UNITED STATES DEPARTMENT OF AGRICULTURE
MEAT AND POULTRY INSPECTION

NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION MEETING

Columbia Room
Holiday Inn Capitol at the Smithsonian
550 C Street, SW
Washington, D.C.

Wednesday, November 6, 2002
8:30 a.m.

I N D E X

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P R O C E E D I N G S

8:45 a.m.

Welcome

MR. GIOGLIO: Good morning. I would like to call the Fall 2002 Meeting of the National Advisory Committee on Meat and Poultry Inspection to order.

My name is Charles Gioglio from the Food Safety Inspection Service. I'd like to call the meeting to order.

Before I do that, I'd like to simply go over a few of the housekeeping issues that we have. First of all, as usual, the FSIS staff are here to help the committee members with any material that you need or anything else. So that, if we can help make this meeting more successful for you and for us, please let one of us know.

Also, if I can remind folks that cell phones and pagers should be on vibrate and so forth during the meeting sessions, that would be helpful. For committee members, we do have a telephone out at the registration table. I'll give you that number that you can give to your offices so that if they need to contact you during this session, one of our FSIS staff will come and give you that message as soon as they can. That number, if you want to know it, is 202-479-4000, and the extension

is 7188.

Inside the left-hand pocket of your notebooks is the agenda and we have a very full agenda for this meeting. Dr. McKee will go over it in a little bit more detail in a few moments. I'd like to point out that it has an insert. The solid page, back and front, is today's agenda, and the insert is for tomorrow. Subcommittee Assignments are behind Tab 3 in your notebooks.

Two other things I need to point out. One, the microphones this time are not voice-activated. So, you do need to turn them off with the button down at the bottom. So, please do that. Remember, please, to state your name so that our recorder can keep the record straight. So, state your name before you begin to speak, and, you know, when we get into the session as usual, please hold up your cards so I can, you know, keep speakers in order.

With that, I would like to turn the proceedings over to Dr. Garry McKee, the Administrator of Food Safety Inspection Service, who will chair this meeting.

Dr. McGee?

Opening Remarks

DR. McKEE: Thank you, and good morning.

I want to welcome you on behalf of USDA and the FSIS. For me being here a little over two months, I'm still learning my way around and meeting new faces which I hope to meet many today. By now, I've gotten over the shock of transition from Union County in Wyoming with a population of 55,000 people to commuting in a metropolitan area with nearly 5.5 million people.

Soon after I arrived at the job in Washington, we were charged with handling the largest recall in USDA's history. The shock of that was quickly paled into the enormous responsibility I see this agency carrying out to protect the nation's public health. I accepted this position on my profound desire to protect public health and to challenge myself. I've had more than 30 years of public health experience at the state level, but I'm now committed to making an impact on public health policy decisions at the national level.

For me, if I may use a football analogy, the whole playing field has changed. I have moved from coaching the team of 1,500 public health professionals in Wyoming and directing policies that affected nearly 500,000 people who are residents in the state, and now I am coaching a team of nearly 2,000 professionals and affecting policies that have an impact on nearly 300

million people across this nation. Now, that is a much, much bigger playing field.

No matter how large the stakes are, all teams go out to win, but the one thing that does not cross over in the football analogies is the fact that we in the public health field always need to win. Unlike football games, we cannot walk off the field with a loss. Whether we are a state or federal program, our mission is the same: to protect the public health.

I'm up to the challenge that is set before me and it invigorates me no matter how difficult it is. Last month, I met with supervisors and managers of the FSIS field team in Dallas and I spelled out my vision for the agency. This vision is to build FSIS into a recognized credible public health agency that is a model for all other public health institutions. FSIS has already laid a solid foundation for an ever-improved food safety system, and this committee's work and expertise in the past has certainly been instrumental in helping us fulfill our common goal to improve food safety.

For FSIS to fulfill its vision, there are three components that are successful public health models that we need to attain. They are assessment, policy development, and assurance. For assessment, we

need to assess public health problems using science. These activities include surveillance, identifying needs, analyzing the cause of problems, collecting and distributing data, case findings, monitoring, forecasting trends, research and evaluation of outcomes.

Once the assessment is done, we then need to develop and implement policies that reduce the risk of food borne illness. Some examples of policy development activities include planning and priority-setting, the development of regulations, directives, and other policy vehicles, mobilizing resources, training, constituency-building, and distribution of public information and encouragement of public and private sector cooperation.

Finally, we need to assure the public that FSIS is a credible public health agency. We do this by seeing to the implementation of legislative mandates as well as the statutory responsibility that we have. One way is through a strong program. We need to assure the American public that USDA marks of inspection found on meat, poultry and egg products means what it says. There are the components -- these are the components of a successful public health agency that I spelled out to our supervisors and managers last month. We are

holding ourselves accountable to fulfill our vision and ensure the public health of the American people.

We're also holding industry accountable. At the AIMH annual convention a couple of weeks ago in New Orleans, I clearly indicated that in order to protect the nation's public health, we will enforce HACCP. Industry will be held responsible for operating under the Pathogen Reduction HACCP Models, that a cut and paste or minimalist approach to HACCP will no longer be tolerated.

As I said to the AIMH two weeks ago, a HACCP plan standing alone is useless if all it amounts to is a ream of paper. For plants to ignore HACCP is to put the public's health at risk and that is simply unacceptable. We are setting the bar high. Plants need to produce the safest food possible. We also need to hold ourselves accountable when we enforce HACCP. The public health of Americans is Priority Number 1.

With that said, I'm very grateful to be here at this constructive two-day meeting and to get to know each of you as the meeting proceeds. As I said to our managers in Dallas and at the AMI in New Orleans a couple of weeks ago, we are inclusive. We are open to change and new ideas to improve food safety and public health. This committee's work and recommendations are

vital to our efforts to make our mission of becoming a public health agency that is the top agency in the nation.

The last committee made valuable recommendations to the states on issues such as new technologies in meat and poultry operations, the Farm Security and Rural Investment Act of 2002, commonly known as the Farm Bill, and the FSI field workforce. We're very grateful for these recommendations and taking these into consideration for our policy-making process. That is why we look forward again to getting your advice and input today and tomorrow on the important issues that we are wanting to identify and ones that are critical for us to evolve into a credible public health agency.

In my short time at FSIS, I've already found a high level of commitment from field inspectors to headquarters staff in Washington which has helped us to evolve into a first-class credible public health agency. I'm also extremely grateful to be working for Agriculture Secretary Ann Veneman who has a huge commitment to protect and enhance and promote public health and working with such gifted scientists from the Office of Food Safety, Deputy Under Secretary Dr. Merle Pierson, and our next speaker, Under Secretary Dr. Elsa

Murano.

Would you please join me in welcoming Dr. Murano here this morning?

Dr. Murano?

(Applause)

Meeting Agenda

DR. MURANO: Thank you, Dr. McGee. Good morning.

Excuse my raspy voice. I'm suffering from the flu after having gotten a flu shot.

Welcome to Washington on the morning after Election Day. Some of you may not have gotten much sleep. As I understand it, the final results didn't come in until way past my bedtime which is 9:00. So, welcome.

I would like to welcome you certainly on behalf of Secretary Veneman to this second meeting of the National Advisory Committee on Meat and Poultry Inspection that you've held this year. The last time you met, we had built a strong leadership team and streamlined the organization of the Food Safety Inspection Service to be more efficient but also more amenable, as Dr. McKee just explained to you.

I believe that your participation on this committee is one of the keys to our success. Your

presence here demonstrates your willingness to develop public policy; that is, people working in a public and private sector partnership to reach consensus on important issues to be used with sound science.

The fact that industry, consumer advocacy groups, government officials, and academia are all represented here today underscores the fact that this committee is a true cross-section of the American public and its highly-varied interests. I appreciate all the time you devote to helping us in this mission, and as many of you may remember, I was also a member of this committee prior to my USDA appointment. So, I do know firsthand the important work that you do, and so I do want to thank you for your time and effort.

I mentioned a meeting just a moment ago, and I would like to spend a little time telling you tomorrow about our new Administrator's efforts. First, I cannot express to you enough how delighted I am that he is working with us, that he's on board. He is the chair of this committee. He has a long career as a public health official, and I know him to be an excellent microbiologist and a dedicated public health servant. So, I am just absolutely thrilled to have him directing the activities of the FSIS.

Certainly the addition of Dr. McGee bolsters

an already-strong team at headquarters which includes, as Dr. McKee mentioned, Dr. Merle Pierson, my Under Secretary for Food Safety, Deputy Under Secretary for Food Safety, and Ms. Linda Swacina, Associate Administrator of FSIS, who will be joining us a little bit later. Together, we have what I believe is a historic opportunity to create a world-class public health agency that is second to none and we will.

On your agenda for this meeting, if you've had a chance to peruse your notebook, includes various tasks that we need your help on. You have been asked to review and make recommendations to the Secretary of Agriculture on for issues. These are education and training of field workforce, to help us achieve the public health vision, 0157:H7 developments, and procedures for evaluating state meat and poultry inspection programs. Certainly the coming session will be full of information and opinions on these subjects and we welcome a lively deliberation.

I would like to take a few minutes to speak about some of the issues in hopes of providing a context for your considerations. First, I think most of the people here today will agree that the best way to protect the public's health is through a science-based approach to food safety policies. We're not

looking to unnecessarily complicate things. I think things are complex enough when we consider the myriad of factors that can affect contamination of meat and poultry, even in pre- and post-harvest food production environments.

The complexity of these environments certainly presents a host of challenges in trying to determine the best strategies that can be applied to minimize or eliminate pathogens from our food supply. One could say that we are confronted with a disturbing fact, which is that controlling all potential sources of microbiological contamination from farm to table is virtually impossible. So, while I reluctantly acknowledge the difficulty at hand, I am committed to expending all efforts to reducing pathogens to the lowest possible levels in order to enhance the health status of consumers.

So, how can we best accomplish this shared goal, and can we actually find the next generation of food safety protections? Well, in my view, we need to have a better understanding of the factors that lead to microbial contamination. Only when we comprehensively identify and document the potential entry points of pathogens can we fully open the door to controlling food borne contamination. We need to better know our

common enemy.

The best way for building effective interventions is through the science of risk assessment which will tell us how those practices may contribute to the introduction as well as the microbial contaminants. This approach builds a bridge of the threats that may be aggravated by certain circumstances. This is what some people call a threat index.

Well, as most of you know, since the 1990s, FSIS has successfully bridged risk assessments to help preventive management strategies. The E.coli 0157:H7 risk assessment was conducted by our predecessors and is a good example of an attempt by them to determine the likelihood that this pathogen may contaminate ground beef during processing. For our part, the Bush Administration has continued and expanded upon this approach. Harvard University under contract to USDA completed a risk assessment for the introduction of FMC in this country. A similar analysis has been planned for determining the risk of Salmonella contamination in ground beef and poultry, and as you all know, we are in the process of conducting a risk assessment on Listeria monocytogenes in ready-to-eat meat and poultry products during processing.

In order to be most effective, I believe that a risk assessment cannot really stand alone. As soon as I began my tenure at USDA about a year ago, I implemented or introduced a tool that scientists like me depend on in academia and that is the tool of due process. So, we decided early on that risk assessment should be subjected to peer review in order to ensure that the conclusions drawn by the assessments are sound and those can be used to develop risk management strategies that will work.

That is exactly what you will be hearing later this afternoon when the National Academy of Sciences comes and presents its overview of the peer review that they have conducted of the E.coli 0157:H7 risk assessment that they have done. So, when these risk assessments are completed, it is crucial that we base policy decisions on these valuable and instructive models.

However, there are times when a risk assessment is not available due to lack of sufficient data to develop a robust model. So, in the absence of this, we must utilize the best available science until a strong risk assessment can be conducted. An example of this is FSIS policies on the Listeria monocytogenes that have been implemented both by the previous

Administration and by the current Administration of USDA.

The issue of dealing with Listeria monocytogenes by FSIS has been based on testing the end product by the agency and to verify whether SSOPs implemented by industry are effective. Certainly the events of the last month demonstrate that this approach is not completely adequate. Testing of product failed to prevent the outbreak of Listeriosis in the Northeastern United States and it failed to catch the contaminated product that led to the outbreak until after an exhaustive investigation that we conducted in accordance with the Centers for Disease Control and Prevention. This one investigation has involved more than 50 scientific and technical experts from FSIS alone with more than 400 laboratory samples having been taken in order to identify the likely sources of the outbreak. As you may have read in the recent press, the investigation is certainly still on-going and we and our partners at CDC will not rest until we have identified all sources of that outbreak.

As I have expressed in other speeches, scientific evidence demonstrates that we cannot test our way out of food safety problems. In fact, we cannot test enough product to find all the Listeria

monocytogenes that is out there threatening food safety and the public's health. The testing must be coupled with preventive and decontamination measures. In addition, testing must be done in a way that focuses on the most likely sources where this organism may be harbored in order that we may prevent its entry into the food supply wherever possible.

So, prevention must focus on addressing the critical entry points in processing systems for Listeria monocytogenes and then testing to ensure that interventions are working as designed. The best way to determine the entry points is through the use of an assessment which is exactly why we are undertaking this task. In the process, though, we are collecting more samples and generating more data to develop a model that will absolutely predict the risk of finding the organism in a specific situation.

I have every confidence that we are following a sound and responsible route for Listeria monocytogenes results, but it can be augmented in the interim with industry's help. Far more data is being collected by industry on its issues such as environmental sources than FSIS could ever hope to generate. Until the risk assessment is completed, it would be of great value to increase the number of

results that can be shared with FSIS in order for us to determine the effectiveness of the efforts in preventing contamination of ready-to-eat product with Listeria monocytogenes.

In the coming days, you will hear how we will operate in the interim period utilizing testing in a way that focuses on finding the organism and the environment at plants producing ready-to-eat product at the highest risk of contamination to prevent to the greatest extent possible the presence of these pathogens in product due to contact with contaminated sources.

When the risk assessment is completed, then we will move expeditiously to finalize the proposed rule. Upon completion, I believe we will have a scientifically-based rule that will successfully reduce the risk of contamination of ready-to-eat product with Listeria monocytogenes.

Again, before I lose my voice completely, I do want to extend my thanks to all of you for your time and your efforts. I look forward to these couple of days. We do value your thoughts, your comments, your questions, your suggestions as we strive to meet our goals and to become the premier public health agency in the Federal Government.

Thank you very much. I will return the microphone again to Dr. McKee.

DR. McKEE: Thank you, Dr. Murano.

Before we get started, I want to ask each of you to introduce yourselves and tell us a little bit about what you bring to this committee, your point of view, and what you're interested in. I know that for a lot of you, you may have already met each other, know each other, but basically for me, I think it would be valuable to go around the room at this point.

Let's start with you, Dr. LaFontaine. If I mispronounce your name, feel free to correct me on it. That's correct? Okay. Great.

DR. LaFONTAINE: I'm Dr. Dan LaFontaine. I'm the Director of the South Carolina State Program, South Carolina Meat and Poultry Inspection Department, and I've had the good fortune to be on this committee for three terms. So, this is my third term, one of the old-timers, and as far as topics, anything that involves meat and poultry, of course, involves our state programs distinctly. So, myself and two other colleagues have a very vested interest in what policies FSIS is developing and how we implement those.

MS. ESKIN: My name is Sandra Eskin. I'm an attorney and I do food safety work for AARP. I also

handle a range of consumer protection issues, both for AARP and other public interest groups, and I believe that one thing that I'd like to discuss in the context of what's on the agenda is the E.coli risk assessment, the impacts of food borne illness on sensitive populations, like older Americans, and I'll also hopefully have some time during these two days to talk a little bit more about what has happened vis a vis Listeria outbreaks over the last few months.

MR. GOVRO: My name is Michael Govro. I'm with the Oregon Department of Agriculture. I'm the Systems Administrator of the Food Safety Division, and I'm on this committee as a representative of a state that does not have a meat and poultry inspection program. I'm interested in pretty much everything that's on the agenda.

MR. HOLMES: My name is Marty Holmes. I'm the Executive Vice President of the American Meat Processors Association. Our members primarily are state operations and meat grinders for wholesale restaurants and food service. I've been here for five years now. Prior to that, I was with the Southwest Meat Association of Texas for eight years.

MR. LINK: My name is Charles Link. I'm Director of Technical and Regulatory Affairs for

Cargill Turkey Products. So, I guess from an industry perspective, maybe the meat industry, I don't know, we do a lot of turkey. Been in this business for a little over 20 years. I'm at the end of my first term on the committee.

MR. MAMMINGA: My name is Mike Mamminga with the Iowa Department of Agriculture, Meat and Poultry Inspection Bureau Chief. I've been with the program 31 years. This is the end of my second term on this committee, and in the state program, we're interested obviously in safety, food safety, whether it be in the state inspection environment, the federal inspection environment. I think we're also very interested in how we can enhance our relationship with USDA.

MS. FOREMAN: Good morning. My name is Carol Tucker Foreman. I'm Director of the Food Policy Institute of the Consumer Federation of America. The Consumer Federation is an organization that represents over 300 local, state and national consumer organizations, including groups like AARP and Safe Tables Our Priority, a number of consumer cooperatives and farmer cooperatives. I'm finishing my third term on the committee. So, this is my last meeting, something that will probably cause some relief on the part of people here. But I might come back to visit

you. I have been following these issues since 1975. So, I've been around for a long time.

I would like to know, since Dr. Murano doesn't have a voice today, there are some issues raised in the comments, Dr. Murano, that I would like to address and would like a chance to discuss some time during the meeting.

Thank you.

DR. JAN: I'm Dr. Lee Jan from Texas Department of Health, and I'm Director of the Texas Meat and Poultry Inspection Program, and like my other food colleague in the state programs, I'm certainly interested in FSIS policy and how FSIS carries out its mission because again we have the same goals for food safety as you do and we want to be able to participate in developing any of these -- dealing with controversial issues that may help provide a policy that is logical.

DR. DENTON: I'm Jim Denton, Professor with the Poultry Center of the University of Arkansas. I had the distinct privilege of replacing of Dr. Murano on the committee after she was elevated to the position as Under Secretary for Food Safety.

In my years of service prior to my current appointment, I was the department head and Director of

the Poultry Center at the University of Arkansas with 32 faculty members and about a 180 support staff dealing with issues, among them being the food safety issues. Prior to that time, I had a 20-year career in extension education at Texas A&M University, having been trained as a foods microbiologist with a specialty in the physical process. I've spent a great deal of time in my career working with education within the poultry industry, education within food service, and also education with the consumer organizations.

I currently have the privilege of serving on the Steering Committee for the Food Safety Consortium in Animal Products Research as well as the Chairman of the Operations Committee for the National Alliance for Food Safety. So, food safety is something that's been very near and dear to my heart for the past 32 years. I think like Carol in 1975, my career started about 1972. So, we share a long, long interest in this issue.

MS. DONLEY: I'm Nancy Donley, and I'm a real estate broker in Chicago. So, maybe I'm at the wrong meeting here. That's how I pay the bills. I'm also President of Safe Tables Our Priority. We are a food borne illness victims organization that started back in 1993, back after the Jack In the Box E.coli 0157:H7

epidemic that sickened over 700 people and four children died. My own son died right after that epidemic in Chicago also of 0157:H7.

Our mission and what we're interested in doing is working with the victims. We put the faces behind the statistics here. That's our role, is to kind of remind everyone that we're talking about things like policies and ideas that can and will save lives, and if we can do anything, I -- we want to work with government, with industry, with academia, for ways that we can put forth the public health mission that we've been hearing about today. I'm very, very grateful to have Dr. McKee as the public health professional heading up this very, very important agency, and Dr. Murano's comments that it's going to be public health focused and the leader in the world in this particular issue.

Like Carol, I may not be around the table, but I'll be in the back.

MR. PAULSON: I'm Myhre Paulson with OPPD.

MS. HICKS: I'm Cheryl Hicks with the Office of Field Operations.

DR. LEESE: I'm Bill Leese. I'm the Director of Federal-State Relations within FSIS. As you probably realize, under the Poultry Products Inspection

Act and the Federal Meat Inspection Act, FSIS has the responsibility to go assess state programs and to provide support and guidance to those programs.

MR. MAJKOWSKI: I'm Jesse Majkowski, Acting Assistant Administrator for the Office of Food Security and Emergency Preparedness. I'll be talking to you in a little bit about what our new office is doing. I think one of our major interests here is how we can -- our office can assist you in our efforts.

MR. GIOGLIO: I'm Charles Gioglio. I'm obviously the Executive Secretary of this committee. My other role is I'm the Director of the Inspection and Enforcement Initiatives staff within the Office of Policy for the agency.

MS. SWACINA: I'm Linda Swacina, Associate Administrator.

DR. PIERSON: My name is Merle Pierson. I'm Deputy Under Secretary for Food Safety.

DR. McKEE: Thank you very much for those introductions.

I'd like to review the new agenda for today and tomorrow to give you an overview. We'll start off this morning with a Briefing on Food Security from our Acting Assistant Administrator for the Food Security and Emergency Preparedness Activity within the

Department.

Then we'll have a break, and then we'll reconvene to start the discussion of the issue to be examined by the subcommittee, Subcommittee Number 3, and that is the Procedures for Evaluating State Meat and Poultry Inspection Programs. I'll kick that discussion off, and then we'll hear from Dr. William Leese in the Office of Field Operations and go over the status of the review of the state programs that were stipulated in the recent Farm Bill. Finally, during this session, Mr. Ralph Stafko from the Office of Food Security and Emergency Preparedness will give us a presentation on the new document "Procedures for Evaluating State Meat and Poultry Inspection Programs".

After that, we'll head straight into the discussion of the issue to be examined by Subcommittee Number 1, which is Education and Training of the Field Workforce to Achieve a Public Health Vision. This discussion will be led by Ms. Cheryl Hicks and Mr. Myhre Paulson.

Then we'll break for lunch and reconvene for the briefing by Linda Swacina on the FSIS Reorganization. After Ms. Swacina's presentation, Commander Judith Arndt and Lt. Commander Kimberly Elenberg from OPHS will lead a Briefing on FSIS

Consumer Complaint Monitoring Systems.

Then we'll take a short break at that point before we reconvene for a Legislative Update from Acting Assistant Administrator for Communications Bryce Quick. After Mr. Quick's presentation, we'll get a Briefing from Ms. Gerri Ransom of the Office of Public Health and Science on the National Advisory Committee for Microbiological Criteria Foods.

Next, Dr. Dan Engeljohn will lead a discussion of our third and final issue today, E.coli 0157:H7 Developments. After Dr. Engeljohn's presentation, we'll have Dr. Michael Doyle, who is appearing on behalf of the National Academy of Sciences, give us the final briefing of the day on E.coli 0157:H7 in Ground Beef - Review of the Draft Risk Assessment.

We'll wrap up this afternoon's briefing and discussion with about 20 minutes allotted to Public Comments. For those interested in providing public comments, it would be very helpful if you would notify Ms. Sonya West.

Starting at 7 p.m. this evening, the three subcommittees will convene for two hours. Dr. Dan LaFontaine, the Assistant Director of the South Carolina Meat and Poultry Inspection Department, will

lead Subcommittee Number 1 on the issue of Education and Training of Field Workforce.

Dr. Mamminga, who is the Chief of the Iowa Department of Agriculture and Land Stewardship, Meat and Poultry Inspection, will lead Subcommittee Number 2 on the Issue of E.coli 0157:H7.

Dr. Lee Jan, who's the Director of the Texas Department of Health and Food Safety, will lead Subcommittee Number 3 on the Issue of Procedures for Evaluating State Meat and Poultry Inspection Programs.

Tomorrow morning, we'll get started again at 8:30, and each subcommittee will provide a briefing on their schedule and recommendations from their sessions. Subcommittee Number 1 will have one hour to give us their briefing of their meeting session and that will start at 8:45 a.m.

Then we'll take a little break and reconvene for a two-hour briefing on the HACCP Models Project, more commonly known as HMP.

Dr. Jeanne Axtell will -- from the Office of Management and Dr. Perfecto Santiago from the Office of Policy will lead us in our discussions.

We'll break for lunch at 12:30 p.m. and then reconvene at 1:30 for Dr. Mamminga's Briefing on Standing Subcommittee Number 2's recommendations from

the evening session. That will be followed by Dr. Jan's presentation at 2:30 on Standing Subcommittee Number 3's recommendations from their meeting session as well. After that, we'll break, and if there is no public comment, we will adjourn.

Before we get started today, when we close, we'll also have a brief presentation to the departing members of the committee as well.

Are there any questions?

(No response)

DR. McKEE: Okay.

Briefing - Food Security

MR. MAJKOWSKI: Good morning. It is a pleasure to be here. I'm going to try to give you a brief overview of what we're doing in the area of food security which is very, very different from the area of food safety which I have been in for some time, dealing with classified documents, classified briefings, not being able to tell my bosses where I'm at, which is kind of nice at times, and not being able to tell them what I read and having them trust that I'm telling them is the truth.

So, the other interesting thing is I've done this talk a number of times in presenting this information out to industry and so forth, but today, I

have the opportunity to present it to my bosses, and so I'll try not to make any fumbles or stumbles as I go along here.

We have an Office of Food Security and Emergency Preparedness. This afternoon or this morning some time, Linda's going to talk about the new organization, but let me take you back to 9/11. Shortly after 9/11, food security was the furthest thing from our minds, and after 9/11, we began to realize as a department and as an agency we needed to do something about food security. Shortly after that event occurred, we formed the Food Biosecurity Action Team in the agency, and we were taking a look at what do we need to do to provide food security.

From that point, we moved to looking at the need for an office. With the demands the Department was putting on us in terms of food security and representatives of departments and other government agencies as well as to the industry, we realized that we needed a full program to be doing that. So, I'm going to be talking a little bit about that and giving you a little brief history about food security, bioterrorism and so forth.

There is a history of bioterrorism. If you take a look at the slide here, we've had some

biological weapon programs from the '50s on up through the '90s. In the U.S., we had foot and mouse disease. The USSR, former Soviet Union, has had a number of programs. There's a lot of concern about the agents/reagents that were used in their programs, where are they, who has them, where have the scientists gone that have been working on them, and in terms of the -- Iraq, the wheat stem rice. Where are we with that? And camel pox. These are just some of the biological weapons that were there in the past and some of our concerns.

There have been a number of recent terrorist events that you're probably well aware of. When you look at these events, the World Trade Center, Oklahoma City, U.S. embassy bombings in Africa, World Trade Center, the Pentagon, and the plane crash in Pennsylvania, all of them have a common thread. Explosives were used to blow up things or facilities or structures. The Rand Corporation has been studying how terrorists have been reacting and acting throughout the world for the past 20 years. Their analysts tell us that right now, they're at the -- the terrorists are at the mode of -- the sophistication mode of being able to coordinate attacks. The question is will they move beyond that to the next level of using any chemical,

biological or radiological agents?

Well, what about the food supply, and what about attacks on the food supply? You can think of this in two ways. One is that this could affect our national defense as well as the citizenry here, too. When you look at what can occur, we could have a disruption of the food supply without any deaths, threats that could be made against the food supply. We could see the destruction of brand names. We think back many -- several years ago, if you remember Vichyssoise Soup. They had a bot problem with their canning process. That brand disappeared. What would happen should there be an attack on a specific brand, one of the large industries or corporations?

We could also see an attack based on trying to get some economic gains on the futures markets. Think back to about four or five months ago where we had a report of foot and mouth disease, an animal being tested in a Kansas feedlot. That was the only news that came out that morning out of the feedlot, that an animal was being tested. The futures market lost $50 to $100 million that day on an erroneous rumor. So, the economics of this are extremely important.

One of the other problems we would foresee on an attack on the food supply is the ability to

distinguish between a natural and an intentional attack. I know you're going to be dealing with 0157 and Listeria and someone has mentioned Listeria outbreaks. Think of the outbreaks that have occurred for the past year or so. What's the connection? Are they unintentional or are they intentional? This would be the issue that would be facing us.

And secondly, when you think about food, think of it as a very, very easy target. How many had some of the pastries out there today? Anyone could have gone by and spritzed them with Salmonella. Look at the salad bars that you have in the retail marketplace. Go to any truckstop and take a look at the food trucks that are parked there, tanker trucks with milk or corn syrup going on to other facilities. So, food could be the -- the food supply could be a very, very easy target.

We have had some attacks on the food supply, and I'd like to run through some of these just to give you a sense of what has happened in the past, and this list is probably not all inclusive, you know. There may be others that you're aware of. Insurgents in Kenya were poisoning cattle. The reason they were doing that, the British soldiers were there in that country and they were trying to poison the soldiers.

In '78, we had Palestinian commandoes contaminating citrus with mercury, again targeted at the military. In Indonesia, tea exports were threatened. In '89, breeders were planning the release of fruitflies in California.

We had the incident in '89 with Chilean grapes that were contaminated, and in addition to that, in '96, we had an event that occurred in the lab, Shigella in doughnuts at a lab. A disgruntled worker at a hospital was upset with his -- I guess what was happening there and decided to provide doughnuts to all his fellow workers and laced them with Shigella.

There have been other attacks, too. Probably one of the more famous ones and this was featured on Dateline several months ago was the Salmonella on salad bars. That occurred back in '84. It was in Oregon. This was the Riniche cult that had a community outside a small town there. The town was having a local election to elect council members. The cult members decided to go around to the various restaurants at that time in '84 and were spritzing the salad with Salmonella. I think 700 to a thousand people became ill, and if you saw the Dateline program, they claimed that it was one of the first attacks on the food supply or biosecurity attacks.

The interesting thing about that attack was all that we knew at that time was that there were a number of people ill from eating at the salad bars. No connection could be made. If you think back to what was happening in '84, we didn't have the DNA patterning at that time. We couldn't relate clusters. Clusters were there. Was it an outbreak in terms of the DNA patterns? How they discovered that this was an attack was when they arrested -- several months later, there was an arrest of one of the cult members, and they admitted that they had been spritzing the salad bars.

In Japan in '94, we had the release of Sarin gas in the Tokyo subway. In '95, there was the anthrax obtained illegally. It wasn't used, but it was obtained. Again, that raised a blip on the radar screen. Think about the anthrax mail, what that did to our confidence in how we handle mail, let alone in the Federal Government, our mail was delayed for months while it was screened and x-rayed. So, an attack on the food supply could have a serious effect on the economy, national defense, and on the citizenry.

Well, USDA has been working in the area of bioterrorism. Did we just start on 9/11 and 9/12? No. We've been working on this for some time. Back in '98, the former Administration, President Clinton at

that time, had read a book on the weekend, a fictional book about an attack in the U.S., a biological attack, and issued a series of presidential directives for all the agencies to begin working on protecting the critical infrastructures that would be within a day-to-day basis.

At that time, we chaired the Agricultural and Food Safety Weapons of Mass Destruction Subgroup. We had scientists of ARS that were working on these issues, looking at these biological agents. We also at USDA had formed a USDA Counterterrorism Task Force at that time. This is just to give you a sense that we didn't just start in 9/11. There's been a lot of work that has been gone into this area and we've been building on it for some time.

We have had a number of federal efforts just recently. We had about $325 million provided to USDA for our biosecurity/bioterrorism efforts. FSIS received about $16 million, APHIS and ARS each got about a $100 million. The Secretary's Office got about $85 million. Some of that money was given out to states in grants.

I was at a meeting a couple of weeks ago where some people in the ARS were talking about the money that they received, and they called their 100

million pocket change in terms of the amount of money available. So, I guess our 16 million wasn't that much, but we are utilizing it.

In addition to that, we have the Office of Homeland Security. You notice here I have the department because we've been talking about this, talking about the Office of Homeland Security. The legislation is up on the Hill, and we thought it would get passed relatively quickly. The question that comes to me many times is will -- is FSIS going to be part of that or some portion of it? Currently, as the legislation is written, we are not part of it. A portion of APHIS at the borders will be involved in the Department of Homeland Security.

That leads me into advisories, and I think we've all heard about the various codes, code alerts, that have gone on, especially during the week of 9/11. But there's some things that I think that you need to understand about this. First off, the alert system is assigned by the Attorney General and there are five sections, and I'll speak a little bit more about those in a second.

Also, in addition to the threat level, there's a type of threat. Is it nationwide? Is it geographic or is in the industrial sector? Shortly --

I guess on the week of 9/11, Secretary Ashcroft came on in a news conference and announced that he was raising the rate to high alert for certain sectors which did not involve the agriculture sector. It's very important when you hear these alerts to listen to what sectors are involved, whether it's nationwide or whether it's geographic. We are prepared to react should that alert involve the agriculture sector or the food sector.

These are the threat conditions. Low is green. There's a low risk of a bioterrorism attack. Blue being guarded, general risk. Elevated, yellow, significant risk. That's where we're at today. We are operating at the yellow level. And for us, at FSIS, what does that mean? Well, we have placed our inspectors on a heightened alert since 9/11, and they report any suspicious activities, and periodically, there are some things occurring out there in the field that do get reported to us that we turn over to our Office of Inspector General to determine if it should be turned over to the FBI. Orange is a high risk. That is when -- the week of 9/11, there were some specific threats, and at the severe or red level, there's a bona fide attack on some sector.

FSIS does have a food security plan and it's

very simple. We want to prevent the use of food as a weapon. In our Office of Food Security and Emergency Preparedness, we have a number of areas that we're going to be working on, and I'm going to talk a little more in-depth about these and some of the activities that we're involved with. Emergency food planning, food security at the federal and state level, a food biosecurity action team, our continuation of operations, keeping the government and our businesses running. The Food Emergency Rapid Response Evaluation Team, FERRET, and the Food Threat and Preparedness Network, FTPN.

Let me spend a little bit of time explaining the differences between these two. The first one, FERRET, is composed of a group of USDA individuals, Under Secretary and Administrators for all the various agencies. Should an event occur that involves a commodity that USDA purchased, an inspected product, we would call this team together to begin to react to that event. If in fact the threat involved other products outside of USDA or the border or the Department of Defense, we would utilize the Food Threat and Preparedness Network, FTPN. This group, which is composed of intergovernmental officials from CDC, DoD, HHS, FDA, CDC, meets just about every other month to

discuss various issues about food security. We have three subgroups on that group that are working on emergency preparedness, another one working on laboratory issues, and another one working on prevention and detection.

The whole idea of those groups is to have the ability to share information between intergovernmental agencies. If you think of what FDA is working on in the food supply, we're working on similar issues, and we need to be able to share that information. This provides a vehicle for us to share that information as well as the context in which some events occur.

The initiatives that we are currently working on, food security, employee safety, continuing operations, communications, laboratory capability, training. I'm going to go into a little more detail and talk about some of the issues that we're trying to look at and some of the problems that we have and dealing with the industry as well as the general public.

In the area of food security and emergency response, we are conducting a vulnerability assessment of the domestic as well as imported food products. We are taking a look at the farm-to-table continuum to see where agents could be introduced into the food system,

what effect they could have and what do we have in place today in our inspection system that would mitigate the effect of those agents or how we could control them, and we're going to be looking at those strategies at preventing and detecting those agents.

One of the issues we are faced with here is when we complete this work, we will have a recipe for disaster. We will have information on agents, how much they have at a certain point in the process to make X number of people sick or to kill X number of people. USDA has just received the authority to classify documents. We are -- we will probably have that document classified once we complete that work.

The question in our minds is how we will be able to share that information when we recognize vulnerabilities in certain industry segments and processes that alerts the industry to be able to do that. One of the vehicles that may be open to us is something called Information-Sharing Action Committee that the FBI has been forming -- has formed a group. These action groups, one represents security, others represent railroads, transportation and so forth. We will have people in that group from the industry that will have security clearances that will be able to share that information and then they in turn will be

able to help us sort of declassify or cleanse that information so that we can get it out to the appropriate people.

In the food security and emergency response, we also have an emergency response team. Many of you who have dealt with the agency before know we've had recalls. We have a Recall Management Division and so forth, and the question always comes up, well, what's the difference between this and what the agency normally does?

Normally, when there is a recall, the agency is dealing with a single situation, looking at it, getting it out of the commerce, and then looking at what happened to make sure that there isn't other contaminated product and whatever went wrong in the plant was corrected. At that point, we focus our attention on that situation.

This team will take a look at that situation and utilize those emergency procedures to have that same effect, but we will also be looking beyond that. What else is happening in that industry? Does it involve any USDA products? It will be a much broader look to make sure that we keep control if it is truly an intentional act, that it hasn't gone beyond that plant, and that will be the function of that emergency

response team.

In the area of employee safety and health, this is a little bit different than food security. Another area we are looking at is the food itself. Here, we're looking at our inspectors in the plants. What could they be exposed to if there was an attack on the food supply? The agents and the steps that could be used in that would be slightly -- would probably be different than what would be used on the food supply. So, we have a contractor that's looking at various scenarios that's going to be coming back to us with some recommendations on how we can advise our employees. We are working on sending out a handbook for them on this issue, and we will probably base most of that information on that work. In addition to that, we're looking at procuring some additional analytical and detection equipment for this.

In the area of continuity of operations, I want you to think back to Washington on 9/11, to the chaos that was in this city. People were leaving their offices. All of us at USDA just bolted out of our offices when we were told to go. Rumors were flying about the State Department had a bomb, the Metro wasn't running and so forth. Inspectors in every plant in the country were there on the job so the food supply was

not disrupted. Some of the reasons for that were planning. We had a plan for Y2K to shift our decision-making capabilities for different locations. They took over the operation of the agency until we got back into our office the next day or the following day.

In addition to that, our own district offices have plans. They have alternate sites where they would operate from, and what we need to do is to maintain that capability to be able to do that should there be some disaster event in Washington.

Another area is the area of cybersecurity. No cell phones worked basically in this area. So, we're looking at alternate means of communications, to get the message to our people on what they should be doing, how they should be reacting.

Now, moving on to the next area, communications, this is probably one of the most important areas I think for us. If you think of the message that we will have to tell the general public should there be an event, it'll be extremely important that we have a means to communicate that message properly. We're in the process now of developing a series of education and awareness materials that we will use for the public and consumers. We are actively participating in national and local conferences. We

now have a display booth that we have gone out at many of these meetings. Myself and others on my staff have gone out to talk to the various industry groups.

Last week, I talked with the National Guard. Tomorrow, I'll be in Atlanta. I'm going to be talking with the poultry executives on food security at a roundtable discussion. In addition to that, we're in the process of establishing some back-up communications. Should some event occur, people go to our website. Our website's in Washington, D.C. I think you can tell from most of my comments, we think D.C. is a prime target for some attack should one occur. Our server would go down. We need back-up systems so people can go to our website to find out what was happening, what's happening to their food products.

The laboratory area is something that was clearly brought home during 9/11 and after that with the anthrax hoaxes and scares that were going on. Labs were inundated with samples throughout the country. The inability to handle those. In addition to that, shortly after 9/11, our Office of Inspector General reviewed all the labs that USDA has, and we have over 350 some odd labs throughout the country. Fortunately, FSIS only has about four, and they looked at 30 of

those labs, and we are in the process now of doing our own security assessments, looking at how we can collate the agents into those laboratories and so forth, and we're improving that security.

We're also looking at how we can improve our capabilities should there be a series of samples that we need to analyze for an attack on the food supply, and we're also looking at equipment that we should be purchasing. A lot of these activities are being funded by that initial $16 million that I spoke to earlier.

In terms of training and education, one of the important things that we need to begin to do is to train our own people, our own workforce, in food security and ourselves. We did issue a guideline, a food security guideline, that went out to the industry. It was well received. If you look at the brochure that we put out, probably one of the few times that the agency has been able to put out a color brochure that's very effective and that holds people's attention. We are in the process now of developing a one-page fact sheet that our compliance officers will be using when they go and visit warehouses and import facilities. So, we are in the midst of developing more industry guidance and information to heighten their awareness on food security.

We're also looking at remote classroom learning for our people in the field. How do we get to the 6,300 inspectors in 7,500 plants, and how do we get the same message to them? So, we're going to be investigating that.

One of the key features of our training program will be doing tabletop exercises. You may have seen the paper several months ago, USDA at the department level had a tabletop exercise where they looked at these issues. We are going to be doing a tabletop exercise for all of us and determine how we respond to an event, and what are the areas that we need to include to protect the food supply. What we would like to do is to take a look at products that involve not only suspected products but something that is going to be the -- so we can test out how our other sister agencies will react should there be an event.

Once we've accomplished that, then we're going to be looking at doing some exercises in the field, and we're going to be pilot testing an exercise in January on trying to heighten our inspectors' awareness about how to look for and detect suspicious activities.

In the area of international area, this is a concern in terms of the imports. We import -- I think

75 percent of the imports come from four countries, Canada, New Zealand, Mexico and Australia. There's a small group of us that are working with the Department and the State Department, with Canada and Mexico, on protecting our critical infrastructures. This could arise in Canada or Mexico that have critical infrastructures or with ours. How can we protect those so we don't get attacked? If you think of the Canadian border, we have some -- about three or four plants that have shipped to plants in Canada and product goes back and forth between the countries. It could be a big disruption to the Canadian economy as well as our own and to our food supply.

One of the things that we are doing very actively is we're in the process of hiring about 20 more import inspectors. If you know our agency operates, we do have import facilities throughout the country. We have about 75 import inspectors. They are there to take a look at products and specifically products that are coming through the sample products on the periodic basis from plants and countries and so forth. That's an additional role.

In traditional imports, we'll be looking at a much broader picture of that facility, not only the product from them but how are the products being

handled in that facility. How can we tie into what Customs is doing in terms of products coming in? Other agencies are looking at these products, also. How can we meld those three together and begin to look at a total system at the import facilities?

These 20 are going to be placed around the country where we've identified some vulnerabilities in terms of the high likelihood that the country would be to attack, and again I mentioned that we are doing these vulnerability assessments. We expect that to probably take six to 12 months to complete that on the imported products. But if you think of the import products that are coming into this country, the vulnerability in the country itself, in the plant where the product is being produced, there are canned products produced here and coming from a foreign entity. The processes are quite similar and the vulnerabilities are probably very, very similar in those entities. The question comes up, how is the product handled? How is it handled when it's shipped over to the States, and then how is it handled at the import facility when it comes into this country? We'll be looking at the vulnerabilities.

To summarize, and I'd like to leave some time for some questions, one of the messages I'd like to

leave you with is to tell you that we are prepared to respond to protect the food supply. We've had a long history of responding to emergencies, responding relatively effectively, I think, in contaminated products in commerce. The systems are there. This office will coordinate those efforts should a regional or nationwide event occur.

Our field staff, in and outside of the plants, really serve as an early link for all of us. Certainly after 9/11, I can't tell you how many suspicious activities were reported, not only on the food supply. We had numbers of investigations going on. In addition to that, our people alerted us when anthrax started. When those events occurred, we had the plants shut down, we did not allow product in or product out until hazmat and local law enforcement went through that area to ensure that there wasn't an anthrax incident.

If there are suspicious activities, our inspectors have this number to report, but we also ask other people to utilize this number, too. We will investigate any information and take a look at it.

So, with that, I'll close and I'll open it up for any questions. Yes?

MS. DONLEY: Nancy Donley from STOP.

I have two questions. One is in the event where there's just a threat and let's say that the threat comes in that it's something that's already been shipped to the public, when will the public be advised? I have a second question.

MR. MAJKOWSKI: Well, give me the second one. That may be easier.

MS. DONLEY: The second one -- well, I don't think so. The second one is, is there -- our recall system right now, I think, has a lot of problems in it. Number 1, the agency doesn't have the authority to do it, it's up to the company to voluntarily initiate a recall. The amount of information that's dispatched to the public is less than adequate in allowing the public, the consumers, to identify the product, and there's just very lengthy delays.

Who's going to be in charge? Is it going to be the emergency response teams? Is it going to be FSIS or is it going to be the company?

MR. MAJKOWSKI: Just happen to have a slide for that. Well, you brought up a point. Let me respond to that.

First off, when we receive a -- and I -- classified information on threats, you have to make a judgment, is it a credible threat, and every other

week, I see classified information about threats to the food supply. We do have the FBI that has a group that is assigned to look into that threat and make a decision on whether or not it is credible. Should that come to us, that is a credible threat, and we will have to react to that in some manner that alerts people, to pull product off -- out of commerce, if we need to.

If there is a red alert and, for example, it does involve the agriculture sector, we do have plans in place, based on the code system that I showed you, how we would react. Think of the orange level. The orange level is the area where we are preparing to deploy our resources. We're getting ready to activate tools, getting ready to activate the field force, depending on the threat. So, a red alert will activate those emergency response teams that I set up. That team will take charge of the situation. They will make the decisions. They will have people going out. They will be sending messages out.

It's difficult to say what exactly will be done because I don't know what the threat it. I don't know what the situation is.

MS. DONLEY: If I can just follow up with one point.

MR. MAJKOWSKI: Go ahead.

MS. DONLEY: You know, right now, we know that under a recall situation, the actual recovery is very, very small percentage, and a lot of that is because the length of time it takes to get the recall organized within the company, to get the information out, and then once the information is out, it's not easy because of proprietary information on the part of the company. It's very difficult to know where the product's been distributed, and certainly for consumers to be able to identify it easily by even saying, hey, listen, it's been shipped to this or that retailer and they know that they have purchased it, I'm very concerned that if we haven't got something, you know, better in mind than how we respond to recalls currently, the public's going to be at very, very high risk should there be a bioterrorist threat on the food supply.

MR. MAJKOWSKI: I would tell you that we will respond differently. If there is a bioterrorism threat, there's a number of different authorities that come into play from the President on down to the Secretary's level, and I would think that our past practices of what we normally do in a normal recall would go out to industry. People will be alerted. People will know where a product came from.

MR. GOVRO: Mike Govro, Oregon Department of Agriculture.

Comments on the lines of authority and which is the lead agency, if an event should occur, in an establishment between USDA and FDA.

MR. MAJKOWSKI: The FBI. Just so you know, if there is a bioterrorist event, the FBI has the lead on the investigation, and we usually think of this as two things going down a parallel road. One is the investigation of what happened, the criminal investigation. On the same road is a parallel investigation of what happened to the product, where is the product and so forth, and how we're going to get that product back and get that out of commerce as quickly as possible. I think it's going to depend on the product that's distributed.

DR. LaFONTAINE: My name is Dan LaFontaine, South Carolina.

I'd like to comment on the Food Security Guideline booklet which I think is a very excellent document and it's gotten out in record time. It's an excellent document for large plants. It talks about real-life things, like having gates and fences and guards and employee identification. That certainly would be applicable across the board and with the help

of Dr. Leese's office, we got copies and sent them to all of our state plants.

But it misses the target a little bit on the very small plants, and if I can digress for a moment, in England, with foot and mouth disease outbreak in 2001, although that apparently was not intentional but inadvertent, foot and mouth disease was detected in a small plant in the Midlands. So, these things can originate at a very small plant.

In FSIS and the states, there are thousands of very small plants if we look at the logistics, both at the federal and state system, and many of these intentionally are opened to the public. They have retail markets in the front end. The farmers and ranchers are bringing their animals directly from the farm. Many pull up on the property every day.

So, what I'm trying to do is sensitize FSIS to this population that is at risk from a food security viewpoint and maybe you have this in the mill already, but I really think you need a second version of the Food Security Guidelines that's geared to those thousands of plants that are community-based that intentionally may be at more risk than the large plants because of the nature of the business they're in and their physical locations. So, I'd offer that as a

comment.

MR. MAJKOWSKI: Your recommendation is that the Food Security Guideline be developed to some way take a look at how we can achieve the various portions of it that would be appropriate for the small and the very small plants and probably, in addition, the format in the book that's quick and easy to read.

DR. LaFONTAINE: The format could be similar, you know, a glossy with photographs, but it would be developed by those, you know, by industry and state and federal regulators that try to get ideas and recommendations as to what they can do in their area.

So, really, the same kind of pamphlet is one that's directed at very small plants because it's -- they don't normally put up gates. They don't have guards.

MR. MAJKOWSKI: I understand.

DR. LaFONTAINE: They're trying to get people to come to them every day.

MR. MAJKOWSKI: Yeah.

DR. LaFONTAINE: All right.

MR. MAJKOWSKI: That's a good recommendation. Let's take this back to the office and see what we can do about it.

DR. LaFONTAINE: If you do, I would certainly

suggest that you invite one or more state representatives to assist you. Most of us have almost exclusively very small plants.

MR. MAJKOWSKI: When the guidelines were developed, Dr. Santiago was leading that group, and he's involved in the industry and various industry groups. So, I think -- do you want to speak to that?

DR. SANTIAGO: Thank you for the compliments. All of us want to ask what's next? When I came to Washington, that was my first assignment, to develop the guidelines. We participated in the development, and it was composed mostly of very small plants, but we did get feedback from them, and after the development of the issues, I went to the Reno Convention at the National Association of Food Processors, which is a system of small and very small plants, and I was able to help them to understand the guidelines. They understand it does not apply to all of the small plants, but we were able to explain a little bit how this will apply to them. So, they did have communication.

The other part is that we have issued a Federal Register Notice for comments on the improvements of these guidelines. So, we will take those comments as part of the development and reissue

these guidelines. I understand it's sold out. But anyway, we will try to see to it that those comments are applied to the guideline.

Thank you.

MR. MAJKOWSKI: Dr. Jan?

DR. JAN: Lee Jan, Texas Department of Health.

I would just like to comment and then make a question regarding the vulnerability assessment. I think that's a critical point, that you have to assess the kind of vulnerabilities and be in a position of classifying those documents and that information to the importance.

I think the next part is, and you did allude to it, but it's important to remember that people at the front line have to know how to -- once the vulnerabilities are identified, the front people need to get that information, not necessarily classified, but what do they do and how do they react. I think that classified secret documents, information from it does need to get down to the people who can make a difference.

My question, though, is, being this is classified information, how would that information be shared with the local and state partners of your agency

that are important in taking care of these things? I doubt that any or very few of them are going to have the capabilities for securing a classified document, and is there a plan to bring these people in that can then deal with actually preventing and therefore facing some of these vulnerabilities? Animal Health Inspection agencies, from Meat and Poultry Inspection, retail food inspection, all those type agencies, will have a role.

MR. MAJKOWSKI: Our plan is to get this information out and down to the state partners and to industry people, and when we identify an agent, how much and where is it at, the information may only need to be shared with you. This type of process, at this point in the process, it's an area that someone could intentionally contaminate product, and there needs to be vigilance in these areas.

I think we may be able to do that, and once we complete it, get it classified, we need to step back and take a look at how can we sort of declassify this information and get that out to people so they can utilize it? But we will be working on that.

DR. JOHNSON: (Inaudible question)

MR. MAJKOWSKI: Well, the CDC has had a list of agents on their website. It may have been taken

off. The FDA had a list, also, and a couple others. There's a list that we were working from, looking at those agents, and we also have a group that is looking at laboratory capability and identifying what our labs can do, if our labs can do that type of analysis, what are the methods, can we get those methods. So, that is in the works. It's not completed development.

MR. GOVRO: Mike Govro, Oregon Department of Agriculture.

I've participated in a number of tabletop exercises. The few that have been bioterrorism events have been, I would say, somewhat formulative at this point. It was sort of developed as we went. I've also participated in tabletop exercises that have to do with the release of nuclear power plants. Those were FEMA exercises involving all the different agencies that would be involved in something like that, and so far, the bioterrorism tabletop exercises I've worked with, I will say, haven't been tested very well. The ones that FEMA runs are extremely instructive, and I wonder if you could comment on the tabletop exercises that you have planned at this point, and how many agencies are going to be involved in those, and what you can tell us about that?

MR. MAJKOWSKI: Okay. In terms of FEMA and

the tabletop exercises, yes, they are much better developed. This was all started back shortly after Chernobyl. FEMA, I guess, was charged with it, and USDA had a role, my offices, that represent the Department, on radiological agents, and so over time, they developed these scenarios based specifically on chemicals from a power plant melted down. What the radiological subtype was, what the result was, what actions to take, and that type of thing.

Now, some of the other type of tabletop exercises, I've been involved with CDC, FDA and some others, and what comes out of those is some generally important information about identifying responsibility, and I know when you think of the different agencies, the one I was involved with was with FDA. There was confusion on whose responsibility was it to notify the foreign countries about it. The responsibility stopped with FDA. That's what the tabletop exercise is designed for, to raise it to the level of a decision-making point.

In our agency, for example, we will probably -- the first tabletop exercises just involved our agency, and we'd like to get our own house in order first before we bring in FDA, CDC, and those other agencies, so we can see what are the decision points

and where is it we have some confusion on who's responsible, who's going to make the call, who's going to make the decision? That's what we hope to get from the tabletop exercises. Does that help clarify it?

MR. GOVRO: Yes. I think the point I was trying to make is that these things rarely happen in a vacuum, and I can appreciate that view, but it seems that the more players we involve, the more areas we find where things can break down. I agree that the scenarios for radiological release are much more serious than, I think, who knows what we might be dealing with in the future.

MR. MAJKOWSKI: I think our first one will involve other agencies within Agriculture and it will be useful to see how we interact with them, and then we'll expand that at the next level and involve FDA, CDC, DoD and other agencies.

DR. McKEE: Okay. Thank you very much.

We'll take a break now. There's refreshments outside the door. Let's try to return right at 10:35, and we'll continue with the agenda.

(Whereupon, a recess was taken.)

DR. McKEE: We will now move on to the issue that Subcommittee Number 2 will address tonight, and that is "Procedures for Evaluating State Meat and

Poultry Inspection Programs".

FSIS clearly recognizes that states are equal partners and play such an integral role in protecting public health. For all of us in the public health arena, the arbitrary lines among federal, state and local government jurisdictions may be dissolved, and we all need to work together.

As I mentioned this morning in my football analogy, all teams go out there to win, no matter if they are playing at the high school, the college or the professional level. The stadium sizes vary, but they all have a common goal. Likewise, we in the public health field, no matter whether we are in federal, state or local communities, all carry out common duties, common responsibilities every day for a common mission, to protect the nation's public health.

There are certainly best practices carried out by FSIS programs and best practices carried out by state programs. We need to share these best practices with each other. We need to foster greater communications of what works and what doesn't, and we will learn from each other to fulfill our common mission.

This afternoon, within this next hour, we are getting a briefing on technical procedures. However,

in the long run, I want to create a collegial homogeneous working relationship with the states. We need to explore many issues, such as cross training, education, testing, etc. We won't be able to cover all these issues this afternoon, but we do want to initiate an on-going dialogue on these issues.

Now, I'd like to turn to -- turn the discussion over to Dr. William Leese who will give us an update on the status of the reviews of state programs.

Dr. Leese?

Issue - Procedures for Evaluating State Meat and Poultry Inspection Programs

DR. LEESE: Thank you, Dr. McKee.

What I was going to focus on for this discussion would be the initiatives being put into place as a result of the previous meeting of the Standing Subcommittee Number 3 and the recommendations regarding the information to the report to Congress that was going to need to be ready by March of the coming year and how that fits into this whole picture of the state programs and working with the states.

The issue was the Farm Bill, signed in May 2002, it directs the Secretary to do a full review of the relationship and further report on the review of

FSIS and report to Congress. It directs the Secretary to include in the review guidance on changes the state systems might expect if the prohibition of interstate shipment is removed and the conference report does not suggest additional appropriations. So, it must be completed even if there are no additional appropriations and, of course, there will not.

The questions presented to the Advisory Standing Committee Number 3 were: Question 1. FSIS supports the concept of interstate shipment but is concerned about expending significant agency resources on the concept before the necessary authorizing legislation is passed. Because there are new provisions, it is not subject to appropriations. How can FSIS best use its limited food safety resources to meet the mandate? The recommendations from the committee were: recommend that FSIS review back as far as the year 2000, which by the way is when the first small plants implemented HACCP, to review as far back as 2000 all state comprehensive reviews that had been completed and attempt to complete the reviews of the remaining cases by March 2003.

Ordinarily, we'd be accomplishing about in the neighborhood of six to eight reviews, but state reviews may take a year. Because the time frame is

probably too restrictive in order to do in one year all 27 reviews with existing resources, because the time frame is probably too restrictive, additional funding and extension of the due date to report to Congress should be pursued. Outsource contracting to complete the reviews should be considered as an option.

Okay. Our response is we have either in progress or completed all but three of the state comprehensive reviews covering the period from 2000 up until the present time. We have three that will be starting in December which will be the last three, and we have every reason to believe at this time that we will be able to have the information ready for the report to Congress that would be scheduled for somewhere around March.

Now, in the same general context, the second question was: what kind of guidance would be useful to states in advance of legislation authorizing the interstate shipment of state-inspected product? The comments from the subcommittee were: request states to adopt all current federal food safety regulations and their implementing policies, including FSIS directives and memorandums. Food security guidelines should be considered. Ensure uniform compliance with state and federal regulatory requirements. Use the efficiencies

identified in the state comprehensive reviews to formulate guidance material, and a statement to have state inspection program personnel participate in the field force training.

As far as our response, these issues will be incorporated, among other things, into the responses to the individual states with regard to their individual comprehensive reviews and certainly kept in the forefront because we're in this on the part of each of these states.

Are there any comments or questions? Yes?

MS. FOREMAN: Carol Tucker Foreman with Consumer Federation.

I have a couple of process questions, please, and then I think a couple of substantive ones.

Would you make available to the subcommittee and then for the full committee tomorrow the written report that -- and the recommendations that the subcommittee -- that the committee made at the last meeting with regard to this subject?

DR. LEESE: You should have that.

MS. FOREMAN: Oh, okay. If you have a copy, I don't believe it's in the materials we got, and I think it would be a handy reference.

DR. LEESE: I do have it with me.

MS. FOREMAN: Thank you.

My recollection was there was one point that was left in this agreement and was noted as a minority report or just noted that there was no agreement on it. Am I wrong about that?

DR. LEESE: I don't see it listed in the final report.

MS. FOREMAN: Oh.

DR. LEESE: Maybe someone else can address that.

MS. FOREMAN: Yeah. I think that there -- that that's the place and that really should be noted in any reference back to the report of that meeting, that we had some disagreement on one of the reports.

I'm on the subcommittee, and do you have questions for us for this evening? Because I didn't find any questions in the book.

DR. LEESE: Well, this topic, of course, is tangential to the issues for tonight's meeting with regard to the requirements that are being developed for the state programs, and Ralph Stafko will be discussing that topic and he can address that. I don't see any specific questions.

MS. FOREMAN: I don't have any in my material. You're going to tell us what you want us to

do this evening?

MR. STAFKO: Thank you. Thank you, Bill.

First off, I'll apologize. My voice is a little raspy. There's some kind of bug going around and it seems I got a good dose of it. I apologize for that.

The committee is going to be asked to take a look at a document that's been around for a couple of years now. It is intended to articulate certainly more clearly and more easily understood the criteria and procedures by which we administer our cooperative state meat and poultry inspection programs. What we're hoping the committee will do is to keep this, discuss it, let us know if we achieve our objectives, and give us any recommendations for making it a better document.

First, a little background. Of course, we have just announced the reorganization. Up until this time for the last couple of years, Bill and I have been working very closely together in an office called the Federal-State-Local Government Relations Office, and prior to that, Bill had been in the Office of Field Operations and has for quite a few years been managing the agency's program that works with the states and administers the cooperative agreements for meat and poultry inspection at the state level.

Myself, I have in the last few years been working with state and local agencies and other organizations on cooperative agreements and other collaborative activities, focused more on outside the plant food safety issues, areas where we have collaborations with other entities to address the hazards to our products outside the plant.

Two years ago, when our federal-state-local government relations staff was formed, one area where Bill and I saw we had a common interest and common concern was this area of how we articulate and how we implement the criteria for oversight of cooperative agreements and cooperative activities with our partners and other agencies.

As you know, back in '68 and '67, the Meat and Poultry Inspection Act and the Federal Meat Inspection Act were revised to provide for state meat and poultry inspection programs. The requirement is that states must apply requirements at least equal to those imposed under the federal statutes. If that pre-condition is being met, then we, FSIS, can provide up to 50 percent of the costs on a reimbursed basis to the states for the operation of those programs.

The areas which they must demonstrate their capacity and capability include meat inspection with

Title I in the FMIA, and also, where appropriate, allied industries under Title II and enforcement activities under Title IV. There is an additional factor which weighs heavily on both us and the states and that is, in the absence of such a state program and our certification that it meets the requirements, we are obliged to designate that state as one in which the Federal Government must provide meat and poultry inspection, even though they're small plants and only so many within the state would have a proviso.

I think we currently have 28 states, and we've been adding more than losing. Unfortunately, with the economy being the way it is, it looks like one state may be giving up its program. We've been advised that Virginia is teetering, that's a fair way to say it. So, we're a little concerned there. But in any case, on the whole, it's a very vibrant program. It provides an essential supplement to our capacity to ensure that the nation's meat and poultry is safe and suitable and properly labeled.

In addition to those meat and poultry inspection program cooperative agreements, there are ancillary kinds of agreements which our agency entered into with states. There are eight agreements which provide for states with their own programs to do

federal inspections on our behalf under that agreement. Another kind of an agreement is a cross-utilization agreement where, for example, our program has trouble getting staffing to a remote plant and the state has a nearby inspector, that we can actually have that inspector work for us directly under that agreement.

Now, those kinds of agreements, kind of ancillary to the inspection, pre-suppose the state programs. There is one area where we do have cooperative programs with states extrinsic of that. Three states do oversight of custom slaughter operations in their states under separate cooperative agreements. Custom slaughter being an inherent part of what the state meat and poultry inspection programs do already.

Now, when I signed up with Bill a few years ago, there was already a long-term concern about the existing directives under which cooperative agreements were being administered. It was and is pretty obsolete in a different ways. It's been viewed by the state directors especially as over-prescriptive. It's difficult for people not really immersed in this to understand what it says, and in addition, the question arises whether the format is really appropriate for everything it covers, practice fees and tender fees,

direct -- provides a vehicle for directing FSIS in agency conduct. The content of this directive does include guidance to the states on how they are to run the program. So, there's a format issued as well.

Now, while Bill was struggling with the meat/poultry inspection and how to upgrade that directive, one of the things I had been doing is heading up USDA's participation in an endeavor called the National Food Safety System Project and this was begun in late '97 where we brought in representatives of all 50 states and the local groups as well, federal agencies, ourselves, FDA, EPA, CDC, different disciplines, epi people, regulatory people, laboratory people, basically anybody in the public sector with food safety responsibilities, and the whole notion was how can we work better together to provide more effective protection to the American public and do so in a more efficient way?

Frankly, the first meeting, a lot of people went in a little cynical, but it was amazing. A lot of these folks had been thinking these thoughts for a long time and they had never had a chance to express them, and we left the meeting with just about everybody saying no, we can make a difference, if not, us, and the logic behind working better together with a goal of

infiltrating a more seamless system where we can take the best of all the public resources available from the states. It's a no-brainer. It's something that everybody strives for. Everybody agreed on that.

The folks at that meeting reconvened later that year and formed into work groups, each one led by a state agency person, to address different facets of how we can better collaborate on food safety. There was a work group for outbreak responses, one for laboratory procedures, one for roles and responsibilities, one for information technology, data sharing, and one for uniform program standards, and that latter group is one that was premised on the idea that state programs, regardless of the commodity that you're regulating, retail food or produce or milk and dairy or meat and poultry, all should have some common elements that one can look at to determine whether or not there's been enough done.

The work group put together a model template which frankly was drawn quite a bit from our own meat/poultry inspection programs, the one that I think historically has been the most detailed and most thought out just because we made the right relationships, and then there were subwork groups to apply those templates to different kinds of

commodities. We have retail foods, seafood, milk and dairy, produce, other manufactured foods, meat and poultry, and eggs.

I think FDA pretty much took the lead on most of those with retail foods being one of the most advanced right now as well as seafood. We took the lead on meat and poultry and eggs. Dr. Jan and Dr. Kamisky was working with us on that at one point. Terry Burkhard, yeah.

So, from the beginning, we had some of our state directors involved and then when Bill and I got together and we formed Common Cause, we decided that a very logical way to tackle this is to do it in the context of revising and replacing our old directives and taking advantage of the work done by the work group and kind of combine those things and come up with a much neater, cleaner, and more outcome-oriented kind of a document than we currently have for the state meat and poultry inspection programs.

So, we worked very closely with the state directors and the organizations on those issues. National Association of State Meat and Food Inspection Directors. I'm getting good at these acronyms. And frankly, there was, you know, a lot of diverse group of views and a diverse group of states out there. The

notion behind our work with the states is that we want to encourage innovation out there. We don't want to be overly-prescriptive, but at the same time, there needs to be accountable under the law as the law requires for achieving the law's end.

So, we negotiated a lot, we argued a lot, and we came to a compromise. We came up with, I think, about as close to a consensus document as we're going to come up with, articulating how FSIS relates to the state meat and poultry inspection programs in the administration of the cooperative agreements.

I think it's important to note that the directive or the document does not impose any new requirements. We talked about some alternatives there, but again every state is different. Some have more discretionary authority than others. Certainly a lot of states who want to inspect different species under the state laws or that want to do additional kinds of activities which we require under the federal law are free to do so and are encouraged to do so but aren't required to do so because the law does not mandate it in the area of, for example, outbreak response. This is something that at the federal level, FSIS is much more involved in, but at the state level, depending on how their ATC jurisdictions are organized, they may or

may not be as involved as FSIS is, so that the bottom line is we can't hold them accountable under a mandatory responsibility. That is not provided for in the statute.

The document itself, I hope everybody has a chance to at least glance at it, includes a background section and it goes over the background of meat/poultry inspection and what it involves. It addresses how you initiate the state MPI programs and it outlines our historical approach to the states which is to request every state have a state performance plan in which they describe how they're implementing the various facets of their programs, such that we can document what they are doing and what they're not doing. These are updated annually, at least annually, as needed, and provide the basis for their programs when those agreements take place.

We have in the documents identified nine program elements. Go to the document itself, they're listed on Page 4, divided between infrastructure kinds of requirements, the authority, program resource, training staff, laboratory support, and more operational kinds of activities, inspections, the uniformity of inspections and correlations among them, compliance and that includes not only enforcement but

outreach, ethics and conduct, and self-assessments. These are all expanded on in the second part of the directive -- sorry -- of the document, and you'll see the format for each one describes the criteria and then articulates the outcome of what you're trying to achieve in that criterion, and then the kinds of documents that we will be looking at in the states to determine whether or not they're achieving that objective.

And finally, the Part 3 of the document describes the procedures by which we schedule our reviews and offices that conduct the reviews. We have expertise in various parts of the agency, all coordinated by Bill and his folks, but the actual work on the ground is done by a much broader group of people throughout the agency, Compliance people, our people in Budget and Finance that review the books, the Civil Rights people that do compliance, and of course, the basic review people, and people who work closely with them out of our home service center.

So, it's a wide group of people who are involved in those reviews and reports are sent up to Washington where Bill and his staff review the documentation and ensures its compliance as appropriate.

The bottom line, the document's intended to be easier to understand and it's intended to be a more -- reflect a more transparent approach to how we do our reviews. It's intended to ensure that format that was adopted in this program that we suspect will be used more broadly among states and among different kinds of regulatory programs around the country and, of course, more uniformity, the easier it is for everybody in terms of understanding what we're doing and how to do it better.

Like HACCP, we can draw a parallel with it, it infers the objectives more than it does prescribed and it has what you have to do to meet the objectives. Again, we want to encourage innovation by states, allow them the flexibility in how they reach the requirements of the law, but at the same time, what is expected of them to meet the requirements.

The general plan is to take whatever input you folks can provide us on this and then some time in the not-too-distant future publish the comments to get a wider acceptance of the document.

I think that's about it. If there are any questions, I'll be glad to take the time.

MR. GIOGLIO: Just one second. That's okay. Before we go to questions, just to follow up on the

performance requests, we will have the full report of the subcommittee that worked on this issue last time, the final one that has been adopted by the full committee. So, we'll have that for you this afternoon some time so you can take a look at it.

MR. GIOGLIO: Dr. Johnson?

DR. JOHNSON: Thanks. Alice Johnson.

As part of the discussion last June, when we had our meeting, we talked about training and allowing the states to have access to the FSIS training, and I see in the document we've outlined the training of regulatory staff, and it's filled with mostly the basic training, but FSIS is doing a good job with the correlation sessions, with the technical conference that are being offered around the country.

Are they -- are the state programs aware and are they given the opportunity to participate? I think the technical conference, the material conference, I understand you did a good job of talking through issues as well as I'm sure there were serious issues coming up.

Are the state officials given the opportunity, and are they included in the -- when you have something like the district correlations and there's a correlation section?

MR. STAFKO: Well, there are a number of folks here who can probably address the details of that better than I can, but the general answer is yes, they are included in virtually any of the training that we provide.

The problem is often the costs involved on the state side of sending people, and like our own people, taking people out of the work they do and finding somebody to cover for them while they're being trained, it makes it sometimes difficult for them to get people trained in their offices, but I think Bud might want to talk a little bit about some of the things we're doing in terms of electronic remote kinds of training that's being made available to people, and I don't know. Bill, do you want to add anything more to that?

DR. LEESE: Well, I think that Bud Paulson will be able to cover that far better than we can.

First, I'm sure you realize that the basic training programs are available, but as these new innovations come up, as FSIS develops new training programs, then the process of incorporating the states into that area is one that's being worked on, but it is not resolved at this point. But most definitely, the agency objective is to include the states, to have an

opportunity for them to look at training.

MS. HICKS: Cheryl Hicks, Office of Field Operations.

I have a couple of examples where there have been training problems in the states. We had our national supervisory conference in Dallas, and we did also provide in-plant performance training and biosecurity awareness for everybody.

MR. PAULSON: (Inaudible comment)

MR. STAFKO: Mike?

MR. GOVRO: Mike Govro, Oregon Department of Agriculture.

If you look at what you've established here and liken it to a HACCP program, it seems that you've established standards for the state meat and poultry inspection programs to comply with a set of requirements that should provide a safe product to the American consumer, and the documentation and the outcomes, for the most part, refer to meeting a set of requirements with regard to documentation.

It seems like the element to me that is missing is an actual correlation of compliance with your standards to an actual production of safe product in the meat and poultry inspection programs, and I'm wondering if USDA has a system for looking at the state

meat and poultry inspection programs and determining how they score on their evaluations to actual results that are with regard to compliance and enforcement, recalls, contaminated products getting out the door, enforcement actions taken and that sort of thing, so that rather than focusing on the compliance with a set of standards for documentation, we're actually at what's going on.

MR. STAFKO: I'll turn this over to Bill for the details. The overall answer is yes, that is inherent in what we're doing. We don't just look at those documents. We're looking at what we find in those documents, and let me have Bill explain that to you.

DR. LEESE: The two key parts of the review, the comprehensive review of a state program would be the review of the compliance program and the review involves the in-plant and records review at the headquarters office, and those would be comparable to the type of work that in the past has been done by the next seller of the orders; whereas, the reviewers look at what records are maintained in the headquarters office with regard to whatever it may be, various control actions or other types of activities, such in their process they keep at the headquarters level.

Then to go out to representative plants and look to do a systematic review of the also sold to, the HACCP plan within the plant, the records that the plant maintains, the records that the inspection program has maintained with regard to compliance with the program and the actual performance within the plant as they do a review of the physical lay-out of the plant.

So, that's the major components of the review. It has been, right or wrong, and it would be still consistent with the framework being looked at now.

MR. GOVRO: My question really went to are you looking at the programs and comparing them to the recall information that you should have on file? Is there any programs to do that? How many recalls of products occur from plants that are in the state meat and poultry inspection program as opposed to USDA?

MR. STAFKO: I'll take a stab at that. I don't know of any. Does anyone else?

DR. LEESE: We have our own. I don't recall reviewing reviews with respect to what we've been doing in the plants, not that we wouldn't be interested in that, but I don't recall ones that I'm familiar with offhand where there are records of state meat and poultry reviews that were recorded in reports. Could

very well that they've had reviews, but as far as the state reviews, I'm not aware of any.

MR. GOVRO: I'm not on the subcommittee, but I might suggest that that would be an area that the subcommittee consider. The bottom line is, is what's happening, you know? Are these programs better? Are they worse? Could USDA learn something from the state programs or does USDA need to make the state programs better? What's going out the door?

MR. MAMMINGA: From a state perspective on the business of recall, addressing recall, I think across the state programs that I am aware of, holding the inspection product as far as that part of our program for microbiological testing programs and in our economic programs, we pretty well -- people don't want them to be held. You can look at the other side of it. One can have an illness that is -- could be associated with ...

MR. STAFKO: The question is how do you compare the work of different plants, and that's one of the reasons we went to performance standards for Salmonella, and as a measure of how well ... Of course, we're looking at ways to improve our present performance standards, but I think the notion of seeing how many recalls might take place in different plants

is probably not a real good measure because the nature of the beast is it's really hard to make an assessment of what that means in any given context, outside of the particular plant. How do you compare plants within a state on that basis? I don't know. To me, it seems like a very difficult measure to use to determine that. Some of our best plants have been involved in recalls despite the best most common measures that we use.

DR. McKEE: I think your point is well taken and that we need another step there to protect ourselves, and how do you measure that, how do you cure that? We can look at all the detailed stuff that they're talking about here, but we clearly need to go to the next step and that's my intention, that we have to look at major outcomes of whatever you want to call it. We haven't asked that question yet.

MS. FOREMAN: Carol Tucker-Foreman with Consumer Federation.

Thank you, Dr. McKee. That's a reassuring statement.

I wanted to actually follow up on where Mike was going. Everything here is an analysis of whether the system is equal to. For consumers, that was of secondary importance. We want to know what data are there to indicate the products coming off the end of

the line are as clean and safe and not likely to cause food borne illness. That's the public health orientation that we want, and historically, in this program, the comparison of state programs to the federal program has been hard to measure because the argument is circular. How do you know we're equal? Well, we wouldn't be allowing them to operate if they weren't equal, and there has to be something that is more than just the structural. You've got to show that what happens at the end of the line is -- meets the public health measures.

It occurred to me as I went through this, a couple of things. One, I don't think anybody has ever asked the question, and I now ask it and would like to pursue it this evening, I am on the subcommittee, what benefits accrue to consumers from having state inspection programs? They were included in the law back in 1967. Frankly, it's a direct political trade-off to get the votes to pass the bill.

What benefits are there to consumers, and obviously the flip side of that is, what risks occur, and unless we know the products are as safe as, in addition to the system being equal to, we don't know what risks occur? I'm not aware of any particular benefit that occurred to consumers.

I have a couple of other things. On the training, I think a couple of the issues were raised about some of the problems with making sure that training -- that state inspectors get access to training. The GAO report that came out the end of the summer was really quite critical of FSIS's training of its own staff, so suggesting that the training of the state inspection personnel is something less than that is not very reassuring to those.

I want to know if the Department is going to support the shipment of state-inspected meat in interstate commerce. That raises a whole series of other questions.

DR. McKEE: I haven't been able to evaluate as to what our stand will be on the policy for that but that will be worked out. The issue that I commented on about protecting the public health has to be worked out, and we need to make sure we have our ducks in a row for that.

MS. FOREMAN: Thank you.

Because this is my last time as a member of the committee, there are some issues that I think we haven't addressed there, and so I want them on the record, please, and one of those is what is the risk of federally-inspected plants to getting to leave the

federal system and going to be state-inspected and therefore undercutting the comprehensive federal inspection program that we have now?

The proposed legislation puts some limits on going back and forth, but no limits, except size, on leaving the federal program and the size that was included in the bill would have included something like 50 percent of the plants that are out there operating. So, the question arises, are we dismantling the federal meat inspection system if we allow state-inspected meat to be shipped in interstate commerce?

I think, in addition, there has to be some discussion. People buy meat assuming it's USDA-inspected. It's not going to be USDA-inspected or it may not be if we have state-inspected meat in interstate commerce. How much does that undermine public confidence in the system, and how much does it undermine the confidence of our trading partners in the system?

So, all of those are issues that I think have to be addressed, in addition to the nuts and bolts here, before the Department goes forward on this issue.

Thank you.

MR. GIOGLIO: I know that there are other questions and comments from the committee members. I

please ask you to please hold those for the evening session this evening. We don't want to fall too far behind schedule here, and I believe we'd like to move on then to the next topic.

I mean, Bill and Ralph will be here. They're both going to be in with the subcommittee this evening. So, you know, you'll have the opportunity to bring up questions and get clarifications and so forth and then we'll come back and discuss them again tomorrow morning in the full committee.

DR. McKEE: Thanks.

We'll move on to the next presentation, which is the Issue of Education and Training of the Field Workforce to Achieve a Public Health Vision. Ms. Cheryl Hicks and Mr. Bud Paulson will make this presentation.

Issue - Education and Training of the Field Workforce to Achieve a Public Health Vision

MS. HICKS: Thank you, Dr. McKee.

* * * *

The Aviation Administration doesn't have its inspectors trained by the airlines and it shouldn't have meat inspectors trained by the meat industry. It just -- different roles, different perspectives and I think those have to be dealt into the training system and the line blurs very easily there.

Now, I also have to say something that the International House of Alliance. There are people out there who believe that it's a governmental organization. It is not a governmental organization. It is a non-profit organization founded by, an whose officers are all employees of Meat Industry Trade Associations. It does have a point of view because of who funds it and who runs it. Originally, it came out of Texas A&M. That stopped three or four years ago.

I have great reservations about the International House of Alliance having the relationship with USDA and its state governments to do training because of the nature of its organization and who it's officers are. There's got to be ways to get this training done in other places that are not owned and operated by the regulated industry.

MR. PAULSON: I think there's a -- support we were talking about -- needing work on the research standpoint -- actual training of the inspector

standpoint. There are resources out there that we can take advantage of and I think that was the point of most focus.

DR. MCKEE: I think we need to adjourn now for lunch. We have a pretty aggressive schedule.

DR. JOHNSON: Dr. McKee, I appreciate the need to adjourn [inaudible].

DR. MCKEE: What I'll do is -- again, I don't want to make this into a divided kind of a comment area, but what I will do is to take Dr. Johnson's comments and hold for about two minutes more we'll adjourn for lunch.

DR. JOHNSON: Oh, that's okay. Alice Johnson, National Turkey Federation. Thank you, Marty. I just wanted to talk a little bit about the distinction and I have to agree with Carol on some points. When we're talking joint training or we're talking International House of Alliance, we're talking the science of the issue and the science of the issue is not any different than if I'm working for the Turkey Industries as opposed to I'm working for the government as opposed to I'm teaching in college. It's the understanding of the consult to the science behind the issues.

Now, I recognize that FSIS employees need

different training than an industry or academic person would and how to properly document, how to determine noncompliance, how to look at deviations and so, in that regard, yes, it does need to be separate training on the, as Mr. Paulson said, the philosophy of the agency you're working for and the requirements therein.

But, as far as the basic science that's probably where the biggest disconnect is right now in -- - between the regulatory agency and the industry is because there is a difference in the group's understanding of the basic science.

And, as far as the International House of Alliance goes, yes, you will find a lot of the International House of Alliance folks are a part of an industry whose trade group itself are the industry itself. Part of that was to protect the purity of HAFA and the HAFA forces. When HAFA first started coming along, it was definitely needed that we have HAFA and the -- presented and the scientific underpinnings and that people went out and didn't just teach something that was not considered credible and part of the reason the industry is so supportive of the International House of Alliance is because it has criteria that are reviewed by academics that say: This is what a HAFA force should look like and it does not get into the

regulatory aspects of HAFA except to go over the regulations.

It teaches the science. It teaches people the microbiological, the physical and chemical concerns in foods and mostly the people doing the teaching are academic folks who are doing it. But the Alliance would keep HAFA pure and to keep the science in a credible training program that's available for industry. Thank you.

DR. MCKEE: Thank you. I think that's a challenge that FSIS has is we need to be able to facilitate the training forum's inspectors and I think we need to consider drawing from all areas. The academic community is certainly an area that we need to utilize, I think, to grow our inspectors, as far as basic education, in addition to specific things.

(Whereupon, the parties recessed for lunch at 12:10 p.m. and the meeting resumed at 1:30 p.m..)

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

DR. MCKEE: First thing on our agenda this afternoon is a briefing on FSIS reorganization and as many of you are, I'm sure, aware -- in the making for several months. I had, before my arrival here, a visit with Dr. Murano on her strategy and activity and I applaud her in the realignment, reorganization that she has -- with has really saved my view and saved me about a year's work by being able to restructure many things to make it more effective and efficient, so I strongly support our alignment. We do have, under her instruction, the flexibility to tweak the system, if you will, and, as I have time to review more of the details of the -- structure, maybe recommendations to my part for some changes in the future, but I strongly support and I think it certainly makes sense. The organization, I think, has to be organized in such a way that you built cynergy. Not only effectiveness and efficiency, but you have to have cynergy -- and people located in the areas where they can do their best job.

So, what I'd like to do is to have Member Swacina, who is an Associate Administrator, to roughly go through the things that -- structure --

MS. SWACINA: Okay. -- some newspaper articles about this -- the main thing to do is to --

offices, assistant administrator positions and these are intended to be positions that are cross-trained positions with all the other areas -- and along those interests was -- the functions of these offices, which is why they're affiliated.

The first one is the Office of Field Security and Emergency Preparedness, which --. After September 11, we obviously, like everyone else -- secure issues and we've reached the point where -- recognized that we needed to get everything in one office -- it's not going to be able to be a huge office, but at least one office that serves as a liaison to the rest of the agency and a one-point contact for all of our emergency security issues.

And included in that is one of the functions that MR. Stafko performs and that is a liaison to the states -- interest to this Committee, but Mr. Stafko will be focused on the -- secure emergency preparedness liaison for the states in his new function.

The second new office that was created is the Office of Program Evaluation, Enforcement and Review. -- government bureaucracy -- shortened -- and that's intended to be an office that business-level communities will take a look at ourselves -- ourselves and try and prevent problems before they occur, if you

will. One of their functions is to make policies of the agency and see if we have the right policies in place and if they need to be changed, if they need to be eliminated, what have you, they will look at those and make recommendations to the administrator on changes that are needed in the policies.

They also will be looking at how the programs are implemented and how the policies are going to be made, so they'll do a lot of field work, as well. There's a lot of field employees who are actually staff, who will be available to, again, look at how well the policies that will be made are being implemented. The problems -- they may have already looked into a couple of circulations -- helpful in identifying problems that we're trying to fix.

The third new office is the Office of International Affairs. And, again, this is partly being formed because of September 11 and also to emphasize the International Affairs we have in the agency. We do do a lot of international work and we want to make sure that -- and we wanted to get this office separated from -- policy office -- we wanted to get this office separated from the high-ranking, international functions that we perform -- and this office will also be a relatively small office.

The other office that we have had before in place, with some tweakings that have already been done, and additional tweakings -- Dr. McKee, one of those is the Office of Communications, which is the -- outreach, which will include, as it did before, the Congressional Public Affairs Office, the Education Staff, and the Executive Secretary. We also had a strategic outreach -- staff that will take over some of the state liaison functions, the small -- liaison function, as well as the -- outreach that we already do.

The Office of Public Health and Science remains. I'm not sure that we made any changes to that office, but we did meet the Recall Management Division out of that staff and over to Field Operations and Recall Committee still exists, if the Office of Public Health and Science has a -- required member. We also need a -- production -- staff to the Office of Public Health and Science.

The Office of Management remains normal as it was before. The Office of Field Operations, probably the key operations -- slipped out of there was the Center for Learning, which was a training center really than -- under the public facility center and that is now an Office of Policy Program and Employee Development. And the Office of Policy Program and

Employee Development is the last office that, again, existed before and became -- any questions?

MS. ESKIN: Could you just explain -- it's my understanding that this Committee is now supervised by the Office of Communications. Is that correct? Or, under the purview --

MS. SWACINA: The Office of Communications.

MS. ESKIN: And Outreach, okay, and could you explain the reason for the change? And also the Micro Committee, has that also been moved to this, you know, to be supervised by this particular office?

MS. SWACINA: I don't know -- coordinate these -- and, again, because of the Office of Communications and how it will be -- the administrator -- that is going to be -- as well. So, the intent is to involve all of the areas --.

MS. ESKIN: Again, the Micro Committee is also going to be supervised by the Office of --

MS. SWACINA: No. At the moment, that may be one of the tweakings that include --.

MS. ESKIN: Okay. Obviously, it raises the question is to my mind, since we are an Advisory Committee that effects policy, that for some reason, that change may have some indirect role -- science. I hope that's not the case and I just would want you to

take a look at the treatment of both Committees, both structurally and otherwise, to make sure that it's not adversely impacted.

MS. SWACINA: We have no plans to --.

DR. LAFONTAINE: Dr. Lafontaine -- one of the changes that I'm aware of -- I don't know the details -- that's what I'm going to ask is: In your compliance structure, previously, the compliance officers and their supervisory training were tied to districts and then, ultimately, to Headquarters and I'm aware that there's been a slurry, so-to-speak, where some are going towards -- what I call and I may be using the wrong words -- criminal investigations, others of operations, so, could you embellish on what's happened in that arena because that is a very important part of the equation?

MS. SWACINA: You pretty much -- the operational function of the -- folks remains in Field Operations and -- which, of course, is -- but they are intended to be in Field Operations -- carry out -- they're the ones who will be going around to the -- the compliance officers -- who are -- will be doing criminal investigations. But, again, as I said, they will also be part of the, sort of an oversight on policies and programs. But because they have that

field of -- they're the ones who are [inaudible].

DR. LAFONTAINE: I have a following question, partly, -- is the transition, you know where, if you have suspected criminal activity -- administrative or -- operator, at least in my experience, many times are just picked up by your operational people, who are out there in the communities. So, how do you -- and maybe I'm getting into too much detail -- how do you visualize this fine line when you transition from operational to criminal investigations?

MS. SWACINA: Well, as you said, it will be the operational people are out there today, beyond the compliance officers, -- supervisors, what have you, if it -- they will work with -- they're still working together on that because that's one of the areas --

MR. GIOGLIO: Fourteen?

MS. DONLEY: Thank you. -- Public Health and Science, are they all --

MS. SWACINA: Absolutely.

MS. DONLEY: -- are they actually physically being moved over into that department, or, again, on just a consulting basis? Are they staying over?

MS. SWACINA: I think -- to the Recall Committee and Recall Management Division, and the Recall Management Division is what was new and they are

to do as the -- says --. They don't make the decision on whether or not they should be a division. There is a -- and the Recall Committee, which is convened by the Recall Management Division, but they convene at such a membership they'll always be in Public Health and Science, along with other members of the other offices. Just as it always has. It has not changed one bit, the Recall Committee.

Now, if the Recall Committee makes the recommendation on whether or not they should be a Recall -- the Recall Management Division is what carries out the Recall. We make sure that the notification goes out. We make sure that the companies are notified -- all of that goes under the Recall Management Division. They are management resources, not making the decision, Public Health decision and whether or not they should be there.

MS. DONLEY: And the actual decision is made by Public Health and Science?

MS. SWACINA: Actually, they -- and I can't think of a similar decision ever made --

MS. DONLEY: And just as a follow-up, can you tell me was this redesigned to -- or was it just one for streamlining or ease of management or do you see this as actually seeing this as being a boost to Public

Health and Science?

MS. SWACINA: Again, I think it is intended to be a boost to Public Health. It's, again, to try and emphasize some of the offices that need to have emphasis and to make sure that within each of the deputy areas that these issues get considered as one.

DR. MCKEE: If I can just add to that, when you have an organization and you have your mission articulated as what you're going to do, it really requires that you have the alignments that I mentioned earlier of who works together closely the proximity of and so forth. So, it clearly enhances the Public Health Mission, but it also, I think, reflects evolution of the kind of work we do, the volume and so forth and addressed that as well.

MR. GIOGLIO: Any other questions?

MR. MCKEE: The next on the Agenda is a presentation on FSIS Consumer Complaint Monitoring System. Lieutenant Commander Kimberly Elmberg and Commander Judith Arndt.

CDR. ARNDT: Thank you very much. The Consumer Complaint Monitoring System was designed to fulfill requests by the Office of Inspector General. They have all FSIS consumer complaints centralized. The system was currently implemented in all districts

in November of 2001. It is a national surveillance system.

MR. GIOGLIO: The slides are behind Tab 9 in your notebooks.

CDR. ARNDT: Okay, what is a consumer complaint? What is the Consumer Complaint Monitoring System? It is an electronic database used to record triage, coordinate all consumer complaints that are reported to the agency. It's abbreviation is CCMS. CCMS now has screened over fifteen hundred cases. In this system, to triage means to classify a consumer complaint to determine the need for further investigation by FSIS.

What is a consumer complaint? Any complaint about a regulated FSIS product reported by a consumer, or on behalf of a consumer, is entered into this electronic database, is triaged and is tracked.

Most of the consumer complaints involve illnesses, and so far there has been four hundred and thirteen reported illnesses in the CCMS. Injuries reported in the CCMS is sixty-two. There has been five hundred and fifty foreign object complaints and allergic reactions complaints totalled eighteen.

More consumer complaints: under processed, ready-to-eat complaints totalled eleven; improper

labelling complaints sixteen; epidemiological adulteration totalled ten; and the "Other" category, which is, namely, the dissatisfaction with the quality totalled approximately two hundred complaints.

Misbranding or labelling complaints: Product labelling or misbranding consumer complaints are first triaged for any illness complaints and for any public health concerns. If there are none, these complaints are central labelling, business and record -- staff -- documents, these complaints into the CCMS and manages their further investigation.

Food security threats or product tampering: When food security threats are first recognized by compliance officers in the field, these complaints are sent directly to the Office of the Inspector General. It is recognized, however, that a complaint may come into our system and not be identified as food security threat until after it has been investigated and, of course, it is then turned over to OIG.

Examples of complaints not entered in the CCMS are whistle blower complaints, school lunch program complaints, industry complaints initiated by a competitor and -- all prepared products.

FSIS responds to consumer complaints. The FSIS uses CCMS to provide quality and timely responses

to consumer-filed complaints. It uses CCMS to help identify unsafe meat, poultry and egg products. FSIS uses CCMS real time computer system to aid investigating potentially hazardous products in commerce.

LCDR. ELMBERG: The hotline is the most publicized method of forwarding a complaint for question regarding an FSIS- regulated product to the attention of the consumer into OPHS. It is brought to the attention of the consumer each time there is a recall in all of our recall notices. It is located on our website and a time -- included by the press and newspaper articles throughout the country.

Other programs responsible for entering complaints is the Office of Field Operations. All district officers and compliance officers are able to answer complaints. The Office of Public Health and Science and the Office of Policy Program Development -- staff.

The first thing we do at OPHS is screen complaints coming in. If it's -- the complaint meets the criteria for inclusion into the CCMS. In fact, is it an FSIS-regulated product. If it is a complaint involving a retail establishment, the complaint is referred to the local health authority.

Although these complaints fall under state jurisdiction and follow-up occurs by the state, they are also referred by us to our outbreak branch if they involve a positive lab-confirmed freeform illness. It is possible that the complaint may be part of a bigger picture that those triaging the consumer complaints are not aware exist and, so, in this way, we want to cover all of our bases to make sure we are identifying any outbreaks.

I want to stress and make absolutely clear that every complaint that is entered into CCMS is triaged. Not all of the complaints are verified and we'll go into that in a minute. So, when we get our breakdown of how many complaints we had -- foreign material, how many complaints we've had for illness, those all aren't necessarily verified.

In a minute, I'm going to go through the process on how we decide what needs to be investigated and what we're not investigating.

Cases are investigated on criteria that was developed by the Steering Committee working on the development of CCMS. There are representatives throughout OPHS on the Steering Committee; microbiologists of the meat and poultry hotline, intake people, all sorts of different backgrounds are

represented on this Committee.

The following consumer complaints were always verified and investigated: any underprocessed, ready-to-eat product; any glass confirmed -- food borne illness; any allergy complaints; and any possible public health or safety concern.

The CCMS database is searched for similar cases using the agency establishment, their standard format, the establishment standard agency format. Cases are investigated if the database contains two or more similar complaints concerning foreign material against the establishment, two or more similar complaints concerning quality, epidemiological adulteration, etc. against that establishment.

Identification of a possible health hazard will override those guidelines. So, for instance, if you have a baby food jar and a mother has found a piece of glass when she's feeding her infant, well, it doesn't take two of those to necessarily begin an investigation. That's obviously a public health hazard. There may be other pieces of glass in other baby food.

For follow-up cases not warranting an investigation, a letter is sent to the consumer and a copy of the letter is sent to the ADME of the

complainant's district. It thanks the consumer and it lets them know that, even though the case isn't being investigated at that time, that it remained in the database, it's there for future reference and that the case may be reopened if other information comes in that would make it relevant to opening that case. A copy of that letter is also sent the ADME of the complainant's district.

The establishment receives a letter with a summary of the complaint enclosed and a copy is often sent to the ADME of the establishment's district. That way the establishment can see what complaints are coming in from consumers. The establishment letter demonstrates our commitment to helping industry identifying and address the central areas of concern.

The establishment letter describes the complaint without identifying the complainant. It does not require the plant to formally follow-up with FSIS. It is the plant's responsibility at that point to address the complaint. However, the establishment district is made aware of the complaint.

When investigative cases are first initiated, the ADME of the complainant's district is notified. The compliance officers is assigned to the case to be investigated and it is that compliance officer who will

verify the complaint and collect samples. We work very closely with our labs for analyzing the different characteristics of the index contained in the sample.

Laboratory analysis, as you know, is important for making objective decisions based on science.

At times, the compliance officer is able to visualize without touching the index sample of foreign material. A lot of times we get complaints of a possible worm or something and it's -- or trachea from chicken -- like that. So, sometimes that can be visualized.

A lot of times we are not able to collect samples. Sometimes the complainant starts them or they send them back to the company and, therefore, we cannot verify the complaint, but that case would still remain in the database for future reference. If we get other like-complaints, then it meed that criteria for investigation. Furthermore, sometimes we are not able to collect like or same proto-sample on the market if that product has already been consumed or that was the last of that product.

All information collected on a consumer complaint is documented and goes through the CCMS. So, it is centralized, which would be OIG's requirement.

When appropriate, the OIG and/or Recall Division are notified are investigation findings.

When a case is investigated, a letter is sent to the consumer and a copy of this letter is sent to the ADME of the complainant's district. The letter to consumer provides general information about investigation findings and information on how to use the Freedom of Information Act to obtain further information on the disposition of their case.

The district manager of the establishment district is forwarded a hard copy of investigation findings and, when appropriate, follow-up with the IIC, inspector-in-charge, for that plant is requested. Documentation then of the 02 and 04 procedure is required to be put into the CCMS.

So, in other words, any action taken in the plant or by the plant and the IIC at the plant is put into the CCMS so that if we go back, if we have a complaint today and we go back and do our search and we find that that is a similar complaint to something that has been investigated before, we can see what was done to address the complaint at that time and to see what was not effective.

So, we can go back there and see if there was another complaint, we've already done an investigation,

we didn't notice or recognize this as a potential hazard, but now you know how the history and we need to address this in a certain way.

When an establishment has numerous complaints about non-identical products, a letter with a summary copy of all the other complaints is sent to the district manager. Those are previous complaints that have taken place usually within a two-year period. This action may involve having an IIC at the establishment follow-up with an 02 or 04 report, which would then be documented into CCMS.

Okay, this is the end of the presentation of the current CCMS database. Since it's inception, CCMS has met the original -- has more than met -- the original intent of the OIG with a large emphasis on public health. Recent events, however, have the potential of ensuring food safety, even making it more difficult for use to ensure the safety of food.

So, we continue to value the complaints of consumers because they may be our only clue to an act of terrorism against our food supply. The events of September 11, 2001 definitely reenforce to need to enhance monitoring systems. President Bush -- Bio-Terrorism Act into law on June 12, 2002. The Act is divided into five Titles. Title III addresses

specifically the securing of our food and drug supplies.

Dr. McKee said earlier today that our goal is to prevent food from being a weapon. In addition, we must be prepared to identify quickly any infiltration is our first lines of prevention. The earlier we can identify acts of bio-terrorism, the earlier we can forward these cases to the OIG. One key way we will achieve the goal of early detection is through having a database that would -- consumer complaints into interoperable with other databases. For example, -- other HHS agencies.

The second key enhancement for the database is developing flexibility to identify -- fluids. We talked about intent just a few minutes ago. That's part of our -- to where we're going in the investigation.

OPHS is reviewing the following projected enhancements to the CCMS: -- the CCMS to the district early morning system; creating this link through the early morning system to alert the district manager to the need for follow-up in the plant and that helps with our follow-up --; linking to recall product data to help us identify the complaints involved to these health products; this will be part of our response to

the consumer; cyber security, -- system security of the database to comply with the Health Insurance Affordability Act to allow us interoperability will help the intensity as well as provide complainants with confidence that their health information -- results would be protected and their privacy maintained.

As I mentioned before, interoperability with other state agencies -- our laboratories and systems just mentioned will make CCMS -- and will enable FSIS to identify and -- more rapidly. Some -- CCMS after one year. We have come a long way from the original origin costs. And there is a story that goes like this: There are two stonecutters who are chipping square blocks out of granite. The visitor the quarry asked what they were doing and the first stonecutter said rather sourly, "I'm cutting this stone into a block." The second -- "I'm on this --. Any questions?

MS. TUCKER-FOREMAN: Going back -- Tucker-Foreman with Consumer Federation -- going back to the examples of complaints that are not entered in the CCMS, school lunch program complaints, can you explain why?

LCDR. ELMBERG: It's a separate program from ours. Right now we happen to have a complaint that is involving the school lunch program -- and so when we

get a complaint like that we refer it to our outbreak branch.

MS. TUCKER-FOREMAN: And they follow-up -- this is the public health branch -- and they follow up as --

LCDR. ELMBERG: Yes, ma'am. They work with the -- in the state to follow-up on that.

MS. TUCKER-FOREMAN: And they are FSIS, and the FSIS people then -- they follow it up as -- okay, thank you. Just follow-up, is there any reason why it can't list the data -- as well? I understand that you don't follow up on it, but that somebody else does, but is there any reason why those can't be listed among the consumer complaints, since, I think, they are of great importance to the public?

CDR. ARNDT: I think that would be an appropriate enhancement to our database and, I think, we follow-up with every consumer complaint -- and we can then add that to our database.

MS. TUCKER-FOREMAN: Thank you.

LCDR. ELMBERG: Even when a complaint comes that it not specifically falls under the qualifications -- we never, ever let it go without follow-up -- have a quick reaction.

MS. DONLEY: Thank you. I think you answered

my question. I was going to make it a little bit broader -- and I'm very happy to hear your response, but I think it would be appropriate because this is one of the children's -- school-age children are one of the vulnerable populations that when -- illness before many other populations. Also, would institutions be included in that as well? You know, many times it's the schools and institutions, nursing homes -- does that get caught in your --

LCDR. ELMBERG: We had university -- well, it was a -- there was a university who had -- and other -- because they sold it again then to the students. They had an establishment and we were able to get back to the establishment and help them out. One of the things you have to remember is that once it's seeping out of the package, you need to -- again. That's where we wanted to institute handles to keep that from happening -- but it's something that's clearly coming from the establishment level -- foam particles in this product --

MS. DONLEY: -- where you have the retail -- product. Is that also a -- product for instance that has been ground, further ground at the retail facility?

LCDR. ELMBERG: Yes, that would be state. -- if a super market chain buys some meat and they don't

ground it, that -- institute.

CDR. ARNDT: We have had a lot of retail complaints come in and when they're lab-confirmed, we walk over to the outbreak and make sure that the epidemiology officers know about this particular case and so it's followed up too. So, it's the thing -- it's the same happening to our CCMS, you know, if we just follow up with the outbreak section.

LCDR. ELMBERG: But it's the -- investigation. There are two separate levels of investigation: our outbreak branch would get it and people at -- and they would work --

MR. GOVRO: Mike Govro. I think I have a comment about the reporting of people and illnesses, but first I have a question to clarify how you handle things. If I were to call USDA and say I got sick from, let's say, eating some sliced lunch meat that was produced and packaged at the USDA plant, what would you do?

LCDR. ELMBERG: The establishment member would -- specific characteristics about the complaint would be searched in the database to see if there's any [silence on tape] -- compliance officer. If it's coming in through the one -- hotline, then we would upgrade the data into the database. The compliance

officer would be assigned to relate any data that was missing and verify the complaint. He would then triage the complaint -- illness would automatically be -- if they do not have a -- illness and -- against that establishment did not -- product, they would not be. If there was a complaint that was similar -- then that would be two or more and then the investigation would -- -

MR. GOVRO: Okay, here's my comment. I think you're making a huge mistake by following this procedure. The reason is that most people who become ill from eating something think that it's the last thing they ate and the first thing they threw up. So, they call whoever they think is responsible. There is a system in place, I think, in most states where information about food borne illnesses is taken in, usually, by a health agency -- yeah, the -- they do an investigation and determine whether or not the product the person thinks made them sick is actually the thing that made them sick. And, many times, in doing a three-day food history, they discover that the person ate something else that is related to another food borne illness outbreak.

If USDA takes that information and bases it on what the person calls in about and doesn't get it to

a local health agency, they're really sitting on a lot of valuable information, which should go to the health agency and, as a state agency, that is not an intake point or food borne illness complaints, however, we do take complaints like a lot of the other complaints that you take about product quality, airborne materials and so forth, we take information from the person, name and phone number, and send it to the local health agency -- the food borne illness investigation to determine what the agent is and then if it should come to us, they send it to us. If it should go to the USDA or FDA, they send it along that way.

So, I really see a coordination problem existing here and this is all part of what's been discussed in the National Integrated Food Safety System and I know there are problems also with FDA's system and I think there are some holes that need to be look at.

LCDR. ELMBERG: Right. You're absolutely right and we -- many of those holes. You're right that the last thing a person eat is often what they believe makes them ill and that's why we don't investigate all of the complaints of illness. You're also right that food diary is something that should be considered to practice and we are working on -- that and how we can

train -- well, what kind of a food diary would be reasonable for us to achieve.

You're also correct in that having interoperability with the state health agencies, both ways, sharing information both ways, lead to greater success of identifying, truly identifying any two food borne illness and outbreak. So, you're right on all accounts and we're adjusting all accounts.

MR. GOVRO: One more thing. This is news to me about this eight hundred number and so forth. I work in a state agency that works fairly closely with USDA. I send complaints that I receive from consumers about USDA products to the local USDA office in Salem. I have a local contact. And I only have that because I met the guy and he gave me that information, but I would encourage USDA to distribute that information about the system to all the state and local agencies that could use that.

LCDR. ELMBERG: Again, you're correct. We need to have a PR blip on this number. Right now we are working on a second-generation -- database with kind of -- the OIG request was much more simple than adjusting public health, so we've been working on rearchitecting the database to adjust these public health concerns that we have brought up and with the --

the rearchitecture would be to support a larger number of complaints and interoperability to meet that time when we can physically support those complaints to this database. We really need to do a huge PR blip. Right. This is our tool. It's our eyes and ears.

MR. GIOGLIO: Sandra Eskin?

MS. ESKIN: Sandra Eskin. AARP. I have a couple questions following up on the other questions. First, on the list of complaints that are not entered into CCMS. We talked about school lunch programs. Is it my understanding that each of these listed are referred to different entities -- so that --

MS. ELMBERG: What slide number?

MS. ESKIN: Yeah, the whistle blower, school lunch program, industry complaints about competitors, retail-prepared products. You mentioned that you refer the retail to state, but that there's another agency or group that handles school lunch programs. Do the other ones listed here, are they also referred to some other body, entity?

LCDR. ELMBERG: Yes. The whistle blower and the industry complaints initiated by a competitor would go to the Office of Inspector General.

MS. ESKIN: Uh-huh.

LCDR. ELMBERG: I believe -- I thought one of

the earlier slides, I think, that we presented maybe today or may be presented tomorrow, but they talk about not wanting to economically ruin another company. Sometimes there's malice in the industry between different companies and we want to make sure we're not involved in that. And, so, we send that to the OIG and let them handle those complaints.

MS. ESKIN: Speaking of companies, obviously, some consumers report directly to companies or their eight hundred numbers that the companies have. Is there any coordination between monitoring whatever they get and what you get through your system? Any sort of communication?

LCDR. ELMBERG: Well, we do send all of our complaints to them. We share our information with them. If it's infected, then -- the IIC of that plant is who gets the complaint and shares it with -- it's my understanding that when we do an investigation -- the letter goes to the establishment. The establishment, it is my understanding, that, today, as we stand here, does not have to share their complaints with us.

MS. ESKIN: But they -- there are other systems of the products -- under different agencies they have a requirement that all complaints are --

LCDR. ELMBERG: We don't have --

MS. ESKIN: I know. I just wanted to clarify that. And, finally, again, I also had a question about ways that the one eight hundred number, the meat and poultry outline how that information is disseminated. Do you have any specific thoughts or plans? You said a media blitz, but is there any specific ideas as to how more widely disseminate this information?

LCDR. ELMBERG: Absolutely. We would like to have web access to this database, so that we could work on the web and input their own data. We think that would reach another population. We recognize that no everybody has access to a database. Right now the consumer complaint hotline is only open from ten a.m. to four p.m., eastern standard time and those are pretty limited hours and if you're a busy person and you're on the west coast, you might have a hard time figuring -- so that needs to be reviewed. Certainly, web is twenty-four hours a day.

MS. ESKIN: Again, right now, currently is it primarily disseminated through public service announcements or information that USDA puts out? Are there other sources?

LCDR. ELMBERG: It's disseminated through the process, disseminated through our press office, it is on the website.

CDR. ARNDT: Most of our complaints are through the compliance officers so far. They really -- I mean I'd say ten, fifteen percent are through the hotline, so we are missing a huge number of people. And I feel that most of the complaints about a food product do go directly to the establishment. I would love to interact more with the QA person, you know, and talk to them. Some of them have called me concerning the letter that we sent and wanted more information because they certainly wanted to look into the matter further because it might be kind of serious and so we would like to develop that sort of working relationship and it would only make sense to do that.

MS. ESKIN: Uh-huh.

MR. GIOGLIO: Dr. Johnson?

DR. JOHNSON: Alice Johnson. National Turkey Federation. I think you answered one of my questions, but I just want to clarify. In your slide, you talked about in cases that are not investigated, the establishments are given a summary and it's up to the establishment to do the follow-up.

Now, when you talk about the cases that are investigated, on the way the slides look, it talks about the district manager of the establishment is given a hard copy of the investigation. Now, the

establishment is made aware that there is an investigation, is that right?

LCDR. ELMBERG: Yes, ma'am.

DR. JOHNSON: Okay, and during the process of the investigation, is the establishment allowed to interact and understand -- I know we have a lot of concerns with the compliance officers may be out there pulling samples and doing things and if the companies new what they were looking for and there's a lot of times the industry feels that they could help speed up and get resolution to some of these investigations, if the company is allowed the information sharing that needs to understand what needs to occur and what is being investigated. And I don't know if there's that kind of -- I think this is a great system, but I don't know that that coordination is built into this system yet and that may be more of a field operation comment, but --

LCDR. ELMBERG: Exactly. This is a question for field operations. We're simply the complaint monitoring system of the consumer complaints and triage them, so that is definitely field operations.

DR. JOHNSON: But the --

CDR. ARNDT: But we can -- we oftentimes do let the ADME of the establishment district know about

the concern we have because it's a real concern in the complainant district. We don't have all the information in, but this is what's happened, you know, and he may make a trip out there to that establishment and tell the IIC what's happened.

So, it's a wonderful, electronic system and it is working. The compliance people in the field love it because they are sort of able to get a hold of what's happening and they have a system where they're looking at what we're doing, we're looking at what they're doing, so it's working.

DR. JOHNSON: Well, I'd really encourage -- that this is not -- but the more you can get the establishments involved, a lot of times the easier the investigation can become --

CDR. ARNDT: Right.

DR. JOHNSON: -- and the quicker these issues can be resolved, which is to the benefit of both industry, the agency and the --

CDR. ARNDT: Right. If the IIC had the capability of having CCMS on their screen, or on the screen, that would be nice too. Then we'd have a link right there to the IIC. That he could look at all the information.

LCDR. ELMBERG: Yeah, we'll definitely work

through on some of the coordination issues. Thank you.

MR. GIOGLIO: Ms. Hicks, did you have something you wanted to add for the field ops?

MS. HICKS: Yes, I just wanted to say that I will take that message back in that the follow-up on consumer complaints is one part of the compliance officer's job that's going to stay with field operations.

MR. GIOGLIO: We're going to take a few more questions. We have Dr. Logue, Mr. Holmes and then Dr. Jan. Okay, we have Mr. Holmes and then Dr. Jan.

MR. HOLMES: I have a quick question. One is the all-federal notices on recalls does have the eight hundred hotline number on it, does it not?

LCDR. ELMBERG: Yes, sir.

MR. HOLMES: Okay, I just wanted to make sure. And then, I hate to be the only ignorant one in the room, but that happens on more than one occasion, how are you using the term "triage?"

LCDR. ELMBERG: I believe it's defined in one of your slides.

MR. HOLMES: No, I understand --

LCDR. ELMBERG: Maybe it's not. Hold on. Okay, triage, in this instance, means to classify a consumer complaint to determine the need for further

investigation.

MEMBER: -- is that the way you're classifying it?

LCDR. ELMBERG: No. We're classifying whether the issue be investigated or not investigated. So, if you're -- and you're out in the field, and you were looking really, really bad, we would classify you --

MR. HOLMES: So, you're putting all the bad things together and calling it triage?

LCDR. ELMBERG: No, we are taking a complaint. We are seeing if it meets the qualifications to be investigated based on the criteria that are in these slides.

MR. HOLMES: Okay. Thank you.

MR. GIOGLIO: Dr. Jan?

DR. JAN: Dr. Jan. I have, I think, a rather simple question, but when you receive complaints via the eight hundred number or compliance officers, do you have -- does the system allow for redundancy? If you received the same complaint from several sources, would the system recognize that or does it log that as two or three different complaints?

And, also, if I'm receiving a complaint, not to say the same product, like sliced ham that caused

someone to get sick from eating a sandwich, if two or three people ate the same lunch meat or lettuce that was in the sandwich, would that show up as three complaints or one complaint?

LCDR. ELMBERG: Okay, the database is pretty simple right now. I can write -- or have our data management write a simple statement. I know there are certain simple statements programs into the database, so we can identify if more than one person were eating a product from the same establishment who's gotten ill from it. That's the answer to your second question.

The first question was: Can the database recognize if it's the same family member, you know, the consumer complaint? It's pretty limited in that ability at this time, but we can like search last names. If there's another one that comes out. But, primarily, right now we average about twenty complaints -- and Judy and myself are the ones who triage it, so we're very familiar with it, so we can easily recognize when it's the same complaint. That happened at that university and it happened, recently, we had a husband and wife call in, and then we would combine those cases.

Oh, and Mr. Holmes, a better answer to triage. I apologize that we weren't clear on it.

Page, I think it's thirteen, triage and consumer complaints. That kind of lets you know how we go through the process. We look at those criteria and if meets those criteria and if it doesn't, if you'll flip through the next slide, then we have further criteria and then the overwhelming thing: That, if no matter what, it looked like a public health hazard, then all bets are out and we investigate.

MR. HOLMES: Basically, what you're saying is that if it looks bad we're going to triage it?

LCDR. ELMBERG: No, every case is triaged. Every case is triaged. We can't tell if it looks bad or not until we run it through the people's statements.

MR. HOLMES: Okay.

DR. MCKEE: Okay. Thank you. What I'd like to do is we'll take a ten minute break and I'm going to start directly at twenty until three. I'd like to cruise along so we might be able to expand on a couple of our other subjects for more questions and so forth, so I will start right back at twenty till.

(Whereupon, the parties had a short recess and the meeting subsequently resumed.)

DR. MCKEE: Next on our agenda we have the legislative update by Mr. Bryce Quick. What I wanted to do is, since we're running a little bit behind, I'm

going to defer the presentations that I had mentioned earlier to the first thing in the morning. That will give us a few minutes as well to maybe get back on schedule where we'll have an opportunity to have more dialogue with our questions. So, with that, Mr. Quick will give us the legislative update.

MR. QUICK: Good afternoon. I've been told to speak very rapidly, so I will try. What I'd like to do is briefly walk you through some of the legislative activity that affects FSIS operations.

As most of you know, before the Congress recessed and went home for the election, they had not passed any of, or most of, the preparations, but including that -- spending bill. So, I'm going to start off talking about what's critically important to the Agency and that's our spending, our funding source.

Both the House and Senate have reported a bill out of the Committees and right now we're waiting for them to come back and conference and work out the details of this.

Neither has been -- the final bill has not been considered on the floor of either House. The House Bill contains $73.5 billion dollars worth of spending. That's a very big number. Ours is relatively small. A portion of that, the Senate side,

was $74.3 billion dollars. Of course, most of that is food stamps and requirement payments.

The line share of the money that goes to FSIS is, of course, in sellers and expenses out to our inspection force. President Bush asked for $763 million dollars. The House version is $755 million dollars and $766 million dollars in the Senate Bill.

Those numbers look, between the House and the Senate, about ten million dollars apart, but if you make the way the bills are constructed, they are closer than they appear. There was some money that was backed out.

The bottom line for the Agency is the House Bill provides about forty million dollars in increases to what FSIS can do and new programs and out in the field. The bill also encourages us to complete the listeria a risk assessment and begin to revise the listeria action plan, using a scientific basis.

The Senate Appropriations Bill, while slightly more, provides about fifty million dollars more in additional spending for the Agency. It also adds on -- it's a rider of five million dollar and put on by the Chairman of the Committee, rather Senator Byrd. Five million for at least fifty additional inspection personnel to work on the humane methods of

slaughter.

Of course, some of the other things that are in this bill are appropriations that fund our partner agencies. AFIS is one. These are some of the things that they will be funding, if it is passed and that is the foot and mouth portions. The Senate Appropriations Bill increases funding to destroy and to dispose of animal carcasses suspected of having TSEs and other diseases.

ARS, another important partner of the Agency increases funding to conduct -- of research on listeria. The Senate Bill also has a similar fund for ARS, listeria and and CWD.

I'll buzz through some of these. FDA is another important source for us.

The bottom line, as you all know, November 5th brought us -- it's created an interesting situation for the Agency of the Department and right now you've got a Congress that the rumors change by the minute as to what they are going to do with the continuing resolution and to fund the government.

When they left us on our second continuing resolution, it gets us through November 22nd and when they return, if they return on the 12th, it's still yet to be determined whether or not they will follow the

OMB recommended course of action, which would fund the government on a CR through the end of the year, the fiscal year, or, if they'll come back and pass the Appropriations Bills.

They could do either or, but it's really up in the air as to what course they're going to pursue on that. So, what that does for the Agency is that it leaves us in a situation where our funding levels are kept frozen after 2002 fiscal level. So, it means that we cannot begin work on any of the new initiatives that we have in the pipeline and that we keep it where we were last year.

Before I move on, I was going to recap some of the initiatives passed on the Farm Bill. Are there any questions on that?

Okay. Six months ago we discussed the Farm Bill that had been passed and some of the initiatives that affect FSIS. Just want to give you an update on where we are on those items. One of the provisions in the Farm Bill was the overtime and holiday pay rates affecting our veterinarians. I can tell you that a proposal has been put forward to the Secretary and we are waiting back to hear from them and their views on that.

Another is the humane methods of slaughter.

There was sent to the Congress a provision in that Bill that asked us -- it actually instructs us -- to continue tracking the number of violations and putting in force the humane methods of slaughter, which we have continued to do and we anticipate reporting our results back to both Committees, Appropriation Committees.

Another provision in the Farm Bill was a Food Safety Commission, the presence of an appointed Food Safety Commission, and the Appropriations Committee has instructed us to proceed forward on putting this together, but expect funding in 2004 for the creation of this important Board.

The last thing is an issue that has been brought up earlier today and that the subcommittee will discuss further in this evening's discussion and that's the state inspection system's review, and Bill Leech and Ralph Stafko gave a good report on that, that we were proceeding, that we are on target, those reviews are taking place, in accordance to recommendations of this Committee six months ago, that we were to use the reviews that we have thus far, that we've done over the last two to three years, and then conduct the ones that we haven't done.

Also, this Committee recommended that if we need additional time, that we can actually do that. We

can send a letter up to the Congress, asking for additional time. I can tell you that the reviews are proceeding forward and we expect to be on target, but as the Committee recommended, if we need to use additional funds, yes, we are going to do that.

Our matrix is being creative, to -- let me just read -- fully comply with the recommendations of the Congress. What they tell us we need to do is that we should report a full review of state inspection's systems. We should offer guidance about changes the state systems might expect should the statutory prohibition against the interstate shipment of state-inspected product be removed and we're doing this with an eye towards including the mandatory requirements of the Federal Meat Inspection Act and the Poultry Products Inspection Act. So, a matrix is being developed following review of all the programs to send up to the Congress.

And that's all I have for now. Any questions?

DR. MCKEE: Okay. Thank you, Mr. Quick. Next on the agenda is the National Advisory Committee for Microbiological Criteria Foods that is going to be presented by Ms. Gerri Ransom.

MS. RANSOM: Good afternoon. I'm going to be

presenting an update on the Micro Committee or NACM. I'm going to focus on the highlights of our August meeting and I'm going to be giving you an overview of a couple of the final work products that were achieved at that meeting. That is a performance standard document and, also, a review of a NACM document.

I'm also going to cover some ongoing and new work. I'm going to give you an update on the Shelf Life Subcommittee. Also, I'll talk about a new -- charge and talk about a new work area on redefining conservation as well.

The largest work product that came out of the August meeting was the performance standard document or the final response to the questions posed by FSIS regarding performance standards, with particular reference to ground beef products.

I'm going to spend most of my time today giving an overview of this work product. Basically, as we know, FSIS designed the salmonella performance standards to verify the adequacy of -- systems. FSIS put forth the charge to enactment that was composed of several questions and what they hope to seek.

And the answers to these questions, which I think we will see that they got, is some general scientific principles allowing you to develop sound

performance standards and, also, how to apply these scientific principles to revising performance standards.

As you can see, this document does have particular reference to ground beef. Due to time limitations today, I'm only going to talk about some of the more general recommendations.

This document outlines for us the performance standards defined and expected level of control in one or more steps in process. It also tells us that establishing and meeting performance standards are means of reaching public health goals.

At the beginning of NACM the -- question one: What are the key scientific considerations that need to be attended to in developing and using risk assessments for applications to developing performance standards?

I'm going to go through each of these questions and try to bring out for us some of the highlights of the NACM responses.

Some general principles relating to question one that were outlined include that the stringency of a performance standard needs to be proportional to the risk and state public health goals. And going along with this NACM tells us that the consideration of risks

is what links the performance standards to public health goals.

Therefore, you can see the importance of risk evaluation and risk assessment in providing supporting material and information for developing performance standards.

Now, in considering revising performance standards, its important information NACM felt it very important to bring out in risk assessment, the information includes what the level of risk of salmonella, salmonellosis is, was prior to the performance standard for particular products.

Also, what the -- risk of salmonellosis is for that particular product; what the potential of new, current or new, technology is, and are, to further reduce the prevalence of salmonella in the product and consideration; and, also, what is the risk under a tightened performance standard of salmonellosis?

Again, risk assessment is very important to supporting information for performance standards NACM turned out for us. That those exposure assessments are very important. Particularly, on the exposure assessment-side, there is some data -- that need to be worked on. NACM pointed out quantitative data on the meat and poultry is needed.

Also, data on the proportion of salmonellosis attributed to FSIS-regulated products is important. Data on industry practices allowing reduction of salmonella in these products. And, also, data on the success of reducing other enteric pathogens -- and -- salmonella.

As you can see, as we go through these questions, we're getting some very sound, scientific information to work on performance standards development and revision.

I'm going to move on to the next question now. Question two: What constitutes the scientific sufficiency to support the -- indicated organism -- of a specific pathogen for measurement against the performance standard. NACM points out to us that an indicator organism indicates a state of condition. -- indicator organisms -- right now, we've got generic and salmonella being used as indicators of states of conditions indicating process control at slaughter facilities.

An indicator organism must meet certain requirements. An indicator organisms must share the -- pathogen of concern, similar growth and survival characteristics -- similar -- and they must be ready and available to --.

In addition, the relationship between the contributing condition to a pathogen an indicator organism must exist. And if you're going to use an indicator organism, you must assure scientific efficiency -- is important to have data showing that the microbe indicates the condition associated with contamination of the pathogen concerned.

Also, that there be data collected, showing that a decrease in the indicator also correlate with the decrease in the pathogen. Actually, at -- operations and, also, NACM points out that it is important to develop -- for tools allowing you to determine whether a decrease in the indicator organism parallels with the decrease in human food borne illness caused by salmonella and food borne organisms in general.

I'm going to move on to the next question. Question three: What constitutes scientifically, appropriate methods for considering variations that may be due to regionality, -- or other factors for developing performance standards?

NACM points out understanding variability is very important in keeping, -- requiring and evaluating data -- scientifically appropriate.

[inaudible]

In designing the study, -- talks about considering a pool process from live animals and client product. It helps if you look at this -- and the modules and -- suggests looking at microbiological -- in animals at slaughter. Also, slaughtered -- at prevention, looking at interventions and, also, the -- of the product. -- factors, these -- arrive in any one of those modules I previously mentioned, some from the from first module being the status of animals at slaughter, seasonality, regionality, animal husbandry practices, weather conditions, feed regime, animal age, health, transport of animals, holding conditions.

You can see some of these things would be not controllable. Other would be controllable. For instance, weather conditions is not controllable versus animal holding conditions.

As equally important to collecting your data, is data analysis and NACM prescribed using appropriate methods, such as reciprocal process control, analysis variance, progression analysis, for other appropriate methods.

Moving on to question four: What special considerations need to be attended to in the development of quantitative baseline data and subsequent use of performance standards?

Well, first of all NACM has outlined some general principles for us, including that quantitative data is more relevant to public health. It's important for exposure assessment, risk assessment. Also, quantitative data more accurately allows us to measure pathogen reduction. We can monitor more -- changes, the processing changes. And, also, NACM points out to us that technical challenges, actually are not substantially more complex, which FSIS suspected that perhaps it could be.

However, the biggest issue seems to be with these methods for quantitation, are more expensive and time consuming. In collecting quantitative data, you want to keep close attention to setting up the studies, statistical input to design is important. Sample collection, shipment, laboratory analysis are critical. Of course, control on time-temperature is very important in your data. It can cause changes in the data.

Balance -- moving onto the next point -- balancing the information gain with the cost is something else to consider with quantitative baseline data. And, finally, NACM points out we really need better methods in order to accomplish quantitative data and baselines. Particularly, we need higher -- methods

and also the cost-effective methods. And replacing MTM would be tough. A good start.

Some additional questions that were posed that helped nicely round out this work that were put together by Dr. Elsa Murano and Dr. Kay Loftsmith. These two questions include: How are performance standards working and are they helping to ensure the safety of the nation's meat and poultry supply? And, also, are there more effective alternatives to salmonellosis performance standards, and, if so, what would these be?

In considering performance standards effectiveness, one thing NACM pointed out that -- performance standards, they have stimulated the development and implementation of interventions.

Also, if you look concurrent with implementation of performance standards and their operation over time, we have seen a decrease in the frequency of salmonella isolation in FSIS verification samples. And we have also seen in -- data, if you look at the 2001 report showing the 1996 to 2001, perhaps been a fifteen percent decrease in overall human salmonellosis.

Getting to the nuts and bolts of the first question, are performance standards working, what NACM

points out and has determined through their analysis is that existing public health statistics do not easily allow you and are not set up for us to be able to determine the reduction in food borne disease attributed to performance standards. Therefore, NACM recommends that CDC and FSIS collaborate to measure the impact of performance standards for raw meat and poultry on salmonellosis and other food borne diseases.

On the alternative part of the question, there are some things that NACM points out, regardless of the approach to control, there should be an underlying microbiological criterion that the performance standards are right on target here. They also point out that performance standards articulate goals leading to increase public health. Further, NACM points out that performance standards do maximize flexibility and improvement strategy.

As far as what possible alternatives might be: Indicator organisms, use of those would be one. Also, there are a number of things that could be mandated in place of performance standards. This includes mandating pathogens in fowl at farms, at grow -- antemortems. Also, mandating performance criteria, specific process steps, mandating interventions that proven work or mandating continuous improvement

criteria, which would include setting a goal, perhaps, a ten percent reduction in prevalent per year until you reach a final goal.

One of the final conclusions of the performance standard work is that performance standards are valuable and useful tools to define an expected level of control in one or more steps in the process. This is provided that general principles are met and many are outlined in the document for us.

As far as the next steps, NACM will plan to continue work planned with specific recommendations on other products and currently charge the actions under preparation.

Changing gears and moving to the additional, the second final work product that came out of our August meeting. This is a review of the Codex discussion paper on supposed draft guidelines for the validation of food hygiene control measures.

This paper, the Codex Committee on Food Hygiene paper that steps out to give comprehensive coverage of food safety control measures, based on a food safety outcome approach that fills in flexibility to control measures. NACM's review of this paper, NACM leant expertise and input; they recommended adding a scope factor, including a discussion of validation

versus verification activities and also including discussion on things such as production procedures, such as cooking and cooling versus employee behavior and good hygienic practices, which are more -- as opposed to production procedures, such as cooking, where validation is just comparable. Those are more difficult to validate and verification may be not appropriate.

So, basically, the NACM review did turn out to clarify issues in this document and strengthen it. The Codex Committee on Food Hygiene will consider these U.S. comments, along with comments of other countries, at their January meeting.

Also covered at our August meeting was an update on criteria for shelf-life based on safety. This subcommittee helped work-in-progress. We hope soon to see a draft document. Basically, the focus of this work is on scientific parameters for safety-based -- for refrigerated, ready-to-eat foods. The main concentration of this work is on psychotropic pathogens. Particularly, the growth over the refrigerated storage of foods and increased risks of food borne disease.

The top three pathogens of concern in this work are: sera mono schizogony, -- and also non- --.

A new campylobacter charge was also addressed at this meeting and introduced. This is a FSIS work charge asking that NACM look at the analytical utility of identification and quantification methods for campylobacters' use in the FSIS baseline study. These were on poultry carcasses.

Charged specifics include that NACM's review and compare baseline methods are particularly looking for accuracy and decisions in determining prevalence and quantification information and also part of this charge includes comparison of these methods, this recent methodological advances, and looking at how the methods are able to produce the information for risk assessment baselines.

Finally, at our August meeting, a new FDA work area was introduced and this is redefining pasteurization, which is going to be a new subcommittee and work area called Scientific Criteria for Redefining Pasteurization. This work is an FDA work to define pasteurization within the scope of the 2002 Farm Bill.

The focus of this work is going to be looking at the most resistant organisms of public health concern and the parameters to control those organisms. A goal of this work is that when pasteurization claims are made, we can be rest-assured that the food is

indeed pasteurized and safe.

There is a great degree of complexity built into this project of the diverse number of foods that are pasteurized and the diverse ways in which they are pasteurized and the parameters. The scope of this work even increase more when you begin to think about some of the newer ways to achieve pasteurization. When you look at radiation and, as I said, there is just a diverse number of foods that are pasteurized from seafoods to juices. I think we can consider things like read-to-eat foods, as well.

So, it's going to be quite an interesting work come of out this project and I'm looking forward to seeing it. Right now a subcommittee is being formed and FDA is working to further define this work charge.

With that, I've given us coverage of what was presented at the August meeting and I think that also includes coverage and update of the Micro Committee Activities. Our next plenary session is slated for March 2003. A date has not been set yet. The actively working subcommittee will be the performance standards of committees, shelf-life and redefining pasteurization. We anticipate that each of these subcommittees will have a meeting in January and also in March, the same weeks we have the plenary session.

Lastly, I just wanted to leave you with URL for the NACM web page for information, updates and available documents. Thank you.

MR. GIOGLIO: Ms. Foreman?

MS. TUCKER-FOREMAN: Thank you. Ms. Ransom had to cover a lot of material in a short period of time and since I read this report very carefully, I think there are some points that are important there that didn't get the emphasis that they warrant. Beginning with the finding on page three, the conclusion of the Committee.

The Committee concluded that performance standards that make the principles as outlined in this document are valuable and useful tools to define an expected level of control in one or more steps in the process. In response to question one, the Committee recommends the consideration of risk, but states: "This consideration of risk may not necessitate in all situations an in-depth, quantitative risk assessment, which requires extensive resources and time. Particularly, if it would unnecessarily delay timely protection of public health."

I got a couple of others because I think they make an important point since these performance standards have been under attack from the minute that

they were begun. If you get over to page seven, question two: What constitutes scientific sufficiency with regard to salmonella performance standard? The Committee points out that when HACCP systems and other pre-requisite programs in ground beef operations are adequate and verified, the measurement of salmonella reflects the total process control. Particularly, the microbial conditions of raw materials.

I have two more. With regard to the question: How are these standards working and are they helping to ensure the safety of the nation's meat and poultry supply?, something which I thing is really basic that we're looking at here, as previously indicated, microbiological performance standards are intended to effectuate a decrease in the presence of enteric pathogens in raw meat and poultry with the goal of improving health, public health.

The Committee considers microbiological performance standards an important tool in advancing microbiological safety of meat and poultry to articulate clearly to the industry the Agency's expected level of control of the HACCP system, including sanitation SOPs.

And, finally, on page seventeen, in response to question two: Are there more effective

alternatives?, I believe, this may be the most important of all, while the Committee has identified some outcome-related alternatives, there is a general consensus that performance standards articulate the goals that are expected to lead to an improvement in public health. Use of performance standards generally maximizes the flexibility in relation to finding new strategies for improvement.

Thank you.

MS. RANSOM: Thank you for the added information. As you know, I was under time constraints.

MS. TUCKER-FOREMAN: You were indeed.

MR. GIOGLIO: Ms. Donley?

MS. DONLEY: Nancy Donley and Carol kind of read my mind here and pretty much did what I wanted to do as well is to emphasis some of those points, but I have one other one that I just would like to make sure I'm reading correctly and, if not, would you please clarify it for me and that is on page sixteen, which states -- this is talking specifically about ground beef and that the Committee also noted decreased incidents of salmonella as reflected in the Agency's verification data in raw meat or poultry has not led to a decrease in disease associated with 0157:H7 in

ground beef.

I just want to make very sure because the Committee obviously recognized the good that a performance standard does in verifying process controls in salmonella. I just wanted to make sure that the Committee here is not saying that give it up the salmonella performance standard for ground beef, but that it's not enough to control 0157:H7.

MS. RANSOM: Well, the document itself talks about that needs to be explored further and I'll call on Dan Engeljohn to see if he would like to add anything.

DR. ENGELJOHN: This is Dan Engeljohn. On that response, I would say that the Committee did recognize that there are benefits to the performance standards in how both salmonella and 015 are reacting to those performance standards, but there seems to be some question as to what that relationship is. And, so, for that reason, and as I recall, that question was also related to the issue of looking at having one pathogen to effect changes in other pathogens and how that would work.

And, so, it raised the question in the Committee's mind that there are other factors in play, that there may need to be other considerations made to

effect a change in pathogens that interact differently. So, that's really where the resolution was, that we needed to look into that issue further.

MS. DONLEY: So, when you say, do you mean other or additional measures that may need to be taken specifically to address the problem of 0157 in ground beef.

DR. ENGELJOHN: I would say that overall the Committee's thought process on that issue would be that it would be additional.

MS. DONLEY: Thank you.

MR. GIOGLIO: Okay, thank you very much. Dr. Johnson?

DR. JOHNSON: Thank you. Alice Johnson with the National Turkey Federation. Just a couple of questions based on what Gerri just told us. The recommendation that CDC and FSIS work together to try to come up with some relationship between the salmonellosis and the products covered by FSIS, have any discussions been initiated with CDC? I know there may be a question of funding. Has any of that already in progress? Have you started working through that?

And I know the Committee talked about performance standards and the need to re-evaluate the data that was used to establish the first baseline and

look at things like regional and seasonal and a number of samples would be taken. Has the Agency looking at any of that currently?

DR. MCKEE: Dr. Engeljohn?

DR. ENGELJOHN: I'm sorry. I missed the second part to that question. You might have to repeat that, but the first part was: Are we working with CDC or beginning the process to try to identify measures to better identify public health impact with regard specifically to our products? And, yes, those discussions have been underway and there are, of course, many issues related to that. But, yes, we are actively looking at ways to better measure the impact of public health with particular regard to the products that FSIS regulates.

And, I'm sorry, Alice, could you tell me what the second part was?

DR. JOHNSON: Thank you, Dan. Yeah, just on looking at their suggestion that you need to take into consideration different parameters and do more intent studies together to conduct another baseline for things like salmonella. Have you looked at -- I know the Committee threw out several factors that needed to be considered. Is there anything in progress to look at how another study would be structured?

DR. ENGELJOHN: With specific regard to FSIS baseline studies, that's the question. The Agency has, in fact, had numerous discussions internally on how to proceed with ongoing baseline studies. I think when we issued the PR HACCP final rule, we had a discussion in there that there was the intention to revisit the performance standards over time and revisit the issue of how we adjust performance standards.

And, as we had them implemented, we've recognized that we do need to ensure that we have some ongoing process to look at that. It's a resource issue because taking time to do baselines takes away the time or the resources that are individuals are using to look for pathogens of public health concern. And, so, we have active discussions underway about individual baselines and then how we can conduct them on an ongoing basis.

DR. JOHNSON: I was just going to add the part about the resources.

DR. MCKEE: Okay, thank you very much. Next on our agenda we have an issue on Escherichia coli 0157:H7 Developments. Dr. Daniel Engeljohn will make the presentation. Dr. Engeljohn?

DR. ENGELJOHN: Thank you. I've going to -- I don't have a Power Point presentation, so I'll just

remain here and make it from here if that's okay. I want to present some information on a pro-active way at looking at how the Agency addresses 0157:H7 and that aspect deals with how we conduct our in-depth verification reviews and how to trigger those reviews.

In Tab Five of your notebooks, you have some information that relates to our in-depth verification activity. You have an issue paper, which I will go over and the questions that I would like the subcommittee to deal with this evening and then, also, contained in your packet is a copy of the Federal Register Notice that came out on October 7th of this year, which identified the Agency's belief that manufacturers of raw beef products needed to reassess their HACCP plans with regard to 0157:H7.

Behind that document is the document on conducting a target, in-depth verification review. It's FSIS Directive 5500.1 and it issued in October of 2001. And that document sets out the procedures that the Agency currently uses in an in-depth verification review and that would be a document that contains information on how we now schedule them and may give the subcommittee some ideas as to considerations that could be used to expand moving forward in a pro-active way.

And then, also contained in this packet is a draft document that relates the role of the microbiological practices and data that would be collected and utilized in those in-depth reviews. It's a document that sort of lays forward the types of microbiological issues that we need to look at and you will note that it also deals with 0157, but, specifically, at the grinding plants and doesn't address the issue of slaughter and fabrication.

And then, I believe, if you haven't already received it, there's a one-page document that identifies the findings, some general findings, that the Agency has pulled together from three of the in-depth verification reviews that we conducted on 0157 to give you idea, in a general way, of the type of information that we have collected.

For those of you who are not familiar with in-depth verification reviews, these are reviews conducted by subject matter experts usually that are controlled and managed by our Technical Service Center as the leading activity for individual in-depth reviews and they generally are requested by the district manager to have a special review done of an operation, which, generally, has had multiple failures for some activity or may be involved in some epidemiological

outbreak and that's what we call "for cause" or "targeted" in-depth reviews.

In the directive that you have access to you, we lay forward the mention that the Agency intends to begin doing random reviews, so the discussion for today and this evening really relates to the random reviews that we would do. In particular, if there is -- cause for looking an IDV at a particular operation.

Some of the aspects that have taken place since we've implemented this program a little over a year ago is that our consumer safety officer program has developed and is actively looking in an intense way, in a comprehensive way, at the implementation and execution of HACCP plans and that team is composed of, generally, specially trained, in-field personnel, but not necessarily a team of individuals and, particularly, a team spread from around the Agency, which the IDV is a team of subject matter experts from across the Agency.

In any case, we've begun those CSO reviews and will operate them in a major way. The first activity related to that is also related to our 0157:H7 reassessment policy, which was issued, as I said, on October 7th and for which the first activity related to that is effective today. Today was thirty

days after we issued that notice and our inspectors in raw beef operations were tasked with finding out today whether or not plants are aware of the reassessment notice and are going to begin that activity.

For large plants, the first reassessments are to have occurred by December 6th, so there's another month before those actions actually take place. But it's important to note that in your consideration of the CSO reviews.

In those reviews, the consumer safety officers are actually collecting four pieces of information and that information relates, in part, to heavy establishments reassess their HACCP plans prior to the notice that came out on October 7th and then, secondly, if they have reassessed their HACCP plans, what did they do? What is the documentation and issues related to that reassessment? And then, finally, if they have not reassessed their HACCP plans, then why not?

So, from those CSO reviews of the roughly twenty-six hundred plants that will be undergoing those reviews, the Agency will have feedback as to what the plants are doing with regard to HACCP controls for 0157 and what types of activity they undertook to address the reassessment. So, that information would be

important information that the Agency would have access to.

Along those lines then, the Agency is looking for input as to how to begin the process of focusing at fabrication in slaughter plants. Our present activity related to 0157, in the short term, in particular, will continue to focus on testing ground beef products for 1057:H7. We have not yet instituted a targeted testing program in which we look at trim that's going to be used in ground beef, although that is an intention for us to develop that program and to focus on carcasses.

But, in the meantime, the way our structure for the IDVs are set up is that, if positives, multiple positives, occur at a grinding operation, that plant then may be eligible in the district manager's determination to be assigned an IDV review. But that IDV review currently is only at the grinding operation.

And, so, what we're looking for is input as to triggers that may be used to start focusing on an in-depth that may, in fact, be triggered by the activity at a grinding operation but which identifies supplies to that grinder, so that the Agency then could, in its systems review of 0157 control, begin looking back into the system and include that activity in the review of an individual establishment.

So, rather than looking at our IDVs in an individual plant basis, we're looking to expand that activity by this technical subject matter group to look at possibly multiple plants in an individual review. That brings up resource issues in terms of how do we narrow that activity down? What would be the types of triggers that we would want to focus on in looking at those plants and then how do we interrelate with other activities that are already underway within the Agency. And, in particular, the activities the CSOs are conducting in their more intensified assessments of individual plant performance in their HACCP systems.

So, on that matter then, the Agency has identified that we're looking for input on whether or not we should expand our resources to begin looking at slaughter and fabrication plants in conjunction with grinding plants when we do an IDV for a 0157:H7 and if, in fact, that would be an activity that we should not do, we would like to get your input as to why we should not be moving in that direction. But, if, in fact, you believe that would be a beneficial aspect for the Agency to utilize its resources to start conducting those activities, then what would be the types of triggers that the Agency could consider, and should consider, in trying to narrow the focus down of where

it would focus its reviews.

So, I would be happy to answer any questions on that. Again, Tab No. Five is where our materials are. The one-page handout that I do believe you do have -- it's titled Data Analysis of 0157 IDV Reviews -- just to go through that briefly with you, we've conducted three IDVs. Those IDVs have been for a small establishment and you can see from the information presented here that, in most cases, the information relates to just improper implementation of the procedures that were in place in those facilities, but the type of information related here also indicates that more than just the grinding plant needs to be assessed in looking at 0157 control.

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

MR. GIOGLIO: Ms. Foreman?

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation. I have a number of questions and I'm going to ask a couple of them and let other people have a chance and I'd like to come back and ask some about the Federal Register Notice. When I go through this, I run into the same problem that I always run into with FSIS in-depth verification reviews. What do you do? I know the process, but what is the action

that is taken in the end? What happened in Plant A, Plant B and Plant C? Did you tell them: Fix it. Did they fix it?

DR. ENGELJOHN: I can respond to the general question. I don't know the specifics about the three, but the way the IDV works, again, at the request of the district manager, when the team goes in and conducts this in-depth review, which generally involves a week in the facility. So, the team is there for an extended period of time. In some cases, those IDVs go for more than a week and, in fact, many weeks in some cases.

But the outcome of each IDV is a report that is submitted to the district manager with specific recommendations as to the execution and implementation with regard to the regulations, HACCP and SSOPs. The follow-up to that is that the district manager then takes that information, puts that in the form of a memo that is submitted to the establishment management with very specific requests that the plant must address those issues with a corrective action planned that's agreeable to the district manager.

So, in all cases with an IDV, there is an action that the district manager takes with the individual establishment and intended enforcement action would follow-up if, in fact, the plant is not

able to identify how these failures would, in fact, be addressed and in a timely fashion.

MS. TUCKER-FOREMAN: So, you're given a corrective action plan. How long does the plant have to develop the plan? How long does the plant have before it has to put the plan into effect and do you have a quantification of the actions taken on the corrective action plans? What happens in the end?

There used to be a saying about if you laid all the economists in the world end to end, they couldn't come to a conclusion. I think, if you put all the IDVs teams together in the end, you never come up with an enforcement action. Nothing happens. Somewhere it has to say in here, if you don't do X action by Y time, Z happens. You get shut down permanently. You get closed down for so many days. I cannot find that in any document related to these. Ever.

DR. ENGELJOHN: The issue of enforcement action does, in fact, occur on a case-by-case basis. We do have our rules of practice, which identify how the Agency would move forward with enforcement actions. We don't have specific time frames built into how quickly a plant has to respond, but in situations where there are, in fact, unsanitary conditions, or the plant

is not operating it in a manner that would, in fact, cause us to believe that adulterated products would be going out the door, the plant would not be operating.

MS. TUCKER-FOREMAN: Wait a minute. That's like this thing about if a state-inspected plant has to be equal to because it wouldn't be operating if it weren't equal to. It's a circular action. Somewhere you've got to qualify these are the things that happened and they happened on specific dates. Can you give me any instance from your personal experience of a specific action taken, an enforcement action, because a plant didn't follow a corrective action plan or wasn't able to follow through on that plan?

MS. HICKS: Cheryl Hicks. Office of Field Operations. I don't have any specific examples to offer, although I do know that they are, and have been, for sometime now developing specific verification plans in response to the corrective actions that the companies are giving us and they are very specific, very lengthy and have specific time frames by which they would have to be met.

Now, I'm not aware of any individual instances, but I am sure there are. If they are not following through on that, I mean, that's what the inspection people are doing is following through on

corrective action plans and if progress hasn't been made for a good reason, then they go to the next step.

MS. TUCKER-FOREMAN: What would be a good reason not being done? I continue -- I had this discussion with Bill -- at the last meeting. There are never any deadlines for these things. There's not a date by which action has to be taken and it is not written anywhere what specific penalties will apply if you don't do these things. I do not believe that's an enforcement program. I think that, frankly, you're killing a lot of trees.

DR. ENGELJOHN: I would respond -- this is Mr. Engeljohn -- that when the letter does go from the district manager to the plant, there are specific items that have to be responded to and each has to be responded to with a time frame for when they would be completed. The district manager then when receives back that letter within a very specified period of time by the district manager, then ensures that's either reasonable or not and follows through on that. I've noted your issue about adding time constraints.

From my experience on the IDVs each is a case-by-case basis that may, in fact, involve differing actions that would take time, but we certainly are collecting data from all the IDVs that we have done.

From a policy standpoint, we're looking at what are the proposed corrective actions for each of the items that are identified in IDV by the IDV team and trying to assess how much time it took until the district manager determined that the actions were, in fact, suitable.

So, that type of information is, in fact, being collected. We are looking at it in an analytical way, from a policy standpoint to see if, in fact, we can move in the direction of placing time frames around actions for which we've already identified. There are some repeat issues here that can, and should be, likely handled in the same way.

MS. TUCKER-FOREMAN: You know, if you were a parent dealing with a teenage child, you'd have a juvenile delinquent because they know nothing is going to happen in the end.

MR. GIOGLIO: Mr. Holmes?

MR. HOLMES: Marty Holmes, North American Meat Processors Association. I have a couple of questions, but I would like to make a comment in that regard. We do help members write letters in response to IDV situations for they are, basically, putting their name on the line and a time for the district office and the IDV team of when they will get what accomplished and we have that situation where if you

don't have that done in time, you do get shut down.

So, there's, I guess, in consideration, whatever time frame they agree to, just like your HACCP plan, you're basically riding -- you're painting yourself in the corner. You're either going to do it or you're going to suffer the consequences. So, in that regard, I'd like to make that statement.

A couple things here I just wanted to double check. Dan, on this one-page document that you handed us, this draft analysis, you were saying that you've done, you're not saying you've only done three IDVs? You're saying you've done three IDVs in where an establishment had multiple 0157:H7s?

DR. ENGELJOHN: Yes. To clarify, these are three IDVs on 0157:H7 alone.

MR. HOLMES: Thank you. The other general comment I'd like to make is that, and I'll certainly discuss this tonight in the subcommittee, we've been preaching since '94 that in a raw and -- plant where we're grinding products and 0157:H7 has -- in my ground product, but is not in my raw material, that we need to look back at the supplier of that organization. So, certainly, we'll make some comments this evening that in only makes sense that if I'm buying the 0157:H7 to begin with, we need to see who my suppliers are.

MR. GIOGLIO: Ms. Donnley?

MS. DONLEY: Thank you. Nancy Donley from STOP. Just a quick follow-up on a point that Marty made and that is that they have to suffer the consequences. Well, that's the problem. There are no consequences and the process just gets strung out and strung out and strung out and strung out and nothing gets done because the Agency doesn't have the tools to make anyone pay attention. And, also, another part to what Carol would say, I will say, this problem isn't limited to just IDVs either.

It's the whole problem of the inspection system. It's right through the whole inspection system. The NRs that are given out. NR after NR, after NR, after NR and nothing gets done because there are no time parameters put on to have anything done. Either you get it done or you pay the price, but there's no price to pay, so we're going in this vicious circle.

I do have a couple of specific questions for Dan. How costly is an IDV?

DR. ENGELJOHN: The Agency does not have information on the cost associated with an IDV. We truly would be appreciative of industry if they would package that type of information and provide it to us

so that we could, in fact, use that. The reason I say that it would be important information is because the Agency does need to be aware of the impact of its programs.

Its enforcement programs have impact, in particular, in small and very small plants for which increasing numbers of executive orders identify that we must take into account those impacts and since we don't have that type of information, we, therefore, make estimates when we put together proposed rules. That's one aspect of what we look at is the effectiveness of the rule and non-compliance. It's an area for which we are beginning to have partners with other economic associations that are looking into these issues to try to document the impact of Agency actions related to IDVs, related to recalls and so forth.

All that information is an important aspect for which if we were to put time constraints into any enforceable document, it would require us to have a regulation and in order to have that reg, we would need to know what it impacts.

MS. DONLEY: I guess, I really don't care how much it costs the plant to implement. I really don't care. Whatever they do to get it done and be able to produce a product that is worthy of USDA -- approval.

I don't care if it's a small business. They shouldn't be in business if they can't do it, if they can't meet it.

My question is how much does it cost the Agency to do the actual verification?

DR. ENGELJOHN: This is Engeljohn. I would answer that, at this time, we do not have an answer for that, but I can tell you that in part of the accountability that Dr. McKee has held the Agency managers to is that we have started a process analyzing all of our programs. In particular, the IDVs is an area where we are, in fact, looking at how effective they are in terms of making change, how much resources they take to implement, because the intention is to continue to have an ongoing IDV operation, but we first have to demonstrate that they?re effective and it gets out the issue of having an IDV and not following through is one thing, but we do need to capture that.

So, I would say that we will be looking into analyzing IDVs in particular because of their costs and their impact on the Agency. We will be looking at that on the industry as well.

MS. DONLEY: And if I can just make one very brief follow-up comment. I am on the subcommittee and I'm really looking forward to getting, and it's going

to be a very lively discussion, but is there any sort of accredited, independent agency that can do IDVs -- and also is there any sort of precedent that companies -- because the ones that need the IDVs, frankly, are the ones who it sounds to me is having a routine problem and probably a problem that's been pretty flagrantly disregarded for a period of time -- do we have any precedents of company picking up the cost that the Agency incurs to have to have an IDV done?

DR. ENGELJOHN: This is Engeljohn. I would respond that within the Directive 5000.1 that you have, there is a brief discussion in there of do we consider these IDVs to be audits and we do use the same type of tools, in part, that an audit is used to look at this system and how it's functioning. So, from the standpoint of: Are there three party auditing associations out there? Yes, there are. But the issue for the Agency is that we're looking at implementation in terms of aspects with our own regulations and policies and the teams that do these IDVs involve policy-makers or microbiologists or public health individuals and a cadre of our compliance in other field operation people and, so, it's expertise from within the Agency that is, in fact, giving sort of a third-party review.

To get at the issue of cost, no, no company has volunteered to pay for that. The Agency has looked at the activity as one for which we have a responsibility to do. It's one way that we can look at improving internally the operations.

From a policy standpoint, for which I am in policy, I view these IDVs as providing very important, critical information on how we need to improve both our training materials for our own employees, as well as the policy documents that employees use on a day-to-day basis and the industry use in terms of the regulations for the policies that are there to articulate what our expectations are.

DR. GIOGLIO: Dr. Johnson?

DR. JOHNSON: Alice Johnson. National Turkey Federation. One thing that I think we are missing when we're talking IDVs or in-plant inspectors or any agency folks is that an IDV team goes in there and an inspector goes in there, if there is something that the facility's doing that is considered the product is adulterated, that plant, that establishment, is not running. I mean, it's not a matter of you have to think about this or you have to reassess or you have to -- its you're not running. And we'll talk about it later.

So, from that standpoint, the Agency has the authority and if an IDV team goes in there with the extra eyes beyond what the normal inspection personnel would see and they feel the plant is producing adulterated product, the plant shuts down and that, unfortunately, is something that we get calls about in the trade association all the time. You know, we're shut down. Here's what's going on.

As far as the IDV team and I recognize your questions was for the cost to the government, they are extremely costly. My first comment was, gosh, do I even know what they cost for industry and my first comment is very costly and as we said, a company, you know, it gets to the point where if a company can't afford to -- because of the time and energy that is put in when an IDV team comes in and the requirements thereafter. So, it is definitely to a company's advantage. The IDV team visit in and of itself is something that the companies certainly try to avoid it, if at all possible.

And Carol mentioned that she was not aware of any type of enforcement based on IDV teams. I am aware of some plants that have been shut down. When you talk about putting some time constraints on these things, I know from a plant perspective, there are several

companies that say we would like to have a time constraint on USDA and that they have to make a decision on our corrective action plan because there's -- you know -- we're not giving timely turn-arounds and things like that, so I hate to see time constraints placed where it's not the flexibility of the district manager or someone who is on-site who can make these determinations, because a lot of times the corrective actions that are needed to put in place and the validation of these corrective actions takes some time and can you put a blanket time down for any one intervention or one process? Maybe not. It depends on the individual or specific situation for a given plant.

But, again, I just want to say if there's any question that USDA can't walk in and if they think the product is adulterated shut a plant down. I know a lot of folks that can tell you otherwise.

DR. ENGELJOHN: Thank you. Ms. Kaster?

MS. KASTER: I guess, I'm going to end up echoing what Alice said, but I'd like to point out that there is a small handful of -- that are actually in the plants every single day, including -- and I just want to say for the record that if Bill -- there are ramifications, actions and time frames associated with all of the activities we are talking about, whether

it's daily activities, CSO, IDVs.

I understand your concerns and where you come from and why you make the point that you do, but I just have to say for the record it sure feels an awful lot like these things are already affirmed.

DR. ENGELJOHN: And I would respond by saying that in my experience with the IDVs is that the team has the authority to get whatever records that it needs and there is intensity in the sense that all records and all activities are reviewed. So, it is a very intrusive activity, but it's also one for which the entire system within that operation is looked at. Dr. Jan?

DR. JAN: Lee Jan. What would the Agency do or what has the Agency done when they've gone in to do an IDV because of a -- has and -- been identified and the results of the IDV were that all the systems were, they found no -- well and -- followed and has a plan -- adequate control points, monitoring frequencies and applications, the IDV couldn't find fault with any of the processing, what would be the next step and what has been the next step in those instances?

DR. ENGELJOHN: This is Engeljohn. We have not been confronted with that situation to my knowledge. In all case, particularly, with regard to

0157, their root causes have been well identified and could, in fact, be corrected by a number of, in most cases, easily changeable activities.

So, I would say that that hasn't been the experience, but I would say that, as our CSO teams and others are in looking at implementation and execution, the Agency does expect that the plans that are in place will, in fact, improve over time and that the reality is that there may, in fact, be a problem link to a plant for which on just looking in a general way, we may not be able to find a root cause. But that gets at the issue of looking at a more in-depth way of what the problems would be.

So, I would say we would follow-up. Our goal now is to look at the grinder, which we believe, in most cases, that product coming from a supplier would be the place where we would focus to ensure that the product coming in the door is, in fact, coming in the door with as low amount of risk with regard to 0157 as possible.

DR. JAN: The next initiative that is in place right now, starting December, February and April to get inside plants. That is the next step and focusing back on the production of the producer of the raw material -- so if your IDV team said they had not

found -- following the IDV team in identifying these problems, the plant makes all the corrections without going back to the suppliers, that process could still produce an 0157:H7 -- product, even if it did everything the IDV team told them to do, implemented that until they get a product that is zero detectable level of 0157:H7, whatever that level is, -- so, I guess, that was my point was that if that did not happen --

DR. ENGELJOHN: Yes, this is Engeljohn. I think with the grinder it will be difficult for us to be able to say we could find nothing wrong there. If, in fact, the -- the documentation that the plant might, in fact, be relying upon may, in fact, identify that all the actions will be done by a supplier and that this particular grinder is simply verifying what's coming in the door and we may, in fact, find that it's not the grinder and that is the reason why we believe we need to start looking back at the supplier.

But it would point out, in the case of a slaughter operation, there we would have the expectation that we may, in fact, do our more intensified reviews find that, as an example, if we were to take microbiological samples, we may, in fact, not find 0157 at the slaughter. Well, we wouldn't stop

there in terms of saying that all is taken care of because if we do have an expectation that it would be a rare event to find 0157 on a carcass simply because of how we would have to construct a program to detect it if it was there.

And, so, I think the issues related to validation and verification at slaughter and fabrication are areas where we are now, in fact, going to be doing more intense activity and developing more procedures in terms of how we want to look at those issues more intently. We do expect that we're going to run into the situation where we can't find something wrong at an individual plant, but because we're dealing with a raw product, that is the reason why we believe we need to go back into the system.

DR. JAN: Thank you.

MR. GIOGLIO: Ms. Foreman?

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation. I know that the plant's probably feel like they had enforcement actions taken, but I'll refer you to the recent GAO report, which says FSIS is not ensuring -- compliance with regulatory requirements.

And none of FSIS notices of suspension with inspection documents that they specified a date by

which corrective actions were expected to be implemented and effectiveness verified. It is one of the basic criticisms in the recent FSIS report. And -- what brought up -- what's her name down there -- I'm sorry -- makes clear that there is a difference in perspective.

We believe that the grant of an inspection and the ability to put that seal on your package gives you're an obligation to be producing safe products all the time and that when the department errs it should be on the side of protecting public health. We're not keeping open a marginally sanitary and effective and efficient plant and then there are those specific dates by which action must be taken.

Common sense tells you we're erring on the side of keeping those people in business instead of protecting public health.

DR. ENGELJOHN: This is Engeljohn. I would respond by just providing you some reassurance that in our documentation of our activities, and, in particular, with regard to IDV, that we will, in fact, build in a process by which we can capture what the time frames are for various corrective action, so that we can begin looking at that issue and using that to design a system, if possible, to come up with concrete

dates.

MS. HICKS: I also wanted to add that -- Sharon Hicks, Office of Field Operations -- that the GAO records that they looked at, I think, were from 2000 and 2001 and it is true that at that time we didn't have as detailed verification plans in place as we now issue with very specific time frames.

And it is also true they identified, and I believe OIG did before, that with the IDVs at the beginning they were reported the findings were delayed. Plants weren't given the results of what was actually found as quickly as they should have and, therefore, the action that resulted from the IDV also took longer than it should have, but the timing on all of that has improved dramatically over those earlier years.

DR. MCKEE: Thank you, Dr. Engeljohn. We are on schedule. The next briefing is 0157:H7 in Ground Beef - Review of a Draft Risk Assessment. That will be presented by Dr. Michael Doyle on behalf of the National Academy of Sciences. Dr. Doyle?

DR. DOYLE: Thank you very much. This report was initiated by USDA, who had conducted a study, a risk assessment, on 0157 in ground beef and it was presented to this group of experts to review under the auspices of the National Academy of Sciences with the

understanding that this was a draft risk assessment and it wasn't a final document, so that is a perspective that our group put as we looked at the product that was presented.

Now, the members of this Committee have a wide, diverse background. I served as Chair. I'm a food microbiologist. Dr. Scott Ferson is an applied bio-mathematician. Dr. Dale Hancock, at the University or at the Washington State University is an epidemiologist. Dr. Myron Levine, who is at the University of Maryland directs the vaccine center there and is very knowledgeable in the area of both response and vaccines that protect against various diseases.

Greg Paoli is an up and coming, and, I think, soon to be internationally recognized, expert in the area of modeling and risk assessments. Barbara Peterson, who is with Exponent, is very knowledgeable in the area of exposure assessment.

Dr. John Sofos is an animal scientist, food microbiologist at Colorado State University and is an expert in the area of slaughter practices and Dr. Susan Sumner is a -- food science program at Virginia Tech and she is very knowledgeable in food processing and food preparation aspects.

And I do want to point out we have with us

today Dr. David Butler, who was the study manager, who's with the Academy and David, in his right, is an expert in the area of risk assessment. So, we're very fortunate to have his expertise to help support the Committee.

Now, the FDA's charge for this Committee was to provide comments on the 0157 draft risk assessment for consideration as the Agency finalizes this document. And, as a I mentioned, this is a work-in-progress and it was considered to be a draft.

This was to include evaluations of the overarching logical structure of the model, the validity and appropriateness of the input data that was used, the reasonableness of the assumptions that were made, the reasonableness of the -- approach and, finally, evaluate the modules? mathematics and equations.

The Committee was also charged to consider whether the risk had been appropriately characterized, and if these sources of variability and uncertainty, critical assumptions and important data gaps had been identified and characterized.

So, this is how we organize a report. We began with a summary. Chapter one, began with a summary of the content of the draft risk assessment.

Basically, an executive summary. Chapters two through four were reviews of three specific modules of the exposure assessment. Specifically, the reduction module, that is the animals produced in the field, the slaughter module and, then finally, the food preparation module.

Chapter five addressed hazard characterization. Chapter six addressed an evaluation of the risk assessment and, then finally, chapter seven summarizes the Committee's comments on the overall approach that was taken to constructing and implementing the module.

Relative to the introductory comments, the Committee conducted a very -- science-based examination of the content of the draft and, as I mentioned, we were mindful that this was a work-in-progress, a draft report, and not a final report, and that's different. -- on the line the draft risk assessment we thought was very impressive and it far exceeded the scope and breadth of the prior 0157 risk assessment.

I think it's safe for me to say that the Committee, as a whole, thought that the Agency should be commended for undertaking this draft risk assessment because it need to be done. It not only helped to identify areas that we have enough data to make

evaluations, but also help to identify areas. There are a lot of weaknesses and we need a lot more data to do a more in-depth and valid risk assessment.

The Committee commends the draft authors on the magnitude of their effort and the principle behind it and then many criticisms were offered, that you're going to see here shortly, that probably could be applied to just all of risk assessments. At least, my -- risk assessments because this is a field that is still evolving. It's not as mature as chemical risk assessments, so there is a lot of learning. We're still on a learning curve in this arena.

So, let's get into the guts of the review. First of all, we addressed the production module. And this particular module models 0157 in cows, bulls, steers, and heifers from the farm all the way through transit to the slaughter plant. There were two primary issues that were of concern and one was the use of fecal prevalence as the sole measure of output for the production module. And, second, the use of prevalence estimates in cows, which are called breeding cattle in the draft risk assessment in feed line animals. And we'll talk about these in more detail.

First of all, the issues regarding the fecal prevalence as the sole measure of output, there is a

paucity of data on anything other than fecal prevalence. And, so, that's why fecal prevalence was chosen as the indicator. Secondly, the animal shedding a wide range of concentrations of 0157 in feces are treated as contributing equally. And the third concern was that 0157 occurs in locations other than feces.

So, let's talk about these in a bit more detail. First of all, the use of fecal prevalence -- knowledge that fecal prevalence was being used as a proxy variable and that some carcass contamination is derived from the hide. Secondly, it needs to provide that there is an impact assessment of animals shedding 0157 at both high and low levels. The point there being that a high shedding animal is probably a greater public health significance than a cow that's only shedding a few 0157 through -- feces.

Issues regarding herd prevalent estimates include the data may have been inappropriately included, excluded or used; secondly, that some assumptions used to generate variables are open to question; and, thirdly, seasonal and temporal variations in the data need to be better accounted for or explained.

So, here are recommendations relative to the within-herd prevalence data. First of all, don't use

data on young animals to estimate within-herd prevalence for the adult animals because the adult animals are largely the ones who go to slaughter and we do know, in past studies, that juvenile animals tend to have higher incidents of 0157. So, we should be using the animals that are most commonly used in slaughter and data from those animals.

Secondly, we should decide whether the distribution of within-herd prevalence by herd -- or by herd was more appropriate through the model and use only studies relevant to this chosen method. Thirdly, we either compute within-herd prevalence estimates as a total positive divided by the -- sample or use a denominator based on the estimated herd prevalence. Fourthly, adjust the estimate for prevalence in food line animals to that expected for free-slaughter animals and, then finally, note as possible weaknesses that prevalence estimates in cull cattle might be higher than those in normal, healthy, adult cattle.

Also, use only data from independent feed lots to estimate herd prevalence. Use appropriate means of adjustment for herd sensitivity that incorporates the effects of temporal clustering or breeding herds or base the estimate for prevalence only on studies in which breeding herds were sampled many

times. And, then finally, for feed lots, you should use one hundred percent herd prevalence.

Then we have the issue of estimation of seasonal effects on prevalence and recommendations we had there was to use more detailed, seasonal data that came from Dale Hancock, instead of a companion paper that came from his colleague Besser. Secondly, adjust all monthly prevalence estimates for inappropriate test sensitivity and, finally, if you're handling the data for multiple -- cases, random surveys of the cattle population, thus, using data on all cattle samples for each month or use only data from one of the two studies that estimate the seasonal adjustment factor.

So, that pretty much handles the production module. Now, we're going to move into the next part of the system and that is the slaughter module, which estimates the prevalence of 0157 at each step in the slaughter plant process, starting with the live animal as it enters the plant and ending with the packaged meat product that is ready for shipment.

And there are three primary issues associated with the slaughter module. The first being a lack of publicly, available data regarding crucial steps in the slaughter process. And there probably is data out there, but the FSIS does not necessarily have access to

that data. And, so, companies and others who have that sort of information, whether it be academics or companies, this information should be provided to the Agency.

Secondly, it is the ability of the operations that are modeled in the module and there is a problem here because there's a great deal of variability in slaughter operations. Major operations may do things differently than smaller operations. And somehow the list has to be addressed in the model. We just can't necessarily say one shoe fits all.

Thirdly, there's a potential unpredictability of the effects of some activities of contamination during slaughtering carcass fabrication.

So, let's talk about these in a little bit more detail. First of all, issues regarding a lack of publicly available data. First of all, the risk assessment largely relies on the results of one study in this area and that was a study done by Eldred All USDA ARS Place Center. It was a very, very well done study, but it's only one study and those of you in science know we need to reproduce things and others have to do it as well to confirm. And, so, we need results of more studies in that regard.

Secondly, hide contamination and cross-

contamination during slaughter procedures are not factored in and there are reports to suggest that hide contamination is an important concern relative to 0157 contamination of meat and this thought of cross-contamination is also believed to be an important factor. And then, thirdly, the levels of contamination and surface areas contaminated are based on a small number of observations and, in some cases, are in support of assumptions.

So, the recommendations include data efficiencies and deficiencies and difficulties associated with data collection, which have been recognized in various parts of the draft, should be more strongly emphasized in discussions of the outcome circulated by the model.

And, secondly, the identified deficiencies should serve as the foundation or the delineation of research priorities to be promoted and pursued so that the model can be improved in the future. And that's what I alluded to earlier in my opening comments is that there are a lot of data gaps and here's an example of where we need to go.

Also, consideration should be given to using available data on other pathogenic and indicator organisms to estimate proportional transfer

contamination. This is the cross-contamination effect I was talking about and there are difficulties in -- studies on 0157 in real life now because it's considered an adulterant and, so, we can go and look at other pathogens or something like salmonella or , generic , that might be useful as an indicator to show the transfer of these organisms in cross-contamination that occurs in various plant processes, such as dehiding and other steps in the process of slaughter.

Another recommendation is that a discussion should be added regarding the appropriate and inappropriate applications of the slaughter module in its present state of development. Specifically, what we mean here is whether the module is ready to be used to -- about the fact that's most important influencing your -- and extent of 0157 contamination -- and possible impacts and interventions. Probably not enough data to draw strong conclusions to enable one to make good policy decisions at this point.

Preparation module. This particular module estimated the incidents and scope of 0157 contamination in serving cooked, ground beef on modeling conditions under which it is cooked, transported, stored, handled -- I'm sorry, browned -- and, ultimately, cooked.

Primary issues. First of all, there was a lack of factory of the contributing influence of cross-contamination on human illness. We really had a lot of debate about that and felt very strongly that this could be a very important factor in terms of public health. That is, the cross-contamination, contaminated 0157 ground beef in the home. It's not just a matter of cooking out the 0157 from the hamburger, but there could be cross-contamination that occurs from just handling the ground beef and that was factored in.

Lack of differentiation between the home, fast-food restaurants and other hotel restaurants and institutional environments, although practices for storage, handling and cooking of ground beef vary considerably among these. And, thirdly, there was a weakness in the data that was selected for use and the means used to analyze.

Finally, the draft clearly notes that -- relative to the cross-contamination area. The draft clearly notes that exposures from cross-contaminations are outside the scope of this assessment. They didn't want this to be included in the assessment, initially, because it was a very focused assessment. And that is, looking at 0157 in the ground beef, but not considering other extenuating circumstances, such as

cross-contamination.

The Committee does understand and respected the decision of the modelers to establish reasonable -- in order to do this particular assessment. However, cross-contamination, the Committee felt, during preparation is an established and important respect and the lack of data concerning its impact is no more sever than the lack of data for some other parts of the draft model.

So, further attention to cross-contamination will help to lay the ground work for analysis and better identify the data gaps that need to be filled by future research.

Relative to a mission of consideration of the cross-contamination issue, this may foster the incorrect impression that proper cooking of ground beef will prevent all 0157 infections that are associated with ground beef. The second we put -- consideration interventions that could have been or could have a material effect on infection if the model is used to simulate the various interventions on human -- therefore, the value of the risk assessment and -- public health policies supporting regulatory interventions will be increased if it is able to factor in the effect of cross-contamination on 0157 infections

and, perhaps, address the influence of interventions.

The Committee, thus, suggests that consideration be given to factoring cross-contamination in the model. If it is not possible, it recommends that the final risk assessment more clearly highlight the role of cross-contamination of 0157 infection and emphasize the limitations in the model engendered by the decision to not factor.

All right. First, let's address differences in the preparation environment. The first issue. Unlike the home, most ground beef used in food service segment of the hotel restaurant and institutional segment, is distributed and stored frozen and cooked in a frozen state. Most ground beef is frozen and cooked in the frozen state. In the home, it may be different; it may be fresh. And that needs to be recognized in the assessment.

Practices for cooking ground beef in major fast-food restaurants are well-defined and validated to kill pathogens, whereas, those in the home, are based largely on the appearance of the food product and may result in pathogen survival.

So, our recommendations are to use more precise information regarding the percentage of ground beef that is stored and distributed frozen and cooked

in a frozen state and at least be obtained and used for determining estimates associated with frozen ground beef. Especially that that's used by fast-food restaurants where the bulk of ground beef is used.

Secondly, the recommendation is for each location, i.e., the home, fast-food restaurants and remainder of the hotel restaurants and institutional facilities, the ground is put should all be modeled separately, not as one big group.

Relative to the data and analysis issues, simple extrapolation of data from USDA surveys were estimating the annual number of raw ground beef soybeans is unsound because there is a rather small number of observation available on some of the data systems. It's not enough to draw solid conclusions.

So, the recommendations are reports should acknowledge that there is inadequate information on the consumption of raw ground beef in the United States. In this circumstance, expert judgment with appropriate accounting for uncertainty may be superior to using extinct data. FSIS should solicit such information for the short time. And then, for the longer term, better data on raw meat consumption should be gathered and plugged into risk assessment.

Another point related to data and analysis

issues is that caution should be used in employing data cited in the draft regarding the mean reduction in 0157 in grilled, ground beef patties because some of the results are counter-intuitive. And our recommendation is to have more reliable data become available about these -- values that is the inactivation role in 0157 in ground beef. It should be used to model -- what we already know about inactivation of 0157 should be used to model the effect of pretreatment storage conditions on -- inactivation.

On to the hazard characterizations section. This describes a method to estimate the number of systematic infections resulting from the consumption of cooked ground beef that's contaminated with 0157. Primary issues here are factory of the disease-burdened of non-0157, hemorrhagic . Another issue is dysentery-type one is used as the upper-bowel of the 0157, those response relationships and a group of organisms known as enteric pathogenic are used as the lower bowel as a close-response group.

Now, regarding the use of the non-0157 -- the draft indicates that because 0157 is the most important -- type in the United States, there is a paucity of epidemiological data on the non-0157 sewer types that the risk assessment is limited to only 0157. However,

there?s -- here that whatever risk to the U.S. public health, the risk assessment attributes to 0157 as the ground beef contaminant, it underestimates the overall risk of because there are other types of hemorrhagic that are not 0157 that can also cause disease and can be found in ground beef.

The decision to exclude non-0157 sera-types should be revisited and, secondly, if the final draft risk assessment is limited to 0157 that decision and its implications for the model should be explicitly discussed. Relative to using yellow dysentery type one as the upper bowel, least of all, data strongly supports the relevance of the decision to use close-response data from yellow dysentery or the upper -- of the bracket.

Secondly, the data further argues that EPEC first response function is likely to be very close to that of yellow. 0157 is very similar to yellow dysentery and close-response. And, finally, the -- of the transmission, mode of ingestion affect responses incurred.

Recommendations are: In order to strengthen the scientific foundation for the decision to use this response data for dysentery type one, to construct the upper bracket and the final risk assessment to address

how the mode of ingestion affects the suspected --. Inarguably, it may be most appropriate to use both response data from experimental challenges with -- yellow administered --. Using meat -- as more -- in the wild, real wide EPEC pathogenic only to the very young -- and when EPEC are fed to adult volunteers, you need a very large inocula and, in order to induce what?s generally a mild illness and the bacteria must be fed with a buffer in order to affect them from the gastric acid in the stomach. And so that EPEC challenge of adults is an artificial system, not usually found in nature, and so this really is not the best upper bowel to choose.

So, if you found any folks that continues to be used in the final risk assessment, consideration should be given to alternative to EPEC that might better reflect the pathogenicity of EPEC.

On to the risk characterization section. This integrates and applies the modeling work that was done in the production, slaughter and preparation modules, integrating that with the -- response assessment, presuming it has a characterization section and, ultimately, just generates analysis of the risk associated with 0157 exposure for individuals, the community, as well as the U.S. population.

Two primary issues: First of all, the definitions of some of the terms in the chapter and they?re also in the draft and, secondly, the use of a typical individual in hypothetical risk scenarios. In terms of the issue with term definitions, some of the draft report definitions are not the standard ones used in scientific literature or other quantitative risk assessments or are inconsistent with the document.

Because -- risk assessment is a relatively new field, it is desirable to promote consistency and clarity in expression. So, our recommendation is where possible, the final risk assessment should adopt the definitions that are established by one of the major organizations of already-generated glossaries and alternative expressions should be used in other circumstances.

In regard to use of the typical individuals or individual in a risk scenario, first of all, risk estimates are provided for a typical person on the basis of point estimates of the model output and -- of the close-response relationships. It is desirable to avoid all 0157 infections, but a patient needs to be centered on the more severe outbreaks of infection so that examining -- of high exposure in the general population and any exposure in the subpopulations

thought to be made vulnerable to complications, such as children and the elderly.

So, the point here is we're really, highly concerned about the subpopulations like children and the elderly, which are more susceptible to 0157 infections and so more emphasis or attention of the assessment needs to be put on the subpopulation.

So, the recommendation for this particular section would be to refocus, to concentrate on the analysis of severe illnesses associated with 0157 and the subpopulations knowing or thought to be most vulnerable to them and the interventions that might have the greatest effect on preventing these infections.

On to modeling approach and implementation chapter. The Committee?s overall review of how the draft model was constructed and implemented. The primary issues with this chapter were that the structure -- first of all, the structure of the risk model; secondly, the use of anchoring, which is the adjusting the simulation of the models to make it more compatible with the current data; and, finally, the transparency with which the draft model presented.

Regarding the structure of this model, the nominal risk equation -- what they used is something

called the embroidered approach -- and this is a departure from the standard approach, which can be justified in principle by the assertion that the primary goal of risk assessment is to better understand the mechanisms of the generation, transmission and attenuation of risk through the system. The drawbacks of this embroidered approach.

First of all, the loss of the face value validation of the output in comparison with independent epidemiological data; secondly, any change in parameters of exposure assessment or an assumption leading to the baseline population health risk estimate changes the basis of the close-response relationship; and, thirdly, communication could result in -- a miscommunication -- could result in readers -- the model to be appropriate on the basis of the quality of the match to what our thoughts would be to independent epidemiological data, which, in fact, are not independent epidemiological data.

So, the recommendations of the committee are first of all, the reports should communicate more clearly the nature of and the rationale for the impact of the departure from the standard risk assessment of -- - and should consider relating any product as a systems risk model to more define that the model generates an

estimate or risk independent of that derived in epidemiological data.

Secondly, the office should reconsider the approach taken to refer to those response relationships in light of the -- or model output validation, a desire to improve -- and concerns regarding whether the uncertainty is actual greatest in close-response characterization.

Another issue was the use of anchoring and by sensoring some simulation outcomes valuable information on low probability, adverse events may be lost; secondly, the rationale underlying the choice of management of sensor values is not well articulated; and thirdly, the ability to validate the model through comparison with observed events or the output of other 0157 risk assessments will suffer compromise.

So, the recommendation is that the -- should replace the current algorithms for calculating those response parameters with model elements based on evidence that is independent of national epidemiological data. That will allow for limited validations of model estimates with the epidemiological data.

The final point is the transparency with the draft model should be, it is presented in Appendix C of

the risk assessment -- there is a partial list of the equations -- concludes that we use for a good start, however, as noted in several instances, in the review, there are still circumstances where it is difficult to discern the assumptions under which the equations, the variables, distributions and equations, that were used to calculate the risk.

So, our recommendations were: The final risk assessment should include an explicit list of all the variables and equations that constitute the model; and, secondly, the analysis environment, which is now a spreadsheet with macros and automated simulation process implemented with or without software to generate some statistical distributions needs to be documented in a fashion that allows other professionals to more easily track the -- equations --.

Other modeling approach recommendations include the authors should reconsider the evidence of in the approach for -- seasonality in on-farm prevalence, including the potential for using data from outside the United States. Secondly, the final risk assessment should address the potential for input variability -- in the model, which is based on casual - and other evidence of such relationships.

And the final report should clearly describe

the magnitude of the model and certainties related to modules in the risk assessment and include strategies for reducing the uncertainty that exist.

The authors should review the scope and allocation of effort in the risk assessment model, with respect to its ability to generate the incite into the burden -- and other severe -- in mortality and the authors should also review the scope of the model in its documentation to ensure a full public health context and, thereby, the value of the future mitigations that can be described and measured by the risk assessment.

Well, that's the overview. If you're really interested, you can go through the National Academy of Sciences website, the NAS website, and get yourself this report. It makes for good reading. It's now available. If you want the website address, it's here.

I do want reiterate the Committee felt that USDA should be commended for undertaking this evaluation. It was a tough review in the sense that we, as the Committee, we did a very thorough and in-depth analysis and it's not like an academic review, so-to-speak, where the paper was sent out just for a review and come back with some comments, but this was clearly evaluated by many experts in all these

different areas.

And, so, the USDA got a very in-depth review, but the Committee felt the Agency should be commended because first of all, it needed to be done to at least get us somewhat of a baseline, to know where the data gaps are that need to be filled, so that long-term we can have risk assessments done in this area on which good policy decisions can be made.

So, with that, Mr. Chairman, if we have time for questions, I'd be delighted to answer them.

DR. MCKEE: Any questions? Dr. Logue?

DR. LOGUE: Hi. Dr. Logue here from -- University and this question is for those -- it's really just simulation -- the Committee -- gaps in the -- and are you going to go back and start working on -- or are you going to start asking outside scientists to contribute data for you and start --

DR. ENGELJOHN: I think Dr. -- from our risk assessment --

AUDIENCE MEMBER: [inaudible]

DR. LAFONTAINE: Two quick comments or questions. You talked about high levels and low levels of the organisms possibly coming in with the live animals -- there is a deficiency from the data we have now -- not only just the prevalence, but what are the

quantitative levels, and that, of course, that's related, could be related to, the potential of contamination in a high level of feces, so, to me, that's speaking -- that's a key missing element. I guess, that's common, but I wanted to reemphasis.

The question I have, and you touched on it briefly, is how much do we know about the pathogenicity of 0157:H7 and I'm talking about not all -- I'm assuming, not all are equal -- you know, just because we identify the organism, does each incident have, or each proof of organisms, have the same pathogenicity to a common population. Is that -- the pathogenicity part -- you touched on it, but I'd like to hear a little bit more about what the study and what the review process had to say about that.

DR. DOYLE: Those are excellent points. Yeah, relative to the number issue, clearly, if there are millions of 0157 being shed by one animal, that would probably have a great impact on public health than ten being shed by many animals. But relative to the pathogenicity, you're correct in your -- when you suggest that there appears to be differences in pathogenicity or -- among different strains that 0157.

We do know that there's variation in

tolerance of these organisms to acid and the like and that's another data gap. We just don't have all the answers, but, I think, that the Committee's judgment in that regard is we have to do the best we can with the data that we have in this regard and, so, -- being the risk assessment, we should use the data that we have, but, in the future, as a point of filling these gaps, more research needs to be done to better our recent data. Mechanisms to pathogenicity and hopefully identify markers that would identify those strains that may be highly greater versus lesser than and then put that into a risk assessment. But not to be put off doing a risk assessment that may be useful for policy-making and -- those data on hand.

DR. LAFONTAINE: I had a little bit of a hidden agenda and that is: This is, when you talk about scientific studies and the need for where USDA and Health and Human Services put research monies, I would suggest that variables of the various strains or pathogenicity that appropriate monies be headed that way so we know more about what bad -- are really bad -- not to belittle the evaluation.

DR. DOYLE: Point well taken.

MR. MCKEE: Ms. Foreman.

MS. TUCKER-FOREMAN: Carol Tucker-Foreman

from Consumer Federation. Thank you very much for coming, Dr. Doyle. I think, the NAS study, a peer review, is very important and I really want to make a comment rather than ask a question. I think, all of us want policy to be based on science and science is, indeed, factual and data-driven, but what gets included in a scientific risk assessment is subjective. As policy, I -- the expert on risk assessment and this perception -- oh, risk assessment. It's subjective because it's put together -- human beings and we are subjective.

There are very important policy implications that arise from the subjectivity of what is included in the risk assessment. For example, in this one, in the initial risk assessment, each decision -- well, most of the decisions -- that were made to limit the scope of the risk assessment also have an impact of limiting what appears to be the total risk from 0157:H7. The decision, for example, to use a typical human being, instead of at-risk population, the decision to include only intestinal fecal matter, the decision -- and I will address this a little further -- to include in the preparation module, only cooking and not cross-contamination.

Now, people like me have to sit every day and

listen to people in the industry say, "All you have to do is cook it and you won't get sick." That's not true. If the raw contaminated meat touches something else, you're going to get sick. USDA includes this in their consumer education materials, but not in the risk assessment.

In a series of speeches last fall, the -- under secretary gave -- to this -- risk assessment in stating that there is an 0157:H7 in cooked, ground beef was really quite low. But a policy implication is in that. -- and the Congress less likely to want to do something about it and I just wanted to be heard that, although we all want decisions based on good science, it's a mistake to suggest that human beings don't make subjective judgments about what is scientific.

Thank you.

DR. DOYLE: Those are very good points, Ms. Foreman, and I might want add to your comment. If we really wanted to broaden this to get a better fix on where the real problems lie in human disease associated with 0157 infections, we should actually do a risk assessment broader than ground beef, because many of the studies that have recently come up with an at-risk factor associated with 0157 infections, but back at the farm and indicate that it's actually contact with

cattle and contact with cow manure and the mud and contact with animals and the farm. That may have more impact, maybe having a great influence on human infection, i.e., eating ground beef and then the cooked, ground beef.

And, so, if we really wanted to fulfill the entire equation, we should even make it a broader risk assessment than focusing on ground beef.

MS. FOREMAN: I agree with you completely. I would suggest that such a risk assessment needs not to be bound by an agency that does not have regulatory authority and ain't gonna get regulatory authority. Although that happens on the farm, but it would certainly be an appropriate thing for the Academy or for -- undertake. Thank you.

DR. MCKEE: I will take the last comment from Janelle Cross, FSIS.

MR. CROSS: Hi, this is Janelle Cross. I'm a risk analyst with the Agency. I have a question for Mike Doyle. We agree. We want to expand the scope to include cross-contamination. There's enough antidotal evidence that that's certainly is a priority. In terms of developing risk assessments, however, it's important for the people here today to understand that the scope of the risk assessment is also driven by the available

data. And, so, one of the things that we would ask is if we came across anymore information on cross-contamination, quantitative information that could be -- and to use this type -- to decision-making, but it's also important to recognize where the limits of the tool are.

DR. DOYLE: There have been studies done with other organisms besides 0157, looking at cross-contamination in the whole. These types of studies may be useful, using, let's say, a surrogate for indicator organisms to represent the types of cross-contamination that might occur with ground beef. And I'm not saying everything is out there, but, I think, as we do risk assessments, your -- better can tell where all the flaws and gaps -- so, what, I think, could be done is to use those types of data as your starting point with the understanding that you're going to have to do a better job getting more data to really hit the target and, hopefully, those types of studies can then be done through -- whatever type of mechanisms might be available.

DR. MCKEE: Thank you, Dr. Doyle. We appreciate it. We have one last agenda item and that is Public Comment and we have five individuals that have requested for public comment. We will have time

tomorrow as well, at the end of the day. What I'd like to do is limit the comments to three minutes each and, if there are additional comments, they can be submitted through a written document.

The first one on our list is Felicia Nester with GAP. I'll have Mr. Gioglio keep time.

MS. NESTER: This is Felicia Nester, Government Accountability Project and there goes five seconds. This is quite a hospitable forum. -- such a short amount of time, Dr. McKee, are you -- that the memo that was released last week -- the New York Times wrote an article on it -- was taken out of context and so -- was taken out of context, does that mean that the supervisor who issued that memo to the people in the plant took it out of context from an official FSIS documents and could you tell us what those documents were? Public Service of GAP wrote a letter to Secretary -- asking about that memo.

DR. MCKEE: The purpose of the comments for the public is to address the issues that we currently have on our agenda and that's a separate issue I'm not prepared to really discuss.

MS. NESTER: It was discussed this morning. I'm just addressing it because of that. Okay, I'll move on. I want to make a comment about the 0157:H7

notice to suppliers. There is no instruction in that for the inspector to review the HACCP plan at the supplier plant. There's an instruction to them to see if the plant filed their HACCP plan in addressing, in performing their duties, but not to review the actual plan.

The IG and the GAO Offices reviews themselves indicate that the majority of HACCP plans that are reviewed, are inadequate in a very substantial way. I would just like to say that GAP thinks it would be an extremely good idea if we're going to be -- supplier plants to review HACCP plans, that FSIS indicates that a supplier plant is a likely source of contamination, that would be a perfect opportunity to send in whatever -- review -- you do to assess the HACCP plan of that plant.

And, I guess, my final comment will be that, again, GAO, IG, our survey of inspectors, many reviews had found the same problems with HACCP, their instructions, confusion, in the field, inspectors not sure of their duties and the Agency so far has responded with IDVs, correlation reviews, HACCP next step, CSOs, in-training materials from inspectors and the retraining of supervisors. I don't know if I got them all, but that's some of them.

Dan Engeljohn says that there's going to be an assessment of the IDVs' effectiveness. How thorough have you assessed the effectiveness of these other corrective measures? I mean, this is -- number five or six and we still don't -- we just had the first and third largest recalls in the history of -- inspection.

MR. GIOGLIO: That's time.

MS. NESTER: Thank you very much. And the public, I'm sure, appreciates the generosity with your serving comments.

DR. MCKEE: Thank you, Ms. Nester. The next public comment would be from Michael Kolchek.

MR. KOLCHEK: First of all, I'd like to thank Dr. McKee and the Committee for the work they are doing and promise to do with respect to food safety and public health.

Food safety is an issue that touches all Americans and most especially our children, which is why your job here today is so extremely important. I would like to tell you about one child. My child and the impact food borne illness has had on our family and our community. On Tuesday, July 31, 2001, our two-year-old son Kevin awoke with diarrhea and a mild fever. On the evening of August 1st, we took him to the emergency room for bloody diarrhea, but were sent

home.

By the next morning, Kevin was much sicker and was hospitalized for dehydration and bloody stools. Later that afternoon, we were given the diagnosis: 0157:H7. On August 3rd, Kevin's kidneys started failing. He had developed the dreaded HUS. Late that night, he was transferred to the pediatric ICU at the University of Wiconsin's Children's Hospital. My wife Barb, and I spent the next eight days living in that hospital watching out beautiful son slip away from us.

On that first Saturday in the PICU, Kevin received his first dialysis. A three hour procedure in which he needed to keep still and I had to hold him down for that entire time. It broke my heart. On Tuesday, August 7th, Kevin was placed on a ventilator and continuous dialysis. I hopes of preventing Kevin from remembering this ordeal, doctors had sedated him.

Doctors inserted tubes to drain fluid off both his lungs. By the end of the week, he was receiving more medications than we could count to stabilize his blood pressure and heart rate. A special bed was ordered to help alleviate some of his pain, but throughout it all, the hospital staff remained optimistic. They said that this was typically the way HUS kids got through the illness. But to Kevin, all

this was not enough.

Finally, on August 11th, at 8:20 p.m., after being recessitated twice, as doctors were attempting to put him on heart-lung machine, our son Kevin, died. He was two years, eight months and one day old. The autopsy late showed that both Kevin's large and small intestines had died. The condition that is always fatal.

The week after Kevin died is mostly a blur for us, but we do remember some things. We remember telling our five-year-old daughter, Megan, that her best friend, her brother, would not be coming home with us. We will never forget the look on her face. We remember meeting with the funeral home director to pick out a casket. We remember going through Kevin's closet looking for his white ring bearer suit so we could bury him in it. We remember walking through the cemetery, looking for ways to bury our Kevin. And we remember the day we buried him.

Since Kevin's death, we have been researching food borne illnesses. What we have now has a --. We did not know that thirty-six percent of reported 1057:H7 cases occur in children under the age of ten. We did not know that it takes less than ten microbes to make you sick. We did not know that children under the

age of five are at highest risk in developing deadly HUS or 0157:H7. We did not know that, once you get HUS, the only thing doctors can do is keep your body alive while the disease -- its course. And we did not know that survivors of HUS suffer life-long medical problems. And we did not know that meat recalls are voluntary.

The meat industry and government can do more to protect us. As a business person, who has an -- economics, I would say this: What cost do you put on a life?

On May 2001, the USDA's economic research service estimated that -- salmonella, , listeria -- cost $6.9 million dollars -- productivity in premature deaths each year in the United States. This should be a high priority for us -- public health and, as a citizen and taxpayer, I hope to offer what I can for this group as a citizen to help make our food safer. I can't get my son back, but I don't want to meet another father, who went through the hell I went through.

Thank you.

DR. MCKEE: Thank you. Our next commenter is Tony Quabo.

MR. QUABO: Tony Quabo from Public Citizen. I also wanted to address the issue of the memo in

Kansas, but since you don't see the connection between that and the discussion that took place this afternoon on , I won't go on. Thank you.

DR. MCKEE: Thank you. Paul Johnson?

MR. JOHNSON: My name's Paul Johnson. I'm actually the Chairman for the --

DR. MCKEE: We can come back to you, if you'd like. Richard Riser? Any other comments? What I'd like to do is go ahead and adjourn where the Committee has a very busy schedule for this evening and I did make a comment earlier that we'd make the presentations today, but with the late hour, we'll make those first thing in the morning and is there any other -- for me to do? Okay, well I'll --

MR. GIOGLIO: Just to remind folks to check on the back page of the agenda on the rooms for the subcommittee meetings this evening. I guess, Subcommittee One is in Apollo and that's on the second floor, Subcommittee Two is in Mercury on the second floor, and Subcommittee Three is in Mars and that's on this floor, and I understand that the elevator you need to take is the one out near the lobby to get up to the rooms upstairs. Mr. Govro?

MR. GOVRO: Yes, just a question about the schedule tomorrow. It does read eight o'clock in the

morning, but, I believe, I heard Dr. McKee say we want to start about eight forty-five. Is that correct?

DR. MCKEE: I'm sorry, did I mispeak?

MR. GIOGLIO: Actually, we're scheduled to start at nine.

MR. GOVRO: Okay, I heard eight forty-five.

DR. MCKEE: Okay, I'm sorry. Okay, we're cool on that, eight o'clock? Okay, thank you. We stand adjourned.

(Whereupon, the meeting adjourned at 5:05 p.m.)