judge this. To date what the group has been able to do is identify sources of data with which to assess the occurrences of listeriosis cases in the country, although there is -- like I said, there's not been enough to gather really meaningful data.

One thing that the group is looking at is: what has been the effect of the Rule on the alternatives that

industry has chosen; have companies changed the alternative that they're using, say gone from alternative 3 to alternative 2 or alternative 2 to alternative 1, thereby exercising more control, or in point of fact is it going the other way, during the course of the effect of the Rule are companies going from alternative 1 to alternative 2, that's one of the things that we're looking at during this period.

The economic impact team is assessing the assumptions that the Agency made in preparing the Economic Assessment that was part of the Interim Final Rule. It is gathering data on the costs and the benefits of the Rule as implemented.

For example, the team is looking at whether the Rule is disproportionately affecting small plants. It is found that 59 percent of listeria monocytogenes-related NRs have gone to very small plants but that this is really not a disproportionate share given that very small plants represent about 51 percent of the plants that produce ready-to-eat product.

The team has found that most of the plants that received an NR had chosen option 3, which is the least protective alternative. However, they've also cautioned in their cautioning that this finding is preliminary and is subject to change as more data is gathered.

The labeling and consumer education team focus in part on incentive labeling. In the Final Rule we said that

people could declare on their label if they were using interventions that were designed to reduce the level of listeria, to address listeria in their product. The team found that no one in industry is using incentive labeling.

The group is recommending -- one of the things we'll consider is using focus groups to research and to develop statements that would provide flexibility in conveying the product that the product has undergone post-lethality treatment to address listeria.

Now, two groups focused on the Agency's ongoing verification of the Rule: that is, how the Agency is verifying that the requirements of the Rule are met; and how it's preparing its inspection personnel to do that verification.

The sampling verification team was charged with assessing the OM sampling that the Agency does and determining whether improvements in that sampling is needed. The group has recommended that the Agency complete the development of a risk-based sampling regime, including an intensified sampling program in response to positive findings.

Now, the Agency's work on risk-based sampling has been hampered because, for a variety of reasons, we've been unable to get OMB approval of the form that we would need in order to solicit volume data from plants, but we're working with OMB and we hope to do that during this period.

The training team is charged with ensuring that our inspection force is appropriately trained to enforce the Rule. The team's recommendation is that the Agency's Food Safety Regulatory Essentials course be given to all consumer safety inspectors and that it be supplemented with CD training that focuses on the Rule.

To date we've trained more than half our CSIs, over 1700, on FSRE, and we continue to develop and revise FSRE as developments with respect to listeria and other rules [phonetic] occur. The group also recommends that the work of the CSIs be supplemented by training the EIAOs on the performance of specialized sampling.

Finally, three groups focused on activities that support the effective implementation of the Final Rule. In other words, these groups have focused on what we can do to facilitate compliance.

Now, I've said there were seven groups, and I talked about three, two, and three, but really that's because the labeling and consumer education group I'm going to talk about here because of their focus on consumer education.

The labeling and consumer education team has recommended that the Agency develop materials for consumers, with the help of focus groups, on the meaning of incentive labeling and on how to handle ready-to-eat product, to ensure that it will be consumed safely in the home. The small plan guidance team found that the Agency needs to find better ways

of getting compliance guides to small and very small plants. The team also suggested that the guidelines needed to be simplified if they're really going to be useful to small and very small plants.

Finally, there's a team that focused on controlling listeria monocytogenes in ready-to-eat products at retail. This team has found that slicing and packaging of deli meats at detail presents a significant source of exposure to Lm. The group has suggested two possible strategies for dealing with this problem: education and outreach; and the use of anti-microbial agents in products that are to be sliced and sold at retail, to inhibit growth.

The group also pointed to efforts already under way in the Agency to compare -- and I alluded to this before in the data section, the questions about -- the follow-up on your data recommendations -- that we have efforts under way to compare the risk of listeria from products sliced in plants with the risk from those sliced at retail.

Now, we're getting data, as I said, for this assessment from the states and from the National Food Safety Alliance. The output of the assessment will be used by the Agency in developing its strategy for retail.

So that's a brief review of what -- and a preview of the work and the findings of the seven groups. It brings me back to what we would like from you. Again: What do you think of the Agency's process with respect to this Rule and

with respect to our own internal review? -- so that we're as well-prepared as possible for producing the Final Rule. Are there ways to improve it, are there other topics that we should be exploring? And: Do you have any comments on the Interim Final Rule itself?

So, with that, I'd be happy to take any questions.

MR. TYNAN: Mr. Schad.

MR. SCHAD: Mark Schad, Schad Meats. First of all, I was interested in your comment that you found new establishments using the labeling incentive, and I just want to pass on my experience, as a very small procedure, and I make ready-to-eat products. I was all but ready to put anti-microbials into my product but I felt -- I found consumer resistance to that, because I went to my customers, thinking that this was going to be a plus, that they would like it, but they didn't -- they thought of it as adding chemicals to meat that was maybe not safe to begin with, they asked me the question, "Well, Mark, isn't your product safe already?" So I wanted to make that comment for you and for the committee.

MR. DERFLER: Yeah. I mean, we understand, I think, the tensions, but on the other hand, after we came out with the irradiation rule, there was a bunch of questions as to whether or not people could disclose the fact that it's irradiated under the rule and particularly say "irradiated for safety" or something like that, and so we did address that then and we anticipated the issue here, and so we wanted

to address it in the Rule.

MR. SCHAD: If I could follow up on that, it was always of concern to me why the Agency looked up -- looked at sanitation only as the most risk-based way of doing it, because I think -- you know, the most risky way of doing it.

MR. DERFLER: Yeah.

MR. SCHAD: Because I think that's not necessarily always the case, if you look at it by -- as a plant-by-plant way of doing things, where an establishment has set up its process to separate raw meat from cooked meat and use good sanitation, that may not necessarily be the most risky way of doing it.

MR. DERFLER: Well, we hope so. I mean, we're providing and allowing for its use, but the reason for that comment in the Interim Final Rule was the risk assessment itself. The risk assessment showed that there was greater potential for reduction of illness by the other methods.

MR. SCHAD: I guess my final comment or question might be, is when you're looking at sampling based on risk-based, maybe it would be better to do on somewhat of a performance-based system on the plant and not necessarily what (inaudible) --

MR. DERFLER: Yeah. As I said, we're going to do it on a series of factors.

MR. SCHAD: Yeah. Okay.

MR. TYNAN: Mr. Detwiler.

MR. DETWILER: Related to the previous question on the incentive labeling, has anyone used the incentive labeling in industry?

MR. DERFLER: As far as we're aware of, no.

MR. DETWILER: Okay. Is there any kind of evaluation going on that would determine if this is -- there needs to be some change in the way that this is being presented? Because I know that about ten -- ten, nine, ten years ago, that the food safety label on all meat products -- there was the same -- similar type of resistance in terms of "this is indicating that there must be something wrong with the product and we do not want to indicate that there might be something wrong with the product because then the customer" -- or "the consumer number might drop then." Is it the same -- obviously -- the same kind of thing g on here, with the incentive labeling?

MR. DERFLER: I guess. I mean, there's -- we know that there's interest in industry in demonstrating to us that incentive labeling is a bad idea. If people have ideas about how it can be provided in a way that's not going to be misleading, that in fact it can be used to provide an incentive to industry to take additional steps, maybe try -- everybody getting an alternative one, I mean, we'd be very interested in that. That's what the comment period is for: to provide those sort of ideas to the Agency.

MR. DETWILER: Thank you.

MR. TYNAN: Dr. Carpenter.

DR. CARPENTER: Thank you. David Carpenter. I'd like for FSIS to clarify FDA's recent request for comments, that they received a petition regarding: a hundred colony-forming units would be okay in foods that were shown not to support the growth of organizations. Is that: foods that are not regulated by FSIS, or does it include all foods, or are you working with them?

MR. DERFLER: Well, it's -- we have not received a petition, to my knowledge, although it may be forthcoming. We regulate meat, poultry, and egg products, and the products that we regulate are -- except for detentions -- are specifically excluded from the coverage of the Food, Drug and Cosmetic Act. We have not as yet, to my knowledge, been petitioned in the same sort of way.

DR. CARPENTER: Thank you.

MR. TYNAN: Ms. Eskin.

MS. ESKIN: Sandra Eskin. Phil, I have two questions about the verification, the sampling verification procedure. First, could you just clarify currently what, if any -- I know there's no minimum testing requirement, but what, if any, testing is the government doing, and, again, I guess it depends on which alterative a copy is using in terms of how much testing they may be doing, that's one.

And the second one is: Let's assume that tomorrow OMB approves this form that you want to use to start

collecting data, to help you move toward a risk-based verification program: how do you see that -- what's your sort of timetable, what do you anticipate -- how do you anticipate getting there: you do this first, and then sort of what's your hope and plan?

MR. DERFLER: Well, I mean, right now we do try and look at the most risky product, but -- I don't think it's particularly formalized that way, but --

MS. ESKIN: No.

MR. DERFLER: -- we are aware of it. And, actually, we know that our sampling is up significantly t his year from last year. Once we get the data, I mean, we will try and get it -- go to a risk-based sampling system as quickly as we can. I mean, we -- this is something that we've wanted to do, that we've talked about doing, and so -- I mean, we would do, you know, what we need to do. I'm not sure of the specifics, about whether we've formulated plans, but I know we have a working group that's been assigned to do this, and so we would -- we would move to it as quickly as we could, but more than that I don't know that I can be specific.

MS. ESKIN: Again, on the current sampling, I mean, again, you just said that it's up from what it was before. Again, is there data that you've collected, that's available, that sort of demonstrates that, that FSIS has?

MR. DERFLER: Well, yeah. I mean, we keep track of

the sampling that we do.

MS. ESKIN: Right.

MR. DERFLER: I'm not sure that it's been posted yet on the website. We try and -- you know. I checked it out before today, and I think we only got up to 2002 on the website, but we'll try and do a better job.

MR. TYNAN: Mr. Elfering.

MR. ELFERING: I have a couple of questions. One is on the consumer education. I'm all for consumer education, I think we probably need to do a lot more of it, but I also see some of the downfalls of consumer education, and one was even brought up as a safe food-handling label. I would think that if you were to poll consumers today and ask a hundred of them, probably only one would know that a food-safety label even exists or what it says.

What is your focus going to be on consumer education and how are you going to be able to really target the appropriate population, those that are most susceptible to listeria monocytogenes, is there any efforts on really coordinating some of those educational efforts?

MR. DERFLER: I believe that the answer is "Yes." I mean, I have to say that this is an area that I don't particularly know about. I know about two years ago, in December of 2002, I believe it was, we had a public meeting, called the Listeria Summit, at which we talked about the efforts that the Agency was making to try and reach out to

some of the professional groups, like the American Academy of Obstetrics and other people who deal with pregnant women, to try to make clear to them the risks of listeria and the need to properly handle food and stuff like that.

I think part of what we're trying to do is make sure that we do improve our messages, that we do reach the right people, but I don't personally know right now enough to be able to give you a more definitive answer than what I just said.

MR. ELFERING: And then one other follow-up question. With the industry, there are some innovative methods right now of testing for listeria, there are some rapid tests that are available, there's even some testing using bioluminescence to be able to detect listeria. How flexible the Agency going to be in allowing some of those more innovative methods of surveillance in plants?

MR. DERFLER: I would think that we're going to be very flexible. I mean, we're going to use methods that we know that we can rely upon. I mean, industry, the methods that they use, I mean, essentially they rely on: at their own risk. I mean, if it gives them a good picture and they're confident of it, then we would encourage them to do it, and probably, you know, the more testing, so they have more confidence in their product, the better. But -- I mean, we're going to focus on our testing and the verification testing that we do.

MR. TYNAN: Dr. Jan.

DR. JAN: Thank you. Lee Jan, Texas Department of Health. I've got, first, I guess more of a comment and suggestion and then a question. The comment would be: under the retail teams, you mentioned that slicing and packaging at retail is a huge risk for Lm, which makes sense, to expect that, but -- and then the paper here says "evaluate FSIS and FDA activities toward developing guidance materials to reduce Lm at retail," that's fine, I mean it's a good way to go, but I think it would be -- it would make more sense to work with FDA and have FDA make a requirement for these plants to at least meet the expectations that producing or inspected established are inspected under alternative 3. Testing -- that they actually have a regulatory requirement to meet, not only guidance material, because guidance material -- there's not a whole lot of incentive for someone to spend that money, and if you take and -- have the producing plants and do everything they can to produce as clean, as Lm-free product, and then say, "Okay, now, you" -- "when you sell it, here's guidance material for you to continue that." I mean, there's not much incentive.

So I think FDA ought to look at it from more of a regulatory requirement and documentation records and all that, so they can review, when they do come in and do their inspections on that reduced frequency, and that's basically a comment, I don't know that you can -- that you have any

response to that.

MR. DERFLER: Actually, I do. Can I just say a couple things?

DR. JAN: Sure.

MR. DERFLER: I mean, first of all, I don't know that we know that listeria is a huge problem at retail, I mean, we have, as you suggested, tried to push the plants as hard and as far as we can, and so the fact that FDA comes through with their risk assessment and says that there's a significant problem of deli meats at retail suggests that there is a problem there.

One of the things that we're -- part of the reason why we're doing guidance only is because we've been deferring to the states and the state program, which is why we're working with AFDO, to try and -- I mean, because it's -- traditionally they've looked at retail, and except, as somebody alluded to before, ground beef sampling and perhaps specie sampling we've sort of tried to stay away at retail.

The question is: if the problem persists and it's our product and it's our mark of inspection, can we continue to do that, and that's really the question -- one of the questions that we're thinking about long and hard.

DR. JAN: My other question would be, under the labeling and consumer education team, the second bullet says "Examine how establishments may be redefining their processes to attempt exemption from the Rule," and I just wonder what

is current FSIS thinking or is this in a -- in an evolution now. At some time before the Lm rule FSIS' position was that if a company produced a product that appeared to be ready to eat and it met legality [phonetic], but if they'd said that it's not ready to eat, by saying "cook to 160 before eating" or anything like that, that that was not a ready-to-eat product, but now I'm not sure that the answer is quite so clear. I've even heard the FSIS -- or some FSIS people say that it's up to the inspector to determine if a product is ready to eat based on the appearance and the processes in the plant.

So I just wondered, where is FSIS on whether a product can be labeled "cook before eating," is that still at the discretion of the plant or now is FSIS to make that --

MR. DERFLER: No. I mean, I think what we talked about, and I think it's one of the attachments to Directive 10240.4, and I think we talked about it at the meetings that we had around the country, is, you know, how is -- we're going to evaluate in total how the product's being represented. I mean, if the label says "cook," that's not a ready-to-eat product.

There are various indices that we sort of point out in the Directive that we're going to consider in deciding whether the product's ready to eat or not, and the plant can control that, but we would expect the plant to be consistent across, and if it sort of says, you know, "real convenient,

just throw in the oven and cook to 240 degrees" or something like that, I don't think that that's a ready-to-eat product, so -- I mean, but it -- even though there's some question as to what some of the representations may be.

So we're going to evaluate the labeling and the treatment of the product through a number of factors and then we'll make a judgment.

MR. TYNAN: Dr. Hollingsworth.

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. Following up on something that Dr. Jan had just mentioned: Phil, you said that the team had found that slicing and packaging were significant contributing factors. There are either studies being designed or studies under way right now at retail, looking at a whole variety of potential contributing factors, slicing and packaging being just two of them, along with time and temperature and product formulation, and so I question how the team reached that conclusion, that that -- those two practices, slicing and packaging, were the contributing factors, if maybe you can respond to that.

Also, the reason earlier I kind of jumped the gun on my question about can we see who's on the team: it's very important for retailers that FDA and AFDO, or the states represented either through AFDO or some other mechanism, be a part of that team, because the practices that are used at retail are based on the FDA Model Food Code, not on USDA

requirements for handling, and so any changes that come about at retail need to be incorporated through the Model Food Code or the states' adoption of a similar code.

And so we'd like to very much request that the work looking at retail include FDA and AFDO since they're the ones who will tell the retailers how to change their practices. So two questions.

MR. DERFLER: I would remind you that at the recent meeting of the Conference for Food Protection, FSIS was present, and FSIS now is a contributing member of the Conference for Food Protection with respect to meat and poultry at retail, so it's unnecessary to rely just on FDA, you can rely on us as well.

I would tell you that these were totally internal groups, and so -- I mean, we haven't -- I mean, we're hoping for comments, we haven't made any decisions with respect to retail, I'm not sure that the Rule even covers retail, but, you know, the FDA risk assessment has gotten our attention and so we have to pay attention to what's going on at retail.

As far as the findings that I gave to you, I looked at a summary to prepare so that I could give you all a sense of our progress in this process. I don't know the specifics on how to defend them, so I can't.

DR. HOLLINGSWORTH: Okay. Is there anything that would prohibit bringing people from outside the Agency onto these teams, or has that been discussed at all?

MR. DERFLER: The Federal Advisory Committee Act could be a problem.

DR. HOLLINGSWORTH: Other agencies?

MR. DERFLER: You know, it -- we have not gone that far in our thinking. If that's a recommendation, we'll evaluate it. I mean, right now we're trying to -- you know, we're just trying to figure out how we go, because we got a risk assessment that is a problem for us.

MR. TYNAN: Dr. Johnson.

DR. JOHNSON: Alice Johnson, National Turkey Federation. I think that this is a new and different approach, and while there may be some ways to improve upon it, I think this is a great way, and I think the Agency is certainly doing a good job in trying to provide a thorough review of the role.

You will be publishing reports prior to the -- and you'll give us time, Phil, to be able to evaluate and -- before our December deadline for comments.

MR. DERFLER: It's certainly my plan.

DR. JOHNSON: Okay. And maybe this is a Dr. Denton question, but the retail surveys that you talked about, you're doing, will those be part -- will those be completed in time to be commented on as part of our comments on the Interim Rule or will that be a separate --

MR. DERFLER: Probably not. I mean, like I said, I'm about -- I mean, as I stand here, so I'm not making any

commitments, but I don't think the Rule really dealt with retail. This is just a problem that's come up as a result, and, I mean, as long as we're reviewing this area, it's an area that we need to be involved in. Ultimately, if we decide to do something, we'll do appropriate public process.

DR. JOHNSON: And I want to talk a little bit about incentive labeling. I know, to Mark's point, there have been companies that have looked at consumer focus groups, labeling's very confusing, and sometimes it doesn't get you where you want to go anyway, but one of the things that the meat -- and I'm going to talk for everybody here -- meat and poultry industry both has done, I think about all of our board of directors have passed a resolution saying "we will share food-safety information and we will not make food safety competitive," and there is a concern on the part of industry that if we go to incentive labeling, that then we become competitive and information won't be shared, and that's not the intent of where we're trying to go.

I think a lot of the alternatives that we see in this Interim Rule were because industry got together and shared information, particularly with regard to formulation and inhibitors, sharing information of what works and what doesn't, and I think that's where we've gotten to today, and there is a big concern within the industry, if you start trying to label it becomes a competitive issue and we lose a lot of our food-safety issue by making competitive food-

safety issues.

Can I make one more comment, while I have one of the microphones. FSIS has sent out some surveys to the in-plant inspectors, asking for some specific information regarding the Rule, and I know that it's the inspectors -- and I know there's issues with OMB on what you can and can't ask the plants, but nobody knows the process better than the plants, and I know we've had calls from some of our plants where the inspectors have filled out the form and have said, "Well, I can't really show it to you, I can't," you know, "share any information, I can't ask you to help me with this, because of some of the requirements," and I just caution, in looking at some of those surveys that you've gotten back, that -- I know when the Rule first came out there was some misinformation simply because of knowledge of the process, and so I'd caution on some of that.

MR. DERFLER: Appreciate that. We walk a tightrope, because of the Paperwork Production Act. I would tell you that we have gotten OMB approval for surveys of the plants and we've done a survey of the egg products industry this year, and it's our intention to survey perhaps both the meat and poultry industry in the coming year, maybe only one, depending on our resources. So, you know, full cooperation of the industry in completing and returning surveys, nothing would make us happier.

DR. JOHNSON: We will push that. Thank you.

MR. TYNAN: Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk, from STOP. I had a question about the sampling verification team's initiative. In the Interim Final Rule, sampling is mentioned with respect to the various levels of what -- various alternatives that plants can select. However, there's no mention of any minimum sampling requirements. Is this team looking at putting together some type of sampling regimen that's consistent based on the alternatives that are presented in the Interim Final Rule?

MR. DERFLER: To my knowledge, most of what we're focusing on is our sampling, to make our sampling as risk-based as it can, as a verification tool, and then we will, you know, expect the plants to sample in accordance with the Rule, based on their -- but we have not been -- we have not been explicit about what kind of sampling the plants are required to have, so the group is mainly focused on making our sampling risk-based.

MR. KOWALCYK: And I had one other question about the consumer education. It seems like the incentive labeling seems to have some -- a cool reception from industry. However, is there any talk within the Agency about safe-handling instructions with some of these products? If you look at the interpretive summary of the Risk Assessment, and the what-if scenarios, there's even cases where if you adjust your refrigeration temperatures when you store the product

after you purchase it, you can reduce the growth of this pathogen. Is there any discussions going on at the Agency with respect to safe-handling on labeling?

MR. DERFLER: To my knowledge, we're not. I mean, I know that FDA, as a result of one of its efforts, they wanted to make sure that people refrigerate and make sure that the refrigeration temperatures are appropriate. I mean, this is supposed to be ready-to-eat product. We expect it to be ready-to-eat product, that people can eat it with confidence that it's ready to eat and they're not going to get sick, and that's what we're trying to accomplish.

MR. TYNAN: Ms. Eskin.

MS. ESKIN: Sandra Eskin. Following up on Mike's point, I would strongly encourage the labeling team or FSIS to look not just at incentive labeling, in terms of having focus groups, but the range of labeling that could be placed on this product, whether it's a safe-handling label, which tells people how to ensure they eat it safely, or, if it turns out it's necessary or a good idea, a label like what's on unpasteurized juice, that FDA has, you know, a warning to vulnerable populations that it's a particular risk for them.

Again, by looking at the whole range of labeling, it is a complicated message, perhaps, that you're trying to tell consumers, but it's important. The education cannot just occur with materials that are sent to them or available, or PSAs, that's a part of it, but having labels on the

package.

I don't necessarily agree with my colleague on the left, I'm not sure that people don't read and use that safe-handling label on raw meat and poultry products. It may be worthwhile, as part of this whole question, to do some assessment of that. That's a pretty big message on a pretty little label, and maybe there -- again, some of it may be useful to this question of what works best in terms of giving people the information that they need, giving people who are at risk specific information when dealing with these products.

MR. DERFLER: There's an Advisory Committee, we're here to get your input, absolutely, your interest.

MS. ESKIN: Well, they're -- and they're doing specifically sell-by dating, right? I mean, that's just a mini-advisory committee, the micro committee, right?

MR. DERFLER: Use-by dates?

MS. ESKIN: Use-by dating. That's my understanding of what they're looking at, which is, again, a small piece of this, there's a lot of other options that have been discussed both in the Proposed Rule and Interim Rule that I think really need to be addressed.

MR. TYNAN: Gerri, did you want to make a comment?

DR. RANSOM: Yeah. They're looking at safety-based date labeling, so it's essentially a use-by date --

MS. ESKIN: Right. It is one piece of the larger

puzzle, and obviously that will inform -- would inform anything else that FSIS might consider doing.

MR. TYNAN: Okay, we're getting close on time, we have three questions up, we'll do those three and then we'll have -- oh, I'm sorry, we have four questions up, Mr. Detwiler, you can put yours back up, then we'll need to finish and go on to the next issue. Mr. Elfering.

MR. ELFERING: Kevin Elfering. Just maybe for clarification, these assessment teams are only FSIS employees and you can't include anyone else, is that --

MR. DERFLER: Well, at this point that's all -- OIM [phonetic] is reporting, not making a judgment --

MR. ELFERING: But the reports will be -- go through some type of a PEER review process with --

MR. DERFLER: Well, the reports, we're going to pull them together, there'll be done some sort of Agency review, and then it's our intent to publish them for public comment, and then combine the comments on the report with the comments that we get on the Interim Final Rule. To the extent that the aspects of the reports are relevant to the rulemaking that's under way, we will consider it as that. To the extent that they raise issues outside the scope of the rulemaking, they'll provide an agenda for where we go in the future.

MR. ELFERING: One other thing, just on the safe-handling-labeling -- very-unscientific -- survey that we

did back in Food Safety month, last September, we had inspection personnel interviewing customers at grocery stores, and less than 1 percent even knew that there was a food safe -- there was a safe-handling labeling on raw meat and poultry products.

UNIDENTIFIED FEMALE: Must be [phonetic] people in Minnesota, right?

MR. ELFERING: That's what it is.

(Laughter.)

UNIDENTIFIED FEMALE: (Inaudible.)

MR. ELFERING: We're still trying to get everybody to be able to read.

UNIDENTIFIED FEMALE: Not scientific, not useful.

MR. TYNAN: I think you said it was 30 degrees before you left there?

MR. ELFERING: It was, up in the northern part of the state, yes, 30 degrees.

MR. TYNAN: So everything stays cold there, right? Dr. Hollingsworth.

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. While we're on the labeling issue, two points. One is that: as the group looks at education, I think they should not just limit education to the consumer but also to the people who sell product and talk to the consumers every day. There was concern raised by both restaurants and retailers that they weren't sure what they

should be saying to the customer when they're asked, "What does that label mean," so I think that the education would have to go to the people who are asked the questions by the consumers, so they can answer correctly.

The other issue on the labeling, too, that because no one has presented product with labeling to retail, it hasn't come up, but we are interested in finding out what the Agency's position on: is that labeling -- or was it expected to be carried through on product handled at retail and how is product identified at retail when the packaging is removed. So that was another issue that would have to be discussed, I think, if this goes through on the Final Rule.

MR. TYNAN: And last, but certainly not least, Mr. Detwiler.

MR. DETWILER: Darin Detwiler, educator. I just want to -- I hope that -- the education of food handling needs to get a little more specific, because a lot of the food-safety handling education I see out there -- and I look for it, and I use it -- is very generic, and specifically the education you're talking about with the special -- the groups, the vulnerable groups, as you point out here, I think that needs to be expanded, because, again, I think part of the motivation behind the consumers not knowing that labeling exists out there, and some of the things I hear out there, and I see that in my state as well, even with the media attention focused on E. coli in my state, is that much of

that lack of knowledge stems from the customers because there is not enough food-safety education. Listeria, I would think even less than 1 percent of those 1 percent have even heard of that word. So they're not looking for those labels and they're not even out there. I think most of the resistance for the labeling is on the marketing and selling the product, whereas I don't see anything that looks at some type of evaluation of, from the consumer end, would the consumer want to see this type of labeling, would they look for this labeling, and would they even -- how would the consumer feel about the anti-growth -- I'm sorry, the growth-inhibiting agent being added to meats. Thank you.

MR. DERFLER: Thank you all for your comments, we really do look forward to the input from the group at the session, Charles Williams from the Office of Policy, Program, and Employee Development will be with you, and thank you very much.

(Applause.)

MR. TYNAN: Okay, we have -- the next issue that we have on the Agenda -- we're making hand signs here over with Charley. The next issue we have on the Agenda is "Applying the mark of inspection to product tested for an adulterant." We have Mr. Charles Gioglio, he's the Director of Inspection and Enforcement Initiatives staff, and unless you have some objection, Charley, if you're comfortable sitting there, unless the Committee has some preference in having him go to

the lectern, we'll let him sit right there.

MR. GIOGLIO: Since I was one of the people that gave Mr. Derfler the hard time about the Power Point --

MR. DERFLER: Yeah.

MR. GIOGLIO: -- I don't have one --

(Laughter.)

MR. GIOGLIO: -- so I can sort of walk through the issue paper now and prepare the sub-committee for your discussions later this afternoon.

As Mr. Tynan had said, the title of the paper that I'm going to be talking from is "Applying the mark of inspection to product tested for an adulterant." The issue itself is: should FSIS delay its decision of applying to apply the mark of inspection to those products where we have -- where the Agency has sampled for the presence of an adulterant, until it has received a negative result; in other words, that we can make the determination that the product is in fact not adulterated.

If you all -- I'm sure you all recall that back in around the January time frame the Agency issued a notice where we announced that we would not apply the mark of inspection to any animal carcasses tested for BSE until those results were returned and found negative and that we could make that determination that the product -- that the carcass, then, wasn't adulterated, and that is based on Sections 4 and 6 of the Meat Products -- the Meat Inspection Act and the

Poultry Products Inspection Act, Section 604 and 606.

The Act states that carcasses and parts and meat food products are not marked, inspected, and passed unless found unadulterated, so that's our legal basis for taking this position.

What we're considering now is sort of extending that same policy, that same position, to other products, primarily processed products and carcasses that we may test for the presence of illegal drug residues, where -- let's say in the processed products, such as ground beef, where we test for O157:H7 or a ready-to-eat product where we may test for the presence of listeria monocytogenes or salmonella or other toxins, staph entero toxin or something like that, where the results of a positive for either the toxin or the particular pathogen in those products would in fact preclude us from making the decision that the product was not unadulterated, in fact could be found that the product is in fact adulterated.

Presently, when we sample products, we sample -- the inspectors in the plants sample the products or physically send them to the laboratory after the establishment has completed its pre-shipment review for that particular product lot. There may be times where an inspector takes a product before, but he would hold the sample until in fact the establishment has completed its pre-shipment review before he or she would ship that sample to

the laboratory.

The instructions to the inspectors are to inform the establishments early enough in advance so that they could hold the entire lot, and in fact the Agency -- since the 1980s, when we started our routine testing programs for ready-to-eat products and other things, for the presence of adulterants, we've strongly encouraged the individual plants to hold any product that would be represented by that sample and in fact not ship those products into commerce. That's not something that the Agency has required through rulemaking or any other policy position but something that we do strongly encourage.

However, when we look at the recall data over the past -- I guess back from about 2000 till now, we find that approximately 40 percent of the recalls are in fact driven by our routine testing programs, and that, I'm talking about recalls of product that bears the mark of inspection, that have been produced at federal plants. So they're, you know, the result of our routine testing verification programs.

Our verification programs are in fact a verification that the establishment HACCP plan and their food-safety system is in fact working, they're not, you know, product monitoring/testing programs or the like but in fact verification that the establishment's HACCP plan is in fact functioning as intended.

When we talk about recalls, we're all aware that

recalls are very costly to both the individual plants, the industry as a whole, the Agency. Moreover, we believe that holding the product, in fact not shipping the product into commerce, and one of the reasons we've strongly encouraged it over the years, is in fact the protection to the public health.

We believe that in fact that's one barrier where preventing the product from being shipped in the first place until all the information is back about the product could in fact be helpful to -- you know, in protecting the public health. Certainly none of us I think would want to get into recall situations.

We presented this issue -- in fact, Mr. Derfler had presented it at a public meeting that we held on the recall process back in December of 2002, we discussed it there, and it met with differing viewpoints at that time. We were made especially aware of, I think, how this might affect small businesses, small -- the very small plants in this case, where it sets up some practical problems, possibly in storage capacity or in their production capacity and so forth.

Before I get to the questions, one of the other points, a practical point, that I'd like to make here is that when we talk about applying the mark of inspection, I'm not speaking about the actual physical -- with regard to processed products now -- the actual physical application of the mark of inspection. From a practical viewpoint, the

actual inspection legend, or the mark, is typically on the labeling material, sometimes on the cooking bags and so forth, as the product is going through its process, before the establishment has in fact completed all of its processes with regard to that product.

So we're not talking about physically holding back -- not actually applying the mark of inspection but the decision where the Agency can make the determination that the product is not adulterated. That decision is made by inspection after the establishment has completed its pre-shipment review of that particular product lot and has made a determination that in fact all the records indicate that the production for this product was in fact in accordance with their HACCP plan and they make a decision that now that product is in fact eligible to ship.

So we're not looking here to change anybody's production practices and so forth but simply to make it -- in essence it would be, then, mandatory that the establishment make whatever arrangement it needs to make to hold that product until any sample that the Agency has collected has in fact returned a negative result for the particular pathogen or of the particular substance that it had been tested for.

Given that, we think this sets up some questions. The first obvious question is, what is -- we're seeking your advice here, and what is your view, as a committee, on this particular issue and this particular policy position that we

would take.

How would such a policy impact the industry, as I mentioned earlier, especially the small and the very small plants, but I think, you know, we can say the large plants and others, and I would expand that out to the public at -- you know, at large, what is the impact here overall, and to the extent that there may be practical problems set up, especially for those small plants, by this policy, what are some ways that we can look at this to potentially mitigate some of those problems.

With that, that's really the issue, in a nutshell, and I'll stop there and try and clarify or take any questions that you all may have this morning before the deliberation this afternoon.

MR. TYNAN: Why don't we break with tradition and we'll start and go counterclockwise. Dr. Johnson.

DR. JOHNSON: Oh, boy. Okay, Charley, thank you, and this is the issue that my sub-group's going to be working on, so I've got a couple of questions, that you may not be able to give us answers now, but it might be good to have them, if you can get them.

One thing we've talked about, just several of us have been talking about this issue, it'd be nice to know the number of samples taken by FSIS during 2003 and the number of positive, so we can kind of get a feel for -- I know a lot of companies already hold products, but there's some cases where

they can't, so it would be interesting to see that number.

And you mentioned the 40 percent of the recall -- recalls were based on your routine sampling. Do you have any way to say whether that's a smaller company versus a larger? I know there's some very big issues with some of the smaller -- particularly grinders, that are grinding to go out the door that day, so it would be interesting to see what poundage was involved in some of the -- in those 40 percent recalls.

MR. GIOGLIO: Your first question, about the testing data and so forth: no, I do not have that data with me here. I will attempt before the afternoon session to get those figures for us. I'm not sure exactly what's available exactly now, but I'll check back with the Office of Public Health Science.

To your other question, Dr. Johnson: Typically my experience has been that most of the recalls driven by our testing program have been from the, you know, small, very small, probably the very small plants. Typically we're looking at smaller volumes of products, we're not looking -- they're, you know, obviously at -- the very large volume recalls driven by these, you can look at the recall data and see sometimes they may be in the hundreds of pounds rather than the thousands or upwards, tens and hundreds of thousands of pounds.

However, that product still -- I guess I would say

that that product still obviously poses a risk, and more so -- if they're preventable, I think our view is -- is that we should take every effort we can to in fact prevent them, to not expose the consumers to, you know, that product, even though the poundage may be small.

DR. JOHNSON: And appreciate that product that tests positive needs to come back, but have you talked with any of the folks that have been involved in these recalls, the smaller guys, to say when the inspector notified them they were going to take a sample -- you know, as someone mentioned, I guess yesterday, that E. coli sampling, it talks about not being disruptive to production. Is there some way to try to do a survey of those guys to find out what could have been done to make it easier on them? Because a lot of the smaller guys don't have the capacity to hold product for the amount of time it takes to get test samples, test results back.

And I want to ask one more question about residue testing. Residue testing, particularly in poultry, is a surveillance and it's not like we can hold a carcass, so when you include residue testing for holding product, you want to go into a little more discussion on that? Because I know sometimes the residue samples takes a while to get back, you know, it's -- again, you hold a whole flock, it gets -- it gets real complicated.

MR. GIORGLIO: I think I'll go to your last

question, that if -- to the extent that this policy would set up particularly practical problems with something like residue testing in poultry, where, in fact, you know, an entire flock may be involved or represented by that sample and so forth, to the extent that -- that's one of the issues that we need to look at, to see how quickly we can turn those results around. If there is something where -- there that may be one of the issues that we look at to try to mitigate whatever practical problems are here. I'm not thoroughly familiar with the residue testing program, but that may well be one of the things that we can look at, to see.

But in fact if the product -- if the results would come back to be, you know, that the product would in fact be adulterated and drive, then, a recall of that product, we're suggesting now that it be held, in the same way I guess in the red meat area, where -- you know, it would be -- the particular carcass or carcasses that were tested should be held before we would apply the mark of inspection to that product.

To your first question, or maybe that was the third question --

DR. JOHNSON: Sorry.

MR. GIORGLIO: -- in the order of questions that you asked: the instructions currently to inspection personnel through all the directives, where we talk about our sampling programs, are that inspectors are to give the

establishments ample opportunity to hold the entire lot that is in fact represented by that sample, and that's where we -- I mean, presently we're encouraging people to hold that product.

So that is in fact the Agency's official position, and that may be -- at times that may be the day of the sampling or could potentially be the day before the sampling, in some cases, depending on how -- the production schedule and so forth, but that should be something that the inspector in charge and the inspection people, inspection team at the plant, should be discussing with establishment management.

DR. JOHNSON: Thank you.

MR. TYNAN: Dr. Jan.

DR. JAN: Lee Jan, Texas Department of Health. This issue has got a lot of potential problems and ramifications, and I don't know if there's any real answers at this point, but when you mentioned the requirement to apply mark of inspection after the product is shown to be not adulterated, the next thing that comes to my mind: is this the first step to requiring a hundred percent sampling of every lot of product, and if that's the case, and even if it's not the case, we say only the product being tested is one sample, statistically sound or -- I mean, how many times when you take a sample and have a negative and that's not a true representation of the -- of that lot.

So are we moving to trying to do a hundred percent

testing, or testing every line of product, to a -- some level of -- so that it's statistically confident that the result of that sampling really reflects the products not adulterated? And, you know, if that's the case, I don't know how many plants, even large ones, can survive, and I know public safety is an issue, but, you know, economics has to be part of it too.

But if -- you know, where are they going to hold the product, and some of the product is such a short shelf life already, then you can't have fresh product -- it's a whole can of worms, I guess. I don't know that there's an answer to these things, but have those things been thought, any of those --

MR. GIORGLIO: I would say our testing -- we're not intending -- okay, the intention here is not to position this so that we will be testing each and every lot before we make a decision or before the product would be eligible to ship. Our testing is in fact, what I stated, a verification that the HACCP plan is in fact working as intended. It's one of the verification tools that we use, and certainly not the only one, and certainly not the most frequent one that we use, to make those verifications.

Dr. Jan, I'd also frankly tell you that our testing programs are not designed to be statistically -- they're not designed statistically or to be statistically sound in making a lot-acceptance determination from that aspect. If we

looked at sampling that way, we would have to get into a much larger number of samples to represent a particular lot, depending on the particular aspects that we were looking at, or whatever, and the risk posed by the particular food.

However, when we do test now, we know that there is this piece of information that's going to be coming to the Agency, coming back to the establishment and the Agency, which will have bearing on whether or not the product would be found to be adulterated, certainly as evidenced by: when a product is shipped in commerce and a result comes back that it's positive, the Agency is I think obligated to request that that establishment in fact conduct a voluntary recall or we will seek to -- you know, we will send our people out to detain the product and ultimately potentially seek a seizure action against -- you know, against the product.

So I hope I've answered your questions. No, you know, we're not looking to go down this road to do lot-acceptance sampling for everything that is produced or even tested, and I think if we do get the testing numbers back, we'll see that in fact it's a very small percentage of the total amount of product that is produced that is in fact sampled, but once we have that piece of information we need to in fact act on it.

I think the practical problems is something I think that we're coming to the Committee here to discuss more fully and potentially we can come up with some solutions that may

mitigate those problems.

MR. TYNAN: Mr. Elfering.

MR. ELFERING: This is Kevin Elfering, Minnesota Department of Ag. I think one of the things you really need to look at is the risk involved with the consumption of some of these products, in looking at the higher risks, of course, with some of these extended-shelf-life products, where you could certainly be able to hold that product from sale for a period of time and not impact the industry as dramatically, but some of these products that are produced with the intent of having a very quick turnaround because of the freshness of the product is certainly not going to be -- would be a definite burden on the small industry, especially, that produces multiple numbers of ready-to-eat products or any other type of product that may be subject to testing.

You looked at -- you kind of equated this to BSE sampling, and we are looking at very small numbers of BSE samples. I mean, you take out non-ambulatory livestock, those that are condemned on antemortem inspection, what are you really testing for, for BSE? So you're looking at a very small number there. And again, those carcasses could easily be isolated out of the system and held in cold storage before -- you're not looking at the same thing with products that have short shelf life.

MR. TYNAN: Mr. Govro.

MR. GOVRO: This is Michael Govro, Oregon

Department of Agriculture. Are imported products tested at the same rate as domestic products and treated the same way?

MR. GIORGLIO: I'm not sure exactly of the rate of testing, you know, on imported products as opposed to domestically, possibly we can look at that when we get -- if we get some figures this afternoon. However, the same policy position would in fact -- would in fact hold.

What we're looking at is in fact we would apply the same thing to products coming in at the border, or, you know, ships, or at the ports, or whatever have you, before they come into the country, before we can make the decision that in fact that product has passed the Agency's reinspection on import if we take a sample for the presence of a particular pathogen say on a ready-to-eat product for L. mono or something, we would in fact -- if we took this policy position, we would wait.

And in that case we quite possibly may physically wait until we get the result before we stamp the boxes or the containers in -- you know, reinspect and pass and allow them to ship now into domestic commerce. Once that reinspection happens, in fact, the product is domestic product now at this point. So I don't know the numbers, but yeah, the same policy position would hold if we take this, and I think, going back to the other point that sets up, I think some of the same practical problems at the docks and in the other import facilities as has been expressed by folks here.

MR. TYNAN: Mr. Kowalcyk.

MR. KOWALCYK: Mike Kowalcyk, from Safe Tables Our Priority. Just a couple questions. In your question to the sub-committee you asked for their feedback on impact on industry, and I have a couple of just logistical questions.

You mentioned that when you do the testing you encourage the producer to hold the lot, although it's not mandatory that they do that. What type of information in the way of -- what percentage of establishments actually do that, is it 5 percent, is it 50 percent? -- just to get an idea of, you know, what would the impact be on industry if you have 80 percent of the producers already doing it, versus maybe 5 or 10.

And then secondly, I know there's a wide variety of tests that are done and there are various time frames for completion, but what way does the Agency have with respect to turnaround-time data? In other words, when the sample's taken, on average how long does it take for the Agency to get the sample to the lab and get it analyzed and sent back, again effecting how long the producer would have to store the product?

MR. GIORGLIO: I don't have, again, hard figures on what percentage of establishments hold the product at this point in my hands. However, I will say, based on experience and based on the number of positives, say, that we've gotten back in the last year and so forth, it's -- actually a

fairly small percentage of the lots that come back positive are in fact not held and shipped into commerce.

Okay, the majority -- the system is working on -- you know, where the establishment has been given opportunity by the inspector or notification by the inspector to hold the lot and they've taken advantage of that opportunity and withheld that product from commerce.

Your other -- your second question? I'm sorry.

MR. KOWALCYK: About -- basically, does the Agency have any information regarding the typical turnaround time (inaudible) --

MR. GIORGLIO: Okay. Thank you. The turnaround time, the -- in O157:H7, E. coli O157:H7, a sample is typically about five days from -- for analysis, so if we say a sixth day for sample collection, and the sample would be shipped overnight to the laboratory. Because of the type of testing that they need to do for the L. mono, it's about eight days' turnaround time.

So that's typically the time frame that we are -- that we're looking at, and the samples are shipped -- collected by the inspectors and shipped to the laboratories overnight, overnight mail, to try to speed that up, and they don't -- you know, once -- once they are at the laboratories they're put into the process to move -- to move through the laboratory system, so that there is no delay at that end.

MR. TYNAN: Dr. Carpenter.

DR. CARPENTER: David Carpenter. I'd like a clarification. From what you've written here, I get the idea that the test-and-hold policy is something that the Agency would like to establish as mandatory policy, to get away from "strongly encouraging" the establishments.

MR. GIORGLIO: Correct.

DR. CARPENTER: Do you intend to do that on a temporary basis until you've assessed the accrued data from HACCP procedures or do you intend to make this a permanent policy?

MR. GIORGLIO: We had not considered taking a position on a temporary basis but in fact issuing it and likely have some implementation time or some date certain whereby people, establishments, could readjust how they need to readjust, in order for us to implement this policy. So, no, not on -- we hadn't considered on a temporary basis to look at it.

DR. CARPENTER: Thank you.

MR. TYNAN: Mr. Detwiler.

MR. DETWILER: Darin Detwiler, educator. Has there been any study or data collected on negative impact of this labeling? For instance, the next end user taking less steps because it's been indicated to be adulterant-free, so practices can be relaxed; or, in the case of end use, consumer, the false sense of belief that it's adulterant-free at that point of being stamped and therefore a lack of

consideration in terms of adulteration taking place after that stamp has been placed on the product?

MR. GIORGLIO: Let me clarify here that there's no special labeling of any kind or over and above normal labeling, which includes the mark of inspection, that would be applied to this -- this product, so there would be no indication that we would be -- that we're considering at this point that this product had been tested by FSIS or USDA and found to be pathogen-free or something like that, and I think that goes back to Dr. Jan's points about the testing programs not being lot-acceptance sampling or, you know, statistically-driven and so forth.

The sampling that I'm talking about is in fact just one of a number of verification tools that the Agency uses, okay, to verify that an establishment's HACCP plan is in fact working. So I hope I've clarified your question there.

MR. DETWILER: Yes.

MR. GIORGLIO: There's no special labeling involved here.

MR. TYNAN: Okay, Mr. Schad.

MR. SCHAD: Yeah. Mark Schad, Schad Meats. I think a couple of my comments have already been mentioned already, I just wanted to say again that the problem is -- I would see -- is holding fresh product or fresh ground beef and it may be counterproductive to safety and quality, holding that lot of product, waiting on the sample results.

MR. GIORGLIO: Uh-huh.

MR. SCHAD: I also wanted to say for the members of the Committee that in my ready-to-eat products, every time I am sampled I do hold that lot of product.

MR. GIORGLIO: Right.

MR. SCHAD: The practical standpoints of extra space and inventory investment, to me, those problems, in my opinion, are not insurmountable. But I do have a concern here just about the precedent this may set. In reading the last E. coli Directive, it mentioned that intact muscle destined for ground products, if O157:H7 in there, is -- it's an adulterant, and there is a school of thought that to develop a food safety process, the best thing to do is to find one good supplier and have a good agreement and stick with that supplier, and I'm just thinking -- I'm not a beef grinder, but I'm just thinking if I was a beef grinder, if I followed that school of thought, I might be five or six (inaudible) from a slaughterer, that I have a lot of faith in, who's producing some primals or sub-primals that are low in micro count, and I know the Agency does not sample intact muscle right now for O157:H7, but if they ever did, that we would be talking about, from a very small processor standpoint, he might have to hold that whole lot of raw materials, and that could be a practical problem, as far as filling his orders.

MR. GIORGLIO: Uh-huh. Let me address that first.

I think if -- and we have not worked out that testing program, but in terms of what we're -- what we have been discussing and thinking about, we'd more likely be at the producer or the supplier and not at the receiving establishment, so --

MR. SCHAD: Okay.

MR. GIORGLIO: -- in case, if you receiving combos of trim from X number of different beef boners, I'm not sure that the sampling would take place at your establishment but rather at those establishments that slaughtered and boned those -- that beef.

To go back to an earlier point I made, where -- when the question came up about the length of time before results come back, okay, and you may have found this over time, typical in your operation, when there are negative results, the results typically come back a lot sooner.

I spoke in terms of, you know, the five and six days and eight days to completion of a confirmed positive, and with O157:H7, they can be turned around in two days, you know, with a negative, and different organisms may take different times, typically a lot shorter, you get to a negative a lot quicker than you would to a confirmed positive. So to that aspect, if -- you know, provided the product is in fact -- you know, where the sample is in fact free of the particular pathogen, the results are turned around a lot sooner and the establishment would have, you

know, then the ability to ship the product into commerce.

MR. TYNAN: We have two minutes, we have time for one more question, if anybody has one. If not, then I would suggest that we take the lunch break that is on the Agenda, 12 o'clock, and come on back here about 1:15 so we can get started with the final issue, on food security.

(Off the record at 11:58 a.m. and reconvened at 1:20 p.m.)

MR. TYNAN: Okay, 1:15. I think we had as -- our topic, our issue for this afternoon was food security. We have Dr. Carol Maczka here to do the presentation, and I think, again, Carol, you do not have Power Point, so if you'd like to sit there, unless the Committee has some objection, we can do your presentation from your seat.

DR. MACZKA: Okay. I am joined by my colleagues here, Ron Hicks and Karen Stuck, who will assist in any answers of questions that we may have. But if you could turn to the item, it's labeled "Food Security," and what I'd like to do is walk you through this paper. Basically the purpose of the paper is to provide you with information on food shields, and those -- another word for "food shield" is a "countermeasure," a "protective measure," and these are countermeasures or shields that FSIS either has in place or is considering, and what I'm going to do is by the end of the paper you'll have a better understanding what a food shield is.

But just to define it up front, it's: a method of

protecting the food supply from intentional contamination at a specific point along the farm-to-table continuum. So when I say a specific point, I'm talking about a specific vulnerable point, that has been identified in assessments that we have conducted, vulnerability assessments, and those points can be anywhere from the production of the product, you know, like if you're talking about ground beef production, production of an animal, to the processing of that animal say into trim and ground beef, to the distribution of the product and the transportation of the product.

As a way of background, ever since 9/11 we've been very aggressive about food security, especially with regards to our products, and we have done a number of things, including creating the Office of Food Security and Emergency Preparedness, but also we've developed guidance documents for industry and we have developed vulnerability assessments.

And the government at large has also been very active, there's been a number of Homeland Security Presidential Directives that have been issued, these are called HS -- they're always numbered HSPD, and I think they go from 1 to 10 now. But HSPD 7 and HSPD 9 specifically talk about identifying and prioritizing critical infrastructure vulnerabilities, conducting vulnerability assessments, and developing mitigation strategies.

So I mentioned our vulnerability assessments, and

we have personally conducted vulnerability assessments on imported products as well as on domestic products, and those assessments allowed us to determine: what are the most vulnerable products, the most likely agents, and the potential sites for delivered contamination.

We've also had issued a bunch of guidance documents. Those guidance documents actually came before the development of the vulnerability assessments, so in a sense the vulnerability assessments, which have been completed as of recently, can actually now be used to further inform the guidance documents.

The guidance documents, as you can see on Page 3 of the handout, they provide suggestions about a number of potential actions to improve food security, and we listed some of them, such as development and testing of food-security plans, and these plans can be used to identify vulnerabilities, address procedures for handling threats, they can address product recall, facility evacuation, safe handling and disposing of contaminated product, address communication with law enforcement, local public health officials, and the media.

And in the guidance documents we also suggest they undergo, if such plans were to be developed, periodic review and revision, as well as testing. We've developed these guideline documents for transporters and distributors as well as for processors.

But again, I want to reiterate that the vulnerability assessments came after the development of the guidance documents, and they are much more specific. If you read the guidance documents, there's a lot of good information there about many places you might want to -- or many things you might want to do. What the vulnerability assessments do is allow you to hone in on the most -- the high-risk products and the most vulnerable points in the farm-to-table continuum.

So what was the purpose of conducting these vulnerability assessments was really to identify countermeasures, we want to protect the food supply, and so we -- there's this term that you'll hear, and it's been coined by the White House, called "food shields," and what the food shields mean is what kind -- and they use this other word, "armor," "what armor can we put over these vulnerabilities in the farm-to-table continuum to prevent those vulnerabilities.

And food shields can be one of three things, at least this is how I think of them. They can be things like Agency personnel and the functions they perform. For example, we have 7,600 inspectors, we have veterinary medical officers, we have import inspectors, import surveillance liaison inspectors, and these people operate in our federally-regulated slaughter and processing facilities at the border, at port crossings, and in the import inspection

establishments.

We also secure our food products in distribution and retail, that's done by our program investigators and our public health epidemiological liaison officers. We have ISLIs, which are individuals that function at the border and port crossing, one of their major functions is to coordinate with customs and border protection.

So all these Agency personnel, basically they provide on-site human surveillance, and if trained properly, these individuals can help to secure the food supply against intentional contamination.

One of the things we've done is we've developed directives. I think on the books right now there's 5420.1 and 5420.2. These two directives are aimed at our inspection personnel and also at our laboratory personnel and they tell our personnel what to do if the threat condition is elevated, in other words if it goes to orange or red or orange and red specific to agriculture, and it tells them what added actions to take if there was an attack on the food supply or -- just -- a non-specific attack.

Other kinds of shields in addition to Agency personnel include databases and systems that we have. An example -- those databases, which I'll get to in a minute, or monitoring systems, provide senatil [phonetic] or passive surveillance, and if you were to turn to Page 4, you could see some of the surveillance and monitoring systems that

we're talking about.

We have the Performance-Based Inspection System, we have the Automated Import Information System, the Plan Compliance Program. Each of these systems direct inspection activities. In the case of the first one, PBIS, that directs inspection activities in plants. A second one, the AIIS, directs reinspection activities at I-houses, and the plant compliance program directs inspection activities at distribution and warehouses.

We also have things like the consumer complaint monitoring system and the Meat and Poultry Hotline. Those two systems can function as early-warning systems, they are systems where a consumer having a complaint about meat, poultry, or egg products can call in, and again, if we actively look at the kinds of complaints we're getting, they can serve, as I said, as an early warning of maybe an intentional contamination of them.

We also have a product recall system, and we have a Laboratory Electronic Applications for Results Notification, or LEARN, system. In addition, many of you know that we play a role on FERN and Alex.net. FERN is the laboratory network that will connect federal, state, and local laboratories to increase search capacity for not only responding to an attack but also for surveillance, and results of the FERN will be recorded into Alex.net.

So in addition -- so these are two kinds of

shields: personnel, and then these monitoring systems. The third kind of shield is the shield we've identified from the vulnerability assessments, and basically, the vulnerability assessments that we've conducted to date have identified four high-risk products, and they are: ground beef, deli meats, hot dogs and liquid egg products, and what we found out when we've conducted these vulnerability assessments is that there's some common characteristics to these food products that cause them, in our mind, to be of higher risk, and I should actually say the methodology that we used to conduct these vulnerability assessments is something called carbaplushock [phonetic] and it was a methodology that was taught to us by the White House -- actually, by the Department of Defense -- and it's an offensive targeting tool to identify vulnerabilities, those points in the farm-to-table continuum which are attractive targets for terrorists.

Some of the common characteristics of food that would be considered of high risk are shown on Page 4, there's four bullets there at the end of the page, and they include things like large batch size. Anyplace in the processing of a food where you have a large batch size that's exposed, that can mean that if an adulteration took place, that you could contaminate a lot of servings and obviously affect a large number of people, either making them sick or killing them.

Other characteristics are short shelf life. We considered anything with a short shelf life to be

particularly of concern because that would mean rapid turnaround at retail and rapid consumption, thus resulting in a lot of people getting sick or killing a lot of people rapidly.

Places in the processing of a product where you can have uniform mixing -- where you have uniform mixing and if you were to throw in a threat agent, you could mix that agent throughout the food product, again, that's a particularly vulnerable point.

And places in the production of the food where there's accessibility, a high accessibility to critical points, so for instance, again, where you have large batches of food that are exposed.

With those four characteristics, those four products that I mentioned rose to the top, and because of those vulnerabilities, which were much more specific in the assessments, that I can't really reveal here because there are secret documents, classified "secret," we actually came up with some countermeasures, and the countermeasures I tried to group on the next two pages, and they fall into two categories.

One is countermeasures that you can apply at a facility, and when I say facility, I'm also talking about not only a processing facility but at distribution or a warehouse, and that's to improve physical security, but particularly around vulnerable nodes in the production of

that food.

Another thing to do is to improve personnel security, and again, personnel security, this may mean conducting background checks of employees, particularly those people working around critical production areas.

What is a critical production area? -- again, getting back to those characteristics that I described: places where you have large amounts of food, that are easily mixed, that are accessible.

Another countermeasure was: to improve process security, and we're talking about like maybe reconfiguring systems, like using a closed system, or changing design parameters, such as pasteurization temperature. Another one is: to ship products in tamper-evident packaging.

On the transportation side of the house, I'm going to go through some of the countermeasures, they include: enhanced cargo security at sea ports; the use of tamper-evident seals and locks on trucks, tankers, and shipping containers; screening truck drivers through background investigations, or training them, to raise their awareness of food security issues; maintaining product integrity, ensuring product integrity, and maintaining a chain of custody; and the last one listed here is: developing MOUs with customs and border protection and with TSA.

I should mention that in the vulnerability assessments that we've conducted and the vulnerability

assessments that have been conducted by FDA, AFIS, the Food Nutrition Service, which is responsible for delivering school lunch programs to a great many children in the United States, transportation has been identified, using this common methodology, as a particularly vulnerable point in the farm-to-table continuum.

The questions that we're putting forth to this Committee are on the first page. With an understanding of these shields, okay -- and again, there are things that FSIS can do, you know, increasing the awareness of their personnel and their functions and enhancing their functions, monitoring databases, but also some of the things that industry can do, okay?

The questions are: Should FSIS require food security plans in plants, and if you believe that such plans should be required, the question: what components of the FSIS guidelines or the countermeasures identified from the vulnerability assessments are of most importance to include in such plans?

I should also mention, before I open it up to any questions, is that there are activities at the level of the White House to actually bring together industry groups, and they often talk about the Industry Sector Coordinating Council, and the purpose of that council, which is called an ISCC, is to actually review the results of all these vulnerability assessments that have not only been conducted

by FSIS but all these other agencies, and to validate the methodology, to validate the vulnerabilities that have been identified, and to work collectively together with governments to put into place countermeasures.

So that activity will take place. It's slow in the process, though, I should say. The ISCCs -- you know, the activities under the ISCCs have been going on for quite a while, so -- which brings me back to our questions again: Should FSIS be doing something now, and again, in the way of mandating food-security plans; and if so, what should be the components of such plans? And I guess that's all I have to say, except I'll turn it over to my colleagues to see if they wanted to add anything. So I'll be happy to take any questions.

MR. TYNAN: Before we take your question, Mr. Elfering, if I might introduce the colleagues, we have Mr. Ron Hicks, and Ron, did you want to point out what office you're with.

MR. HICKS: Good afternoon, folks. I'm with the Office of Program Evaluation, Enforcement, and Review. (Indiscernible) talk to you guys, I'd say it was just organized but it's been a couple years now, so I guess we're here to stay.

MR. TYNAN: And we also have Ms. Karen Stuck.

MS. STUCK: With the Office of International Affairs, which is involved with, among other things, import

and export policies and operations.

MR. TYNAN: So that's the Three Musketeers for food security. And Mr. Elfering, you had a question.

MR. ELFERING: Yes. Kevin Elfering, Minnesota Department of Agriculture. Who does the background checks for FSIS employees?

MR. HICKS: There are a lot of companies doing it, but OPM basically contracts with an organization that conducts background investigations both at the lower levels and for the higher levels.

MR. ELFERING: So all the FSIS employees, there's a background check conducted?

MR. HICKS: Yeah. For all of us there's an initial kind of first-level background check done, then as you get put into jobs of more complexity and where more security is necessary, there are higher degrees of background investigations, secret and top-secret investigations, but all of us get a very preliminary basic background check.

MR. TYNAN: Ms. Eskin.

MS. ESKIN: Sandra Eskin. A question. When you went through the discussion of the vulnerability assessments and the countermeasures, does that cover both domestically produced as well as international product or are there different -- is there a different approach taken with imports?

DR. MACZKA: We use the same methodology to assess

both domestic and imported products, it's carbaplushock, and I listed some of the countermeasures and vulnerabilities, those apply to both domestic and imported products. I should say, though, that each product, and even imported products, offer its own unique vulnerabilities, but what I've done here in this particular paper was to specify generalizations across both.

MS. ESKIN: Again, my uninformed impression, just thinking about it, would be: well, gosh, it's a lot easier to taint a product outside the country, you know, do something, and then let it -- just because of the nature of inspection and everything else, that's not based on anything factual, and I don't know if there's been any inquiry looking, again, about the specific vulnerabilities of imported product. I don't know how much we're talking about for -- obviously I mean poultry products.

DR. MACZKA: In fact when we did the import assessment we started from the country of origin, where it's produced, taking it over the seas or over the lands, if it came from Canada, and all the way to -- through customs inspection, reinspection at the I-houses, and then after that it's treated like domestic product, and during that whole chain we look for vulnerabilities, and I can say that you are correct that, you know, we don't control what happens in other countries as much as we do in our own country, and there were more vulnerabilities identified in that process,

especially during the transport of those products.

MS. ESKIN: And I guess the question would then be -- but you can't answer this -- what kind of a response, in terms of regulation, inspection, whatever, does that prompt? Again, many of the things you're talking about, that apply to deliberate -- possible deliberate contamination, would also protect against, arguably, non-deliberate contamination.

DR. MACZKA: Well, I know that's often said, that, you know, what applies to food safety would apply for food security, but if you think about it, some of the agents that can be added intentionally are things that we don't normally monitor for, and so there are things that -- you know, that we're not looking for right now.

MS. ESKIN: Right. But then there's the issue of likelihood, if you can somehow -- you know, you know there are some statistics telling you about the likelihood of just non-intentional contamination versus intentional. I think that the -- what we're seeing is just -- generally, pathogens is far more likely than a deliberate contamination.

DR. MACZKA: Well, you mean it's to occur on a daily basis, normal food safety (inaudible) --

MS. ESKIN: Just the likelihood, yeah.

DR. MACZKA: Well, that's -- that's true. I mean, I think with food security and with bio-security and terrorism, these are unlikely events, but they -- you know, obviously they happened in this country, and it's a new day,

so -- but I -- when we did look at the kinds of agents that could potentially be added to food products, and especially the food products that we regulate, we did look at things like: well, how easy is it to get that particular agent? can somebody manufacture it? do terrorists -- we were given briefings by the CIA and FBI, do terrorists have knowledge of those agents? -- and so that all went into these assessments.

And we do have like a list of about, you know, 20 or 30, 40 agents that we consider, you know, likely candidates to be used, and in fact our laboratories now test for a great many of them, not all the time, but, you know, they test for some of these threat agents.

MS. ESKIN: On both domestically-produced and imported product?

DR. MACZKA: Yes. Not at the expense of food safety, though. I mean, basically what we do is we split samples and we look both at food safety and food security.

MR. TYNAN: Mr. Govro.

MR. GOVRO: Mike Govro, Oregon Department of Agriculture. Dr. Maczka, I sent you several questions earlier, that I think would be helpful to the sub-committee in answering the questions that are posed to it. Could you please run through those for the benefit of the full Committee.

DR. MACZKA: Yes, I will. And please call me Carol, by the way. It's a tough last name.

Okay, the first question that Mike asked was: Has FSIS evaluated the current level of adherence to the Agency's Security Guidance? And if so, does that evaluation indicate a pressing need to achieve a significantly higher level of compliance? If not, then on what basis does FSIS pose this question? And I'd like to answer that, actually.

We are not presently evaluating the current level of adherence to the guidance, we are not doing that at this point, so we do not know if -- you know, what the level of compliance is.

But why bring this paper or issue before you yet again? because I think it was brought to you once before, and I think the answer there is that the guidance documents, as I said before in the presentation, were developed prior to the conduct of the vulnerability assessments, and now we have these vulnerability assessments that help actually prioritize what is more important in those guidance documents, what's more important than other things, and for that reason alone we're -- you know, since we've conducted these assessments and we're more knowledgeable, we're bringing the question forth to you again.

Now, the second question: How will FSIS use different plan requirements for plants of different sizes? -- you know, just off the cuff, I don't really see the need to actually have different plans for different plants of different sizes, because I think there's some general things

that have to be done across the board, and if we could just pick at those things first, then maybe someday we can hone into more specific things, but we -- you know, we haven't touched the tip of the iceberg yet.

Third question is: How will FSIS enforce the rule? And the fourth question I'll read along with that: What will the penalty be for failure to comply adequately? And I do not have answers for 3 and 4, and I think that, my colleague here would say, is something we would love for you to sort of comment on, if you think that these plans are a way to go.

And the fifth question, and these are two of my favorite questions, actually: What type of training, if any, will FSIS provide to plant personnel to help them make competent decisions about security? And the second question is: What type of training, if any, will FSIS provide to FSIS personnel to help them competently evaluate the plant plans.

And I want to state that for the last -- we've actually started a training program of our own employees, and we've been conducting that, I guess, maybe now -- it's a two-year program, and it's been under way for about a year, I think. However, I actually think, now that the vulnerability assessments have been completed, that there probably is a need for more training.

One of the things we've done is we've revised the directives that we have put out in response to the

vulnerability assessments, training on those directives would be important, but also training at a local level. A lot of the activity has taken place at the federal government, but it's really time to reach down, maybe, to state level and to actually try to work collectively together to train and raise awareness at the state level, with local school food authorities, public health departments of health, education, agriculture, with local industry, also maybe -- trying to kill two birds with one stone -- raising awareness among our forces, personnel, and also even working collectively with other agencies, I've had -- I've tried to reach out to some other agencies and they're very interested in together developing training programs and working, right now in a preliminary way, with FDA and with another -- two other agencies within -- underneath the umbrella of the USDA Department, which is the Food Nutrition Service and AMS.

So I do think training, and especially at the local level, is particularly important, and to try to reach as many as possible.

And then your last question: What will the cost be to the Agency to implement this require and where will it get the money? That's always a good question (chuckles). I think a lot of what we're doing can be piggy-backed on some of the food safety activities that we undertake. There are other things that we need to do, and I think it would require more resources. And where we would get it, I'd hope that we

could raise awareness that there's a need for such additional funding, especially from the Department of Homeland Security.

MR. TYNAN: Other questions related to food security? Dr. Hollingsworth.

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. I really just have a request for the sub-committee, and that is, is there a way we can get a copy of the recommendations and the report that was submitted from this Committee to the Agency when the question was posed to them, I guess it was, two meetings ago? This group was asked to respond about security and FSIS's role in that -- with the federally-inspected plants, and there was a response and recommendations made at that time. Can we get a copy of that?

MR. TYNAN: We'll try and get that, Jill.

DR. MACZKA: One thing maybe the sub-group might want to consider when we actually meet is what parts of plants, if you think that's the way to go, might be mandated, and maybe things, you know, you might want to consider, like inside security or processing and slaughter security, I mean, I'm just throwing out some ideas here, or storage security, but there may be -- if there is a recommendation for a plan, it may not be all-inclusive, it may be picking out some particularly important elements.

This is our food security guidelines, and I do have copies of this with me.

MR. TYNAN: Other questions and comments on food security? Mr. Kowalcyk.

MR. KOWALCYK: Mike Kowalcyk, from Safe Tables Our Priority. I guess this is just a general question, maybe someone from industry can help answer it as well.

Has FSIS received any feedback from industry with respect to any vulnerability -- can't talk today -- any assessments of risk of intentional contamination that they may have done on their own? I know a lot of manufacturers do their own contingency planning. Has FSIS received any feedback from industry regarding that?

DR. MACZKA: We had formed a group of about 13 individuals from industry, and we actually met with this group of individuals to sort of share best practices, and one person was particularly active, from GoldKist, and he actually invited us down to his plant to see what he was doing in terms of addressing vulnerabilities. So, you know, industry is -- you know, is paying attention to this.

And so, you know, through that group of 13, we have received, you know, some -- you know, ideas about things they are doing.

MR. KOWALCYK: Are there any particular areas where they would want the Agency's assistance?

DR. MACZKA: Well, I think that it's important to open up this dialogue to talk about the vulnerabilities that have been identified in these assessments, because even if

you were to look at one of our directives, it directs people to focus in on the periphery, at the -- to check perimeter fences. Well, that's important, but it may be even more important to look inside the facility at certain places where you have those common characteristics of food that I was mentioning that would indicate high risk.

So I do think it's important to actually engage them on some of these vulnerabilities that we have identified so that they could put more effective measures in place.

MR. TYNAN: If there's no other comments or questions related to food security, we'll close it out. Thank you very much, Carol.

The next item we have on our Agenda relates to public comments, and I have some logistical things that we need to talk a little bit about in terms of the sub-committees, but with that, I'll open it up to the public. We didn't have anyone sign up at the registration desk.

Are there any public comments that -- yes, sir. Could you introduce and your affiliation and --

JOHNNY: Johnny (inaudible). I have a couple of questions and a comment. On the issue of food secretary, is the Agency contemplating any reorganization of the allocation of resources in order to deal with this issue?

DR. MACZKA: I'm sorry?

JOHNNY: As far as the issue of food security, are you contemplating any reorganization within the Agency of

reallocation of resources in order to deal with the issue? What piqued my curiosity: when the subject came up in the constituent update [phonetic], it seemed that there's going to be -- they're going to have to -- there's going to have to be some attention paid or either additional staff resources or additional training that needs to be allocated (inaudible).

DR. MACZKA: Yeah, and I think that's happening. We are definitely focusing on some training of the employees. During the next eight months people are particularly concerned about something happening during the next eight months, because so many activities -- like, you know, you had Memorial Day, thank God we got through that, but you have Labor Day, you're going to have the elections, the White House has been particularly interested in any additional measures we can take during this time as preventive action, and in fact they've been talking about additional funding to the Agency to do additional inspection activities, and within our own Agency we're very much trying to focus those directives that I talked about on certain foods, things that would be conducted under an elevated-threat condition.

You know, we are spending a lot of time looking at what our laboratories have done and what more they can be doing. This is all -- a lot of this has been with existing resources, but we will need additional monies, especially if we're going to do some more -- additional activities during

this eight-month period.

JOHNNY: Additional personnel?

DR. MACZKA: I'm not so sure about -- well, yeah, it could be additional personnel too.

JOHNNY: I wanted to follow up on a point that Mr. Govro raised earlier today about the recall process. In California, which is a memorandum-of-understanding state, there is a bill that's winding its way through the legislature, SB 1585, that attempts to deal with some of the problems that even California had during the BSE recall, and I was wondering whether the Agency has taken a position on that bill.

DR. MASTERS: The Agency has been evaluating this, and the Agency is looking at publishing a Federal Register notice and evaluating the best way that we can provide consumers the information they need while protecting the propriety information of the industry, and that should be coming out shortly.

JOHNNY: So what's the position on the bill itself?

DR. MASTERS: The Agency's not particularly taking a position on the bill; they're working on their own process to ensure that they can accomplish the needs of the consumer as well as that of the industry.

JOHNNY: The last point is on the issue of training. A year and a half ago this Committee met to deal with the issue of inspector training and made some

recommendations, including an emphasis on classroom training, where the inspectors had the ability to ask questions, and I was very alarmed to see a story that appeared last week regarding the lack of training opportunities that can be provided to the inspectors to deal with the new E. coli Directives.

Now, the Under Secretary of Food Safety has trotted up to Capitol Hill, testified on both the House and Senate side, talking about all of the training money that's being spent on the inspectors, even to the extent of taking the position that the Agency does not need any additional legal authority because of this training, and yet you're not affording the inspectors the training on this very complicated directive that's coming out, and I think it's reprehensible, it's made a mockery of the work of this Committee, and I hope you reconsider.

DR. MASTERS: I appreciate your comments and I appreciate the opportunity to clarify for the record that our inspection personnel do get eight hours of official time to go over the materials for this directive and they are afforded that time on the Agency's clock, so I appreciate the opportunity to clarify that.

MR. TYNAN: Are there other comments from the public or -- Mr. Kowalcyk, let me get the public in first and then we'll go back to you. Yes, sir.

MR. YERR: I'm Dan Yerr [phonetic], with Pier

[phonetic] Foods. On the listeria Interim Final Rule, it seems like on the labeling, you know, we've looked at the additives as a category of change from one to two, but have we considered the -- if I have a fully-cooked product, that's frozen, with intent to be further heated after -- at the institutional level, why couldn't that be a labeling additive, to get to a Class I, where we have -- you know, it's not like a sliced lunchmeat, that is fully cooked but not intended for reheat, but if I have a frozen hamburger patty, that I know an institution is going to use one of three methods to cook and I can validate that cooking instruction, why couldn't that become one? It works for raw products, it works for partially-cooked, why can't I get a, I guess, institutional-use, ready-to-reheat type validated cooking instructions for ready-to-eat product.

DR. MACZKA: Again, I don't think that was the intent of the Interim Final Rule, but certainly that comment can be taken back.

MR. TYNAN: Other comments from the public?

(No response.)

MR. TYNAN: Okay, Mr. Kowalcyk, would you like to --

MR. KOWALCYK: Michael Kowalcyk, from STOP. Again on the point of training, the eight hours of train-ing, is that CD-ROM-based, independent-study-based --?

DR. MACZKA: We spend a little bit of time on

training, since there seems to be some interest in training. Our inspection personnel are getting considerable training this year. We have already trained over 1700 consumer safety inspectors in our food safety regulatory essentials this year, which is a two- to three-week classroom training session.

This training has been updated to include the E. coli O157:H7 Directive, so those going to the classroom training get this in the classroom training. For those that are not slotted into the training for this year, they are getting eight hours of time to go through the CD material, which covers the Directive, which is new for us as an agency, it is the first time ever that we've issued a directive and actually provided CD-ROM and time to go through training for an individual directive.

In addition, they're afforded the opportunity to attend workshops that are being held on the weekend, if they choose to attend those, but those are not training, those are workshop opportunities, particularly designed for the small and very small establishments. For the E. coli O157:H7, the CD time is eight-hour time that they're getting. They have the resources of the technical service center.

There have been individual Interactive Knowledge Exchange scenarios developed, IKE scenarios developed, that have gone out to all inspection personnel through our e-mail system. They also -- again, it's been added to the FSRE, for

which 1700 employees have been to this year.

It's also been addressed and covered in our front-line supervisor training, that all of our front-line supervisors have been to, starting in April, and finishing in October, we will have trained all 150 of our supervisors.

We also have been -- getting handed notes here. We've also been training EIAO Officers, Enforcement Investigation Information -- and Analysis Officers, we have trained 150 of those this year, down in College Station, they get information on the new updated E. coli O157:H7 Directive.

We also have included that information as we've held special sessions with our EIAOs, we had a special session in Phoenix, I believe Mr. Smith talked about the AER process this morning, and we included information at the Phoenix session that we talked about the AER process there.

So we've had many means of getting that information out, but for the eight hours of time, that is a CD, but I think it's significant in that it's the first time that when we've implemented a directive we've actually had some training that accompanied a directive.

I understand that with all of your training questions that you have, Karlease Kelly has a long list and would be happy -- we can get you a package of that, if you'd be interested. She has actually put a chart together, of: here's the training that we've done, here's how many people have been through it this year, here's what it consists of,

if it'd be useful to this Committee we'd be happy to share that, because we are very proud, we believe what we're doing is playing catch-up, we believe that we are reaching the point of almost being back where we need to be, as an agency, so that we can get ahead again, but we have made considerable strides this year.

So we'd be happy to provide to the Committee a copy of that chart that shows the amount of training that we have done this year, if it would be useful to the Committee.

MR. TYNAN: Other comments and questions? Dr. Jan.

DR. JAN: Lee Jan, Texas Department of Health. I just -- since training came up, I'd just like to let the Agency know that at least from our perspective as a state program, that CD-based training is a step, a giant step, in the right direction, it gives us an opportunity to provide our inspectors on-time training on a new directive, and there's a lot of changes, and I know our staff, our inspectors, and I'm sure FSIS's inspectors can't stop what they're doing to run to another training every time one comes up, so this is a great interim step, and then, like I say, opportunity to come up in -- a classroom kind of can round it out, but it's something a long time coming, and don't stop it.

DR. MASTERS: Thank you, Dr. Jan.

MR. TYNAN: Mr. Govro.

MR. GOVRO: Mike Govro, Oregon. A subject that has

come up before this Committee several times, in several ways, has been the subject of state meat-inspection programs and allowing the product that's produced under state meat-inspection programs to be shipped interstate, and I know that this is a topic that is being discussed at the National Association of State Departments of Agriculture at the present time, and I just wondered if you could update us on anything that might be happening on that front.

DR. MASTERS: The best answer that I can give you in that area is -- and I'll look to Mr. Hicks, who may want to jump in there a little bit: the PEER office is the ones -- the group that has been charged with doing the reviews of the state programs for equivalency, they have --

(Momentary loud microphone buzz.)

UNIDENTIFIED MALE: I just wanted to highlight that point.

(Laughter.)

DR. MASTERS: Successfully done on the first four on-site assessments [phonetic].

They have received the self-assessments from all of the states, and they are putting together all that information in hopes to get that out to the state directors in the very near future -- when I say very near, within the next week or so -- to have a full discussion of that when the state directors are in town two weeks from this week, in hopes of providing that as a means of moving forward, to

demonstrate that as we move forward, that the states are in fact meeting an equivalent standard of inspection.

So we're making progress in that regard. Ron, do you have anything?

MR. HICKS: No, pretty much that's what we're doing, we're in the process of putting together a report that has to go to Congress, that we were asked to do, in large part, to be able to provide an overall picture, or snapshot, of where the state programs stand and verify or confirm, however you want to say it, their (indiscernible) status, they feel good about the report and what the states have done, and hope they do as well, and part of that report may need to deal with -- I've been put on notice that it's going to have to deal with the idea of interstate shipment, and as a result of our efforts, you know, what it may mean in that regard.

So we do have some meetings scheduled with Dr. Masters and others internally to talk about just to what extent we should be commenting on that in the report. At this point the report is merely the results of our four on-site reviews and the 28 self-assessments that we've done.

(Pause.)

MR. TYNAN: Have we exhausted all comments and questions?

(No response.)

MR. TYNAN: Mr. Shire, would you like to come to a

microphone and introduce yourself and give your affiliation.

MR. SHIRE: Good afternoon, everyone. My name is Bernie Shire, I'm with the American Association of Meat Processors, and I was going to make a comment before my phone rang, and instead of just ignoring it I went out and answered it, so I'm glad I have a chance to do that.

Our association represents, as many of you probably know, small and very small meat and poultry processors, and I'm very interested in the topics that are going to be discussed this afternoon, and unfortunately I can't be in three places at one time, but I have people in other -- that can go to other ones and give me information.

The thing I wanted to talk about just very briefly was the issue of food security and -- in terms of what Carol talked about earlier. We are very interested in this issue and we were involved in the Agency's efforts and, actually, accomplishments in setting up guidelines for plants to follow last year, and Dr. Santiago is sitting over here, who actually came to our national convention last year and did a session, did a workshop at our meeting on this issue.

The only concern I want to raise before the meeting and the discussion this afternoon, it seems like guidelines have worked very well in this kind -- for these kinds of issues. The concern that some of our folks have is: what happens when the guidelines turn into regulations and directives.

When we -- when this project, the -- on the guidelines were done last year, one of the points that we made in our input into that process was that in many ways small plants operate differently than large plants do, just differently, because of their size and the kind of things they do, and I heard a few minutes ago Carol say that they were going to start out possibly doing some of the things that would be more or less general to everybody and get into the specifics later on.

We pointed out, and I think successfully, when those guidelines were developed that there were things that small plants do that would necessitate different types of security measures and maybe not as much in terms of security when you have plants where there are people working who all belong to the same family, where you have retail facilities where people come in off the street and park their cars and buy products, so you can't very well, in that kind of facility, ban parking the same way as you can in say a large plant out in the countryside somewhere, where there's no retailers -- or nobody coming in around.

So I guess it's just more or less I'd like to offer maybe a word of caution and a word of warning, not warning but caution, in terms of the Agency coming out with directives that would require plants to set up security. It's not that it's not a good idea to have security, but when you get into that kind of thing, the question we would raise

is: what would the Agency require? And if that is going to happen, it would have to be a very -- we hope -- open and transparent process, where the concerns and issues that affect everybody in the industry would be brought out and be part of it, and that's just the word of caution I wanted to raise before this discussion by the sub-committee this afternoon. Thank you.

MR. TYNAN: Let's close out the public comment period and talk a little bit about the logistics for the sub-committee meetings this afternoon. I think in Tab 3 of your notebooks we provided you the sub-committee membership that we've organized for this session.

There are three sub-committees. I think Dr. Denton is the chairperson for Sub-Committee Number 1 and will be dealing with the issue of listeria monocytogenes and the Interim Rule. The members on his committee will be: Mr. Elfering, Ms. Eskin, Ms. Baldwin, and Mr. Link.

You all will be meeting here in the main ballroom, so perhaps after we break we'll get together and figure out how we can do that with the configuration that we currently have.

Sub-Committee Number 2, the chairperson is Dr. Alice Johnson, and the members of that committee will be: Dr. Carpenter, Dr. Logue, Joe Harris is not here, Dr. Jan, and Mr. Detwiler will be participating in that, and their issue will be: Applying the mark of inspection to product

tested for an adulterant.

The last sub-committee, Sub-Committee Number 3 -- and did I say -- Sub-Committee Number 2 will be in the Jefferson Room, and that's upstairs, the stairway across the hall, to the right, if you go upstairs, it'll be in the Jefferson Room.

And Sub-Committee Number 3 will be in the Madison Room, and the chairperson of that will be Mr. Govro, and Dr. Bayse, Dr. Hollingsworth, Mr. Kowalcyk, and Mr. Schad will be the members on that group.

So we'll be breaking in a few minutes. The people who presented the issues this morning, I think they have some of their staff here, that will provide facilitation and recording services. We also have people from our recording company that will be transcribing those portions of it. If the chairpeople feel that there is a need, toward the end of the day, to continue into the evening, if you'd let us know so that we can make sure that you have transcriber services and appropriate facilitation and recording in your room, I would appreciate it very much.

So with that, as I say, Sub-Committee 1, Dr. Denton, will be here in the main ballroom; Sub-Committee 2, Dr. Johnson's group, will be in the Jefferson Room; and Sub-Committee Number 3, Mr. Govro's group, will be in the Madison Room, and the Madison Room, again, is upstairs, someplace in the hallway up there, I think pretty much the

same place we were in last year.

So are there any questions regarding this afternoon's meeting? I'll leave it to the chairpeople to get with their group and get started. I think on the agenda we had a 2:45 start. I'll make sure that you have everything upstairs, but if you want to, take a few-minute break and then get back together again in the appropriate rooms, so we should be good to go.

Before we take a break: Tomorrow morning we'll be starting again at 8:30 with a brief recap, and then we'll be having the sub-committees do their report on what their findings are in relation to the questions that have been posed by the Agency related to each issue.

So if there are no questions about the process for this afternoon, I think we'll adjourn for today, if that's all right with Dr. Masters, and we'll go from there. Thank you very much.

(Whereupon, at 2:15 p.m., the meeting was adjourned.)

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CERTIFICATE

In Re: NATIONAL ADVISORY COMMITTEE
ON MEAT AND POULTRY INSPECTION MEETING
Place: ALEXANDRIA, VIRGINIA
Date Held: JUNE 2, 2004
Time Held: 8:30 A.M.

We, the undersigneds, do hereby certify that the foregoing pages, number 1 through 166, inclusive, is the true, accurate and complete transcript prepared from the reporting by BOB ADDINGTON in attendance at the above-identified hearings, in accordance with applicable provisions of the current USDA contract, and the below-signed persons 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.

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