GRIEVANCE BOARD

UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE:

NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY

Hearing held on the 23rd day of June, 2003

at 8:50 a.m.
Hilton Hotel
1767 King Street
Alexandria, Virginia

TRANSCRIPT OF PROCEEDINGS

REPRESENTATIVES OF USDA, FSIS:

Dr. Elsa Murano, Under Secretary for Food Safety
Dr. Garry McKee, Administrator and Chairman, NACMPI
Mr. Robert Tynan, NACMPI Coordinator

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[None]

P R O C E E D I N G S

June 23, 2003

MR. TYNAN: I wanted to welcome you all to the National Advisory Committee for Meat and Poultry Inspection. We sincerely appreciate you coming. I know some of you traveled considerable distances to get here, and to participate in the meeting. So I'm very grateful for you to be with us today. We've got a pretty full agenda, several issues. I think Dr. McKee will go through the agenda shortly, when he does his remarks. So I won't take you through that. A couple of housekeeping things, the men's and lady's room across the hall, those are important things to know. There is a bank of telephones across the hall as well, if anybody doesn't have one of their cell phones. I would ask that anybody that has a cell phone, if they could turn it off for purposes of the meeting so we don't have any of the speakers interrupted. Also, messages for anyone or faxes, will be coming to the registration desk outside. And you can catch those there on the breaks. If you have not registered already as a participant or as a visitor, the registration table is outside, so please do that at your earliest convenience. There are handouts on one of the tables adjacent to the registration desk, they're loose handouts. I think all of the members have

notebooks with all of the handouts and materials as well. The meeting is going to be transcribed, so we have a transcriber here. And so everything that you say can and will be used against you later on. We'll have a record of it. Also, as I mentioned, Dr. McKee will be doing the -- going through the agenda. But I did want to point out one minor change, I think originally we had talked about doing the evening sessions, the subcommittee sessions this evening, from 7:00 to 9:00. We've moved the time up to 6:00 to 8:00, since we'll be done probably at 4:00 or 4:30; it makes the most sense to have those parts of the meeting a little bit sooner than later. For those members of the public that are here and would like to make a statement, toward the end of the day there is time in the agenda for public comment. If I could ask those people who would like to do that to perhaps register outside at the registration table, you'll have probably five minutes or so toward the end of the afternoon, I think at four o'clock, on the agenda. And I think that's about it. And with no further adieu, we may launch into our agenda. And I'm going to turn it over to Dr. Elsa Murano. Yes, Dr. Jan.

DR. JAN: Would you give us the phone numbers here for the -- if we need somebody to call in?

MR. TYNAN: Yes. I will get those for you,

and I'll announce it at the break time. Okay. I'm sorry. I don't have that on my little cheat sheet here. So with no further adieu, Dr. Murano, our Under Secretary for Food Safety.

DR. MURANO: Good morning, everybody.

ALL: Good morning.

DR. MURANO: Welcome to my town. I live in Alexandria, Virginia, so this is my neck of the woods. I could have just come here from home instead of going all the way downtown, and all the way back here. It would have saved me a little time this morning. But I'm glad to have you all be here. And I know we have a full agenda for you, and also the fact that we have new members of this committee, as well as some returning old timers. So it's an exciting time. And I know during the course of these couple of days, we'll have a lot of great exchanges and input from you. I know that a lot of you, in fact, all of you who are participating in this committee as members, you're doing so out of a personal commitment to food safety and to public health. For most of you it's been a professional mission, so to speak, and for some of you a personal mission. So I thank you for your dedication and willingness to serve in this capacity. This committee includes members from the industry, consumer advocacy groups, government

officials, and academia's. So I think it's a good mix of all the interested groups that strive to do their part to improve food safety in this country. So I think it's a good committee. It's a committee that we are going to depend on and have depended on for advice for several years, and again, encourage you to not be shy and give us your advice, good, constructive advice is what we're here to listen to. The worldwide data on food borne illness demonstrates that Americans really enjoy one of the safest food supplies in the world. And certainly at the Food Safety and Inspection Service, we constantly and continually work to improve our program, so that we can maintain this fact. And, in fact, take us to the level where we can say that we have the safest food supply in the world. Since 2001, we have been working to pursue a vision of enhancing public health through improving food safety. And along with that vision, there's been five goals that we've identified early on that have helped us focus on the types of activities that we needed to carry out so that we could achieve this vision. You may have heard me talk about these five goals in the past. I thought that it would be fitting this morning for me to go over some of these briefly with you, given the fact that some of you are new to this committee, and also because some of the

topics that you're going to be discussing at this week's meeting are related directly to these five goals. These are, by the way, not in any particular order. We are aggressively pursuing each of the five goals simultaneously. Well, first it's ensuring that policy decisions are based on science. And as a scientist, that certainly has been a major goal of mine since I came on board about 20 months ago. Science is our strongest ally in the fight against deadly pathogens. I truly believe that. So we are committed to continuing our emphasis on the use of science, research, and technology in framing food safety policy and prevention, as much as possible. Secondly, improving the management and effectiveness of all our regulatory programs is something that the agency has definitely been working on very actively. This lies at the heart of what we do. The workforce is a key to ensuring that this goal is met. And that is why training of our workforce is so important. The agency has expanded its training of consumer safety officers you may know to reflect this increasing reliance on science and technology. And we look forward to your feedback of suggestions, especially subcommittee one, I believe, will be looking at our training objectives and giving us some advice on how we can improve that training program. That's very

ambitious and very aggressive, but one that we're very committed to, and Dr. Garry McKee, especially, is committed to pursuing. Number three is safeguarding our food supply against intentional contamination. And this is certainly a real threat, unfortunately. We have to constantly watch for this. And we have responded to this challenge by strengthening coordination and preparation efforts so that we can prevent, detect, and respond to these acts of terrorism as quickly as possible. We have increased the number of import surveillance inspectors; have assessed our most vulnerable products, and the points of contamination that can be subject to attack. So I'm certainly looking forward to the work from subcommittee number two, who is going to advise us on how we can further improve food buyer security. Goal number four is coordination of food safety activities, with other public health agencies, not only in the federal government but also within the states. And this is a vital part of our public health mission. This improved coordination ensures that the food safety net has no holes. So subcommittee number three, I understand, will be talking about our state review methods, and will try to give us some good advice on how we can do these as best as we can, and certainly in good coordination in conjunction

with the states that have their own inspection programs. So I trust that it will help us determine how we can improve not only state inspection, but also how we can improve our relationships with the states. And lastly, goal number five is our ongoing effort to enhance food safety education. And that is all along the farm to table continuum. Our objective has been to ensure that every segment of the population has access to food safety information that is useful in contributing to a safer food supply. And so we will update the committee on our latest initiatives. I think it is tomorrow morning. And, certainly, we look forward to hearing your ideas on this front as well. So in closing, FSIS, I believe, has certainly made a lot of progress in the past year and a half or two years, in protecting the safety of our meat, poultry, and egg products. And we continue to implement new initiates so that we can continue striving to become the best public health agency. We couldn't do nearly as much as we have undertaken without the support of President Bush. He has requested a record level $42 million increase in our fiscal year 2004, budget, so that we can strengthen our food safety programs. And many of the training initiatives that we've begun and will seek your advice on would not be possible without the President's request

to double the training funds from the previous fiscal year. You're going to hear from many representatives of the agency over the course of these couple of days on the various issues that I have talked about. And I certainly urge you to ask questions, think critically about the path that we're taking, and give us your best advice. Your work will go a long way in helping us develop and implement policies that will best serve the public's health. So, again, I thank you for your time, for your service, for your continued commitment to working in this committee, and for those of you who are new to it, for your willingness to serve. And so we look certainly forward to your input in the next couple of days. So at this time I'd like to turn this back over to Robert Tynan. Thank you.

MR. TYNAN: I didn't realize what a long walk it is from over there. I also -- when Dr. Murano was talking about new members, I failed to point out at the beginning, that I am also a new member. Actually, this is my first time coordinating the committee. My name is Robert Tynan. I work on the strategic initiative staff with Mary Cutshall, and have had the pleasure of doing this. It's been a lot of fun, busy, but a lot of fun. So with that, let me -- phone numbers. We have some phone numbers for you. This is hot off the presses. If

you need some messages, it's (703) 837-0440. And the fax number is (703) 837-0454. Thank you much. I appreciate that. And with no further adieu, let me introduce our administrator of the Food Safety Inspection Service, Dr. Garry McKee. I think I'm going to sit over here, so I won't have to walk so far.

DR. MCKEE: Thank you, Robert, and thank you, Dr. Murano. On behalf of FSIS, I certainly want to welcome each of you here. Some of you, as Dr. Murano mentioned, are new. And I think you'll find this a very productive and exciting meeting. This is my second meeting of the National Advisory Committee on Poultry and Meat Inspection. And I'm encouraged by the dedication and enthusiasm that all of you have brought with you here today. I look forward to a productive forum. Having served in this position for almost a year, I realize more than ever the challenge that's confronting us all. Yet, I remain as committed as ever to protecting public health and making sound public health policy decisions at the national level. Throughout the course of my brief tenure with FSIS, I spelled out division I had for the agency, to transform FSIS into a world-class public health agency that all other public health institutions will use as a model. Even though many of you have heard this before, I

believe it's necessary to reiterate this vision regularly, to keep focus on our objectives, and gauge our progress along the way. Also, with a regular review and understanding of this vision, FSIS and its partners in academia, consumer groups, industry, and other government organizations can structure short and long-term activities and goals within a public health oriented perspective. To recap on how we need to function as a model public health agency, FSIS needs to implement three important functions to ensure the public health is protected. The first function is assessment, which simply means identifying problems. The second function is policy development, which means taking action, and actions and resources are needed to solve the problems. And the third function is assurance, which means making sure that the job gets done, and that the problem is solved. FSIS already has a solid foundation in place for improving food safety. We are holding ourselves accountable to fulfilling our vision, and ensuring the public health of Americans. We must always remember that our number one priority is the public health of all Americans. With that said, I am very grateful to be here at this two-day meeting. This is an opportunity for me to get to know many of you further, and to meet you for the first time, if you're

new to our committee. I'm excited about the possibilities of hearing new ideas and recommendations to improve food safety. Once again, I reiterate, this committee's work and recommendations are vital to our efforts to make our vision of becoming a world-class public health agency a reality. I know that we have seven new members starting with us today on the committee. And I want to give all of you a special welcome. We recently found out last week that one of our new members, Charlotte Kristin, has changed positions and is no longer on the committee. We will begin the process of soliciting nominations for another consumer representative, as soon as possible. For that reason, we've made a small adjustment in the subcommittees to ensure consumer representation at each subcommittee. Before I review today's agenda, I'd like to go around the table and have everyone introduce themselves. And if you would, please state your name and the group you represent. Could we start with you, Ms. Baldwin?

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

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

DR. ELFERING: Kevin Elfering, the Minnesota

Department of Agriculture.

MR. HARRIS: Joe Harris, with Southwest Meat Association.

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute.

MR. KOWALCYK: Michael Kowalcyk, with Safe Table is our Priority.

MR. SHADD: Mark Schad, Schad Meats, Cincinnati.

DR. BAYSE: Gladys Bayse, Spelman College, Atlanta.

MR. DENTON: James Denton, with the University of Arkansas.

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

DR. JAN: I'm Lee Jan, from the Texas Department of Health.

DR. LEECH: I'm Irene Leech, I'm with the Virginia Citizens Consumer Council.

MR. LINK: Charles Link. I'm with Cargill Meat Solutions, in Harrisonburg, Virginia.

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

DR. MURANO: Elsa Murano, Office of Food Safety.

MR. PEARSON: Ralph Pearson, Office of Food Safety.

MR. HICKS: I'm Ron Hicks, with FSIA, Office of Program Evaluation Enforcement and Review, otherwise known as PEER.

DR. ROTH: Jane Roth. I'm head of the Evaluation Office in PEER.

DR. ENGELJOHN: I'm Dan Engeljohn. I'm with the Policy Office in FSIS.

DR. MCKEE: Okay. Thank you. What I'd like to do next is to quickly go over the meeting's agenda for the next two days. We have a lot of subject matter to cover. And first we'll start off with a presentation of certificates to all members of the National Advisory Committee. Then we'll head off into a briefing on *E. coli* O157:H7 developments and the *Listeria* Rule. Following that we'll have a discussion of our first issue, the State Review Methods. We will then pause for a short break. Once we reconvene, at approximately 11:10, we will have a presentation on our second issue of the day, which will be the training delivery. We'll then break for lunch. We'll reconvene after lunch at 1:30, for a briefing on the content and status of FSIS's

plan propose a HACCP Regulation for egg and egg products. At two o'clock, our third issue discussion of the day will cover recommendations to increase industry awareness of food security. Following this, we will take a short break. After our break, at approximately 3:05, the committee will be briefed on the status of baseline studies. Next we'll head straight into a legislative update from the Congressional and Public Affairs Office. Following that we'll wrap up today's presentations with about 25 minutes allotted for public comments. For those interested in providing public comments, it would be very helpful if you would notify our staff, Mary Cutshall, in particular, if you have comments. Starting at 6:00 this evening, the subcommittees will convene for two hours. Subcommittee one will address delivery of training, subcommittee two, increasing industry awareness of food security. And then subcommittee three will review the issue of state review methods. Tomorrow morning we'll get started at about 8:L45. And each subcommittee will provide a briefing on their discussions and recommendations from their evening sessions. Subcommittee number one will have 55 minutes to give us a briefing from their evening session, and that will start at 9:00 a.m. After a short break, we'll reconvene, and subcommittee number two will

brief us on its Monday session. Immediately following subcommittee two, subcommittee three will give its briefing on state review methods. At noon, we'll break for lunch, and we'll reconvene at 1:00 p.m., to hear what the USDA's food -- to hear about the USDA's food safety mobile. At 1:30, we will learn about the Memorandum of Agreement between the FSIS, the United States Public Health Service, and after a short break we'll talk about any remaining issues, and have public comment as well before we adjourn. Are there any questions regarding the agenda? Okay. What we'd like to do next is to have the presentation of certificates for the members of the advisory committee. And, Robert, if you'll help us with that.

MR. TYNAN: What I plan to do is call off the names of each of the individuals that are on the committee. It's important to note that this year we've reconstituted the committee. We have a new charter, and a number of new members. So this has gone through the department. So what we'd like to do is maybe call each name, and I'll try and remember to point out who's a new member, versus an old member. And maybe I could ask Dr. Murano and Dr. McKee maybe to step out a little further. Where do you need them, Keith, if you were going to...

DR. MCKEE: Anywhere you want them.

MR. TYNAN: You get your picture taken, and we'll put little numbers under them and all kinds of things. The first person to come up would be Dr. Gladys Bayse. And she's a returning member of the committee. Notice how well oiled and planned this is? We had to bribe her. The next person is Ms. Deanna Baldwin. I should point out Ms. Baldwin is a new member. Dr. David Carpenter. And I think, Dr. Carpenter, you are a returning member. Are you not? Oh, a new member. I'm sorry. I apologize. My cheat sheet was wrong. And we have Dr. James Denton. And, Dr. Denton, I am positive, is a returning member. Dr. Kevin Elfering. And Dr. Elfering is a new member.

DR. ELFERING: Yes.

MR. TYNAN: I got that one right. Thank you. You have to get it from the important people. Dr. Joseph Harris, also a new member. Mr. Michael Govro is a returning member. Thank you, Marshall. I'm getting help from everyone. I can use this help. Dr. Lee Jan. And Dr. Jan is a returning member. We have Dr. Jill Hollingsworth. And while she's a new member -- nice to see you. How are you? Mr. Michael Kowalcyk. And Mr. Kowalcyk is a new member. Oh, I'm sorry. Mr. Mark Schad. And Mr. Schad is a new member. Dr. Irene Leech. And Dr. Leech is a returning member. Mr. Charles Link.

And Mr. Link is a returning member. We have two other members, Dr. Alice Johnson and Ms. Sandra Eskin. And they have not arrived yet. But as soon as they do, we'll do a private ceremony for them. Thank you, Dr. Murano. I also have to correct, I called Elfering, Mr. Elfering. I apologize. My reading skills, when you get older, are not quite as good as they used to be. On the agenda we have the first topic of the day is Dr. Dan Engeljohn, and he will be talking about *E. coli* and the *Listeria* Rule.

DR. ENGELJOHN: Good morning, everyone. I'm going to walk you through briefly the *E. coli* 0157:H7 updates that we have within the agency, and then give you a briefing over the new *Listeria* regulation that issued earlier this month. With regard to *E. coli* and *Listeria*, within your tab, number three, the first page should be about *E. coli* 0157:H7. To give you an overview, the agency identified *E. coli* 0157:H7 as an adulterant in certain beef products back in 1994. Since that time the agency has issued new policy statements about *E. coli* in the form of Federal Register Notices, or through FSIS directives. Most recently, the Agency issued a Federal Register Notice in October of 2002, that identified information we believed presented that the prevalence of *E. coli* 0157, was more prevalent today

than it was at least two years ago, when we began working on our 0157 policy, through the Federal Register Notices. In that October Federal Register Notice, the agency identified that due to the increased prevalence in live animals, that those individuals producing certain beef products needed to reassess their HACCP plans in order to address the hazard that we believe was present within the products. Based on that, the Agency established a timeframe under which the plants producing ground beef and beef products needed to conduct that reassessment. The large plants, which are those plants with 500 or more employees, needed to conduct that reassessment by December 6. Small plants, which have fewer than 500 employees, but more than ten, needed to conduct that reassessment by February 4. And the very small plants, which have ten or fewer employees, or produce $2.5 million worth of product or less, had to reassess by October 7. The agency's consumer safety officers were tasked with conducting those reassessment reviews. In those reviews, the agency inspection personnel conduct more than just a look at the *E. coli* 0157:H7 controls that are in place. They do a very thorough review of all the HACCP plan procedures, and all the associated control program and measures that are listed within the plant's programs. And so the

assessment is quite intense and expansive, and takes from a day to a couple of days for each of those reviews. The Agency estimated that there were roughly 2,000 plants that needed to undergo the reassessment. Within that October 7, notice, we asked our CSO's to answer four specific questions about the content of the reassessment. The first question was whether or not the establishment reassessed based on the relevant data that we believe presented increased prevalence of this particular organism. The second question was whether the HACCP plan was changed based on this relevant data. And if the HACCP plan had changed, than the third question was how did it change. If the HACCP had not changed, than why was there no change, or why, in fact, was there no addressing of that particular hazard, within the HACCP controls. In general, the agency has received many of the reports that have come in from the review of those reassessments. We have a large number to go through. I'm presenting information on roughly ten percent of those reviews that we have received. And these reflect those from mostly the very large establishments. In general, approximately 30 percent of the plants did not identify *E. coli* 0157:H7 as a hazard reasonably likely to occur. Now within the Federal Register Notice that issued in October, the Agency did

identify that we would, in fact, accept the development of control measures through the use of prerequisite programs, particularly for grinding establishments, if they, in fact, had purchased specification and other control measurers with the suppliers of those programs and product to the grinders with assurance that, in fact, the hazard is being controlled through a critical control point in the slaughter facilities or the fabrication facilities, and that the establishments using prerequisite programs would use those programs in a manner in which they continually verify the effectiveness of those programs. So the 30 percent number was one for which we did not really know how many plants were using this particular approach. But based on the information we have thus far, we have -- we do know that a fair number of the grinders are, in fact, using the prerequisite program approach. We did also identify, through the CSO reviews, of the entire control system that the establishments had that there continue to be some design problems with regard to the content of the HACCP control procedures. Those involve mostly those related to monitoring, record keeping, verification, and corrective actins. These issues, in our opinion at this point, do not present imminent health issues in terms of being totally out of control

with regard to this HACCP issue. But the Agency does recognize that now that we're conducting more in depth reviews of the content of the programs, and in particular the support documentation for them, that there is a need for additional development of either guidance to the industry or an additional focus by the agency and its policy documents, on correcting some of these design problems. Because we do know from our own data, and from the published literature, that the prevalence of *E. coli* 0157:H7, does, in fact, rise at the beginning of the summer months, the agency issued, through a FSIS notice, a correction or at least a modification to the existing inspectional procedures, and removed any exemptions that establishments may have with regard to their control programs. So beginning in April of this year, the Agency, through a FSIS notice, identified that it would no longer exempt any establishment from being tested for verification testing purposes by FSIS. Our testing is ongoing. And at this time the Agency is developing its directive on 0157:H7, that, in fact, we will address new inspection procedures for the inspection program personnel, and will, in fact, identify procedures that address more than just a focus on the grinding operations, but will focus on the trim suppliers as well. With regard to the second issue,

which is *Listeria monocytogenes*, behind the *E. coli* 0157:H7 paper -- if I could get your help please -- is the *Listeria* briefing materials. The agency published a new final regulation in June of this year, June 6, on *Listeria monocytogenes*. For your information with regard to how we set up this interim final rule, the paperwork burden requirements related to *Listeria* monocytogenes are to be submitted to the agency by August 5. This relates to the issue that the agency added a new paperwork burden requirement that requires the establishments producing ready to eat meat and poultry products affected by this rule, to provide the agency with information about how the establishment intends to control for this particular organism, and what they're producing. So for that reason we need to receive comment on that particular component of the final rule, and those are due by August the 5th. By August -- then after that, the final rule will go into effect on October the 6th. Although this is identified as an interim final rule, the rule will be effective as if it were a regular final rule. But the component that's different about this regulation is that the agency is committed to looking at the effectiveness of this regulation in terms of how well it's addressing the hazard that is present as well as the implementation of

this regulation. And so we have committed to studying the effectiveness of this rule over the course of the next 18 months. And so by December 8, 2004, the Agency will accept comment on the interim final rule, at which time the agency will remove the identification as an interim and consider it a final rule. But it is important to note to the industry in particular that the rule does go into effect on October the 6th, of this year. When the rule does go into effect, the Agency will issue a new directive that will provide instructions to our employees as to how to conduct verification activity for those establishments producing product that are affected by this rule. With regard to the products that are affected, the products relate to those ready to eat meat and poultry products that are exposed to the environment after the lethality treatment. For those of you who aren't quite familiar with the operations of a ready to eat meat and poultry facility, in many cases a ready to eat product is produced inside of a casing or a package, and it receives its lethality treatment to destroy pathogens at that time. The product then may be removed from that packing material and sliced or put into a new package that's then available to the consumer in that final packaging. The act of removing the product from its

original casing for which it received a lethality treatment and transferring it to another package, or conducting other further processing activities such as slicing, increases the potential for *Listeria* to contaminate the product. And so for that reasons these products, in particular, will be affected by the rule. So they must be ready to eat or designated as such by the establishment, and also are exposed to the environment after the lethality treatment. Within the final regulation itself, we've added a new section, which is Section 430 of 9 CFR. And it addresses specifically *Listeria monocytogenes*, and identifies that product that is positive for *Listeria monocytogenes* or food contact surfaces that are positive for *Listeria monocytogenes* are, in fact, considered to be adulterated by the Agency. Within the regulation we added a section which contains a number of definitions, many of which were contained in the directive that we issued this past December on ready to eat products. And then there are some new definitions that we believe provide greater context to the use of those terms within the final regulation. The structure of the regulation is set up that establishments need to determine how they're going to control for this particular hazard to one of three alternative approaches. Alternative one approach is the

one for which we believe to be most effective in controlling *Listeria monocytogenes* throughout the shelf life of this particular product. And that product will have received an additional post lethality treatment and has a growth inhibitor contained within the product or the packaging that if cells of this organism survive the additional lethality, that this organism would not grow throughout the shelf life of the product. In alternative two, the options are that the product is either handled by a Post-lethality treatment or has a growth inhibitor formulated into the production process or into the packaging material. For those operations that elect to use the growth inhibitor only option, the Agency identified that there are additional needs for prescribing controls with regard to the sanitation program. And for that reason, the Agency is requiring that in those programs that the sanitation program has to be modified to address product testing of food contact surfaces, the hold-and-test procedures for if and when a positive result is found for *Listeria* species or *Listeria monocytogenes*, the establishment would need to identify when it would hold product and when it would be -- when it would stop its holding and testing of that particular product. In addition, the establishment would need to identify the frequency of testing,

identify the size and location of the sampled cites, and provide an explanation as to why the design of the sampling program and the testing frequency is sufficient to ensure the safety of the product. For alternative three, this particular product would have the least amount of additional enhancements to food safety and rely strictly upon sanitation to prevent *Listeria* from being exposed to the ready to eat Post-lethality exposed product. And within this alternative, those operations that produce deli meat and hotdogs, must, in addition, have additional controls with regards to the hold-and-test provision. They still must have the sanitation program, much as in alternative two. But because sanitation becomes more critical with regards to identifying the control measures, the Agency has added an additional requirement that if hotdogs or deli meats are produced, which we know from data provided in the 2001 *Listeria* risk ranking by FDA and FSIS, that these products produce a greater relative risk for Listeriosis. And, therefore, there's more prescription as to how the establishment must hold and test this product, and when that product can be released, and the conditions for that. The additional features that the Agency added with regards to how it would, in fact, control operations was, again, to identify that

establishments producing these products had to identify to the Agency, at least on an annual basis, how much product is produced, and the types of control measures that are used by the establishment. The Agency is expecting to have an electronic submittal process developed so that this can be conducted through the Internet, as opposed to sending in hard copies to the Agency. But this information, we believe, is critical to the Agency's design of its verification testing program, which we intend to construct in a risk base manner, focusing most of our attention -- or at least increasing our intention through those operations that rely solely upon sanitation for the control measures, and in particular, those operations that produce deli meat or hotdog products. And then finally, the Agency identified that although establishments could use labeling to identify the enhanced safety features of their products, the Agency is identifying, through this final rule, that we believe that there can be increased focus by industry on identifying on the label that the products produced in that establishment had received an additional lethality treatment or, in fact, is formulated or controlled in a manner to prevent growth of this particular organism. We find this to be an important feature of the final rule in that for those

case ready products that are available to the consumer, particularly the deli meat products that are not warmed by the consumer prior to consumption, that the consumer can search for labels that identify this additional enhances safety feature, which, again, would be that the product has received an additional lethality treatment or is formulated in a way to prevent growth of the organism, should it be present. And that way individuals, particularly vulnerable populations, can seek out this product and request it, and in cases where it's not available, can ask their supplier to pursue making that product available to them. Are we entertaining questions on the briefings that I've provided?

MR. TYNAN: Yes, we are.

DR. ENGELJOHN: Yes, Dr. Jan.

DR. JAN: I'm Lee Jan, Texas Department of Health. I've got actually three questions. They're all related. And I'll just run through them. And if you need me to repeat them when you answer then, then I can do that. First off, I'd like to point out one of the objectives that Dr. Murano mentioned was science based food safety, or food safety being based on science. And I think this is moving in that direction, both of these programs. But what I'd like to know, and the first

question that I have is establishments that slaughter must currently test for generic *E. coli*, the carcasses that they produce, as a process control. But FSIS has never established a standard, using the sponge method, and the methods that are commonly used are producing results that are not useful or not beneficial. If you go to plants that do slaughter, their results that are coming back are generally less than a value, maybe .8 units per centimeter, or something of that nature, and less than is essentially to a zero. And if a plant continues to get zeros, there's no data to use. Most of the plants aren't -- they're not far enough advanced to understand process control or statistical process control, and what does it mean. And I'm not sure that I understand what it means when all I get is zeros, and I don't get any values. So my question is, can FSIS consider doing away with this requirement for generic *E. coli* testing in lieu of this new, more specific testing requirement under the *E. coli* plan, this new policy where they -- plants are required to control *E. coli*, and part of that control is going to require testing. Plants that are now spending money on doing testing that are providing no data that's useful kind of flies in the face of sound science. If they could take that money and spend it on some more specific testing related to a

program that is more scientifically based, that's my first question. The other question, on processors, if they're not doing testing of their own, they can do -- have a prerequisite program if they're purchasing their raw gram products, and that specifications set date or start to require that the plant somehow that they're buying from, or the producers or suppliers somehow provides them assurances that the product that they are purchasing has gone through and processed to control and eliminate to below a detectable level, *E. coli* 0157:H7. I thought that that would have been the responsibility of FSIS. When they put the USDA mark of inspection, should that not indicate that that product had gone through that required process, and that mark of inspection, it seems to me, could the producer of a raw product could rely on that, rather than getting a note or a letter from a plant -- and some of these letters are very generic -- and they're basically saying, we have an *E. coli* sampling program. In my opinion, that's the responsibility of FSIS inspectors, if they're allowing the market inspection, the public, including the further processors, should expect that that product has gone through these steps that are now required. And my final question goes to *Listeria monocytogenes*. And I just would like to know who determines, or is there a

way to determine what is sufficiency of testing frequency. How do you determine that? So you might have to -- I might have to repeat some of those, but you can start on them.

DR. ENGELJOHN: I'll give it a try. On the first issue related to *Salmonella*, really, but, in fact, could it have some impact on *E. coli* 0157:H7 policy, the Agency is, in fact, looking at the generic *E. coli* testing requirements that we have in the regulations today, which requires, you had noted, that all slaughter establishments must test product for generic *E. coli*. And we recognize that in today's environment, the establishments may, in fact, be producing product that is so clean, in the sense of generic *E. coli*. And I'll just remind you that the generic *E. coli* requirements in the regulation which it should with the pathogen reduction HACCP regulations in 1996, relate specifically to their find for fecal contamination. Generic *E. coli* was intended to do that. The Agency opted to test for *Salmonella* as an indication of process control. So for fecal contamination, generic *E. coli* is, in fact, our best indicator of the effectiveness of those procedures. We are, in fact, aware of establishments that may be using improper technique for finding generic *E. coli* on their products. We have, in fact, conducted baseline

studies using sponge methods and excisions in terms of having the information available about that level of generic *E. coli*. And the Agency is working on policy at this point, formulating how best to make information available to industry about the proper techniques used to sample for generic *E. coli*. One of the things that the CSO officers do when they conduct their verification activities is, in fact, look at how the establishments are conducting their testing. We, as an agency do, in fact, want to better ensure that when industry is doing verification testing themselves, that they are using methodology that will, in fact, be designed sufficiently to find the organisms if they're present, and use sampling techniques that will actually find the organism as opposed to using techniques that may not find it if it were present. So I think the overall issue of testing is one for which the agency is looking at now. There is a need for standardization of methodology, particular with regard to O157:H7, in terms of how frequently testing should be conducted by industry. That's something the Agency does not, at this time, intend to prescribe. I believe that when we get into the prescription of how much testing has to occur, that we need to be focusing on rule making as opposed to using our directives. Right now our directives are used

to provide instructions to our inspectors. We are looking at the types of programs available to industry today, and what is being done on the slaughter floor on trim and on grinding, and trying to get some idea of the confidence that's being built into those testing programs. So testing, in general, is something that agency's looking at. On your question about applying the mark of inspection on slaughtered product, going to grinding, and that that should be sufficient for the grinders, the issue with *E. coli* 0157:H7 is that that organism, if present, is generally present in extraordinarily low levels, and is present in a sporadic manner. It's not consistently present on carcasses, even when other indicators, such as fecal contamination, or hygeneric *E. coli*, or high total plate counts are present, it's not an assurance that 0157 would not be present. And we believe the data would support the fact that testing carcasses is not the most effective way of looking for 0157:H7. It's the same with trim. As the product is reduced in size and more surface area is exposed, the likelihood of finding the organism is greater. But the greatest likelihood of finding it would be in the ground product. So for that reason, the Agency has established the policy such that the slaughter operations need to have in place effective

controls, primarily through the HACCP Program, and have verification testing that would demonstrate that their control measures are effective. To that extent, the degree to which they conduct their verification testing may, in fact, provide greater or less confidence that if it were present, they could have found it. And that is the reason why the Agency established its policy in the October Federal Register Notice, to have and ensure that grinders purchasing product also conduct verification testing, that the products that they're purchasing are, in fact, meeting the specifications under which those programs were to be produced, and to have increased assurance that if, in fact, the organism was present, that through their verification programs, they may have the opportunity to find it and prevent it from going into commerce. So testing is not the most effective way to find this particular organism, it's a way to verify process control, or at least the procedures that are in place, and would remove high levels of contamination. But I think the focus on testing is what we're not able to use at this time, because of the sporadic presence and low levels of the organism. On the issue for *Listeria* -- I'm sorry -- what specifically was that?

DR. JAN: What -- who, or how is the frequency -- sufficient frequency determined for the testing?

DR. ENGELJOHN: Okay. When the Agency issued this final regulation, at the same time we made available compliance guidelines that are posted on our web pages, related documents. And I believe our intention is to make available to all small and very small plants in particular, a copy of this compliance guideline, which does, in fact, provide what the Agency would recommend in terms of control programs to meet the intent of the regulation. One of the regulatory requirements that we have when we produce regulations, is that if we establish some type of performance level that must be achieved by the industry, the Agency's obligated to provide guidance to industry on how to meet those regulatory requirements. And so we did issue a compliance guidance -- guideline, that does, in fact, identify levels of sanitary controls that we think are more effective than versus those that may be less effective, but in any case would meet the intent of the regulation. And the Agency identified levels of growth control for the organism, whether or not the organism is growing at greater than one log over the course of the shelf life, or with regard to post lethality treatment, whether or not that treatment is at a level that would effectively destroy any potential contamination that's present. And so in that guidance, the Agency put levels

such that if the industry was designing their programs to conduct post lethality treatment or growth inhibition, or sanitary controls that are verified at a certain level of frequency, than the Agency's intention or expectation would be to verify the effectiveness of those programs through its FSIS testing program. And then for those operations that exceed those minimal requirements that we believe are necessary for additional control, that the Agency then can focus its verification resources on those establishments that are doing less. So we establish what we believe are minimal requirements. And then within those, we identified what would exceed those minimal requirements to provide an incentive to industry to do more than what we think is minimally necessary, and to provide us with some means for focusing our verification resources. So I think we have provided that information within that compliance guidance. We will continually update that guidance as we receive comment or information that demonstrates that there are, in fact, other effective ways to control for *Listeria*.

DR. JAN: I looked at that guide you're talking about, but I don't remember if anywhere finding what would be considered an acceptable or a frequency that's sufficient that they have stated frequency of

testing for the sanitation procedures -- I mean, if they use alternative three, or they use the growth control in alternative two, they must explain the sufficient testing frequency, and that's -- I didn't see anywhere that they used any term other than that. And then, you know, who's going to determine between the industry and FSIS, what is sufficient. That's the question the industry's going to have.

DR. ENGELJOHN: And, again, the last page of that compliance guide, which does, in fact, identify those frequencies that we believe are, in fact, minimal, and those for which if they're exceeded, we believe provide additional enhanced verification control measures. The Agency did not mandate minimal frequencies, as it had proposed, because, in part, through the scientific support documentation that we were able to generate and to consider, we were not able to identify, except under conditions where there was continuous ongoing testing, that there would be a significant impact on reducing the risk for Listeriosis. There are, in fact, benefits to be derived, simply by mandating that there are written programs for which there are sanitation procedures that must be verified. We know that that is, in fact, providing some additional level of assurance that *Listeria* is being controlled.

So I believe the last page of that document does contain that specific information. Yes, we'll just go down to the end of the table here, Dr. Bayse.

DR. BAYSE: I believe Michael was next, if you would like to go first.

DR. KOWALCYK: Mike Kowalcyk, from STOP. I have a question regarding the *E. coli* testing, the monitoring procedures and record keeping. As far as the consumer safety officers involvement with this process, is there going to be continued working in these areas, especially with respect to record keeping? It seems like there's a lot of data that's probably getting lost in the verification process. Is that an issue that FSIS is dealing with?

DR. ENGELJOHN: Yes. I think record keeping is one of those areas for which we recognize a need to provide additional policy to the industry, but more importantly to our inspectors in terms of how to read and understand the data, and specifically to look at the data. Recently, the Agency issued a new directive, 5000.1, which contained new instructions to our employees in the filed, also in terms of how to conduct their daily inspectional activity. And within that documented, it does specifically address the issue that verification testing or monitoring data by the industry

is something for which our employees are needing to take more time to look at, and to seek it out, as opposed to waiting for the industry to just simply provide it to them. And so there are new instructions contained within that directive that came out quite recently. When the Agency issues its new directive on *E. coli* 0157:H7, the goal will be to provide additional guidance to industry on the types of records that are important to look at, and the way to present them. We understand that there's a need to provide instructions to our employees in particular as to how to interpret data. So record keeping is a focus that we have, in terms of a regulatory requirement. Establishments that rely upon data to make their decisions must, in fact, make that information available to the agency. And so we constructed our policy on *E. coli* 0157:H7, through the October notice, to specifically identify that if a prerequisite program is being used, and for which data is being used to verify its ongoing effectiveness, that it must be available in the support documentation, so that our inspectors can, in fact, verify the effectiveness that's there, demonstrated by that data. Yes.

DR. BAYSE: Yes, Dr. Engeljohn, I guess referring back to Dr. Murano's and Dr. Lee's comments

about scientific basis really for testing and evaluation, I noticed that there is an article in press, in The Journal of Agriculture and Food Science, indicating that at least from the -- that it's very helpful to use fluorescence as a measure of fecal contamination on a beef carcass. And it's essentially, you know, impinging laser light, and then the fluorescents from the chlorophyll breakdown products from the grazing. It's in press, you know, so we haven't seen the full article. But it seemed to me, at least at the level of the light to help the inspectors to have a rather fast and very efficient sensitive method for detecting the fecal material, at least at that point in this whole process.

DR. ENGELJOHN: Yes. Thank you for identifying that. The Agricultural Research Service here at USDA, in fact, conducted much of that research with regard to online or easy ways to detect whether or not fecal contamination continues to be present on product. There are a number of pieces of equipment that can look at the entire carcass versus smaller pieces, and they're hand-held equipments. And I think from the Agency's perspective, we are, in fact, looking into the issue of the potential for the use of those types of technologies that can better present information to the

Agency about the effectiveness of the trimming operations, particularly if fecal contamination is found and the industry is then obligated to remove that contamination and to prevent ongoing contamination, it could, in fact, serve as a tool for that. It's far more sensitive than a visual inspection. And it certainly would present new issues for the Agency as to the degree to which we could find fecal contamination, or in this case chlorophyll, that may be on the product. And because fecal contamination is believed to be one source of distributing adulterants or other contaminants on the product, it is an area that we're looking into in terms of the feasibility of the technology that would assist us more than just the visual inspection. One more question. Yes, Dr. Baldwin -- no, Dr. Carpenter. Sorry. But the...

DR. CARPENTER: David Carpenter, from SIU School of Medicine. Thank you for the update in addressing *Listeria* in the final rule. And I think that it's very commendable that the Agency had put a focus on the importance of this organism. Referring back to Dr. Murano's fourth goal in interacting with others in public health, when you consider soft cheeses, dairy products, is FDA mounting a comparable effort to warn consumers about the potential of *Listeria* in things like

soft cheeses?

DR. ENGELJOHN: Both FDA and FSIS are the two primary agencies that are public health related and regulatory in the sense of all foods. The FDA agenda, with regard to how it's handling its product, is one for which they're establishing. And I do not know the details to that, although the risk ranking that was conducted by FDA and FSIS in 2001, certainly did identify a number of FDA regulated commodities that served as relative risk factors for Listeriosis. And so I do know that that agency is looking into their policy development. I will say on the issue of public health and Listeriosis, the Agency is in particular looking at how it can better identify whether or not meat and poultry products, and at what point meat and poultry products are contributing to the overall burden for this particular disease. We -- although we have good information to pulse net and food net about Listeriosis and the prevalence of *Listeria* in products, or in clinical isolates, we still don't have a really good tracking of at what point in the distribution chain *Listeria* is, in fact, a more pronounced problem. So we're looking at how to better improve our finding of *Listeria*, and where better to apply control.

MR. TYNAN: Excuse me. If I can, in closing,

I think, Mr. Govro, you had a question, and maybe we can close it out with that.

MR. GOVRO: I have some questions related to the implementation of the interim final rule. Dr. Murano talked about wanting to make science-based decisions. And then her second point was about making sure that these were effective food safety programs. And in past meetings, we've talked about the directives that FSIS has issued, and some research that's been done about whether or not those are fully understood by the people who implement them. And I'm curious about what the Agency has done, if anything, or what it intends to do to make sure that the rules are enforced and implemented consistently across the country, what the timeframes for compliance with the rule are, and what types of enforcement will be taken to ensure that it's implemented correctly. Thank you.

DR. ENGELJOHN: *Listeria* is an ongoing issue for the Agency. And we have current inspection-drive tasks for the inspectors to pull samples of product for our verification testing program, as well as for verifying the overall design of the program. So on a daily basis, our inspectors are continuing to address the issue of *Listeria* through existing directives. The Agency will continue to look at those existing

procedures from now until the time the rule goes into effect. The rule will be effective on October 6, of this rule -- of this year, I believe -- yes, October 6. And so at that point the industry needs to have its programs modified and ready to address the new regulatory requirements. Having said that, we have several thousand establishments that are obligated to meet the requirements of this rule. And so through the new director that we'll issue in advance of that effective date, and where our goal is to have it issued at least 30 days in advance, but not be effective until the effective date, that we will have, by that time, conducted a sufficient amount of review with the District Offices, so that they, in fact, can ensure that the employees within their plants understand the procedures. We have a number of ongoing efforts that other program areas within the agency where we'll be looking at to see how we can ensure the effectiveness of the implementation. Part of the reason why we issued an interim rule with an 18-month comment period, is so that we, as an agency, would commit to designing a mechanism to study its effectiveness. Whether or not it's being understood, whether or not our employees are, in fact, understanding the instructions that they have, and whether or not the industry is applying the requirements

of the regulations in the way that they're intended. So there will be a number of activities throughout the course of the 18 months, to study the effectiveness of the rule. The directive, however, we'll issue in October, and will set forward new instructions for how we will conduct our verification.

MR. TYNAN: Thank you. If there are other questions, I think Dan has a commitment back at the office, so I don't know if you'll be able to stay. But perhaps during the break, if there's any additional questions, we could use that time to talk with Dan a little bit further about some of the issues you may have. What we were planning on doing is having the speakers come up here to the lectern, but in this particular case we're going to make an exception. We have actually two for the price of one. We have Mr. Ronald Hicks and Dr. Jane Roth -- I apologize for putting the wrong thing on your sign -- to talk a little bit about state review methods. And Moshe Dreyfuss from my office, is going to work the computer so that we'll get done, as opposed to me doing it. I'm technologically illiterate.

MR. HICKS: Good morning. There's probably one just very fundamental basic key reason why I'm sitting here and not up at the lectern. And that's

because the computer's there. And as most people know, it is best that I be here or most of what's up there will be -- it was just disappear. So before I'm even asking, people offered to do this for me. So I appreciate that. Good morning to all of you. It's good to be here. I want to talk to you a little bit about currently there's a study that the Agency's doing of the review of a State Meat and Poultry Inspection Programs. Jane Roth is here to help me present this issue to you. The primary purpose of the review is to update and strengthen FSIS's policies and procedures for reviewing state meat and poultry programs. As it's been indicated, the Agency is doing a lot of work in terms of looking at various programs from cross agency lines. And this is one of the areas that the Agency feels is important to take a look at this time. There's an office of PEER Programming Evaluation Enforcement and Review. It's a newly formed office, as a result of the recent reorganization within FSIS. What it does is it combines the various review, audit, and evaluation functions that currently existed in different parts of the Agency, along with the two enforcement parts of the Agency that deal primarily with outside of the plant, and puts all of those into one office, under one leadership. There is quality assurance for the

administrator. Dr. Murano indicated in her opening remarks that one of the key goals is to ensure effective management of Agency programs, and having that function reside in the administrator's office helps perform that function optimally. There were reviewing and evaluation functions, like I say, in other parts of the Agency before. What this does is just expand the use of it, and makes it more visible, the use of those functions. It provides objective information for and about FSIS programs. It looks at root causes, identifies root causes of problems in particular program areas, and looks for agency-wide solutions, in terms of how to deal with those problems. So that's what this office of PEER is striving to be about. Two of the key components within PEER is domestic reviews and foreign reviews. We also have Royce Sperry, from our Omaha, Nebraska office. I'm happy to see that Royce was able to make it in this morning. I understand there were tornadoes out in Nebraska yesterday, so I was glad to see that he was able to make it. But the Office out there, which is headed up by Don Smart, who many of you may know, is primarily responsible for domestic and foreign reviews. And that office reports to PEER. And some of the factors that are driving this study, the 2002, Farm Bill mandate, which asks the Agency to determine the

effectiveness of state programs, and context of interstate shipment, the HACCP Final Rule that was implemented back in 1996, and the director that governs or deals with the state reviews precedes that. So it's critical that we take this opportunity now to, after implementation of HACCP, look at how we do state reviews to try and make sure that we are consistent with the HACCP rule, increased need for -- to protect food supply with the bio terrorism events over the last few years, as well as the recent concern with BSE. It's critical that -- not just with state programs, in this case concerning state programs, that we take a look at the procedures and methodology that we utilize to assess the state programs, and also just to incorporate the input that we've gotten from this group last year, I think it was in May. And in November, we got feedback for the advisory committee dealing with the review of state programs. So we need to put that into some kind of manual and to a directive, and to some strong, good guidance for the Agency and for the state. So those are some of the factors driving the study. Some of the recommendations that came out of the advisory committee meeting from last June, you can see there, is that the committee asked that we assess all the reviews, summarize the reviews from 2000, on, to see what the

trends were, what the -- may be, and what some of the problems might be. We were also -- it was also suggested that we look to see if we can get an extension of time. The Farm Bill indicated a timeframe by which we would complete this review. And the committee suggested we get an extension of time to conduct the review, and that also we seek funds to maybe contract out to review this process. The recommendations also asked that we ensure that there's uniform compliance between the federal and state programs, asked us to look at deficiencies that may exist within the programs, to develop better guidance so as to trying to show that we'll reduce problems in the future. FSIS offers training for a variety of people. One of the recommendations is that we allow state staff, participate and be part of that training. And lastly, it requires stage to adopt federal regulations and implementing policies. So those are the recommendations that came out of the June 2002, advisory committee meeting. In November, the committee met again. And much of the discussion in that meeting centered around a document that was prepared by Ralph Stafko, and who was working with the committee and some of the state directors. And the document was perceived this way, evaluating State Meat and Poultry Inspection Programs.

And some of the recommendations coming out of that meeting were that the Agency should take samples of product produced by state establishments, clarify documents needed for self-assessment, and on site reviews. There was concern as to whether or not there was consistency and clarity with the documents that were being utilized for those -- the two aspects of the state reviews, allows states to participate in training. And this training is primarily consumer safety officer training and district veterinary medical specialist training. To make that training available to the states, and also advocate it right in a new directive for oversight of states as soon as possible. What the Agency is doing right now in terms of the review of our manual and the processes address these recommendations as best as we can. FSIS's response to all of these is that -- is the following: We have an agency-wide participation in terms of looking at how we review our state programs, Office of Policy, Office of Field Operations, Office of Management, Office of Homeland Security, and other parts of the agency are all involved and have provided input to us in terms of how we should be going about looking at state programs. We developed a new two-part review manual, which goes over the methodology for how we should be conducting our state

reviews. We've met twice with state directors, once from the eastern part of the country, and then most recently with the entire group of state directors, met with them to get input on the manual, get their concerns and feedback. And it was a good two-day meeting, I think. We heard a lot from the state directors about their concerns about what they needed from us. A lot of it also centered around the need to strengthen relationships with the Agency. So while that's not part of the manual that's being developed, it's obviously part of what we see as important and critical to the overall success of how we go about this process of reviewing the state programs. And we also need to get input from the advisory committee as to how we should proceed, input as to how we can improve enhanced methodology about which we review state programs. So what I can do at this time is to ask Jane Roth to walk you through some of the key components of the manual that we're now developing, and answer any questions that you may have.

DR. ROTH: Ron has provided a good background to where we are today in terms of working on improving the way that we review state programs, and ensuring that State Meat and Poultry Inspection Programs are at least equal to the federal program. What we have is a new

manual and methodology. They mirror each other. There are ten review components. The review components were chosen to cover all the main aspects of the Meat and Poultry Inspection Programs. They are comprehensive, and mutually exclusive. They start with the statutes and the laws, and they work their way all the way through civil rights and financing and accounting. And there are two parts to the manual, the same two parts that are involved in the review methodology. Each part is organized by the ten review components. The first part of the manual is the self-assessment checklist. It is an opportunity for the states to demonstrate at least equal to, that they show that they meet the federal requirements. The second part of the manual clearly lays out how the onsite review process will be done. The states receive the entire manual, so the process is transparent. They are responsible for completing the first part of the self-assessment checklist, but they will also receive the instructions that go to the reviewers as well as the instruments that the onsite reviewers will use. Now let me go through the ten review components. The first review component covers the statutory authority and food safety requirements. Statutory authority is the Federal Meat and Poultry Inspection Acts, and then all of our food safety

regulations. The second component covers inspection, which is actually the implementation and carrying out of the first component. The third component is titled, Product Sampling Requirements. By that we mean the labs, facilities, equipment, sampling, protocol. The fourth component ensures that the State Meat and Poultry Inspection Programs have staffing that's adequate, at least equal to the federal staffing requirements. The fifth addresses humane handling. The sixth: other consumer protection that is the non-food safety areas that deals with nutrition labeling, products of identity, and so forth. The seventh is enforcement regulations. Eight: training requirements. Nine: funding and financial accountability. And, finally, the civil right requirements. Again, all State Meat and Poultry Inspection Programs are reviewed. We use both the completed checklist and the submitted documentation that we received from the states. And then we conduct the on-site reviews. All of that together helps us make the judgment to support the at least equal to determination. Let me continue by going through the first tier of requirements. What we've done is we've looked at the Meat and Poultry Inspection Acts, and we've determined that the first seven review requirements actually require the states to have at

least equal to criteria. We call these seven the first tier of components. And these are the Federal Meat and Inspection Act, and the Poultry Products Inspection Act require mandatory anti-mortem and post-mortem inspection, re-inspection, sanitation requirements, record keeping and enforcement provisions. All of these components, the states will be required to have laws and regulations that are at least equal to the federal. The second tier is the remaining three review components. We also have strict review criteria. But we have made the determination here that the Meat and Poultry Acts themselves do not require at least equal to. So for training what we're requiring is that the states have adequate training to ensure that inspection personnel has the knowledge, skills, and ability to perform inspection. They have to demonstrate that their training program results in inspection personnel who can apply the inspection methodology, according to the regulations or the directives, make decisions based on the correction application of inspection methodology, document the findings, and implement appropriate regulatory action. For the ninth component, funding and financial accountability, there are a number of documents. There is the FMIA and the PPIA, which do lay out certain requirements. There is also the directive

33,000.1, which provides guidelines for budget submission. And then there are two additional guides which the states have been using, and we ask that they continue to use to meet the review criteria. And finally, the Civil Rights Requirements, those requirements come from Title VI, as well as other federal laws and department regulations. So these three areas, the states will be reviewed. And we will look at these to ensure that these three areas support and at least equal to state program. But if you turn, earlier we mentioned there are two parts to both the review manual and to the actual review that the federal government does of state programs. Once again, the first part is the self-assessment. Each of the ten components has its own checklist. And we ask the states to go through each part of the manual, and to support -- and to provide supporting documentation based on the requirements that are laid out in each of the respective sections. For each of the ten sections, we have the criteria of which I just went through. We actually list the relevant documents, whether they're regulations, directives, or guidelines that the states need to review their program against the federal. And then we suggest outcomes. So we're looking for the states, in their supporting documentation, to provide documents that show

that they are at least equal to, as well as that they are following what is written on paper. The documents that the states support, that they provide to us, are reviewed closely by FSIS staff to verify that the state program is at least equal to. And their supporting documentation is used as the basis for the second part, which is the on-site review. So the second part of the manual, as well as the second part of the FSIS review process is the on-site review. This is where the FSIS review team goes out and verifies that implementation in the respective states are occurring as the documents state. There is an FSIS team leader who coordinates the team from start to finish, the interdisciplinary team of individuals who have expertise in all of these subject matters. The on-site review begins with an entrance meeting with the states. There are a sample of plants and laboratories which are selected from an established statistical procedure that we use when we go over and visit foreign countries. We'll be using the same statistical table for determining the number of plants that we visit. The review team will visit those number of plants, using the standard methodology laid out in the review manual, using the instruments that are part of the review manual. This will ensure a uniform implementation, consistency in all the reviews that are

done. At the end, similar to the way that foreign reviews are conducted at the exit conference, there will be a PowerPoint presentation made by FSIS reviewers. This is one of the things that the state directors asked in the June meeting, that they do receive some written -- some type of written report based on the review. And, finally, these on site reviews can take anywhere from several days to several weeks. And that, of course, depends on the size of the state, which would then dictate the number of plants that we would be visiting. The next slide. Finally, there are two types of state reviews. What we've been talking about here is the initial state review, which closely mirrors the initial equivalency determination that the Agency makes with foreign governments. It has the two parts that we've discussed here, the self-assessment checklist and the on-site review. Once the initial state reviews have been completed, the states will be reviewed annually. The annual reviews will continue to have two parts, the self-assessment checklist, asking the states to continually update as necessary their supporting documentation, and the on-site reviews, which will be conducted as needed, as resources allow, and as policy dictates. So once again, the two parts to the review process which we will be involved in for both types of

state reviews. So this ends our overview of the state programs and the manual, and provides some background for the subcommittee that's meeting this evening. What I'd like to show you with the next slide are the two questions that we're going to be asking the subcommittee to address. The first one is what does at least equal to mean with regards to state program requirements? And the second question, how best can FSIS make review determinations of each of the ten review components? And then just the last slide, if anyone has any questions for Ron, Royce Sperry, who is our expert of both the state, the domestic, and the foreign reviews, or myself. Irene.

DR. LEECH: I'm Irene Leech. I understood you to say that you use the statistical table to decide how many plants to inspect. How do you decide which ones, and do they know that the inspectors are coming? What's the setup there?

DR. ROTH: The table is an established table that we've been -- that the state reviews have used. And the state -- and the plants will be randomly selected based on the table. Royce is here. He can answer specifically. But the plants do know.

MR. SPERRY: In the past, when we've done state reviews, we had to notify the state directors that

we were coming, but had not given them a list of plants until we arrived to their office. We have found in foreign audits, also in federal reviews, that giving the list of plants ahead of time makes a little difference. But the plants are selected by computer randomization before we go.

DR. ROTH: Lee.

DR. JAN: You mentioned -- one of the earlier things you mentioned, that the Farm Bill was one of the driving forces for changing the whole review process. And I just wanted to make a comment regarding that. The Farm Bill only requires a full review of state inspection systems. It does not imply that a new methodology should be used, or that FSIS could not use the results of past comprehensive reviews, which this committee suggested in a previous meeting. But the Farm Bill also recognizes that the goals of providing a safe, wholesome, abundant, and affordable supply of meat and meat food products, could not be met in the absence of viable state programs -- State Meat Inspection Programs, that help to foster the participation of smaller establishments in the food production economy. And that comes from the Farm Bill. FSIS -- my point is that FSIS does not have to wait for congressional action to change or mend the federal acts that would -- that are

currently prohibiting interstate shipments of state inspection product, because that's what the Farm Bill was all about anyway. They want that report from the Secretary. The Agency can act immediately to ensure state programs, continue to survive and provide that environment conducive to the survival and growth of small plants by arranging or changing the funding of inspection of TA establishments. TA establishments are federal establishments. They're generally small establishments that have actually graduated from a state inspection program to an -- so they can go in interstate commerce. They are federal programs, but they're inspected by state inspectors. Currently, those are funded 50 percent state, 50 percent federal. If those were funded 100 percent federal funds, and allow all state programs to participate, than that would help ensure the survival of state programs that would allow more small plants the opportunity to ship in interstate commerce, and it would eliminate the objections of the critics of state inspection programs because there would be no equal to. It would be a federal plant. So I think if FSIS seriously looks at the changing of funding, the issue of state inspected product going across state lines may become a moot issue. So those are my comments.

DR. ROTH: Thank you.

MR. GOVRO: Yes. Mike Govro, Oregon. I have two questions. How many State Meat Inspection Programs are there currently?

DR. ROTH: 28.

MR. GOVRO: 28. And could you please elaborate a little bit on review criteria number eight: training. How do you determine that there -- that the training is adequate to ensure inspection personnel have adequate knowledge, skills, and abilities to inform inspections?

DR. ROTH: That's an interesting one. That's one that the state -- you are a state director -- were particularly interested in. What -- it's pretty much what I said. We want to be certain that the states have personnel that can carry out the responsibilities in an equal to manner, that they can ensure that the regulations and the directives are being implemented properly, and that appropriate regulatory action is taken. At the state director's meeting in June, there was a lot of concern that we were -- that the Agency was requiring that state directors actually attend FSIS training per se. And there was concern among the state directors that we hadn't provided enough space for the -- for them to do that. Bill Smith heard that, and

talking to, I think, Phil and Bill -- Phil Derfler and Bill Smith, the Agency is making an effort to open up the food safety regulatory essentials training to states. And also, I think that this initial review, we are not requiring states to have FSIS certified training, but to show that they have training at least equal to, that covers the areas that are being covered in the food safety regulatory essentials training. And we plan to share that material with the states.

MR. GOVRO: Was the evaluation of the training or of the effectiveness of the training -- that is with the personnel and how they actually perform their duties?

DR. ROTH: What we would -- what we have in the manual is examples of what the states can provide paper-wise, in terms of documents, which would be course syllabuses, attendance in the training, any tests that were given at the end of the training. How successful the training is would be demonstrated during the on sight and the actual carrying out of the regulatory activities. We really are working quite hard to be logical, to make sense in what we're doing, and not to be a prescriptive. Kevin.

DR. ELFERING: Yes. Kevin Elfering, from Minnesota. I think one of the things that we really

need to look at is whether or not equal to is a mirror image. And I don't think it is, because I think there's a lot of different approaches to end up with the same result.

DR. ROTH: We totally agree.

DR. ELFERING: And I think one of the concerns that may come up are trying to shape state programs into being a mirror image of FSIS. And I think some of the issues that are brought up are, for example, staffing. And we feel that we have adequate staffing, but probably maybe look at ourselves as using efficiencies. For example, in the Minneapolis District Office, there's a District Director, two Assistant District Managers, there's a Humane Handling Specialist, there's a Processing Expert. You have Consumer Safety Officers, you have In Distribution Inspectors, you have Circuit Supervisors, Area Supervisors, and Inspectors. In the state program you have a Director, a Supervisor, Compliance Officer, and an Inspector. And I think the channels of reporting work out even more efficiently in that regard, where we probably are a little bit more efficient. Now some of the areas we're staffing, there's no way that state programs would be able to put in the amount of staffing that FSIS has. What we need to be looked at is whether or not the final result is

the same in producing safe, wholesome product.

DR. ROTH: The manual -- the objective of the manual is to do that. We are not asking for same as. We're talking at least equal to, and we're focusing on the outcome.

DR. ELFERING: And I think you'll also hope recognize that many state programs do things quite well. And I think you'll see that sometimes the state program does things better than the FSIS. And I think that you'll see sometimes FSIS does things better than the state programs. But, again, end results.

DR. ROTH: Yes. We agree. Lee.

DR. JAN: Thank you. Lee Jan from Texas. And I'm on the committee that's going to meet tonight. So I would like a little information that might help us with number one, and that would be what is the type of reviews that are done on federal programs, domestic federal programs -- inspection? Is there a review process? And where are they? Where are the federal inspection programs, the different districts, so that we can at least know what we're supposed to be equal to? Is there a review process for them, and what's the result?

DR. ROTH: Are you saying -- do you want me to talk about that now, or do you want to talk about that

for this evening?

DR. JAN: Well, we can talk about it either time. But I think that's going to be critical for us to try to decide what is equal to, because we don't know what the status of FSIS inspection is.

DR. ROTH: Okay. We'll talk about it this evening. Joseph.

MR. HARRIS: Yes. Joe Harris. Just a quick question on timing. What -- and I probably missed this from the presentation. But what is the timing on implementing this? Are we still developing the procedures, or is this already being implemented? And if so, what is the timeline for completing the state reviews?

DR. ROTH: We are in the process of continuing to revise the manual. We will be sending out another draft manual to all the state directors, July 7, which will give them another opportunity to respond back. And we plan to conduct the initial onsite reviews of a certain number of -- in a certain number of states in the fall of this year. And then as resources permit, we'll complete them all. Any other questions? Thank you.

MR. TYNAN: If we don't have any other questions related to the state review, I think the next

major item on the agenda is a break. Okay. Why don't we just add a little time? See if we can't come back at 11:10 promptly, so that we can get into the next topical area. And there's coffee, Cokes, and so on outside.

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[Off the record]

[On the record]

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MR. TYNAN: 11:10 is the Center for Learning's Dr. Karlease Kelly. And she's going to talk a little bit about the delivery of training. Karlease.

DR. KELLY: Thank you, Robert. First let me say I'm happy to be here. This is the first time I've attended a meeting of this committee. I've had the opportunity to meet a number of you, but I see a lot of new faces as well. So I look forward to having some conversations with you, probably more after this, as we stimulate some thought and some input. And I was reviewing some input that the committee had provided last November, when I was -- after I got into town last night, and realized that this committee has had a significant impact on the future direction for training and education in FSIS. So as we walk through this presentation, I think those of you who have been on the committee previously will see a number of ideas and

input that you had provided us in the past that we are beginning to move and to act on these things. So the first thing that I want to -- the first point that I want to make in our second slide here is the main thing that's really driving us today in training and education in FSIS is the vision that the administrator has set forth for the Agency. And if you're not familiar with this vision, it's something that you do need to become familiar with, which is to become a world-class public health agency that's a model for other public health institutions. And that's really only a few words. But when you start to think about what it means, it's a tremendous challenge, a tremendous opportunity, and as I said, it's really the thing that's driving us forward with the future for training and education in FSIS. If we look at the next slide, what we see there is that we've got a couple of strategies that relate to the people aspect in FSIS that we need to focus on to make it possible to achieve this vision. And one of those is improvements in recruiting, which we're not going to talk about today. But I think the committee has recognized and provided input in the past on the need to raise the educational level of incoming employees. And FSIS is taking some steps in that direction. But the second strategy there is the one that we're going to

focus on and have some conversation on about today, which is improvements in training and education of our current employees. That, actually when you think about it, is a tremendous point of leverage for change in an organization, when you improve training and education for your current employees. So as Dr. Murano said this morning, and you probably have heard Dr. McKee say in other speeches, training and education is a priority in FSIS. And as we go further, you'll begin to see that more clearly. Just a little bit more background on this vision. The vision is consistent with President Bush's management agenda, which calls for the strategic management of human capital and performance based budgeting. We are going to link our plans for training and education with budgeting and strategic management with this vision, which also, by the way, links with Dr. Murano's priorities. Also, FSIS needs the strongest return for its money when we're developing the human capital in protecting public health. Just like the majority of us we all have limited resources. And what we're trying to do is make the best advantage we can take for those resources. And we have all of that in mind in our plans for training and education. The next couple of slides we'll walk through, basically show you a little bit about our workforce. The most new

occupational group in our workforce is the Public Health Commission Corp Officers. I believe that currently we have 11 of those in the Agency. And we have plans to bring more of those on board soon. These are people who in other parts of their career, have had an opportunity to have probably as part of a retention access to training and education. So we're going to have to keep that in mind if we want to attract and retain this type of individual in the Agency. Most of you are also familiar with another occupational group that's fairly new to FSIS, which is our consumer safety officer. That number is currently 132. And I believe that it will be growing in the future. We do have special training and education for that group. We need to ensure that that group's training and education needs, initial training and education needs are met, but also that there is some kind of follow on training, as they mature as an occupational group within the Agency. We also have 226 compliance officers. Some of you are familiar with the fact that organizationally, we have compliance officers in PEER, as was discussed earlier, but we also have compliance officers in field operations. So we need to consider the different types of duties that these different types of compliance officers have. And we need to make sure that the training and education needs

of that group are met. We have 1,080 veterinary medical officers, the majority of whom are in our field workforce. We also have VMO's who work at a headquarters, and also in different types of job duties other than the inspection type duties. We've had some major studies underway in the Agency, looking at training and education for this particular group of people. We also have a task force right now that's looking at redesigning training for entry-level veterinary medical officers. The bulk of our resources in human resources, are devoted to the Food Inspector, which is an online personnel, and our Consumer Safety Inspectors, which is the off-line personnel sometimes referred to as the floor aids and the processing inspectors. We'll go to the next slide that shows that we do have some other occupational groups, particularly in the laboratories and in our Office of Public Health and Science, as well as other officers in FSIS. We have chemists, microbiologists, program analysts, we have pathologists, so we have a huge diversity of occupational groups, each of which has their own specialized training and education needs. In the next slide what we'll see is some of our challenges, which I know most of you are very well aware. We have a highly disbursed workforce, a large number of people spread out

over a large geographic area. That is particularly challenging to train people in that kind of setting. There's no way to get these people together quickly, and easily, and timely sometimes. Another challenge for us is to keep pace with emerging science. We've got emerging policy issues. And people need some kind of training. They need some kind of dialog, in some cases, about some of the changes that are occurring, so that they can keep pace with emerging science. And we combine that with the geographic challenges, it's fairly daunting. Also, the challenge of raising the bar for training and education is to evaluate the training programs themselves to determine that they are effective, that they are on target, and that the content that they have is effective. And then also, testing our students to determine that they have learned what they need to know, that they have mastered the content of the training. So those are some of the challenges that we're looking at. In our next slide, what you'll see is about a year and a half ago, recognizing all of these things, FSIS established the Center for Learning, which manages all training and education for FSIS. Prior to that we had several organizational units. And the management of training and education function was fragmented. But the Center for Learning has brought

some cohesiveness there. The Center for Learning also coordinates agency contracts for training and education. We're also developing an annual plan for training. And we're conducting strategic planning related to training and education. Our next slide shows that current situation, which many of you are quite familiar with. Right now we have primarily one training provider in one location. We may have some smaller contracts. But predominately, we have one large contract, and we have one location where students go to receive training and education. We're encountering a lot of high travel costs. I know a lot of you have seen that lately. The travel costs have really gone up immensely. Having everyone in this geographically distributed workforce go to one location for training presents some challenges, because people have more time away from the job that has to do with training. We also have difficulty in filling our classes at this one location, and covering assignments at the same time. So we've been having a problem with our fill rate of the classes. And most of our training is classroom based. So when you start looking at that large geographically distributed workforce, and going to a classroom at one location, you see we have really -- it's like a bottleneck problem. We can't train people fast enough with this process to

address some of the emerging issues. So here are some thoughts that we have about the future for training and education, some things that we believe will help move us toward that public health vision that the administrator has established for us. First of all, we want to strengthen the knowledge and the skills of our workforce so that they are more consistent with the public health goals. Also, we need to ensure the training is flexible, so that we can respond to the emerging needs. That's absolutely essential. Also, making training more accessible, and what that's going to mean is some of the things that you have suggested in the past is to provide training through alternative means besides the classroom training. Sometimes classroom training is absolutely essential to master concepts. But sometimes things like video teleconferencing or commuter based training can help make training more accessible to that geographically remote workforce. So with all of those things considered, we're proposing six strategic goals for training and education. And these are some of the things that we would like to have your input and feedback on. So let's walk through those one at a time in a little bit of detail. The first goal that we have is to strength the public health, scientific, and technical skills of the workforce. And I believe that

is something that this group has told us would be beneficial. For example, some of the things that we have as strategies to help us accomplish this goal are to provide some updated advanced education programs that lead to certification and credit. We have had programs in FSIS, education programs in FSIS that were scientifically based. However, in the past we haven't really focused on providing programs that lead to education degrees certification. We've done more -- you might call a one shot kind of approach to training and education. So this is more of a program approach that we're talking about. A second strategy that would help us accomplish this goal is to provide some updated HACCP training. And we've already begun to implement that. How many have you heard of the Food Safety Regulatory Essentials Training, the updated HACCP training? That is essentially what we're implementing there. We train about 400 people. And beginning July the 11th, we did hear some input, some requests that we open the doors so that states could participate in this training. So beginning July the 7th, actually, states will begin to participate in this training that's designed to strength public health, scientific, and technical skills of our workforce. So we'll be sharing that with states. We're also going go be working on addressing the training

needs of the new types of employees, as we said, such as the CSO's, such as the public health officers; not just their needs as they come on board, but their needs as they advance in their career. I just want to backtrack for a minute about the updated HACCP training. There's something I wanted to share with you about that, that I didn't want to pass over. One of the things that we worked into this program is we provide a pre-test and a post-test to measure the learning that is taking place during training. And we are also evaluating -- we have plans to evaluate the application of the training on the job. So after people have completed the training, they go back. We intend to find out, are they applying what they've learned in an on-the-job setting? Okay. Let's look at our second goal. Our second goal is to enhance the ability of a workforce to protect meat, poultry, and egg products from intentional harm. And most of you would recognize that as a goal that links up with Homeland Security. Right now we're in progress of providing bio-security training to our field workforce and to headquarters. And I understand at least one of you, Dr. Jan, has participated in some of this training. Has anybody else participated in any of this training that FSIS is providing? More than likely, some of you may be invited to participate in this training, as it

rolls out across the country. Right now we've got two initiatives that are ongoing. One is to provide specialized training to district offices. And that's the training that Dr. Jan participated in. We also have some training at the in plant level, where people in plant settings actually participate with FSIS in the training that will be occurring. We have done some import liaison surveillance inspection training. And as that program matures, we'll continue to provide that training. We're also making efforts to incorporate specialized animal disease topics into VMO training. And those are just some examples of the training that is ongoing. So that's our second proposed goal. Our third proposed goal is to make training education accessible to the work site. As I mentioned, this will help to resolve that bottleneck problem that we have. Because with 8,000 people out in the field, it's just not possible to be brining them to one location for all of their training. We're taking steps right now to implement a strategy. It's one that was recommended actually in November by this group, and by a number of other groups as well. And that is a regional approach for training. In other words, we're going to take training closer to the work site. We are going to send trainers to regional locations rather than have people

come to where the trainers are. We're going to have the trainers go to where the people are. So that's a big change for us. And, Moshe, if you want to just go ahead to the next slide. This is sort of a graphic to represent that we're going to be going to where the people are. We don't have a lot of specifics developed on this idea, but we are moving in that direction. There's a lot of details to be worked out about that. But that is the direction we are moving in. Can we go back to the fourth slide? Okay. Thank you. Another strategy that we're working on to implement this goal is to train entry-level employees within their probationary period. I think a lot of you have heard -- and this is a chronic problem that we've had with difficulties that we've had in maintaining staffing levels. In some cases people are not trained within their probationary period the way that we'd like to see them trained. So one of the models that we're considering is to move that training that we provide to employees as close to the point where they enter on duty. That way we provide them with their basic skills training with training on professionalism. We get them started outright. We get them on a track that's much more effective than if they have to go on the job, kind of learn catches as catch can and then come back and learn the way they're

supposed to learn in the setting later. So we're moving that training closer to where they enter on duty. It will also allow us to perhaps weed out the people where, you know, in some cases this is just really not the appropriate job for them, and we can do that much quicker in that sort of setting. So I think there's tremendous leverage with that approach. Last but not least, we're looking at computer-based training. And that, by saying that, I want you to think about the full range of any kind of electronic based learning. It could be online learning with the web. It could be video teleconferencing, it could be some kind of CD-ROM or video DVD that we're using, computer based training of some type that we're going to provide to employees. Those are the things the Agency has purchased recently, a new and upgraded video teleconferencing system. So we're going to be piloting some training in that mode in -- within the next three to six months. So you'll see more in that arena as well. Okay. Our fourth proposed goal is to improve training for managers. This is an area that we feel is very important. We have a number of managers in FSIS. Most of them have been promoted from technical ranks, and need some management training skills. This is also an area that Dr. McKee has told us we need to pay more attention to. It's to improve our

training for managers and supervisors. One of the things that we're -- we have plans underway to do is to update courses for our frontline supervisors. We have some frontline supervisor training. But we intend to have a much broader range of kinds of topics that will be covered. We also intend to do some rotational assignments, which give people a broader view of the organization, and help them really understand things from an Agency point of view, rather than a program point of view. We have a Leadership Assessment and Development Program that we plan to expand. That program gets 360 degree feedback from peers, from people reporting to that individual, from supervisors. It provides people with feedback about how they're doing, and gives them some suggestions for how they can improve. And we're also going to coordinate our management training with our succession planning. And if we look at the next slide, what we'll see is that we -- succession planning is something that the Agency really, absolutely has to engage in. More than 55 percent of our FSIS leaders, supervisors are, we'll say, eligible to retire in 2005. And that goes up to 70 percent in 2007. So there's a lot of institutional memory, institutional knowledge that we might stand a chance of losing if we don't try to do some kind of

succession planning. We may find ourselves in a situation where we have a lot of people filling positions who don't know agency business or understand some of the complexities, some of the nuances that are really important to make key decisions. Succession planning is going to include training of qualified replacement candidates. And our goal is to have some kind of a seamless transition, so we don't have real gaps to fill in times where it's very difficult to recruit people, but not a lot of people filling those positions. And, in fact, I believe that it's this week that we're launching our management council that's going to look at succession planning. So we're already moving in that direction. The next slide shows our fifth goal, fifth out of six, six goals, and that's to maintain and improve the training infrastructure. With all of these changes going on, we have to make sure that our infrastructure is functioning effectively, that it has the kinds of changes that need -- it needs to be able to support these goals. One of the things that we're going to begin working with seriously in earnest within the next several months, is to work on policies and procedures to make training a condition of employment. And what that means is to set in place policies and procedures such that if a person fails training, be it

some kind of performance or job audit after the training, or some type of test that they take when they complete training, than they cannot actually be deemed, I guess, competent, to perform the duty of the position. So that's where we're headed with that, so that people must pass the training. It puts a certain burden on the training. The training has to be one that's job related. It has to be clearly have clear goals and objectives that are linked to job competencies. But we believe this is really important in having a successful training program. Testing employees, we talked about that. We may be testing them for their content mastering, we may be doing a job audit when they return to the job to see that they can apply those skills. Conducting needs assessments, that's another thing that's a very important part of maintaining the training program. Dr. McKee has created a training and educational working group, which is sort of the roll up your sleeves and get the job done group, as opposed to the training and education steering group, which is more of the oversight and general policy direction for training. But the training and education working group is in the process -- we just initiated the process of doing a needs assessment in thinking about our training for 2004. We know that we already have a budget that

has been proposed for 2004. We're trying to ensure that the needs that we address for 2004, are needs that are linked to the strategic plan and to the budget. So we are going to do that kind of activity. And also we have to evaluate training. We have a lot of different approaches to doing that. But we probably need to make it more systematic, maybe even consider sometimes in some cases a third party look at our training, because that might help us drive us towards better improvement in that area. Our last goal that we're proposing is to respond to emerging and specialized needs. So in other words, it's to plan for the things that we can't plan for. Because there are always those things, and it seems like those things sometimes take a lot more energy than the things that you did plan for. For example, we are planning to address specialized groups, such as products which you'll hear later about this afternoon, you'll hear some more about. Foreign government officials, any group that has some kind of specialized need or merging need, maybe an occupational group that is emerging. Also, we are working on some strategies to quickly develop training programs to support new policies and procedures and regulations. We heard this morning about some emerging policies. And training is going to have to be linked to those. So we are working

on strategies to do that quickly and effectively. So to kind of wrap it up and bring it to a place where we can discuss, first lets talk about some recent accomplishments. The Center for Learning has just recently, in March, the administrator essentially reorganized so that the Center for Learning does now report to him. And I believe that that has clearly sent a signal that training and education is a key priority in the Agency. We have, as we mentioned, initiated updated HACCP training for our field workforce. We have initiated anti-terrorism training to the districts that we talked about earlier. And also, we've initiated professionalism training for our field workforce. We also have a Memorandum of Understanding with the Public Health Service. And that Memorandum of Understanding has been bringing to us the Public Health Commission Corp Officers that we talked about earlier. So we are also exploring some opportunities for joint training with industry. These are some things that we seem to be asked for continually. We understand that we're going to have to do that in the proper context because they're, you know, there's always the concern about the conflict of interest, and also a concern for us about effective use of our resources. But for example, just to give you a flavor for some steps that we're taking in

this direction, we have started to work with Dr. Kerry here, as the International HACCP Alliance, so that we can provide training materials to the International HACCP Alliance, and they can distribute those materials to industry groups so that they are accessible. And we're also working on posting the training materials on the FSIS website. And that simply makes them available to anyone who would like to have access to those training materials. So you should see those in the -- within the next month or so. But particularly what we're working on currently is training that seems to be of most interest to a lot of folks, which is the Food Safety Regulatory Essentials Training. We're also making plans to work with states on joint training effort. As we mentioned earlier, the Food Safety Regulatory Essentials Training is going to be opened to state participation beginning July the 7th. And we will continue to maintain slots in the FSIS training for state participants. But we're exploring those areas. So that would be an area that we probably would like to have some input from you on. Just to wrap up and to show you that clearly we are going to see some changes in training and education, and that training and education is definitely a priority, our current contract for training which is $5.2 million, which actually is

1.5 for our field automated information management training, our computer training for the field, and $3.7 million for training and education. That contract expires at the end of FYO-3. It's actually a one-year extension of that contract. That will be expiring. And for fiscal year '04, the Bush Administration has requested an addition $5.7 million. So that's going to be a significant increase that will help us move forward to making some of these changes that we've been talking about. So I want to close out with you -- I do have a couple of questions. But I want you to realize that the implementation of these initiatives is definitely going to raise the bar for training and education, and move FSIS forward toward its vision of becoming a premier public health agency that's a model for other public health institutions, or at least that's what we believe that it will do. And in your issue paper that you have, it's the last page under tab five, there's a couple of questions that we have for you. And mainly they focus on whether or not you think -- now that you've seen these six goals, do you think that these goals will help us move forward to achieve that public health vision. Do we have the right goals? Are we headed in the right direction? And the second question we have for you is do you have suggestions or input for us on delivery of

training and education, just in general. Since those things -- we feel like that's a real significant issue to reach our geographically disbursed workforce. And with that, we've got about 15 minutes or so for questions or discussion. Thank you. Dr. Jan's was up first, or Dr...

MR. GOVRO: Michael Govro, Oregon Department of Agriculture. I'm not going to be in the subcommittee that's going to discuss this tonight, so I'd like to throw out a couple ideas right now.

DR. KELLY: Great.

MR. GOVRO: One of the things that I think is used fairly successfully around the country with various agencies is pre-hire testing requirements. And one of the things we do in Oregon and many other states is a requirement for sanitarian registration, which requires taking of a very rigorous written test. And I know that there are many training, private training companies out there, as well as state agencies, and groups such as the Association of Food and Drug Officials and its regional affiliates, which could provide training that FSIS could use as a pre-hire requirement, or at least something that might give someone an inside track. I don't know if actually having a pre-hire requirement, testing requirement, would then limit the number of people that

you would have access to. But it would certainly be something that you could put out there. And I know that the Association of Food and Drug Officials has provided training such as a Seafood HACCP training, and the Meat and Poultry Processing at retail, that they have done with the trainer program, and provided to the states. That has been done fairly successfully. So I think there are a lot of other resources out there that you could use to provide the training.

DR. KELLY: Okay. Thank you for that input. Dr. Jan.

DR. JAN: Lee Jan, Texas. I just have -- actually a couple of questions. One, when you mentioned, I talked about training qualified candidates to replace the retiring. I wonder how you avoid EEO issues, or how do you select those that you will train, or do you have to train everybody that is in a inspector force, so that there's not a pre-selection preference made of some sort prior to interviews. That's always an issue for states. And then the other, I'd like to just wonder or ask if you'd considered, or is it worth considering not contracting but maybe communicating with technical colleges and institutes to provide the training that would be necessary to hire inspectors, or they could go in other areas, industry as well, but that

would have the qualifications an inspector needs that then when they go to work, they'd just need OJT, and wouldn't necessarily have to go through a formal training process.

DR. KELLY: Okay. Your first question had to do with selecting individuals to go into a training program. In this case we're talking about for our managers and supervisors. I will have to say that we're working out the details of that so I can't say that we definitely have a procedure or a process. But I see that Mr. Billy Milton, in the background, knows some more information. Do you want to share that with the group, Billy? Can you please come to the microphone?

MR. MILTON: In moving forward to address the succession planning and the question raised, the Agency is required to undergo a Civil Rights Impact Analysis Study. So we had to do it during the reorganization. We'll have to do it in implementing the training as a condition of employment, and it would apply to the succession planning for our supervisors and leaders.

DR. KELLY: Thank you. And your second question about utilizing technical colleges to provide some training for inspectors, we're considering utilizing all the types of resources available to us. And, in fact, I'm aware of at least one community

college in the Midwest that's made it known that they have a program that they think might be effective in training inspectors. So we're exploring opportunities. I think the main thing that we know that we have to provide to our employees is the regulatory aspect of our training. And we don't know if the academic environment is the best one for that, although it may be. So we're keeping our options open, in that I think that's definitely something we'll look into. Thank you. Dr. Leech.

DR. LEECH: What do you mean about the regulatory -- what aspect makes it difficult to do it an academic environment that you're thinking about?

DR. KELLY: It's just the applied part. A lot of times where people talk about you can read some of the things in the regulations, but then sometimes the bridge between what it says in the regulations and how you actually do it in that environment.

DR. LEECH: Okay. Just as an educated curious, the question that I had, I was intrigued by your interest in certification and ongoing things, and thinking about how education programs get put together and so forth, wondered what you really have in mind there if you know that there are any institutions that you're thinking about working with or organizations,

because I can -- I know sometimes professional organizations do certifications. Is that something that's kind of coming down the pike already, or something that you all are going to initiate, or...

DR. KELLY: I think it's something we're exploring. We are aware that there are a variety of institutions that have certification and education programs that I will say have sort of sprung up as a result, in particular, of HACCP implementation, that we're, you know, we have some interest in. So we're really just in the stage of exploring those right now. We have an internal certification program, 180 hours of self-study for employees. But, unfortunately, that is not linked to any career progression. So we really kind of have to think through a lot of this, as we spend our resources and ask people to spend time, not just on the job, but in a lot of cases off the job. So we don't have the answers to all that yet. But we are -- I think we're more interested in that as opposed to essentially -- we're interested more in a program than just a smattering of things. Okay. And, Dr. Elfering.

DR. ELFERING: One of the things that I think that it really seems like that you're taking a good approach to look at more science-based training, and maybe expanding a little bit on not only technical

colleges but even land grant universities. One of the things that we have available at the University of Minnesota is we have the School of Public Health, College of Veterinary Medicine, and the Department of Food Science, pretty much all in the same campus. We also have a pilot plan for slaughter facilities and processing facilities right on campus. And I think one of the things that we've seen to be very beneficial is to maybe conduct training for state programs and federal programs of the same type, because at least you have the inspectors are seeing a little bit of the differences and the nuances of each program. And they tend to go into their inspection work, not having the feeling that one program is any better than the other. When they go through training together, they really start welding more of a working relationship. The other thing I think that we have there is the Center for Animal Health and Food Safety. And I would be very willing to offer any assistance that the University could provide, even looking at putting together a pilot program for doing training for inspectors, at least entry-level inspectors.

DR. KELLY: Okay. Thank you. Dr. Hollingsworth.

DR. HOLLINGSWORTH: First, Karlease, thank you

for the briefing and the update. Because I'm not on the subcommittee dealing with this, I just wanted to pass on one thing for them to consider, and that is this question of credibility with certification. And I actually think Michael mentioned it too that for certain sectors of the industry in retail, both supermarkets and restaurants, there is a certification food handler requirement that is very rigid and must be met. And I think that that kind of credibility is something you should think about. The idea of the person who has a certificate printed off the computer, based on an open-book exam that they graded themselves, just doesn't give a lot of credibility to the public when you're trying to tell them that people are certified. And we would suggest that any program certification you look at meet and accreditation standard. It's one that we have to do at retail. It's difficult. It is probably more costly. But we also think in the long run it adds a lot of credibility. And you also have to have a continuous plan for those people who can't pass the exam, and we do have that occur. And they don't become certified food handlers. Thank you. Dr. Denton.

DR. DENTON: Thank you, Karlease. I will try to address some of the questions that have been posed with some of my own thinking with regard to how we

address this particular issue, I think starting with some of Irene's questions, and maybe finishing up with Jill's. We have been working at the University of Arkansas for about two years in developing a food safety and quality program that is administered through the University that is basically in two tiers, designed primarily to get at the portion of your clientele that would be considered the current employees. We have not considered so much trying to get into the certification side of this and the education side with regard to incoming new employees. But we have developed seven of 12 online computer-based, web delivered modules that cover a range of topics, from principles of food processing, food micro epidemiology and so forth, which I don't want to burden you now with all of these. But the entire goal of this is to provide the level of education that's necessary, not only for industry but for folks that would be working within the Public Health Agencies, particularly FSIS, I think, where some of the needs have been identified in some of our earlier discussions. But this is administered by university faculty. They have a testing program that's associated with the completion of these particular modules. You must complete six of the entry-level courses to get the certification and the lower level certification. And

then we move to an advanced curriculum that is very much like a beginning level graduate program for the certification on the second tier of that. We ultimately will probably be offering an online, web based master's degree, again, with all of the intended questions with regard to how the students are qualified to enter into the program, and also with the examination for completion of these particular modules. I'll stop there and reserve the rest of that discussion for this evening. But that's a little bit what we've been moving toward, primarily to address the educational needs of folks that are already in the workforce.

DR. KELLY: Thank you. Any other questions? I look forward to the input this evening. Thank you -- or in the hallway during breaks, whatever.

MR. TYNAN: Or wherever it just happens to happen.

DR. KELLY: Right.

MR. TYNAN: We've finished up the morning's agenda by my watch, and correct me if I'm wrong, it looks about twelve o'clock. And on my agenda, that says it's lunchtime. Because we have evening sessions tonight, we've allowed a little bit more time for lunch. So we have about an hour and a half. So if we could please be back here by about 1:30, that would be great.

There is a restaurant here in the hotel that's, I understand, is very, very nice. And there's certainly a number of places right out on King Street that you can enjoy as well. And if anybody decides they want to do that, we'll try and get some information on where those locations are. But we'll meet back here at 1:30, to continue the agenda.

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[Off the record]

[On the record]

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MR. TYNAN: For this afternoon, we have a couple of items. I think the first one on the agenda relates to the HACCP Egg Regulation. And we have Dr. Perfecto Santiago here to talk a little bit about that. And, Perfecto, I'll leave it to you.

DR. SANTIAGO: Good afternoon.

ALL: Good afternoon.

DR. SANTIAGO: I think the last time we were together we were talking about HIMP, maybe sometime in November. Thank you for the opportunity to share with you where we're going on the Egg HACCP regulations. Before I give you an update where we are on that initiative, let me share with you some observations I had when I visited probably one of the largest egg

products operations two weeks ago. This plant, I was amazed by three things at least in this egg products operation, the volume that they handle, the state of the art facilities, especially the cleaning placed systems, and the extent of this market of eggs. It's truly changed my focus from a dozen that I see in the grocery stores in the day-to-day existence. The volume of this plant is 7.5 million eggs a day. I never thought I would see that many eggs in one place at one time. I can't imagine the poor layers trying to supply that. So that made an impression on me when I visited this -- probably the largest eggs products plant in the world. But I look at the state of the facilities also was the state of the art, in that the cleaning placed system was the one that made an impression on me because the cleaning placed system, there's a redundancy built into it, but also several attributes within that system can shut down that system immediately by a change in temperature, a change in pressure, ultimately switch that CIP system to another system to back it up. I was very impressed by that. And, of course, when I saw all the products coming out, surely the domestic consumption cannot be utilizing all of these products. And I found out they're shipping throughout the world the powder products that they produce. So it's really my

observation that the eggs products plant really changed my perspective of the dozen eggs that I see in the grocery store. So what are we doing with eggs? For the past several years we have been building on the foundation to convert the Agency's command and control of egg products inspection program. It's regulatory based HACCP Program. The element of that foundation is, number one, developing the training for FSIS inspection program personnel. I'm referring to egg product inspectors. And to date, we have 110 of those egg products inspectors assigned in 82 egg products establishments. We're also thinking of training the surveillance inspectors that we have, the 77 that we have now, that's assigned in 570 shell egg establishments, and if you count the three hatcheries that are visited also by AMS at the present time, about 362 hatcheries, that's a lot of establishments to cover, to implement this HACCP based program. What is this training that we're talking about? We're talking about training first on PBIS. We would like to, before the HACCP regulations comes into -- to be issued, we'd like to train our egg products inspectors on how to monitor the establishment of operations using the PBIS program. So we're developing that PBIS program now for that. We also would like to continue with the Egg Products

Correlation to supplement the on-the-job training that these egg products inspectors receive, even when they were under AMS. We expect the PBIS training funds to become more available to be completed by September of 2003. By PBIS training, we're talking about non-HACCP PBIS, just to get them used to entering this into the computer and documenting the deficiencies that they found. Again, this is a standalone system, not -- it will not be linked with the PBIS we have right now. We're also developing training, the formal egg products training. And I have -- I'm expecting the CFL to help us develop that. It's a formal egg products training. We're developing guidance documents for shell egg packers in egg product plants. We're working with the University of Puerto Rico to develop the first guidance documents that we will proudly issue in sanitation. That document was presented to us by -- to some members of the work group in Puerto Rico, I think about a month ago. And we're looking to see the final documents on that so we can build on it if we have to, so we can start working and distributing these guidance documents, particularly on shell eggs and particularly in sanitation. We are preparing a scientifically based proposed rule. We expect this rule to be published at least as a proposal by summer of 2004. I will tell you

more about the elements of this rule as I continue. Next, please. What are the current activities we're doing now? We just completed a baseline study which consisted of taking over 1,000 samples of liquid and pasteurized products collected at the highest possible risk location. And we took almost 300 samples from three classes of products. Those three product groups are the liquid and pasteurized whole egg, the liquid and pasteurized egg white, and the liquid and pasteurized egg yolk. They're now -- they have -- the data has been completed and is now being used in the preparation of this *Salmonella* assessment to establish the standards. We're developing egg and egg products HACCP models. We're working with RTI in developing four HACCP models that we hope by the time we publish the rule as a proposal, that we can share with the egg industry. The four product groups that we are developing models on is raw shell eggs, raw liquid, not pasteurized egg products, heat treated shelf stable egg products, and heat treated, not fully cooked, not shelf stable products. Those four product groups will be the models that we are developing with RTI. We have to have the models ready for final review by the end of December. Next, please. I mentioned earlier about developing the scientific rule for the proposed science based proposed

rule. Let me go over quickly the components of that rule. The first two bullets, HACCP and Sanitation SSOP's will be the primary focus of that rule, and will all egg shell -- shell eggs and egg product plant would be required to develop and implement HACCP systems and incorporate needed controls to produce safe eggs and egg products, and to develop, implement, and maintain Sanitation SSOP's. Also, one of the proposals also is they require the refrigeration labels and special handling labels on containers of liquid and frozen egg products, and the requirement for shell eggs that's already in place in the existing regulatory structure. We plan to expand the generic labeling for egg products to expedite the approval of labels. And finally, another one of the proposals, whether this assessment now is trying to establish, is to establish the totality standards in shell egg handling standards as the performance standards for eggs. Another key component of the proposal is the elimination of the prior labeling requirements for egg product going -- egg product plants drawings, specs, and equipment. We plan to apply the Rules of Practice of 9 CFR 500, to egg packers and egg product plants when we take action. We propose to allow ionizing irradiation to pasteurize egg products. This was approved for use in egg and egg products by the FDA,

as early as June of 2000. But nobody has used that procedure, to my knowledge. Shell eggs so treated are not considered ready-to-eat, and would have to be broken and re-pasteurized. The proposal also will include the prohibition in repacking for retail sell of shell eggs that have been shipped for retail sale. There is a directive from AMS prohibiting this practice that was in place since 1998. But the prohibition covers only those eggs that are graded. And this rule will cover all the eggs. They return to the egg packer, eggs that have been shipped that can only be broken for further processing or destroyed. Next slide. What is the next step in this initiative? As I mentioned earlier, we planned to publish the proposal in summer of 2004. We expect the final rule, we are hopeful that the final rule will be published the year after that. And then the implementation will be phased out between two to three years to allow the shell eggs and the egg products to implement HACCP and SSOP. The biggest initiative we're doing now is to conduct several activities before the issuance, during the issuance, and after the issuance of the rule. We have developed a very aggressive strategy divided into three phases, phase one being before the issue of the proposed rule. Phase two is after issuing the proposed rule, and phase three will

be when the Final Rule is finally reissued. The key elements of those phase three outreach activities, will be the outreach activities, the numerous information and technical meetings we hold -- we plan to hold at strategic locations where these shell egg establishments are located. We are planning to distribute sanitation guidance materials to shell egg establishments especially in these outreach activities. And as we continue with our information and technical meetings, develop and identify -- identify and develop whatever assistance we see are needed to help the egg -- shell eggs and the egg product establishment to implement HACCP and SSOP. And we plan to expand the outreach activities at the second phase, when the rule is ready and HACCP proposed -- has been issued as a proposal to include the SSOP and HACCP guidance. Thank you very much. Are there any questions? Dr. Elfering.

DR. ELFERING: I think one of the things that I look at is that maybe the difference between shell egg products and liquid egg products. I had the opportunity to come in to Washington a couple of days early and was able to tour the Air and Space Museum yesterday. In one of the displays was a display of the food products that are used in space. And I couldn’t help but think back on why HACCP was ever developed. And it was developed

for the NASA Space Program on the principles that you needed to either eliminate, prevent, or reduce to an acceptable pathogenic microorganisms that may make people sick. I can see that in egg products. I can see how a HACCP plan, in a sense; they've been following a HACCP plan for many years by the use of pasteurization to eliminate harmful microorganisms. But I can't see that same application with shell eggs. And I'll give you a couple of examples. In 2001, we had two food borne illness outbreaks because of *Salmonella enteritidis* in the State of Minnesota. One was a chef at a restaurant chose to use shell eggs in an undercooked product, and about 45 people became ill. The second was in a Perkins Restaurant. And although eggs were implicated in every one of those illnesses, all of the employees that were working in the kitchen we also shedding *Salmonella enteritidi*s. How would HACCP prevented those two food borne illness outbreaks at a shell egg packing plant? I can certainly understanding having sanitation standard operating procedures. And I think those are some real good things that she shell egg industry needs to have. But I just fear that HACCP is going to be used as the silver bullet that's going to cure all of these ills, and will really do nothing at all to prevent food borne illness outbreaks or to

increase food safety at all.

DR. SANTIAGO: One of the models that we're developing at HACCP is on raw shell eggs. And we're looking -- and I hope when we get the models for our review, those -- we understand that SE infection can go -- now. So it's -- the contamination in the shell eggs might be not something that we're as sure as it will be taken care of. But I think the model that is being developed, we have asked them to address HACCP the answers that are likely to occur in those operations, and we will review those very closely to make sure they are.

MR. KOWALCYK: Michael Kowalcyk from STOP. Dr. Santiago, I have two questions, one of which is in the model development, four different samples were drawn for the RTI group to conduct their analysis. How many different production facilities were sampled? Were these all from one unique production facility, or how were the samples draw across the facilities for the...

DR. SANTIAGO: Are you talking about the baseline or the HACCP models?

MR. KOWALCYK: The HACCP models.

DR. SANTIAGO: Vicki, were there any samples taken of this? No. This is just model is being prepared for us. We did samples on the baseline, but

not for this one.

MR. KOWALCYK: How were those samples selected?

DR. SANTIAGO: For the baseline?

MR. KOWALCYK: Yes.

DR. SANTIAGO: Okay. I think I identified the establishments that are producing those four product groups that I mentioned were sampled. And a sample frame was established, and how to collect those for different establishments identified. Do you have an idea how this sampling of those establishments were established? This is baseline.

DR. ENGELJOHN: Yes. Dan Engeljohn with FSIS. The sampling for the baseline that was conducted by the Agency was designed much like our other baseline studies in which it was a statistical design in which all establishments producing products at various times throughout the sampling frame would have some likelihood of being sampled. So we had a number of variables that we looked at to get a statistical sample. So they were random, but within a population based on the variables for that particular plant. So all plants were included in that frame.

MR. KOWALCYK: And the second question I have is with respect to removing the prior approval of

requirements for egg products plants, drying specifications and equipment. Are there any sanitary issues that could be of concern to FSIS if they don't know the design of the plant and the configuration of the machinery in the plants that could arise some sanitation issues? Was that taken into consideration?

DR. SANTIAGO: Vicki, in the drafting of the proposal, I'm sure that was considered.

MS. LEVINE: Yes. Before a plant comes on line, it will still have to have a final -- before a plant is allowed to come on line, they are still going to have to have a final inspection by circuit supervisor or someone of that level. Once we have HACCP and SSOP's -- the -- they will -- it's just like with meat and poultry. We no longer have prior approval of specifications, drawings, so on and so forth. That has to be part of either your sanitation operating procedures, or it has to be part of your HACCP plan, if, in fact, somehow the layout of the equipment or the equipment itself could somehow be a, you know, result in a hazard likely to occur. So we have considered this, and we are simply moving egg products into the same place as meat and poultry plants.

DR. SANTIAGO: Alice -- Dr. Johnson.

DR. JOHNSON: Alice Johnson, with the National

Turkey Federation. I think the committee discussed the HACCP regulation in eggs back a couple of years ago. And the Agency was working with FDA at that time to try to coordinate the rules. Is that still the case, and do you still kind of anticipate that the rules will come out together? Is there a thought of any type of joint training with that agency?

DR. SANTIAGO: Well, we -- I think that's still the talk, to develop the rules together. And I think they -- yes, and they met with Dr. McKee and the United Egg Board and Poultry Association, for the same reason that they want the rules to be published at least at the same time, and so they will be able to review -- at least comment on those as a stimulus operation. I had tried to -- I'd been in touch with FDA to see -- to look at the rule that they are preparing. And that's not ready for review yet, according to them.

DR. JOHNSON: I know that we've heard the Agency talk about how they're working with the meat and poultry inspectors in enhancing their HACCP training. As far as egg inspectors go, will they receive training similar to the way the Meat and Poultry folks did pre-HACCP, or will they be included in the enhanced efforts to begin with?

DR. SANTIAGO: Right now we're in the

development of this training. In addition to the correlation training, correlation activities that we're doing, we're developing the egg products training for these egg products inspectors incorporating HACCP and SSOP also. And they will also be made part of the FSRE training that we have now. That's actually lined up under activities under phase two of the different activities we're doing to prepare for the final rule.

DR. JOHNSON: Is there any thought given to joint training between the Egg Industry and the inspectors?

DR. SANTIGAO: No. We have not discussed that yet. Ms. Eskin.

MS. ESKIN: Yes. Sandra Eskin. On the risk assessment, can you give us a specific target date that you hope that will be completed?

DR. SANTIAGO: I was given by the risk assessors, the end of August as the completion of that.

MS. ESKIN: And do you anticipate there will be an opportunity for interested parties to comment on that?

DR. SANTIAGO: I'm sure we will have opportunities to discuss the results of that risk assessment.

MR. TYNAN: Other questions on the HACCP Egg

Regulations?

DR. SANTIAGO: Thank you.

MR. TYNAN: Thank you, Dr. Santiago. The next item we have on the agenda relates to food security and its increasing industry awareness of food security. And the presenter is Mr. Jesse Majkowski, who heads the Food Security Office for us. Jesse.

MR. MAJKOWSKI: Good afternoon. It's a pleasure to be here. In your tab, tab seven, I think it is, there's an issue paper. In there also is a green booklet. It's a report that we put together that goes up to January of 2003, of our activities, as well as a blue book of the food security guidelines that we issued some time ago to the industry, voluntary guidelines. I want to make sure you all have them. What we're going to try to do today is try to give you an update, at least, of what we've been doing in the area of food security where we're coming to the advisory council to get some input on how can we improve awareness by the industry. In order to do that, I think you need to have an understanding of where we've been and what we've been doing. In addition to that, the interest in food security has risen to extremely high levels. Myself, Dr. McKee, Dr. Murano has spent numerous briefings briefing people at the White House, the Vice-President's

Office, and so forth, on what we're doing to protect the food supply, as well as our counterparts at FDA. There's a high level of interest and concern about the food supply today. But what can we expect in terms of multiple terrorist attacks in this country? If you've been reading the papers just recently, a truck driver in Ohio was convicted of targeting the Brooklyn Bridge, various sites in Washington, DC, had been in county for four years, a citizen of this country. That could be someone working in a federally inspected plant, for all we know. We are looking at considering weapons of mass destruction and an attack on the food supply. Some of the information that -- some classified information, results of the campaign in Afghanistan, you know, have lead people to believe that there is interest and capability of using these weapons of mass destruction against targets here in the U.S., as well as the food supply. There have been a number of recent terror attacks, in the World Trade Center in '93, a bomb went off in the basement, the Oklahoma City bombing, the U.S. Embassy bombings in Africa, and of course, most recently the World Trade Center, the Pentagon, and the plane that went down in PA. The Rand Corporation has been studying the terrorist events throughout the past 20 or 30 years. And one of the things that they are seeing is the use of

explosives, and now moving to a higher level, coordinated attacks using explosives. And the question remains, when will they move to that next level of using any weapons of mass destruction? In terms of attacks on the food supply, what could we expect? Well, one of the things we could certainly see is a disruption in the food supply without any deaths, a bona fide threat or a hoax even could disrupt this food supply in the U.S. We could see the destruction of brand names, a corporation, or a fast food chain could be targeted for attack, economic gains on the futures market. Six or nine months ago we had a report of an animal being tested in a Kansas feed lot for Foot and Mouth Disease. That report got out into the news. And by the end of the day, I think there were close to $50 million lost on the futures market. So there could be some real economic consequences for an actual attack or a hoax on the flood supply. Also, we may have trouble distinguishing between a natural occurring outbreak and an intentional event that occurs. It would take us some time to determine that it was an intentional event, as we begin to see clusters of illnesses. And finally, if you think about food, it's an easy target. The food that we had sitting out here all day, an easy target for anybody to spike with *Salmonella*, or whatever. So those are some

of the things that we're looking at when we think about an attack on the food supply. Have there been attacks on the food supply? Yes, there have. And this is not an exhaustive list, just some representative examples that I've picked up and come across. Insurgence in Kenya were poisoning cattle, cattle was destined for meat for the British troops. Palestine commandos contaminated citrus fruits. We also had breeders claiming a release of fruit flies in California. Chilean grapes were contaminated in '89. And, in fact, just recently we had a threat on apples coming in from Chile. That threat was turned over to the FBI, and they found out that it was a bona fide terrorist group operating in that country, and they're still investigating that. An interesting case back in '96, with Shigellian donuts at a laboratory. A worker was kind of irritated at his fellow workers in the lab -- I think it was a hospital lab -- and laced the chocolate donuts with *Shigella*. One of the other attacks, and probably one that we're most familiar with is the attack on salad bars with the Rajneesh cult group out of -- in the northwest. There was an election going on. City council seats were up for grabs. And this religious group decided that they wanted to have -- and it wasn't until about a year later that we were able to determine

that it actually was an intentional event. This was back in the mid ‘80s. We didn’t have the DNA fingerprinting or patterning back at that point in time. It was only after once someone was arrested for some other activities, and said that they had poisoned these -- or put the *Salmonella* in the salad bars. And that was the only way that we found out that that was an intentional act. We’ve had the sarin gas release in the Tokyo subways. In ’95, we had someone buying bubonic plague and anthrax was obtained illegally. That individual was caught. They had not had a chance to use it. In 2001, the anthrax mail campaign. Think of the disruption in the mail service that we had when that occurred. We had, I think, about four deaths. But the disruption that we had in the federal government, two to three months delays in getting mail, mail being x-rayed. The Brentwood postal facility is still closed down, perhaps opening very shortly. What if that happened in any one of our major -- in a major plant that was supplying food? We’d be shut down. More recently in 2003, I think this was in January, a person in a retail market mixed some pesticides in with some ground beef, and we had about 60 to 70 people become ill. So it’s a real viable option for an attack on the food supply. Since 9/11, we’ve had a number of federal efforts going

on in terms of what are we doing to protect the food supply? The Bio-terrorism Preparedness Act of 2001, provided USDA with about $325 million. FSIS received about $16 million of that money. And I'm going to walk through a number of the initiatives we have so that you'll see what we've been doing in terms of within the Agency and outside of the Agency, to make people more aware of food security. Also, at that point in the past year, the Department of Homeland Security was stood up and formed. As you know, they've created this Homeland Security Advisory System. And I want to go over that with you because we have some specific actions that we take, should we change alerts. The alert is assigned by the Attorney General, and there's five threat conditions, which I'll review shortly. The types of threat conditions could be nationwide, they could be geographic area specific, or they could be an industrial sector. And if you listen to when the threat levels are changed, sometimes the Attorney General will say that it's nationwide or it's targeted to specific sectors, utility sectors, and so forth. This past Memorial Day weekend when we went to orange alert, that was based on some of the intelligence and interviews with the truck driver in Ohio that came out, because they were targeting Brooklyn, the Brooklyn Bridge, and some sites

in Washington, DC. There are five different threat conditions. We've never been below yellow. We've been operating at yellow since 9/11. Orange, it's a high risk of a terrorist attack occurring. Severe, red, at the highest level, attack is imminent. We've gone to orange several times. We went to orange just recently, Memorial Day weekend. Then we've also been at orange alert during the Iraq War also. We've developed a plan on increasing our inspection and monitoring activities for both of those levels. And I'll share those with you in a little bit. One of the things we did when we first had our office formed -- and this was back in August, just about a year ago -- we developed a food security plan for the agency, listing about seven different initiatives. And we have a very simple goal, and we're still looking at this food security plan and revising it as we speak. But our goal is very simple, and that's to prevent the use of food as a weapon. We have, like I said, about seven initiatives, food security, employee safety, continuity of operations, communications, laboratory capability, training, and our international products coming into this country. And what I'd like to do is highlight for you in some of these areas what we're doing. In terms of food security and emergency response, one of the things that we've completed is our

vulnerability assessment of the domestic food supply. We are working on a vulnerability assessment for imported products. We'll probably complete that about, I believe, in September of '03, we should have that completed. The question that always is asked, what are the vulnerable commodities? What are you looking at? What does it say? The Department has the authority now to classify information at the secret level. This vulnerability assessment will be classified, and the agents that we've identified and commodities that we have identified will also be classified. The challenge that we have is how do we get that information out to the industry, out to plants? One of the areas we've been working is with these ISACS [Information Sharing and Advisory Councils], of trying to use that as a vehicle. Ones for foods and agriculture now is in the midst of being revised slightly. And so we'll be working with them. Based on that vulnerability assessment, we developed some strategies for preventing and detecting something occurring in the food supply. If you remember, on the eve of us going to war with Iraq, the President alluded to a program that the entire government was going on, Liberty Shield. This program was put together throughout the federal government, in looking at how do we protect the homeland or the

critical infrastructures that we're dealing with? One of our tasks at FSIS was to protect the food supply, and our task was to increase our monitoring and inspection, to protect something from occurring. We developed a series of actions, one for inspectors and for sampling of products. We issued a directive. That directive, I believe, is in that tab seven. It's 5420. The directive basically spells out what we would do when we went to orange, or what would we do when we would go to red, if it involved food or agriculture. During the Iraq situation, we put this directive into effect. Our inspectors received test, food security inspection tests, based on the food security guidelines that they would do in plants every day. In addition to that, we also were taking close to up to 50 percent of the food safety samples coming into our labs and analyzing them for various agents of concern, and looking for agents that we identified in our vulnerability assessment. So we increased our inspection, we were monitoring food security in the plants. If an inspector found something that was somewhat egregious, they were instructed to report that to the District Office, discuss it with plant management. People have asked, well, did they make any reports? What were the results of all those activities? We purposely decided not to have them write

reports or record their findings. One of the concerns at that point in time was those -- that information would be foible and available to anyone, should be begin to collect it. So we just had inspectors indicated that that tasks were complete. And if something was really egregious, it would get to our office or up to the tech center, that we could discuss it with the plant. The other area that we've improved upon is our agency emergency response team. We've created an emergency response team. And there's a notice that we issued close to over a year ago, detailing how that emergency response team would function. We are in the midst of revising that at this point in time, based on some of the tabletop exercises we have done, as well as some of the information that we've learned from putting these inspection tasks into place over the past year. So we expect probably in the next -- probably in the fall to issue some revisions to that directive 5420, also a revision to how the emergency response team is going to function. This team was basically stood up to deal with intentional acts, not acts that were naturally occurring, or accidents that occur in the normal day-to-day activities of food safety issues that we come up with with *Listeria* or *Salmonella*, or processing failure in the plant. It was specifically set up to deal with

the intentional act. And by dealing with the intentional act, it was just not corralling the product that might be affected; it was really to take a look at what else was going on in the food system. Once we identified it was an intentional act, this group would then turn it over to the agency to handle it, to get that product out of commerce, and than they began to look at the other plants that could be involved, other agencies that could be involved in this intentional event. So it was a much broader scope than our normal day-to-day food safety activities. In terms of employee safety and health, we've had a contractor that's developed some scenarios in looking at how this could affect our workers in the plants. We are also developing an employee handbook that we have out on bid. We have the bids in, and we're now in the process of evaluating those contractors to see who's going to develop this employee handbook. Shortly after 9/11, there were anthrax hoaxes throughout the country. We had several of these in our plants, inspectors noticing white powder on pallets, someone opening an envelope in a plant, white powder coming out. In those situations we had our inspectors notify local law enforcement, the local haz-mats come in to see if they could clear that plant, and then retain anything in the plant, not let

anything in or out, or not let our inspectors go back in until we get some idea that the plant was clear. We are in the process of looking at different analytic detection equipment. One of the questions that arose after those hoaxes is even at some point in time, local haz-mat was coming in, just taking a visual look saying, no, this is a hoax, there's nothing to worry about. How do we ensure our workers, our employees that are going back in the plant that it's a safe environment? Was there any other additional testing that we could do? So we were looking into that also. In terms of communication, we've developed a lot of educational materials and awareness materials. And one of the things that I have to say about communication is the message that we communicate to people is going to be extremely important. As it happened in the Kansas feedlot, the information that was given out to the public caused a panic and a scare. A lot of money was lost in the future markets that day. We need to be very careful in how we communicate in an event. In fact, the Department of Homeland Security has a communication office, and they are going to be the lead on any communications. And our USDA communications office is working with them to develop messages. We, ourselves, are developing fact sheets on the various agents,

radiological devices, and so forth, if something should occur, that we could get information out to the consumers to explain what was happening and what they should do with their food. We've been participating in a number of national, local conferences. And in terms of the communications to consumers, we do have a meat and poultry hotline. We've been looking at expanding the hours of that. They are also developing a plan, should we go to orange alert, and then to red alert, how would they expand their operations to handle consumer questions on food? In addition to that, we've established this consumer complaint monitoring system. We've had this for some period of time. Consumers would call the District Office, report something to the compliance officer. They would go and investigate that complaint. A piece of paper would be filled out, and it would travel from one District Office to headquarters, and back and forth. We've computerized this now, so where we can look at all the consumer complaints that are coming in, and really see if we can detect, is there a pattern going on? We're in the midst of using that $16 million to upgrade this system so that we can automatically have the computer beginning to look for trends, as consumer complaints get reported. So that would be a good feature in helping us prevent and detect

something that's happening with the food supply. In terms of the laboratories, we have four laboratories; three of them handle food safety samples. And then we have an -- what I would call our outbreak lab. They're renamed it a couple of times, but it's easier to refer to it as the outbreak lab in Athens. We've done some security assessments. Early on the Office of Inspector General went out to take a look at the USDA laboratories. And in the USDA alone, there's over 360 laboratories. And this accounts for university laboratories that we have cooperative agreements with. There were certain improvements that they suggested that we make in terms of security. We've installed video cameras, ID's for people coming in and out of the plants. We're improving the security. One of the areas that we're working on is the receiving area, having a separate receiving area for samples coming in. After 9/11, in one of our labs, we opened one of the sample boxes. A brown powder came out. And we had to shut that lab down for several days to figure out what that was before we could let people back in. In the meantime, we had samples running in that lab; we had sample results that plants were waiting on for 24 to 48 hours, to know if we had a negative and holding product. It could be very devastating, should we have our labs go

down, one of the reasons why we're looking at improving that security. We're also in the midst of installing some radiological devices that will take -- that will detect any radioactivity in samples coming in, and use that as a clearing mechanism. With the Iraq War, we earnestly began to test for agents of concern. And we've been doing that at a very high level during the Iraq War. When Liberty Shield was stood down, we then dropped that down to a much lower level. And the reason we're doing that is so our chemists, our microbiologists can maintain their skills, they can validate the methods that they're using, and, in fact, they're working with FDA on correlating the methods that they're using on various agents and the different food matrices. In terms of training and education, you've heard a lot about that. But one of the things we did early on was to develop these food security guidelines. And I'll talk a little bit later about what GAO had to say about that. But we've also been looking at how can we reach the 7,500-7,600 inspectors in the field. We've been looking at remote classroom learning. To give you a sense, if we want to bring our inspectors in for half-day training on food security for a half-day, we're looking at a cost of well over $2 million to bring them in out of the plants. We'd have to do that on the

weekend. We can't bring them out of those plants without replacing them with someone. So we're looking at different ways of getting to our field force. We've conducted a number of tabletop exercises through the past year. Starting at the USDA level, at the department level, all the agencies participated at a very high level of an exercise looking at how agencies would respond to a terrorist even involving the food supply. After that exercise was completed, we then got down to the agency level of taking at look at how FSIS would respond. It was called Crimson Winter. If we had an event with an intentional act that occurred, and began to take a look at how our agency would respond, how would the emergency response team function? It was during that exercise and through that exercise we realized that we needed to make some revisions on how we responded, to make us, so that we could respond more quickly. In addition to that, our Center for Learning has established a training program, an awareness program for the field. The District Offices, they've been conducting these tabletop exercises. There were plans to bring that down to the inspector level within the next year, in '03 and in '04, also. So the tabletop exercises have been very useful in pointing out how we can improve our response and our detection capabilities.

In terms of the international area, we are upgrading our import inspection. We've created a new position, Import Surveillance Officer. There are 20 of these individuals out there. They are working with Customs and APHIS now, which is DHS, part of the Department of Homeland Security, in looking at the entire facility. We took these -- the ports of entry. A group of people took a look to see where there were violations, where there were possibilities that product could come into this country. That's where we deployed these 20 individuals. During the Iraq War, when we increased our food security inspection tests, as a result of them working with Customs and the APHIS inspectors more closely than ever before, we found a lot of product that had left this country, came into other ports of entry, and were trying to get back into this country, a product that was refused entry that was traveling across the United States to other ports of entry. So that work really paid off. And we're working more closely with the Customs and the APHIS inspectors. In addition to that, we're trying to get our computer systems that Customs and AFIS has and that we have to interact also. They are three different systems with different products. Just to give you a sense of the problems that presents for us, we had some product at an import facility that

was cleared by customs. There were 50 boxes there. There was some foreign material in that. The importer went through ten of those boxes, thought they were pretty well cleared, and then presented them for inspection. There's 40 boxes sitting there, but they're not there. They've gone to another port, port of entry. So we're trying to get better computer systems so we know what's coming into these ports. We're also doing, as I said, mentioned earlier the vulnerability assessment on imported products. We expect that should be finished up in September of '03. COOP stands for continuity of operations. Any of you that were around here shortly after 9/11, on that day we saw the city in chaos. Government buildings were emptied. As we got out onto the streets, we heard that the State Department, a bomb just went off. The Metro was closed. There was no way to get out of the city. Meanwhile, we had 7,500 inspectors up in plants throughout the country. Product kept flowing that day. Product kept being inspected. And the reason was that we had an alternate site. We delegated the authority to run the agency to that site. And the inspection program kept running without a heart, you know, without dropping a heartbeat that day. Part of the reason -- people say, well, that was great planning, well, obviously, it was.

But we had been planning some time for Y2K, you know, with the electricity going out, and the ATM machines going down, and so forth, and having no electricity. So we had done a lot of planning of having alternate sites available to use to run the agency, should something happen. And it really paid off for us at that time. We are continuing to maintain that capability. We have alternate sites here in DC for our headquarters, people to move out to. We've tested it out briefly. We plan to do more testing in the fall, as well as testing our emergency response team also. The area of communications in cyber security, we're working on. If you were here in this area during 9/11, you couldn't use a cell phone, you couldn't use your regular phone, there was -- communications were severely limited. So we're looking at that and evaluating that to see how we can best improve that, should an event occur here. In terms of the GAO report that took a look at our food security guidelines, they also took a look at what FDA was doing at the industry also. And one of the strong recommendations came back from them, was that we should mandate our food security guidelines. As we were dealing with GAO at that time, we were -- we felt fairly comfortable that we really didn't have the regulatory authority to regulate all of those provisions. And we

had our Office of General Counsel review the guidelines. And they did determine that we have some limited authority to regulate some of the items in the guidelines. Two of the areas, I think, that are off limits are the perimeter or the outside of the facility, as well as personal -- the people working in the plant doing background checks, that sort of thing. Those are areas that we would not have any regulatory authority over. One of the reasons for bringing this to your attention is that we want to engage in the industry an awareness of food security. We issued the guidelines. Just about three or four months ago we had an incident where an individual was attempting to collect information on plants, and what they were producing. Some that are involved in the associations may recognize his name, a fellow by the name of Bob Miller was going out and calling plants, and collecting information. I was getting phone calls, districts were getting phone calls, was the USDA collecting this information? Was Homeland Security? Who is this individual? We turned it over to our office Inspector General, because it just didn't sound right, for whatever reason. And they found out that this was a legitimate business. There's a counterintelligence industry out there for the industry, where competitors can hire this company to find out what

you are producing. In fact, he told me -- he came into our office and discussed it with me. It's a very low-tech operation. They'll hire kids out of college to make phone calls. And he cited a couple examples where someone in the trucking industry wanted to know what ABC Trucking was producing, and how their assembly line was arrayed. They called the company, arranged for a free tour, and then after they got the free tour, several times, got the name of the president of the company, called him to tell him what a great plant that he had, and then they asked him about what their future expansion plans were. So they had the whole business plan and the layout of the plant laid out to them with little effort. Apparently, they had -- a competitor was interested in producing a new product, and wanted to know what was out there. And he was able to collect this information readily. That -- I tell you that story because the interest from the industry was key. They called our office. They were calling our District Office. So that tells me that they are very aware and quite aware of food security, and had some concern about that. We get reports from our inspectors, from plant managers to inspectors. There's a truck out there. We don't know what that truck is. Someone's taking pictures of our plant, and so forth. So there appears

to be an awareness. And I think these are the questions that we want to pose to the advisory committee, in improving industry awareness. First off, how should we go about that? We've issued some guidelines. Should we now be engaging the industry in consumer associations, more accurately? If so, how should we be doing that? Should we be training with the industry and our people jointly at this point in time? Should we mandate some provisions of these food security plans, or should we supply to all plants, or should we exempt some of the plants? So these are some of the questions that we posed, and some of the areas we wanted you to consider tonight? So I'll take any questions. Yes.

DR. LEECH: I'm Irene Leech.

MR. MAJKOWSKI: Irene.

DR. LEECH: As I listened, maybe I missed it, but I know that in my state we have got a state committee operation in deal with security. As I heard about the cooperation and so forth, I didn't hear that level mentioned. Is there a connection between what states are trying to do and what you all are trying to do?

MR. MAJKOWSKI: We are working on really developing contacts with the states at this point. What we're focusing in on is the physical -- the plant itself

and people owning that -- those plants. Are they aware of who their workers are? Are they aware of who's coming in and out of those plants?

DR. LEECH: That's the same kind of thing I'm hearing at the state level. That's why I'm asking the question. That kind of thing is what the states...

MR. MAJKOWSKI: Well, that may be a good recommendation to come up at the meeting tonight, because we've recognized that the states are doing a lot of those activities. And quite frankly, we have just been at the level of getting ourselves in line of trying to deal with food security at the agency level. And we've gotten to the point now where we've got some procedures in place, we're testing for agents. We've got activities that -- inspection activities, inspectors can do. So we've got our people in tuned and the awareness built up. And I think this is where we want to go to the next level. Yes. Jan.

DR. JAN: Lee Jan, Texas Department of Health. You're mentioned Crimson Winter, that tabletop scenario, and there were three stages participating, and we were one of them. And I thought it was a very good exercise, but -- and I'm glad that you recognize that there were some problems or some things that you needed to look at differently. But there's supposed to have been a follow

on Crimson Spring that was supposed to take those findings and then try it again after you refined that. Did that happen? I heard that...

MR. MAJOWSKI: No. No. That did not happen. Let me explain what happened. After Crimson Winter happened, we recognized that we needed to do a lot of revisions in terms of our emergency response. We had the inter agency food working group at that time. And there was some debate on how they should be functioning, what their role should be. And we sat back from that and we realized that we could fix some of those things internally. When we were looking at going to that next level with the agency -- and so was APHIS, by the way -- they decided that really where we needed to go was at the inner agency level of how does HHS, FDA, USDA, FSIS, connect [ph], and Department of Homeland Security, how are we going to interact? And so instead of going down to the agency level, we actually raised it up a notch, and we had some high-level tabletop exercises. In fact, one that we had with HHS, the Vice-President actually attended for at least 45 minutes to an hour that day, and was engaged in that exercise with the Deputy Secretary for HHS, and the Deputy Secretary for USDA. So that’s what happened to that effort. Dave.

DR. CARPENTER: Hi. David Carpenter, SIU.

You just mentioned that you sent guidelines out to the industry.

MR. MAJKOWSKI: Yes.

DR. CARPENTER: When did you do that? Did you get any impact -- any feedback, a good thing, not good, suggest additional?

MR. MAJKOWSKI: We -- see, that's been over a year ago, I believe. And the general feedback was good in terms of the brochure that went out, the style of the brochure, the readability, and the information in it. I don't remember seeing any negative impacts -- I mean, comments coming back. I think we've put that out into a Federal Register for comments. And I don't remember that we got any comments. Perfecto, do you remember, if I could ask you?

DR. SANTIAGO: I think the only comment we received regarding the operation on these guidelines, is some of these guidelines do not apply to small and very small plants. And we are looking at those comments. I think there was only one set of comments that came in. And we're offering, of course, these guidelines to pick and choose whatever applies to you. So they sound too complicated for the small and very small. They can use other alternative procedures for that.

MR. MAJKOWSKI: Mrs. Eskin, whoever was first.

MS. ESKIN: Thank you. I have a few questions. First, you mentioned that they're doing, or undertaking a vulnerability assessment, both for the domestic food supply and the international.

MR. MAJKOWSKI: Yes.

MS. ESKIN: Is there any attempt to compare the relative risk between -- meaning at some level common sense would say, well, it's a lot easier for someone to put something in an imported product than to infiltrate the domestic plant. Again, that's not based on anything except common sense or lack thereof. Do you have any sense that you're going to be looking at those comparatively, relative to resources and other issues?

MR. MAJKOWSKI: Well, what we looked at domestically, we looked at the issue of farm to table, recognizing that we have certain regulatory provisions that we can only regulate within. And then we basically asked, you know, several questions, you know, are the agents, are they easy to get? Are there points in the processing chain where they can be added? Are there things in our regulatory process that would mitigate those agents? So then we came up with somewhat of a ranking. Okay. What the import vulnerability assessment is looking at, similar questions, but on top of that, then you have product that has left the plant

that's sitting someplace, and then coming into this country. So they're going to be looking at the vulnerability of those -- of that process. And when we take a look at that, and then take a look at our domestic side, we may have some inkling of do we have more concern about imported products? Do we have more concern about domestic products? But that's a good point, and I'll raise it with the risk assessors and the people that are looking at that.

MS. ESKIN: Now, again, in terms...

MR. MAJKOWSKI: Go ahead.

MS. ESKIN: I have another quick questions that are related.

MR. MAJKOWSKI: Sure.

MS. ESKIN: Obviously, the personnel from the FSIS point of view, the same personnel that are doing all the other tasks in the plant are also responsible for doing these security related functions. And that's probably true for industry employees as well, plant employees. We're not looking at adding a whole other set of whatever you want to call them.

MR. MAJKOWSKI: No. We're doing this on a random basis. And basically, what we're doing is we have a set of consumer safety tasks, someone checking labels, net weights, and what we're doing is

periodically substituting food security tasks on a random basis that the inspector would do, that would come up on his inspection schedule.

MS. ESKIN: And how -- to what degree, again, a lot of these activities are prevention based. And in terms of detection, what role does product testing going to play or does it even play, whether we're talking about import -- imported product or a domestically produced product.

MR. MAJKOWSKI: It plays a role in telling us if there's something happening. You know, obviously, with any testing it takes time. You know, you pull a sample on a Monday, it takes a day to get it there, and so forth. But, certainly, if we got a positive on a product that would tell us that something's amiss, and than we could ramp up our other testing as well as our inspection activities too. I think, you know, I think you have to look at it's a two prong approach. One is a physical look at what's happening in the plant, as well as some low-level product testing. Yes, Mike.

MR. GOVRO: I have two questions. I'll ask them separately. My first question is, I think, fairly similar to Dr. Carpenter's question, with regard to the documents that you've already put out. And the first question, how can the Agency improve food security

awareness? In order to answer that, I think we need to know how effective these have been, and where you think these have failed to reach the mark, and why we need to improve.

MR. MAJKOWSKI: Well, we don't know if they've been effective, because we have not gone out to survey the industry of how many plants have adopted these food security guidelines. We just have anecdotal information of attending meetings. We do -- I mean, association meetings or other meetings that I've attended, people have installed video cameras, they're screening employees. While they're screening employees for criminal background so that this person doesn't work in the accounting department, so they work on the loading dock. It's not the same purpose. So we really have not been able to really go out and do that survey. And if we did, we'd have to, you know, if we're going to do that survey and survey the industry, we've got to go through a long process of getting approval for questionnaires and so forth. So we have not done that. We're looking at, you know, one way of improving the awareness has been going out to the national meetings, talking about what we're doing, the importance of this, getting the guidelines out. And I think the question is, what else can we do? What more should we be doing?

Or maybe the question is, should we be doing anything more also?

MR. GOVRO: I have a second question.

MR. MAJKOWSKI: Go ahead.

MR. GOVRO: I'm going to be thinking a little too creatively, but I'm wondering if the Agency doesn't have the ability, through existing requirements -- and it appears that you've addressed that. But the food security guidelines appear to be very much like HACCP, in terms of doing a risk assessment and putting measures in place where they're needed. Did the Agency give any thought to simply considering food security as a risk that is reasonably likely to occur, and having the plants address it in their HACCP plans?

MR. MAJKOWSKI: No. We haven't gone that far yet. But one area that we've been thinking about is whether or not to have -- require plants to have a food security plan, and to really do their own -- somewhat similar to what you're saying, do their own internal assessment, what does this -- what do I need as an owner of a large plant to improve my food security, and if I'm a small plant, my requirements would certainly be different. And the other question too is then should some plants be exempt? Should we not be concerned about some of the small or very small plants? Okay. I think

Mr. Schad. Yes.

MR. SCHAD: Mark Schad. I had a comment. And I think it's been touched upon, or somewhat addressed. And I just wanted to make sure there was some flexibility there for small and very small plants, because a lot of them, the processing -- the wholesale processing that's done is in the same operation where out front there's a retail operation. So we don't want to post no trespassing signs in front of a retail operation.

MR. MAJKOWSKI: That could be very devastating.

MR. SCHAD: Yes. And also, most owners of small plants know their employees on a first name basis. They're aware of who's in and out of the building pretty much at all times. And a lot of very small plants are in a rural area, as opposed to an urban area. So I just wanted to make sure there was some flexibility involved in those guidelines.

MR. MAJKOWSKI: Okay. Dr. Jan.

DR. JAN: I just wanted to touch on -- it seemed like maybe everybody didn't know about these, how extensive or how well FSIS got it out. And initially, when they came out last year, they went to every establishment owner or plant, and Ms. Swacina, as an

acting associate administrator at the time, or as associate, signed a letter asking everyone to look at them and implement them. And then when the threat code orange, Liberty Shield, I think, is what it was called, which is some potential threat against food, again, every inspector was instructed to go and take that, and sit down and talk with the plant management about that again. So I think that guide -- and, you know, it may not be a perfect guide, but they had a lot of good points. And I think the industry, the Wholesale Industry or the Meat and Poultry Industry, ought to have a good awareness of this possibility. I just want to bring that out to those that are not in the plants.

MR. MAJKOWSKI: Yes. I think we've distributed over 36,000 of these to inspectors and plants over the -- since we've put this out. And the requests keep coming in, the numbers keep growing. No other questions? Thank you.

MR. TYNAN: I note we're all a little bit early again just before the break. I don't know if there's a pattern here developing, but whatever the case may be. Why don't we go ahead and take a break, and we'll come on back at 3:05.

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[Off the record]

[On the record]

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MR. TYNAN: It's on my agenda near and dear to our hearts is the status of baseline studies. And we have on the agenda Dr. Hulebak. To my right is Loren Lange, who is not Dr. Hulebak, in case anybody knows her. You should be able to tell right off the bat. But just in case, Loren Lange, and he's going to talk a little bit about the baseline studies. I should point out also there is a handout that we have in our notebooks here. But for some of the visitors, we're going to make copies this evening, and we'll have some of those out on the table in the morning. They're available for you if you want those. So with that, I'm going to turn it over to Loren, to talk a little bit about baseline studies.

MR. LANGE: Thank you. Good afternoon. That sort of reminded me of that phrase someone used, I've met Dr. Hulebak, and you're no Dr. Hulebak. It went something like that anyway. As you all may be somewhat aware over the last couple of years there's sort of been reviews of the whole area of performance standards and performance criteria in food that had been undertaken by both the National Academy of Sciences, and the National Advisory Committee for Microbiological Criteria in Food.

And they've, while commenting on performance standards, they've certainly also both given us advice on how we should do microbiological baseline studies. The recent -- they both commented on that, and certainly their recommendations are, as you will see as I go along, have helped shape our current plans. The Academy of Science has recommended that we sort of continue to conduct baseline studies, and recommended that we put a particular emphasis on beef trim. The national advisory committee, which after this -- that's such a mouthful -- I'll just say NACMCF -- that's the way we refer to the group. NACMCF recommended that studies also should allow for discrimination between controllable and non-controllable factors affecting the frequency and/or concentration of contamination to help identify means to reduce contamination across the food chain. NACMF pointed out that an analysis of data, or a good analysis of data, should facilitate determining whether variation can be reduced through controls, that is intervention technologies or best practices. They also pointed out that analysis should be able to determine whether the variation, which is uncontrollable due to regionality, seasonality, or other factors, is significant in terms of public health consequences when developing performance standards. In the specific case of ground

beef, NACMCF recommends that we do conduct a baseline survey of trimmings, as the intermediate product stage between carcass and ground product. And they can recommend that we consider stratifying that study by looking at different products such as boneless trimmings, head meat, low temperature rendered materials, product from advanced meat recovery systems, lean meat, finely textured meat, and frozen, imported beef. NACMCF further noted that determining the microbiological profile of trimmings and other products will better reflect the prevalence of pathogens and other organisms in the source materials for ground beef. And they recommended that we should establish performance standards if that is deemed necessary. So we've had a lot of sort of guidance from these two organizations in planning our future baseline studies. And with that, I'll move onto just a brief history of baseline studies at FSIS. Since the early 1990's, FSIS has conducted statistically designed microbiological baseline studies to determine the microbiological profiles of FSIS regulated commodities. These baselines have been used to set performance standards, as was included in the 1996 HACCP Pathogen Reduction Rule. And they've been used to measure the effectiveness of pathogen control. Baseline studies have also been used

as inputs to risk assessments and to help guide and support agency policy decisions. On this slide, I sort of just listed the sort of different baseline studies that have occurred. I'm not going to read them. I'll point out a couple things. The very first one was actually the fourth one down, which was the baseline program for steers and heifers. That began in October of 1992, and was completed in '93. The next two were the original ground beef survey and the cow/bull baseline. These earlier baselines, as you'll note, were conducted actually prior to any discussions at FSIS in the development of the pathogen reduction role, which I think planning and discussion of how to use those baselines probably started sometime around September of October of 1994. So we were doing baseline studies prior to the development of that rule and continued, you know, through about the end of the 1990's. There's one that's not on here. There was a baseline study for fresh pork sausage. In fact, there was a proposed performance standard for fresh pork sausage in 1998. That's probably still an open proposed rule. It was never published over a methodology issue. And then it just sort of became a low priority. But the proposed rule was a 30 percent performance standard. In other presentations I know I talked about the only thing for

the performance standards that we really used from the baselines is the estimate of national product prevalence. And there's a lot of disagreement sometimes within statisticians of how to best account for non-responses and things like that. So that one isn't in there. And I have to apologize to Dr. Santiago, that I recently completed, egg products baseline study isn't also on that list. When we look at the need for additional baseline studies, we know that our verification date is indicated that microbiological profiles of our FSIS regulated commodities have changed "significantly" since the advent of HACCP. And I put significantly in quotes to sort of remind you all that I'm not saying statistically significant. But we do need to be able to determine whether this change is statistically significant, because every time we sort of publish our verification data on the website, you know, we get criticisms that, you know, it's misleading because it's not statistically valid. So I think it is important to sort of have statistically designed studies so that one, you know, people will not sort of debate whether, yes, it is down or it isn't down. There's a need to assess current microbiological profiles of regulated products so that today's benchmarks can be used to measure future improvements. One comment here,

to date in the 15 or so baseline studies that we've done, the one thing we've never done is repeated a product, you know, bug pair, I mean, whether it was a pathogen or even an indicator organism, there's always been some difference. The closest, I think, we've come is within broilers and young chickens, we've looked at *Salmonella* in two different time periods. But the methodology was different. And one early baseline we collected whole birds and shipped them to labs, and rinsed them one way. And the follow-up, we had our inspectors rinse birds and plants. So there's never been really a completely duplicated thing. Which we want to do, but there's at least a question, how do you handle when there's a better method comes along? You want to use the best methods available. But if you're trying to sort of really measure change, you've got to be able to account for any change in method. There's also -- we have a strong need for, you know, additional data for risk assessments. And there's always a need for better and more valid current data, to drive policy and program initiatives. The next slide just sort of points out a couple of changes in our current thinking. We really do need to emphasize always measuring the numbers of organisms present. Many of the more recent baselines were sort of limited to, you know,

positive/negative results or microbiologists refer to as prevalence as opposed to level, you know, somewhat out of cost. It costs a lot of money to do quantitative, you know, analysis on samples. But the risk assessment people really do need that. So we are putting an increased emphasis on that. We also need to develop, you know, have sufficient data so that we can examine what NACMCF has been pointing to. We should be looking at geographical variability, seasonality, plant volume, plant size. Almost all the early baselines had sort of one goal in line as to sort of look at the profile of the product and sort of, you know, estimate a national product prevalent. So we didn't get -- we probably didn't have the number of samples, or we didn't have the design right to really answer questions about seasonality or geographic regions. Sometimes we ran the tests. The statisticians can always run the tests. I can say, do you see a difference, you know, is there a statistically significant difference from month to month. And you can say, well, there's not that. But that's a different question than asking, did you have sufficient samples and analysis to, you know, come up with a level of confidence, that there is no difference between geographic areas and seasonality. So it's a little different question in how you look at it. The

next slide just sort of looks at the, you know, the full range of commodities without egg products on there. But it's all the carcasses and the ground products. And the last one is sort of the newest element in terms of interest, and that's raw ground beef components. The organisms we're looking at, the list shouldn't surprise anyone. I'd just note that not all of these will be part of every baseline we conduct, but the list of pathogens we will look at is *E. coli* 0157:7, *Listeria monocytogenes*, *Salmonella* species, *Campylobacter*, *Staphylococcus aureus*, and *Clostridium perfringens*. We also have four indicator organisms of sanitation and general process control that we will concern, that's generic *E. coli*, Enterobacteriaceae, Coliforms, and an Aerobic Plate Count. With that I'll move under our sort of current thinking for raw ground beef component baseline studies. Just one comment. This is now our top priority. In a minute, I'll mention that our budget initiative in the FY-04 budget requests were baselines. If I go back to when that was put in, we were thinking of that was money for doing the sort of traditional carcass studies, or ground finish product studies. We always thought at the time we could handle the raw ground beef components in house. But Jesse's food security issue sort of changed that right now because

we're doing a lot of food security testing, and we've made that sort of change to get these done and to get them done in a manner so we don't have a risk of interruption with a, you know, a code orange increased testing and stuff that we have made raw ground beef, you know, our number one priority. And I'll get to that. And we intend to do that outside of FSIS. For the raw ground beef component baseline studies, we're going to looking at *E. coli* 0157:7 and *Salmonella* species. We will do, you know, initial screening for positive and negative, and enumerate all positive samples. We will enumerate, you know, for each sample generic *E. coli*, Coliforms, Enterobacteriaceae, and do an Aerobic Plate Count. For 0157, we want to determine both the prevalence and levels of 0157 in raw ground beef to develop strategies to improve the safety of raw ground beef, we want to potentially use the information from the studies to improve our verification sampling strategies and improve on the existing *E. coli* 0157:H7 risk assessment. For *Salmonella*, we want to determine both the prevalence in levels of *Salmonella* in raw ground beef components. And these data can be used to provide input for the *Salmonella* risk assessment, which has been initiated and for subsequent policy decisions. People might ask, well, why do we spend a lot of money

on looking at organisms that are not pathogenic? And before -- I mentioned before, Generic *E. coli*, Coliforms, Enterobacteriaceae, and conducting Aerobic Plate Counts. To answer this, I'll sort of use what NACMCF, you know, sort of said in their report. I think that's a pretty decent answer. They recommend data should be gathered to demonstrate that the non-pathogenic microorganism can be used to indicate conditions associated with contamination by a pathogen. They recommended that, you know, we should demonstrate the reductions, and indicators will lead to reductions in pathogens. And we should be determining whether analytical tools should be developed, which can assess whether a reduction and indicator organisms could lead to a decrease in food borne illness by the pathogenic question, and to determine whether a broader microbial indicator can be used as a performance standard. Next I will sort of review our current plans for carrying out raw ground beef component studies. As is always been usually done in the past, samples will be collected at establishments throughout the country. Sample analysis will be contacted out to a third party commercial laboratory. Results will report both presence and levels of selected organisms that we've talked about. Results will be expressed as both the national average

or broken down by geographic location, season of collection, or other variables, as appropriate. Our staff sort of took a detailed look at the production of ground been in the United States. And I think they identified in the marketing about 18 different ingredients that actually go, you know, can be purchased to put into ground beef. And we've sort of separated those into five different categories at this time, based on perceived risk. And I underline perceived. We don't really have the data. But it's sort of the professional judgment call of the microbiologists. And we intend to sort of have each of a separate baseline study for these sort of five categories, the raw ground beef ingredients. The first category includes the head meat, the cheek meat, and the reasons, the second, the product from advanced meat recovery, the third, the low temperature rendered products, and that includes partially de-fatted chopped beef -- I think there's another one -- partially de-fatted, beef fatty tissue, lean, finely textured beef, also known as lean beef tissue. The fourth one would be the traditional thing that people think of is the different types of beef trim and the sub-primal cuts, such as boneless chucks, that are destined for ground beef. And, five, we have the imported frozen beef that goes into ground beef. The

current status, we don't have production volume or even except I think in the case of advanced meat recovery beef, we know where that product is produced, but we don't have the data to actually initiate a discussion of sampling frames. So the survey is going to be sent to FSIS inspectors, either in July or August of this year, at the establishments that are producing these products so that we sort of get a confirmation of, yes, who's producing the product, and what is the volume. And then sampling frames will be devised based on these data. Some issues we're still discussing around raw ground beef, as I mentioned earlier, we originally were going to do these types of analysis in house. So we're now discussing the issue of what does it mean to have a private laboratory testing raw ground beef components for 0157:H7. Certainly, if these are ingredients that are going into raw ground beef, if they have a 0157:H7, you know, they are adulterated as product going into raw ground beef. So we have this, you know, system now, if you're familiar with anything about our sampling programs, when we conduct an analysis in our lab we have an electronic alert system, when we're analyzing ground beef for 0157, the world finds out we have a potential positive. And then a couple days later these are confirmed negative or a message goes out to the world

that we have a presumptive positive, and finally a confirmed positive. So there's a whole system of informing plants that, in many cases that have held product pending our laboratory results, that's one issue that raises a lot of complication about considering a private laboratory. So we're -- we have that under discussion. There's an issue about the number of samples needed for seasonality and regional analysis. Friday, when I was finalizing this, I went back and looked at the market hog baselines from around '95 and '96. And someone on the staff, at one point, had sort of separated that out for me by the former FSIS five regions. And you look at it at first glance, and, my gosh, the northeast, you know, had this really high rate of *Salmonella* compared to the north central, you know, that had a far lower rate. And I looked at the numbers. So out of the north central, which includes the great state of Iowa, I think that baseline study had 1,200 samples. In the northeast, it was less than 200. So I said, I don't even know, you know, you'd have to really examine that. It could have been one or two plants influencing that. So it really raises a lot of question in design for those products that certainly hardly any of them are produced -- probably none of them -- uniformly, you know, across the United States. So we

have to give a lot of serious thought to that, if we really are going to sort of come up with testaments of, you know, regional or geographic, you know, prevalence in levels. And there's sort of a related question about when regional analysis makes sense. When we look at some of these raw ground beef components, we know that they're only produced at a very small number of plants. And it just may not make any sense to worry about, you know, where they come from. It may just make sense to look at the season of the year. I'll move next to sort of some of our, you know, what I labeled budget considerations. We're always trying to predict how much it costs to do baselines. There's a lot of variables that really change, you know, the number of positive samples, what you're looking for if you expect a high number of positives, and you're going to do a numeration that's going to get real expensive, the second issue that I just talked about, the number of variables, if we're really going to look at geography and, you know, and seasonality, we've got to make sure we have enough samples. Then, of course, then the number of establishments available for sampling. This next bullet about a minimum of 2,000 was sort of developed when we were really thinking about the traditional baselines of carcasses and stuff, that we sort of -- it was a

planning figure that we should at least have 2,000 samples. And that may not hold when we look at some of these things like, you know, low temperature rendered ingredients and beef from advance meat recovery, because there's not a large number of plants producing these products. 14 months is there because it's our traditional methodology to run a baseline, and a couple months for just shakedown purposes. I think we would do this whether we're doing it in house or using a private, commercial lab. There's just glitches, there's things that you didn't think about that have to be clarified. So there's usually two months of data. And any baseline study is not considered part of the actual baseline. And that's usually five, you know, there's a bunch of samples that have -- that are part of that early shakedown, and we don't count them. In the FY-04 budget request, we sort of did -- we put in for $1.7 million. Our current planning would indicate that we can get approximately 3,000 samples conducted and quantified, you know, at a private lab for that amount of funds. So depending on how we sort of shake out in terms of how many we need for these different components, we could have three 1,000 sample studies, two 1,500, or one and a half 2,000 sample studies for FY-2004. And finally, I'll just conclude with some of our future baseline

issues. After we get through the raw ground beef components, there's a question of how we should set our priorities. Is it by our risk assessment needs? Is it by risk management, you know, priorities? You look back at that list. We've never had a baseline study on lamb and sheep. Is that -- the fact that it's never been done, should that put that as a high priority? Don't know at this time. This question of how frequently they should be repeated, we've been kicking around ideas every three years, every five years, probably, you know. And then there's that issue of, you know, every time we come up with a new method, should we sort of restart a baseline if we really are serious in measuring change? And, finally, you know, there's this question about allocating resources to minor species, like, you know, there's -- we actually did do a sponge baseline on geese, and I think there's -- you can count the total inspected geese plants on one hand, if not two hands. And is it really worth our spending resources on that? So with that, thank you. And I'll entertain questions. Dr. Hollingsworth. Now either know people or I need new glasses, because everybody -- all these names over there are really blurry.

DR. HOLLINGSWORTH: In the slide that you showed us -- and, first of all, thank you for the

update. I think your presentation was very useful. In the slide with the five categories of products, you indicated three of those are perceived as high risk. Can you explain why that -- why you have that perception? Is that based on data? Has AMR, for example, been screened for 0157:H7 in the past, and you've found some reason to believe that it presents a higher risk than say domestic trim?

MR. LANGE: This is really just judgment of our in house microbiologists. Obviously, on the stuff that's low temperature rendered, they have, for years, been concerned about that if the pathogen is present that there is a potential for growth during the production of that. Honestly, I can't answer why our staff has sort of identified AMR -- why they think that particularly, because we really don't -- there is no data on the microbiological profile. We don't have data on that for that.

DR. HOLLINGSWORTH: I guess the reason I was interested in that is because if you only have the money to do one or two of the products, would you be looking at those high-risk in lieu of doing trim?

MR. LANGE: Not necessarily, because some of these are produced by a small number of establishments. And, of course, there's a lot of people producing trim

and sub-primals that go in. So we -- it may be -- and we wouldn't want to -- we've got to think about that there's inspectors out there that need time to collect these samples and stuff. So I don't think we -- we haven't made that decision yet, to necessarily go with those three that had the highest...

DR. HOLLINGSWORTH: Okay. Thank you.

MR. LANGE: Judgment risk may be a better term. Dr. Carpenter.

DR. CARPENTER: Have the microbiologists -- well, first of all, jus clarify for me, you said that pork sausage was or was not in baseline. And I apologize for...

MR. LANGE: There was a baseline study conducted for fresh pork sausage. And it was -- and there was a proposed rule for a *Salmonella* performance standard in 1998, for fresh pork sausage. Then it got wrapped up into a broader plan, rule making that got put on hold because of the pending National Academy of Sciences and NACMCF reviews.

DR. CARPENTER: That leads to my other question. I mean, if you talk about a broader evaluation, I mean, a pathogenic organism associated with pork is *Yersinia enterocolitica*, I mean, was that added, or thought about being added as one of the

indicator organisms?

MR. LANGE: I'll take that back to our microbiologists. Thank you.

DR. BAYSE: Gladys Bayse, Spelman College. You mentioned using outside commercial laboratories. And I'm just curious, these are chosen based on past experience with their results. You used the same one because that, or how does that work?

MR. LANGE: We have put in for money explicitly identified that we would contract out. We have to go through a competitive, you know, process. We will put out a request for proposals on the street and evaluate different laboratories, you know, based on what, you know, their response to evaluation criteria that will be laid out in that request for proposals.

DR. BAYSE: So for example, if you had two such labs that you felt were equally qualified, I mean, do you have ability to let them test the same sample and compare the results that come back and that sort of thing?

MR. LANGE: Well, we certainly could select -- we have the flexibility to select multiple labs. But as a same sample, we've been through this on a lot of products. If you have a -- if you're rinsing a bird you can split that, and you really probably do once you've

shaken it real good, at least, you probably do have the same sample. But with something like ground beef or beef trimmings, it's only an adjacent sample. So, I mean, it could be considered a similar sample. But there's only certain types of samples that can actually be split and sent to places, you know. Does that answer your...

DR. BAYSE: Sure.

MR. LANGE: But we will do a competitive -- we have to do a competitive, you know, process, to select our contract laboratory. Mr. Schad.

MR. SCHAD: Yes, Mark Schad. On your determination of indictor organisms, I'm just curious how you plan to do that or determine that because we know that a positive correlation doesn't always mean cause and effect. So I'm just curious of your methodology here. How are you going to determine whether an organism is an indication of a pathogen?

MR. LANGE: I think I understand your question. We've sort of labeled these as indictors without having shown to the world that they're indicators. So we will be testing for these organisms probably to test the hypothesis that they are good indicators. That's probably a little clearer way of putting it. That was your question, correct?

MR. SCHAD: You addressed the question. I'm not sure you answered it specifically.

MR. LANGE: Oh, okay.

MR. TYNAN: Do we have other questions on the baseline? Yes, we do. Ms. Eskin.

MS. ESKIN: Thanks. Again, at the outset, you mentioned that trim was a particular concern. And in the slide again in which a question was asked earlier in which you identified five different categories, and trim is not one of those that's given at least an asterisk.

MR. LANGE: We believe that when the academies mentioned trim, they used it as the generic...

MS. ESKIN: As generic.

MR. LANGE: Generic as it's the raw ground beef ingredients, or now we call those components, you know, that this is all beef trim.

MS. ESKIN: Everything.

MR. LANGE: Yes.

MS. ESKIN: Okay. So you're defining it differently. Here, it's limited -- it's a much narrower category.

MR. LANGE: Yes. When we separated it out. We're talking about our people went out and looked what was in the marketplace. And people advertised, you know, 80-20 trim, 50-50 trim. There's different things

that are actually marketed as beef trim. But we certainly understand the academy's recommendation that we ought to be looking at trim as an ingredient to raw ground beef, but certainly, if we're looking at it as one ingredient, we should be looking at all the ingredients.

MS. ESKIN: Thank you.

MR. TYNAN: Other questions? Okay. Well, thank you, Loren, I appreciate it. I think the last briefing topic we have for today is our legislative update. And I have Mr. Rob Larew from our Congressional and Public Affairs Office. And I'll turn it over to him to bring you up to date on legislative issues.

MR. LAREW: All right. Thanks. I guess I'm already breaking a couple of the cardinal rules of presentations. First of all, coming here just before my boss and the public comments, not a good idea normally, secondly, to come here in between this and dinner. But if you guys can hang with me, I promise you that my 120-slide presentation will only take about 40 minutes. So we should be in good shape here. The briefing here will just be very, just that, brief. To kind of highlight some of the things that you've heard through the other briefings about what has taken place since enactment of the Farm Bill back in 2002, as well as I have a short

discussion about the fiscal year ’03 appropriations, and the current cycle that we’re focusing on, that is the ’04 budget. So, first of all, starting with the Farm Bill, a couple of the highlights that were FSIS related provisions within the bill was first of all authorization to the Secretary to set overtime and holiday pay rates. There was also a mandate for FSIS to conduct an education program, this mainly about those technologies to reduce the level of pathogens on meat and poultry products. And there was actually a few separate provisions similarly related to this, including a direction to FDA to redefine the term pasteurization, and then also the direction to the Secretary to review State Meat and Poultry Inspection systems. On the first item there, overtime and holiday pay, just a quick review of what has taken place since then. On November 22, of this past year, the Secretary did approve a request from FSIS’s administrator, Dr. McKee, to adjust the hourly rate to one and a half time. Since that point, a proposed rule has been published. That was published in February. And it’s my understanding that we should expect a Final Rule to be published most any day now. It’s very near publication. So this is moving right along. On the issue of pasteurization and irradiation -- if we can have the next slide, please --

first item there in response -- in direct response to the Congressional mandate to -- or direction to perform an educational program, develop and implement a program on those technologies with significantly reduced pathogens in meat and poultry products, we have started the process of putting together the program, and we expect that to be launched in the next year. So that is an ongoing process right now. And just as a side note here as well, but related, USDA rules do still stipulate that radiated foods be labeled as such, and still carry the logo. Because of the mandate the FDA look at their definition of pasteurization, the way this would relate to our agency, we would still be able to address any label changes without any rule making on our part. So I think that once that takes place, and FDA is still working on that, we should be able to kind of seamlessly work through that process here in the Agency. Next on the State Meat and Poultry system reviews, you've certainly had quite a bit of discussion here on this point. Obviously, this committee has been an integral part of that review. And just quick summary, the committee obviously recommended that FSIS first look at all their past reviews in 2000, completing the rest of those state reviews by March of 2003, that has been completed. And currently, we are in the final phases of

putting together the comprehensive review. And there's ongoing discussion within the committee here on this. Yes. Backing up to the 2003 Appropriations Bill, this was an interesting cycle in that Congress did not finish their Appropriations Bills at the expected time. The omnibus Appropriations Bill was not completed until February of this year. And this big omnibus bill did include funding for USDA. Overall, the bill included about $74 billion for AG programs. This was a little over $600 million for the budget request, but a sizable $1 billion over the earlier year. Within FSIS, the 2003 Appropriations Bill had nearly $760 million. And this was an increase from the 2002 budget. In 2004, the current cycle, we have requested -- the Agency has requested $797 million, as well as $102 million from user fees for the total budget level of nearly $900 million. This is an increase from the earlier year. And some of the provisions that we -- or initiatives that we have included in that budget request include -- if we could have the next slide please. And there again, some of these initiatives have been discussed in your earlier briefings. But it includes $5.7 million for training, an integral part of this year's budget request, $1.7 million, which was referred to in the briefing just before this, to establish the continuous

baseline program, $4.5 million to bring on new microbiologists, chemists, other technicians, to increase the ability of the agency to identify trends. I think those are kind of the meat and bones of the request. But there are some additional ones as well, equally, I guess it's important, but $4.3 million to increase workforce, the number there being 7,680 in plant staff, $1.8 million to increase the number of foreign program auditors. And this is not only the Agency's initiative, but also in response to Congresses interest in making sure that we are looking as closely as possible at where food is actually produced before it's coming to the US. And finally, $1.5 million for a mass media campaign on safe food handling practices, mainly targeted towards the consumers. This initiative has kind of at least been started with a very large campaign with the food safety mobile. And we see this is kind of an outgrowth and continuation of that effort. And, finally, just as a somewhat of where we are right now, the House subcommittee did meet this past Tuesday, and marked up the 2004 Appropriations Bill. They are the first subcommittee to do this effort. The budget number that they currently have for FSIS is $11.9 million below the President's request. However, I would stress that although that is the case, this is very

early in the process. We do expect the full committee to have their markup this Wednesday. And it is expected that the Senate could start markup within subcommittee as early as -- the committee should do their markup as early as early July. We're right here at the time. But are there any questions about either appropriations cycle or where we're at on some of these requests from the 2002 Farm Bill?

DR. JAN: Lee Jan, Texas Department of Health. I don't have a question about the budget, but I do have a question about some other things you presented.

MR. LAREW: Sure.

DR. JAN: One of them you said early on about FDA redefining pasteurization. How is that -- what is the current definition, and how is that expected to affect irradiation of meat and poultry products?

MR. LAREW: Just a second here. Let me actually pull up the language that they use. As included in the conference report, it provides for a common definition of pasteurization, it clarifies the Food and Drug Administration's approval process for claims of pasteurization and includes a provision to facilitate the use of effective food safety technologies. And then it encourages the Secretary of the USDA in consultation with HHS, to pursue a

comparable pasteurization labeling program. I think where this -- there was some confusion -- and it's initiated out in the Senate, as to there was no common definition of pasteurization, in that there was some confusion, not only in the public, with what products could be -- that you could use this definition on. I'm getting a little confused here. But let me just make -- I guess I'm getting confusing. But I think the point is that we want to make sure that we have a definition in place that treats all products equally for the level of pathogen reduction that you can achieve with pasteurization. There again, we don't have a final determination on that, because FDA is currently working through that. But the -- I think the ultimate goal here is to be able to use pasteurization on other products, but making sure that it's a, not only a common definition, but that it has meaning tied to it.

MS. SWACINA: Are you saying that FDA defines pasteurization by regulation?

MR. LAREW: No. I'm not saying that. I guess it wasn't very clear there. FDA, of course, does have regulations on pasteurization right now, certainly, with milk and some of the other products. But what we're trying to do here is they have been directed by Congress to look at that definition and to work with the

Secretary of the USDA to make possible changes to that definition to be able to use it for other products.

DR. JAN: Am I understanding that the pasteurization that were before irradiation was a process that we were even thought we might could use in food, I'm talking about pasteurization of like temperature, time/temperature type pasteurization. But for meat and poultry products, that may or may not be. And you mentioned, you know, radura and use of that statement, so now we're looking at irradiation or electronic beam processes are considered pasteurization, which is, you know, I think that some of us already considered that to be a pasteurization process. But when you tie that in to not requiring the radura in the labeling, is that saying that if you use an electronic beam or cobalt radiation, that after this definition changes you will not have to use that, or is that only if you do not use those processes, but use another type of pasteurization that you won't have to be using that radura, or do you all not know yet?

MR. LAREW: Yes. I think that that's probably still a question out there. I'm not sure that you can necessarily tie those two together. But they may be, as we move through the process. But I think as Congress -- and this is obviously in response to what Congress has

asked, and those are two separate issues.

DR. JAN: I have another question on a -- or maybe it's not a question, it's kind of a comment. Or maybe it could be a question, I don't know. When you talked about the state inspection USDA programs, you used the words, a more comprehensive review required by the Farm Bill. And I don't read that the Farm Bill requires a more comprehensive Farm Bill. What the Farm Bill says is monitors intend that when the Secretary of Agriculture submits any report to Congress on activities or food inspection service, the Secretary should include a full review of state inspection systems. The review should also offer guidance about changes the state system might expect, should the statutory prohibition against interstate shipment or state inspection products be removed. That doesn't say -- or I don't read that it says a more comprehensive review. It says a full review, which states have been subjected to since probably 1967. And there have been different kind of reviews. But I don't know where it says in here a more comprehensive review than what we've already had.

MR. LAREW: Well, they're pretty comprehensive all along.

MR. LANGE: Well, I appreciate your comments there, and I certainly am not trying to put words in the

conference report here. But I stand corrected that the term does use full review. But as I mentioned also, obviously, this committee's been an integral part of the Agency's process through that.

DR. JAN: Okay. I just make sure -- I pointed that out.

MS. ESKIN: Sandra Eskin. I'm wondering, in light of Secretary Veneman's speech a number of months back, when she raised the question of whether perhaps the Department needs more or could benefit from additional legislative authority, civil fines, et cetera. I'm wondering if, one, there's any activity internally toward that end, and two, if you're monitoring in some active way, legislative proposals that are -- have been introduced or being considered along these lines.

MR. LAREW: Sure. To answer the second question first, our office in particular, and certainly the Agency monitors any legislation that has any direct or indirect dealings with FSIS and food safety activities. But then secondly, in response to the Secretary's comments earlier, I think it's safe to say that the Agency and the Office of Food Safety have continually been looking for ways to improve, and if that includes possible new authorities, that's an

ongoing process that we're currently reviewing.

MS. ESKIN: But again, do you know if there's any specific activity that's like reviewing the current legislation? I don't mean like your office, obviously.

MR. LAREW: I'm not sure, I mean, my first comments, we're certainly actively engaged in watching legislation that has -- is moving or is being introduced up on the hill. And that's an ongoing process. And it certainly continues now. I guess, you know, just to add on that, each bill that is introduced, a comprehensive -- I'm not sure more comprehensive or full -- memo is produced to provide to the Under Secretary and the Administrator to provide details on not only the status of those bills, but what is included and the affect that they may have on agencies' authorities.

MR. TYNAN: Are there other questions related to legislative issues?

DR. JOHNSON: Alice Johnson, National Turkey Federation. When we talked about adding employees in the in plant level, you said 80 new positions. Is it the intent that those positions would be line inspectors? Are they -- I guess if they're in plant, would they be considered CSO's, you know, is there a distinction as to what the added positions will be, or has that been determined yet?

MR. LAREW: Well, we'll have a breakdown on that. But my understanding is it's a combination of all of those. And I'm not sure. We'll provide more detail on that.

DR. JOHNSON: Thank you.

DR. TYNAN: Other questions? Going once, going twice. Okay. Thank you, Rob, very much.

MR. LAREW: Sure.

MR. TYNAN: I think the next item we have on the agenda relates to public comments and adjourn. I'm going to ask Dr. McKee to take this portion back, but also ask him before we adjourn to allow me to do a couple of logistical things toward the end. And with that, Dr. McKee.

DR. MCKEE: Thank you. It's time now for our public comment. And we had asked those that wanted to speak to sign up. And what our practice has been is to limit the comments to five minutes. And then after we go through all those that want to comment, then you'd have an opportunity to speak again one more time. But with just two today, the first one is Bernie Shire, and if you could state your name for the record and who you represent.

MR. SHIRE: Good afternoon. My name is Bernie Shire. I'm with the American Association of Meat

Processors. And I have really a couple of questions more than a comment. The questions have to do with an issue that the subcommittee is going to be discussing later this afternoon, and I plan to be there. But I'd like to raise the issue now. And it has to do with the state review methods. And I guess the first part of what I guess I would say is more of a comment than a question, and then a question. I guess I'm a little concerned about the fact that the agency is taking in terms of looking at the state inspected meat and poultry programs, and the reviews that are being done of these programs. And Lee Jan, from Texas, raised a similar issue before. A year ago, almost to the day, two meetings ago, I guess, of this organization, there was a lengthy discussion of the Farm Bill. And at that time after the subcommittee met in the evening, this committee decided that they were going to go ahead and recommend that these state comprehensive reviews be done as quickly as possible with the goal of advancing the issue of interstate shipment of state inspected meat and poultry as quickly as possible. And I remember the discussion. There was a lot of discussion about that it needed to be done very quickly, that some of the -- part of the reviews were already done. Some of the state programs had been already reviewed, and that if

necessary, the Agency needed to go outside to outside contractors, and ask Congress for additional money in order to get these things done as quickly as possible. Now, from what I can see, the Agency is now going to start discussing how to do the reviews. In other words, review the process of how the reviews are done, and do those. And it just seems like this lends itself to an endless process that's never going to get done, the idea being that the state reviews were to be done as soon as possible, and then with that happening, that legislation could be introduced in Congress to move this issue forward. I met, as you know, Dr. McKee, with you and several people from the Department a couple of weeks ago, and discussed this issue. And one of the things that came out of that discussion was the whole question of state reviews. And the reviews have been going on for a long time. And I guess I just raised the question, how long are these reviews going to be going on before it's decided that they're done in a sufficient way that this issue can be moved forward. It seems to me that by going back and now looking at how we're going to do the reviews of these -- how we're going to actually carry out the reviews, the reviews have been done in the past. And it just seems like this is just pushing the issue on further and further. And the

American Association of Meat Processors has a lot of state inspected members who would like to be able to ship their products across state lines. And this is an issue that's been -- that probably started back in the late '60s, with the revision of the Meat and Poultry Act then, and so 30 some years. Over the last ten years, there's been a great deal of effort. And about three years or so ago, there was legislation introduced and it was pushed quite hard at that time. But it just seems -- we get the impression that instead of moving forward, we're moving backward. So I guess that's the one question I would like to ask, you know, and I plan to bring it up again this evening. How long are these reviews going to go on? And if you're now looking at how you do the reviews of the state programs, how long is that going to take? The other question I would raise is previously, the previous administration had come out with a position in favor of interstate shipment. And when is the current administration and USDA planning to do that? Thank you.

DR. MCKEE: Well, Bernie, I think you missed the first part of our meeting this morning, in that we had a presentation on that, and that the final report will be provided on schedule in February. I believe that's right. Isn't it? I believe February. And so

the purpose of the review that we had when we brought the states in to look at the self-assessment was part of making sure everybody understood how to go forward with that, and how to do that, and get suggestions for changes. And so there will be a return of those, and then selected states audited by that February deadline. And the answer to the other question is is that I think that's one of the reasons that the review was requested is that the information isn't really adequate at this point to make recommendations or decisions. So that review will need to be looked at, I think, before there's any policy recommendations by the Agency. Next on the list is Tony Corvo.

MR. CORVO: Tony Corvo, from a consumer group, Public Citizen. I wanted to make several points. First, I wanted to compliment Dr. Kelly on her presentation. I thought it was one of the most comprehensive presentations on an education program that the Agency has presented. I've come to these meetings for three years now, and I thought it was very well done, very comprehensive. And it also reflects some of the points that some of the consumer groups have been raising about the need for additional training for the inspection staff and decentralize it. And I appreciate the fact that there is somewhat of a recognition that

the sun doesn't rise and set over College Station, Texas, that there is some thought in terms of moving it out. The other point I wanted to raise is the continuation of discussion that we had last week when the consumer groups met with Dr. McKee. I raised an issue of the quarterly inspection reports for 2002, in particular those that dealt with import re-inspections. It seems that the Agency has changed its sampling technique, and as a result the level of meat and poultry re-inspections has dropped precipitously. And in light of the concerns that Mr. McCaskey ([sic] Makjkowski) has raised, it seems that it's counterintuitive that while we're trying to elevate the concern for possible intentional contamination of our food supply, that the actual inspections of imported meat and poultry products is going down. And so that's a concern. And I would like, whether now or sometime during the next two days, if there is a discussion or an explanation as to how that new sampling technique dovetailed into the food security program that is now in place within the Agency. The last point I wanted to raise is the presentation that was made by the Congressional staff here on trying to redefine the word pasteurization. If they're confused in terms of what all that means, you have two sets of focus groups that were conducted among

consumers, FDA and USDA, that clearly state the consumers do not want to make that analogy between pasteurization and irradiation. It would cause more confusion. And as a matter of fact, the labeling staff of FSIS had taken the position that making those two terms synonymous would be confusing to consumers. So those are my points. Thank you.

DR. MCKEE: Okay. Thank you very much. Is there any other comments before we close for today? Not seeing any, we'll adjourn for this evening. We'll have early time to go to lunch. And then I know you had some work this evening. And we certainly appreciate your efforts, and look forward to reconvening again in the morning. Thank you. Could you wait just a second? I think we have a couple of housecleaning comments. Sorry.

MR. TYNAN: I apologize. We've got just a couple of things to mention to you for this evening's sessions. In the booklets that we sent to you the other day, we had a listing of the subcommittees. The correct one is in the books you received today. And the reason we did that, as Dr. McKee mentioned earlier, that Charlotte Christin was not able to, or will not be able to participate as a member. And so in order to get a better balance of the committees, we made a few minor

changes. So the committee -- subcommittee structure is under tab two in the larger notebook that we sent to you. That is the correct listing. I should also mention that there's been a little bit of a change on the agenda as a result of the hotel having some difficulty with some of the breakout rooms. So the delivery of training, Dr. Denton's group, he will be the chair. And they'll be meeting in the Jefferson Room, as indicated on the agenda. Similarly, Mr. Govro's group on food security will be meeting in the Madison Room on the second floor. And the State Review Methods, however, Dr. Johnson, your group will not be meeting in the Washington Room, but rather in the Franklin Room, which is on the second floor again. It's in the same area. But it would be just a slightly different room. What I'd like to do is if I can impose on the chair people and the recorders and facilitators that we have that will be helping you with your discussions tonight, if perhaps if you could come back maybe half an hour early, maybe 5:30, between 5:30 and quarter of, so we could talk a little bit about the meeting and the reports, as you'll have to do, and make sure everybody's on the same page so that we don't have any glitches for the morning. So -- yes, we can meet right in -- I think in this section. If I'm not mistaken, I think the hotel

may be using the back portion of the room. So anyone that is sitting in there may have to take their notebooks with them. Everyone here can -- as far as I know, can leave them on the table if you'd like. Okay. So if I can see you maybe between 5:30 and quarter of six, back here, the chair people, and the facilitators, and recorders. And with that, we'll adjourn.

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IN RE: Meat and Poultry Inspectors' Meeting

HELD AT: Alexandria, Virginia

DATE: June 23, 2003

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