UNITED STATES
DEPARTMENT OF AGRICULTURE

In the Matter of:	)
	)
NATIONAL ADVISORY COMMITTEE ON	)
MEAT AND POULTRY INSPECTION	)
MEETING	)

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IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

NATIONAL ADVISORY COMMITTEE ON)
MEAT AND POULTRY INSPECTION)
MEETING)

Quality Hotel & Suites
Courthouse Plaza
1200 North Courthouse Road
Arlington, Virginia 22201

Wednesday,
November 3, 1999

The parties met, pursuant to notice, at 8:30 a.m.

APPEARANCES:

THOMAS J. BILLY, CHAIR
DON ANDERSON
CHERYL HALL
DONNA RICHARDSON
MICHAEL MAMMINGO
CAROLINE SMITH DeWAAL
MAGDI ABADIR
TERRI BURKHARDT
JAMES DENTON
COLLETTE SCHULTZ KASTER
CAROL TUCKER FOREMAN
LEE C. JAN
ALICE JOHNSON
DALE MORSE
ROSEMARY MUCKLOW
PAT STOPLER

DANIEL LaFONTAINE
NANCY DONLEY
KATHLEEN HONIGAN
GARY WEBER
KAREN HULEBAK
CAROL GREEN

APPEARANCES (CONTINUED):

MICHAEL MICCHELLI
CATHERINE WOTEKI
MARGARET O'K. GLAVIN
KAREN WILCOX
JOHN SURINA
CHRIS CHURCH
MICHAEL GRASSO
JANE ROTH
CHARLES EDWARDS
DAN ENGLEJOHN
PATRICIA STOLFA
JUDITH RIGGINS
ROBERT POST
NEAL YOUNG
JEANNIE SOMMERAUER
JILL HOLLINGSWORTH
KIM RICE
DENNIS SEXAS
KENNETH RERALSON
FELICIA NESTER
MARK MINA
JOHN McCUTCHEON
PHIL DERFLER
RON HICKS
MARLIN WALLER
JOHN ENGLEJOHN
DEL HENSEL
MARTY HOLMES

P R O C E E D I N G S

(8:30 a.m.)

MR. MICCHELLI: -- National Advisory Committee on Meat and Poultry Inspection Meeting. My name is Mike Micchelli. I am the coordinator for the meeting. If you have any questions or concerns or comments, please let me know, or Cheryl Green. Cheryl Green is sitting at the table there, or at the registration desk, and will be glad to accommodate you.

Before I introduce the chairperson, Mr. Billy, I would like to cover just a few administrative details that hopefully will be helpful to you. If you haven't found the restrooms, they are straight back on this floor. There are also are public phones available in that area as well. If you have driven today and you haven't registered at the registration desk your car license, please do that. The parking is free, but if you are not registered, they may tow you away. And I don't know if I can help you there or not. I'll try my best if you get towed away.

But we do have a phone that you can receive calls. We ask you not to try to make calls from the phone. But

there is a phone back there in the registration area, and we will be taking messages with a message board, so you can check that and check your messages if you are using that service. The phone number is on the message board, but I can give it to you now if you get out a pencil or whatever you need to write on. And I'll let you do that while I do this last comment.

There is a public comment period, both today and tomorrow. And we do have a -- we ask you to sign up ahead of time. You can sign up during the day. Right around after the final break is when we bring the people who have registered to the chairperson for coming up to the meeting to make public comments. So please take advantage of that if you like.

The phone number is area code 703-524-4763. I'll repeat it, 703-524-4763.

So without any further comments, I would like to introduce Mr. Thomas Billy, the Administrator of the Food Safety and Inspection Service, who is the chairperson of our committee. Thank you.

MR. BILLY: Thank you very much, Mike. It is my

pleasure to welcome the committee to this session of getting together and talking about what are very important issues in some instances and new ideas that help us carry out our responsibilities in terms of the safety of meat and poultry products. We have got a very full agenda. Many of the items are issues that the committee has been working on for some time. We had some news in terms of one of the items the committee has worked very hard on in terms of progress. You'll hear about that in a few minutes.

We also have some new issues that I think that are important for first, the committee to be aware of the issues and then to dig your heels in as you always do and provide us as an advisory committee good advice and counsel in terms of your appropriate input to the Secretary.

This is a very important part of the overall process of developing and monitoring public policy as it relates to meat and poultry inspection and safety. And this committee plays a very important role in terms of providing us advice that helps us establish or modify that policy.

I wanted to welcome a new member, in fact two new members. I'll introduce them and then provide them just a

chance to say a little bit about themselves and in a sense what they bring to the table. The first is Magdi Abadir, and he is a operator of a small plant here in the Washington, D.C. area. Magdi, would you like to say a few words?

MR. ABADIR: Thank you. Thank you for joining forces in the committee here. My name is Magdi Abadir. I manage a facility here in Alexandria, Virginia that is producing a variety of products from retail to institutional. And I have been in the food business from '85. And hopefully my input here will be of benefit to this committee. Thank you.

MR. BILLY: Thank you very much. And the second new member is Dr. Donna Richardson. She is with Howard University Cancer Center. Welcome, and if you would like, you could say a few words.

MS. RICHARDSON: Good morning. And I feel like I have come full circle. I started my regulatory career at USDA with the Farmers Home Administration. So I have come back. My background is as a regulatory attorney, and I am also a nurse. And I just recently finished an appointment

with the FDA Food Advisory Committee, so this is a nice segue.

MR. BILLY: Thank you very much. Okay. Now I plan to review the agenda in a few minutes and see if any of the committee members have ideas about additional items or issues with the particular interests of the committee. But before I do that, I wanted to provided Dr. Cathy Woteki a chance to provide you an update in terms of the President's Food Safety Council and also some of the work that is underway in the area of biosecurity. As all of you know, Dr. Woteki is the Undersecretary for Food Safety, and in that capacity plays a very important role within the administration in the broad area of food safety.

So at this time, it is my pleasure to turn it over to Cathy for her opening remarks.

DR. WOTEKI: Thank you very much, Tom. I am going to speak from up there. I am sorry for those of you who have got your seats pointed in this direction, but I have a couple of overheads. I find it easier to talk this way than seated at the table.

As Tom said, I wanted to provide to the committee

some updates, one on activities related to the President's Council on Food Safety, and secondly, another set of activities in which my office has been engaged, and also in which the Food Safety and Inspection Service has got a very important role to play. And it has to do with the security of our food supply from a national security standpoint.

But before I do that, I did want to mention that the concept that this committee has worked so hard to develop to permit interstate shipments of state-inspected meat and poultry products is coming very close to fruition. Just yesterday, the Secretary of Agriculture, Dan Glickman, transmitted the bill that is based on the concept paper that this committee advised the Food Safety and Inspection Service and the Secretary on. That bill was transmitted from the Secretary to the Vice President in his role of President of the Senate. So that -- the bill is also being transmitted at the same time to the Speaker of the House.

So I think that this is an extremely important milestone in not only the work of this committee, but also in that greater goal towards which you have provided advice, which is moving forward and creating a national, seamless

meat inspection system in which state-inspected product will be able to move an interstate shipment. So this is a very important milestone in this work. And also, I think it is very important to recognize the contributions that this committee made in development of that concept.

Later on in today's agenda, Chris Church is going to be talking in more detail about the legislative proposal. And at that point in time, I think you'll see that it clearly reflects all of the concepts that were in that original concept paper. But I just wanted to start out by saying thank you for all of the work that you have put into the development of that concept, and also to indicate that we really reached a really important point.

The last time that this committee met, I provided you with an update on the work of the President's Council on Food Safety. Just to briefly refresh your memories about that, the council was established in August of 1998, and it has two major responsibilities assigned to it by the President: to develop a comprehensive strategic plan for food safety, a national comprehensive strategic plan, and also to develop a coordinated budget for the agencies that

have responsibilities for food safety at the level.

The President also requested that the council review the report that had just recently been released, and that just a few days earlier, by the National Academy of Sciences that made recommendations about how to improve the public health and safety by better organizing the activities of the federal agencies. The report also made recommendations about the need for legislative change. And at the time that you last met, I reported to you the nature of the recommendations that you had made and the committee's -- the council's response.

That response was transmitted back to the President. And since that time, the council has established two task forces, one that is working on the comprehensive strategic plan. And that task force is chaired by Commissioner Jane Haney of the Food and Drug Administration and myself for the Department of Agriculture.

A second task force has been established that is developing the coordinated budget strategy, and that is cochaired by Deputy Undersecretary Caren Wilcox, who will be joining you this afternoon, and also by Mr. Lester Pash, who

is budget officer in the Department of Health and Human Services.

These two task forces have been working this year to fulfill their assignments. And I wanted to spend some time today talking about the strategic planning task force, what we have undertaken so far, and what our calendar is in order to complete our work and develop and deliver a strategic plan to the council and for them to forward it on to the President.

I'd just like to note, though, that the budget task force has also been working very diligently. They have completed for fiscal year 2001 a budget initiative under the President's food safety initiative that is currently under review within the Office of Management and Budget. And as you know, these budget documents aren't things that we can share until the point in time in which the President announces the budget in February of next year. But that budget request has the primary work of that budget task force so far this year.

They are now turning their attention towards questions of how do you develop a coordinated base budget

for the food safety agencies, which is naturally a very big task because different agencies in different departments have different definitions that they use in developing their budgets. So they are dealing with some fairly basic issues of how budgets are developed and how terms are defined so that for the FY2002 budget, we will have a coordinated budget for the food safety agencies.

Now, going back to the strategic planning activity, I actually looked at the strategic planning activity as having had its beginning at the point in time that we began working on our response to the NAS debits recommendations. You may recall that there were a series of four public meetings that were held throughout the fall last year in which we asked for comments on the academy's recommendations, and we also asked for comments on a strategic vision for food safety that is actually the strategic vision that we are building the strategic plan around.

So I look at those four meetings, public meetings, that were held through the fall and the work that we did in reviewing the academy report as really laying the groundwork

for the strategic planning activities. We have got a lot of really good ideas from those public meetings. And we worked through the spring then in analyzing those comments that we had received, both the written comments that had been submitted to the dockets that had been set up, as well as the transcripts of the public meeting. And we developed a framework, we could call it, for the strategic plan, a set of goals that we then brought to a public meeting that was held last summer.

The public meeting actually has had an enormous amount of impact on the task force's thinking about the strategic plan because essentially the comment that was coming -- the nature of the comments summarized very briefly about the original framework were while it is very academic, it kind of reflects what is going on right now, but it doesn't speak to us. It doesn't really tell us the broad directions that you envision taking in order to achieve the strategic vision.

There was essentially agreement on the strategic vision. People liked that, but didn't see that the overall framework that we were proposing really helped to move us

towards that. It certainly didn't communicate, was the message that we took away from that meeting.

So we have been working since that meeting this past summer to revise the framework, the overall goals, for the strategic plan, and then to put with them a set of objectives, and then some very concrete action steps that will be undertaken in order to achieve the overall goals and objectives. And many of you who have been either participants in that public meeting or have been monitoring our progress are probably aware that we have been thinking about having another public meeting in October just this past month in order to get another round of comment on the revised framework.

Well, we tried very hard to have that revised framework ready to have essentially distributed for a public meeting in October, but we are not really there yet. It has required a lot of rethinking of our approaches. So at this point, we are planning on having a public meeting probably in mid-January at which we would have the revised goals, objectives, and concrete actions for discussion.

Now the strategic plan is due to the council in

July. So that still would offer us an opportunity to revise that plan based on the comments that we get and have a further public dialogue on that revision before we submit the final plan to the council in July.

I might also point out to you that we do have a meeting of the council that is planned to be held on November 10, so it will be a week from today, in which we are going to be essentially presenting to them the current thinking on the goals and objectives. They will be reviewing the safety action plan which has been developed related to the strategic plan, but a very specific plan that relates to safety, and also being updated on the work that is being done by the budget committee as well as by the Joint Institute for Food Safety Research.

So we are looking at this council meeting as essentially getting validation from the council that our planning activities are going in the directions that they think that we should be going, and then we'll be working to put together the next draft of the strategic plan. We will, as we did for the earlier public meetings, make that available in a Federal Register notice when we announce the

meeting. So there will be an opportunity to come and both -- if you are able to come to the meeting in person. If you are not able to come to the meeting, to comment in writing.

So I wanted, as I said, to take this opportunity to update you on that work of the President's Council.

The second point that I wanted to cover with you today is some work that has been going on within the Department of Agriculture and also broadly with the federal government on issues of national security as it relates to strengthening our ability to prevent or deter terrorist activities in the United States, and in the unfortunate situation of a terrorist actually being able to commit an act of violence in the United States, to improve our ability to manage that crisis environment, as well as the consequences of the use of what the defense community calls weapons of mass destruction, but it includes nuclear devices as well as biological and chemical devices.

Now a lot of the work that we have underway to improve our responses to foreign outbreaks of disease under these planning activities that we are doing to improve our ability to respond, we're really looking at some of these

activities that we have already put in place to deal with the natural outbreaks as being extremely vital components of our ability to manage a crisis as well as to manage the consequences of the crisis should a terrorist or an individual or an organization choose to use the food supply as the vehicle for disseminating either an infectious agent or a chemical agent.

So among the things that we have in place and have put in place just in recent years is a Foodborne Outbreak Response Coordination Board. Remember back to the original food safety initiative document that was published in 1997, we had pledged in that document to develop this foodborne outbreak response for the nation group. It is meant to be called into place when there is a situation that crosses jurisdictional lines and involves in this case the Departments of Agriculture and Health and Human Services, EPA -- we have since added the Department of Defense -- and State -- officials.

The intent of this Foodborne Outbreak Response Coordination Group is to provide a mechanism for coordination of the responses of these various agencies and

organizations whose real focus is crisis management and the exchange of information. And having planned already to have this group in place, it can be called up very quickly.

The second assignment that is given to the Foodborne Outbreak Response Coordination Group is the development of a comprehensive and a coordinated outbreak response system. So from that perspective, the group has been working to develop some common protocols for the epidemiological investigations of outbreaks common to FDA and the Food Safety and Inspection Service, and then to be shared with all of the states so that there is a common understanding of how to go about doing these outbreak investigations.

So we have been working, as I said, to improve our capabilities for managing crises when they cross agency jurisdictions, and may involve -- our original intent here was natural occurrences of foodborne outbreaks.

The second activity that we have also had under way is the development, within the Department of Agriculture, a similar organization that helps us in coordinating our responses, and it is called the Food

Emergency Rapid Response and Evaluation Team. We call it FERRET. But there have been, in the two years that I have been in this position a number of food-related emergencies. Sometimes they have been outbreaks. Sometimes they have been the identification of a contaminant in a commodity that has been purchased by the consumer. No illnesses associated with it, but it is not something that we would want to have in any of the commodities that are going out in our various programs.

But in order to respond to these findings, they frequently require an enormous amount of either very quick communication. Sometimes it has required additional laboratory support that did not exist within the agency which has the primary responsibility for the commodity. So we saw the need in establishing --

(Interruption to proceedings)

DR. WOTEKI: Anyway, we saw the need to establish a similar infrastructure within the department that could be called together very quickly and would be at a sufficiently prime level within the department to be able to command the resources that would be needed in order to get that rapid

response, whether it is laboratory testing, or if you need assistance from the EPA laboratory to get that rapidly brought into place.

We also looked at FERRET as being the support within USDA for the Foodborne Outbreak Response Coordination Board. You need a similar infrastructure in order to support that interdepartmental structure of the Foodborne Outbreak Response Coordination Group.

So we have been working within the department. This group, FERRET, has been meeting regularly to develop plans and procedures. And it has also been called into place on several occasions to respond to problems that have been identified with specific commodities purchased for our programs.

I might just add as a footnote, because I think you are getting a little bit tired of talking about Y2K and the computer problems and are you Y2K okay -- but among the things that we have been working toward is to make sure that not only our departmental systems are Y2K okay, but also that the whole food sector, from the farm all the way through the retail level, are aware of the Y2K problem, have

done what they can to alleviate it, have contingency plans in place, and that they communicate with the public to assure people that there will be food available, and it will be safe.

So we have been working through the food supply working group, which I cochair, along with Gus Schumacher and Mike Dunn, that includes representatives from that whole food sector from farm to retail. We have also had the assignment from the Office of Management and Budget to examine a high impact area food safety inspection. And we have partnered with the Food and Drug Administration, as well as with the states that run inspection programs to also assure all of ourselves that our inspection systems are Y2K okay, and that there are contingency plans in place for any computer failures that may affect food safety inspections.

So this is another area in which we have been actively engaged over the last year plus in the case of the Food Supply Working Group, and since March with the High Impact Food Inspection System.

Lastly, I wanted to let this committee know that we are also actively engaged with the federal -- other

federal agencies who have national security concerns. The National Security Council has a set of committees that are examining our state of preparedness, our ability -- developing abilities to prevent and deter terrorist acquisition of weapons of mass destruction. Again, those are the chemical, biological, and nuclear devices. And very recently, the National Security Council has established a working group in food and agriculture. So the Department of Agriculture is now an active participant with the National Security Council.

Now at first blush, it may seem kind of puzzling. Why are we engaged in this issue, and why should I even raise this to this committee? I think there are a couple of reasons why I think it is important and why I have taken this opportunity to at least brief you on these activities. One is that there is a threat, and it is a real threat. The intelligence agencies are very concerned about the vulnerability of American agriculture and our food supply as a potential vehicle in which either an individual or a group of people who want to either for economic gain cause problems in the United States, or because they want food

causing illness and death to make a statement.

And again, the food supply is a reasonable vehicle if you wanted to disseminate, particularly a biological or chemical agent. So it is very important that the Department of Agriculture be involved in these discussions. So we are -- as I said, we do have a separate working group in which there are multiple departments represented that are looking at our infrastructure in agriculture within an agriculture working group.

We are also active participants in some of the other National Security Council working groups, and I have listed a couple of examples here, one of them focusing on R&D issues, the development, for example, of new technologies that would permit the very rapid identification of pathogens or chemicals in food substances. These have been developed by the Department of Defense for other types of applications. That technology can be transferred into food systems. And it also offers the promise in collaborating in the development, the research and development, of these new detectors. It offers the ability perhaps to eventually have some type that will be very cost-

effective that can be employed routinely to detect the naturally assigned organisms that we are concerned about.

We are also participants in a budget working group that is examining across the federal agencies the amount of funding that is going into these types of activities, again to prevent and deter terrorist activities first and foremost, and then also to play for managing a crisis and to plan for the consequences, how you clean up, how do you deal with this one of these situations once it occurs. And within the department, we have also recently established a new council on counterterrorism that deputy secretary Rich Rominger shares and for which I am vice chair, which is coordinating our departmental policy, the development of that policy, the development of the various budgets that will support these activities.

So that council was established also this summer. It has met once and established three working groups, one of them dealing with the biosecurity issues, a second dealing with the cyberterrorism issues, which has also been a major concern of the administration, and a third working group that is examining our continuity of operations plans.

That is another activity that we have had ongoing this year to plan for how we would continue to deliver our programs if we were unable to have access to our buildings in the Washington, D.C. area.

This continuity of operations planning, we have finished that this year for the Washington metropolitan area, and we'll be planning over the next year to broaden that out for other facilities across the country.

So as you can see, there has been quite an enormous amount of activity that has been ongoing within the administration in this whole area of counterterrorism in which the Department of Agriculture is an active participant. I think I'd like to leave you, though, with the thought, at least from my perspective -- and it is a point that I make over and over again in these meetings. From our public health perspective, we need to have a very strong infrastructure every day that deals with the naturally occurring organisms and the accidental kinds of contamination that occur.

It is the kind of situation that the food industry deals with all of the time. It is the kind of response to

crisis management situation that the regulatory agencies at the state level as well as at the federal level respond to all the time. It is part of our job. This added concern about what specific individuals or groups might choose to do -- our response, I think, to that has to be the strengthening of the existing infrastructure. That infrastructure is going to be what first attacks a problem, whether it is intentional or not, or whether it is naturally caused. And that infrastructure has to be as sound as possible.

So for that reason, I thought it was important as well to bring to your attention that the department is actively engaged with the national security infrastructure within the country in planning, in building our infrastructure, and also in exercises participating in exercises, some at the state level, some at the regional level, some at the national level, in testing that preparedness.

So we will continue to do so at FSIS to play an active role in these activities. But anyway, welcome to this meeting. And I look forward to the discussions today,

as well as all day tomorrow. Unfortunately, I am only going to be able to be here through the morning today. I will miss this afternoon's meetings because we have a weekly meeting on the strategic plan for the President's nutrition council, and I have to be there to chair that meeting. So I do want you to know that I will be with you all day tomorrow. And I hope that you understand that my not being able to be with you this afternoon is a reflection of the importance that I place on the strategic planning activity in keeping with this group.

I'd be happy to answer any questions you might have. And if you don't have questions, then we'll move on to the rest of the agenda.

MR. BILLY: Are there questions from the committee? On any aspect?

MR. LaFONTAINE: Just a quick comment. Your very last comments about the infrastructure being prepared -- you have the infrastructure, whether it be the FDA, USDA, states. Is there any efforts or thoughts being given to what I'll call special training for the line people because they will be the first -- probably the first to detect this.

But it may be something unusual that they don't normally see. So that was my question, is what is the outreach plan.

DR. WOTEKI: Yeah. Well, we are very much engaged in at this point development of budget requests to do that kind of training that you have talked about. We do recognize how important it is. And we all recognize exactly the point that you made. The initial identification most likely is going to be at a local or a state level. It is going to be an astute veterinarian. It is going to be an astute physician making diagnoses and putting things together.

So, yes, we are developing a training plan that will also reflect the fact that at the federal level as well as at the state level, this engages the health authorities as well as the agricultural authorities. So we are trying to do this jointly as a package.

MR. BILLY: I can add a little bit more to that. On Monday, I attended a meeting of another of the groups at the National Security Council level which I am a member of which deals with coordination and training of the federal, state, and local levels. And that is a very active part of

the goals and objectives that have been set up. And they have talked about establishing training centers around the country that would reach all the way down to the policy and firemen level in terms of responding to various kinds of situations.

So it includes the food area, and then our people throughout the country. But it goes beyond the how to coordinate, establish lines of communication, and better define goals. So there is a lot going on at that level. It does include training.

MS. MUCKLOW: Dr. Woteki, do you have some plans at some point to engage in discussions with industry leadership on this?

DR. WOTEKI: Most definitely, Rosemary. And in fact, one of the things that I am considering doing is convening a meeting of the trade associations in the fairly near future to talk about the presidential decision directives that essentially set out the different ways for dealing with a crisis when there is a -- when it is ascribed to terrorism. One of the things that I didn't mention in my comments is the fact that if an issue in our case of food

contamination -- a situation is attributed to a terrorist, then the Federal Bureau of Investigation becomes the lead agency for the investigation.

That has a lot of implications for the way that food safety and inspection, if it involved a meat product, how FSIS is involved in the investigation. So there are changes that this series of presidential decision directives imply for the way that a crisis is handled.

MS. MUCKLOW: Is that presidential decision directive available at this point, or is it a classified document?

DR. WOTEKI: There are unclassified versions of these presidential decision directives that you can get right off the White House Web page. PDD-39 and PDD-62 are the ones that are most relevant. PDD-63 deals with -- largely with the cyberterrorism issues. But 39 and 62 would be the ones with the greatest use.

MS. MUCKLOW: Could we ask that your office maybe disseminate that information to the various --

DR. WOTEKI: Sure.

MS. MUCKLOW: -- industry organizations that are

representing firms in the food industry that were under your jurisdiction so that at least they could catch up with the unclassified information in case they are not in this room today?

DR. WOTEKI: Yeah, most certainly. And I would be happy to bring copies of the unclassified fact sheets to our meeting tomorrow for the committee's use.

MS. MUCKLOW: Thank you.

MR. BILLY: Caroline, and then Dale.

MS. SMITH-DeWAAL: Can you speak -- good morning. Caroline Smith DeWaal with CSPA. Can you speak on the issue of the joint budget that is being produced by the President's Council for Food Safety and whether that effort will assist in driving towards more rational regulation of food products across the board? In other words, right now we devote about three-quarters of the total food safety money over at FSIS at the inspection program we have that this committee monitors. But I'm wondering if the budget process will actually drive better inspection also over at FDA.

DR. WOTEKI: Well, I think, Caroline, if -- at

least the way we are conceiving it, the strategic plan should be driving the budget. So, you know, I am looking to the articulation within the strategic plan of the overall goals and objectives that will then drive the budget process, as opposed to the other way around.

MS. SMITH-DeWAAL: But do you see an outcome being -- whether it is the strategic plan driving the budget or vice versa, we have an historical setup where one segment of the food supply is very heavily regulated, and the other parts of the food supply are barely regulated at all. And I am wondering whether one of the outcomes we can expect is a more uniform regulatory system across the agencies.

DR. WOTEKI: I think, Caroline, that the issue is not the budget and it is not the strategic plan. The issue is a risk-based allocation of resources. I am looking to the strategic plan to provide that vision of a risk-based allocation of resources and the budgeting activities then to follow along behind it. The issue, though, is where are the risks, and is the current budget allocation appropriate to those risks. And that is what we are hoping to get out of this process.

MS. SMITH-DeWAAL: But some of the data we have developed at CSPA has shown that we have significant risk in the area of eggs, shell eggs, in the area of fruits and vegetables and seafood products, all of which are regulated by FDA. So I mean, we have looked -- we like that approach, a risk-based approach. But it certainly suggests that we need more comprehensive regulation in the areas of the food supply which aren't currently getting it.

DR. WOTEKI: Yeah. I understand the point that you are making, and I think that concentrating on the risk-based approach, laying the groundwork -- some of the studies you have done are very helpful in that regard. But in addition to that the risk assessment that can be applied is the basis then for moving forward on reforms is going to be extremely important. Those concepts will be incorporated -- they have been so far -- into the overall strategic plan.

Yeah. Oh, and Tom is reminding me -- and it came in a little bit late. I did mention the egg safety plan. And there is a separate plan that really focuses on Salmonella enteritidis in eggs that is going through a final clearance -- it will be presented to the council at its

meeting on the tenth -- that specifically addresses that subset of the food supply and does take a risk-based approach, examines allocation of current resources, and makes recommendations to the council about how to improve that allocation of resources.

So from that perspective, that plan, I think, does respond to your initial question about budget allocation, budget allocation as a representation of resources going towards a problem, and how that should be changed.

MS. SMITH-DeWAAL: If I could just add to that. There is some effort on the Hill to better utilize the inspective force at FSIS that is looking at eggs by giving them greater authority over shell egg products. Is that consistent with the concepts of better resource allocation that might come in out of the strategic plan? Or is the strategic plan going to keep those 125 inspectors that look at pasteurized egg products just on that lower risk product and leave shell eggs essentially unregulated, as they are today?

DR. WOTEKI: Well, not to go too far out beyond what the council decision is going to be next week, let's

say it is not inconsistent.

MR. BILLY: Dale.

MR. MORSE: Just a quick comment on the food security. I'm glad to see that there is some discussion and emphasis sort of preparedness in that area and also in building on the infrastructure and links to other agencies. In New York, we have had several recent episodes which have forced us to think differently, ranging from anthrax hoaxes to an E. coli waterborne outbreak with over 1,000 people ill, 65 hospitalized, 12 HUS, and two deaths, which was water borne, but -- and also West Nile virus in New York City, with over 60 cases and seven deaths, which have sort of forced us to think about the need to collaborate with other agencies. We may not -- the health department, Agriculture, law enforcement.

So in an outbreak setting, it is difficult to establish all those relationships, so that advance planning is helpful. Hopefully, it will never occur. But the infrastructure, I think, is important to emphasize, as you suggested, because, unfortunately, with the outbreaks -- or fortunately, having to respond to those on a national basis,

there have been several sort of trial runs, whether it is the listeria with 100 cases, 20 some states, or the Salmonella agona with another 20 states, or the E. coli outbreaks that is helping prepare the infrastructure setting.

I encourage to continue in that area and also build on the relationships that USDA has with other parts of the health department, FOODNET, the PULSENET, electronic reporting. The need to move toward electronic reporting of outbreaks and sharing of information is an area that needs to be addressed as well.

So I'm glad to see the emphasis. Hopefully, it won't occur. But the infrastructure, by improving that, it will be used for other situations.

MR. BILLY: Any other comments or questions? Okay. Thank you very much. Next, we would like to ask John Surina, who is with the USDA ethics office, to provide some input to the committee on area of the rules that apply in terms of the advisory committee. Some of the members of the committee raised a series of questions at the last meeting regarding the roles and the responsibilities of individual

committee members as they participate in this kind of a government advisory committee. So we thought it would do well to have an expert come share the sort of the general ground rules and then be available to answer any questions that committee members may have.

So it is my pleasure to call on John Surina to provide insight in this issue.

MR. SURINA: Thank you, Tom. It is interesting that a whole scheme by which the Ethics in Government Act tries to protect governmental ethics in program administration is somewhat based on means of keeping the decision-makers insulated from conflicting interest. There is a criminal statute, and there is an executive, branch-wide, regulatory regime that reinforces this. And the primary focus is looking at financial interests. And the way it works is that political appointees and senior career managers are obliged to disclose in a public financial disclosure report all of their financial interests. And we have staff that peruse these in detail to make sure that there is no conflicting interest.

And the law is very specific, the criminal code.

It speaks to the fact that if a senior government employee has an interest in a business that they can have a direct and predictable impact on in performing their duties, you have a criminal conflict of interest. Employees below that level, below the senior level, the career employees who may have decision-making roles but not quite at the same level, are obliged to file a confidential disclosure report. It is not available to the public, but it is given the same scrutiny. And any potential conflict is resolved there also.

Interestingly enough, within FSIS, there is a global requirement of employees of all levels to file a certification of no conflicting interest. And this applies down to the lowest level. And this is something, quite frankly, that the U.S. Office of Government Ethics that has oversight over all of departments took a little bit of exception to in a recent audit, and we are now reinforcing that requirement in promulgating what they call supplemental ethics regs that are supplemental to the governmentwide standards.

So what is the purpose of all of this, and how

does that fit with an advisory committee? The purpose of these disclosure requirements, the purpose of a criminal code, requires one, one's spouse, or one's dependent child from having a conflicting interest, is to insulate public policymakers from financial interests that they may themselves hold. It basically is a bar against self-dealing.

It goes further when it comes to the regulatory scheme because, while the criminal code speaks to one's holding or a spouse's holding or a dependent child, if there is an appearance problem that goes beyond that, even though it is not a criminal violation, it violates the government regulations. For example, if one were engaged to somebody, and that person had that conflicting interest, or you had an adult child, that would impair the impartiality, and it could cost a person a job if they went ahead and continued to work in an area that would benefit that person's financial interest, or to the detriment of a financial interest that is a competitor to that interest.

So you have got this whole scheme set up that basically removes federal employees, federal decision-

makers, from the financial interests of the industry they regulate, in this case. So the advisory panel system -- and it exists not just here, but throughout government -- is an interestingly carefully crafted counterweight to that insularity.

The whole system of governmental ethics is to keep the federal employees aloof from those interests. And the advisory panel is a way of bringing those interests in in a carefully structured fashion so that federal employees are not -- while their actions may be impartial, they are not detached from the industry sector that they have responsibility for. And I can give some other examples of this.

As I mentioned, full-time federal employees that are in a decision-making role have to disclose their financial interest. At the Food Inspection Service, all employees have to certify that they have no financial conflict. For example, you don't want the lowest level meat inspector having an interest in Oscar Mayer, for example. It's not just grade level determined within FSIS. Special government employees, people who work on an intermittent or

part-time basis, expert consultants that we may hire, also have this requirement because they are in a position to make specific recommendations or make decisions that affect public policy.

Advisory panels, on the other hand, are brought together in a very conscious and specific effort to bring with them their individual partialities, if you will, or their own particular interest. But they do so in a very public fashion. This is not penetrating an organization. This is a very public meeting where we want a broad spectrum of views, and those views are assumed to be narrow interests of that section.

This doesn't mean, necessarily, that the people that have these narrow interests are not public-spirited themselves. But we go beyond the assumption of somehow the person is totally detached. We want them attached to their point of view. But to make this work, an advisory panel has to be representative of all the varying, competing interests within a given topic. And it appears to me that this panel has that broad spectrum.

Secondly, the advisory panel can only meet in

public, and that is by law, and that is why we have a court reporter here, so you don't find any dealmaking being made in private.

And finally -- and this is the miraculous way in which advisory committees seem to work -- they tend to come together in a civil setting moderated by the government agency that is getting input from the advisory committee. It is amazing how often constructive, collaborative efforts can come out of that, where all interests feel reasonably sure that their particular narrow interest is adequately covered.

I can speak to this from experience. I used to work at the Federal Election Commission, which has sort of a quixotic mission, if you will, of trying to keep special interest money out of politics. But we also had a rather minor role in the administration of elections. And we had an advisory committee made up of interested parties in how elections are administered. And it was a rather dry topic most of the time. But in 1993, a bill called the Motor Voter Act passed, which made it almost a semiautomatic process whereby voters would be registered. And it was an

extremely contentious bill. It took many efforts to get out of Congress.

And at the advisory committee level, we had Republican Party members there, we had Democratic Party members, we had some public interest groups trying to broaden their franchise, we had law enforcement types concerned about voter fraud. And honest to God, we thought we would never achieve a reconciliation of these competing interests. But somehow, over the course of a year and four meetings, we came up with a model plan for state governments to implement this unfunded mandate, and it worked like a charm.

We ended up with many millions more people registered to vote without apparent partisan bias and without any evidence of voter fraud. And if anybody had told me that this committee would come together on an agreed plan to implement that model motor voter law, I would have bet dollars to donuts they would not have.

So that is the basic structure. Just by way of recap, the public employees have an obligation to not have any interest that conflict with their official duties. And

there is a reporting scheme whereby they have to demonstrate that to the various departmental ethics offices. The advisory panel is a very carefully structured counterbalance to that to make sure that we're not so insulated that we are detached from the business of what we are doing. And the advisory panel is set up in a broad spectrum of interests in a public environment. And my experience in 30 years of federal service is that it works amazingly well.

I'd be happy to answer any questions on that.

MR. BILLY: Okay. Are there questions?

MR. WEBER: I have one. What is, from your perspective, your involvement in reviewing the potential involvement of a federal official or employee with an NGO that may have an interest in a certain side of the issue?

MR. SURINA: Well, it is interesting. The NGOs themselves --

MR. BILLY: Does everybody know what an NGO is?

MR. SURINA: I'm sorry. Nongovernmental organization. And oftentimes in this setting we are talking about nonprofit, sometimes charitable, educational, and

sometimes membership organizations. But they are nongovernmental. And public employees, like any other citizen, can be a member of a nonprofit organization. Oftentimes, it has an ideological rather than a financial interest, or it has its own view of how public service should be.

If the federal employee is an officer of such an organization, they are obliged to report that, whether they are paid or unpaid, and their financial disclosure report. If they are there in their personal capacity, that is permissible. If they are there in an official capacity, we have a conflict situation because you have fiduciary responsibilities both to the organization and to the government, and those conflicts are very difficult to resolve.

So what we are looking for there also is full disclosure. But when one is a member of such an organization, they can only be there as an individual citizen, not as a representative of the government. Does that respond to your question?

MR. WEBER: Yes, thank you.

MR. BILLY: Any questions? Rosemary?

MS. MUCKLOW: In today's terrible complex world of multinationals, we all know that a public official cannot have stock in Oscar Mayer. But it gets lost as being part of a very large company called Philip Morris. And the trail becomes very convoluted, particularly as firms acquire other firms. So I ask that you speak to that issue.

MR. SURINA: Certainly.

MS. MUCKLOW: The other question that I have is related to the same public official relationship. And again, it can become a very convoluted one because of the large expansive of companies. And for instance, we're looking at new kinds of technology all of the time, applied technology to improve inspection systems. And those technologies come through a very interesting array of companies, whether it is radiation or microbiological detection, and so on. And the kinds of people that would reach senior positions that would be concerned about on that are also the kinds of people who are very inventive people in bringing those technologies.

Speak a little bit about those conflicts, because

they are not the regulated industry. They don't own a piece of a company that is under the regulation. They may be bringing in the kinds of technology and be a revolving door there. So I would be interested in your comments on that issue.

MR. SURINA: Well, I think both of those questions are very good. And at the same time, I think at the conclusion of that, I can talk how we remedy an apparent conflict.

First of all, your point is very well taken on the growing globalization and merger mania that is going on and trying to figure out where the interests are. And technology ends up helping my office identify that. The Internet itself and the online financial services are our vehicle by which to find these topics.

When I came to the department about a year ago, the first time we came across this, we had a scientist in the Agricultural Research Service who was evaluating pesticides. And the person had interests in an oil company. And on its face, you wouldn't think there was a conflict, and he didn't. But it happened to be Chevron. Chevron

happens to own Ortho, okay? So there was an inherent conflict that on the face of the financial disclosure report wasn't there.

As I can assure you, every public filer at the Department of Agriculture knows excruciatingly how closely my office reviews those reports because they have to be -- we have to do an initial review within 60 days of receipt. Then there has to be a certification where we put our signature down that there is no unresolved conflict. And with as many people today as are in various mutual funds, et cetera, everybody basically -- over 50 percent of the public now is engaged in the stock market. And even a mutual fund by itself is not sufficiently broadly diversified to meet our standard. If someone is in a sector mutual fund, it presents a problem.

Let's deal with your second point, speaking about the technology. We would view, let's say, stock ownership in a national laboratory type of environment, or laboratory testing equipment environment, as a potential conflict within the Food Inspection Service. And we would have to address that specifically to see if in fact the products and

the services by that type of a company are used in -- for food inspection purposes and food safety purposes. And if they were that sort of a connection, we would have to find a fix.

So let me speak to the types of fixes that we can come up with. In some cases, the individual employee's personal responsibilities do not necessarily address that financial holding as a matter of routine. And in that case, we can have the individual recuse themselves or self-disqualify, that any time that particular company or that corporation's matters would come to their office, it would be known to their superiors and their coworkers that they are disqualified from addressing that matter. That is a rather straightforward and easy fix.

If one has an outside -- if one is a board member of a special interest group with a rather narrow view on the matter, and even though it is a nonprofit organization and it is uncompensated, we would require through the vetting process if they are a presidential appointee or through an administrative process if they are not, that that person resign that job. It is a free country. We can't force them

to resign. But they may have to pick between a job at the Department of Agriculture and that job. But that choice is then presented to them.

And finally, the third remedy that we do employ is that one divest themselves of the conflicting interest. And oftentimes that divestiture can be not without some financial pain if you happen to be tied to a stock which is sailing over the marketplace. But if that is the only remedy that is possible, we can order a divestiture as a condition of employment.

Did that hit both of the points you raised?

MS. MUCKLOW: Yes.

MR. SURINA: Thank you.

MR. BILLY: Carol?

MS. TUCKER-FOREMAN: I just want to tell you how adroit they are at making accommodations. When I was at the Department of Agriculture, my husband, who was a salaried employee of a nongovernmental organization, acquired as part of that organization some employees who worked in the meat industry. And I didn't want to divest him.

(Laughter)

MS. TUCKER-FOREMAN: So we have a 23-page opinion from the Justice Department that says I can share his bed, but we shouldn't speak to each other.

(Laughter)

MS. TUCKER-FOREMAN: And we have been married for 35 years, I think in part because of that.

(Laughter)

MR. SURINA: These are important issues. But believe me, the Office of Ethics in this type of an operation is not one of the most loved elements of any federal agency, not because our employees are not straight shooters and very conscientious, but the very nature of this law is a little bit of an insult, and it is a bit intrusive, that we can delve into employee's financial holdings. And I am extremely pleased with the responsiveness that I have found in my short tenure at the department. My office alone collects about 650 public financial reports from appointed officials and senior executives throughout this huge department. And it is amazing how forthcoming people can be, and how much personal financial sacrifice some people have made to hold onto their federal job, because they are

interested in public service. Nan.

MS. DONLEY: Now does your office just examine individuals, just look at individuals? Or does it also look at activities within departments or agencies themselves?

MR. SURINA: The Ethics in Government Act speaks to employee ethics, and there are the executivewide -- executive branchwide standards of conduct. The department itself, through our general counsel's office, is concerned about agency gift acceptance, if you will, and collaborations that can go on between the agency and other people. We work jointly with our general counsel's office to make sure that those sort of arrangements do not compromise agency programs or compromise agency employees. And many of these collaborative efforts can be in almost everybody's mind a benefit, public benefit.

We have organizations, for example, that want to help the Forest Service. We have an organization -- we have a National Arboretum dealing with ornamental agriculture, and there is a Friends of the National Arboretum, there is a very nice Friends of the National Zoo. And it is hard to conceive of this being somehow a public evil, but we still

must intervene and say that there is a prohibited source because they have an interest in what the Arboretum does. And their benefit that they confer on the Arboretum shouldn't be in any way in a position to say I think you need to focus more on roses and less on azaleas.

Those are public decisions that have to be made, and we have to make sure that our employees are not, if you will, biased in their delivery by the interaction with such outside groups, if that is what you are speaking to.

MS. DONLEY: Right. And also, just that the responsibilities, let's say, within agencies can be conflicting in nature themselves, meaning -- and I know how the Department of Agriculture has tried to separate the regulatory versus the marketing responsibilities, that type of -- does your office take a look at those types of situations?

MR. SURINA: My office does not. Those are programmatic decisions, and that is why we have a secretary and a subcabinet. We have, for example, though -- we have an Agricultural Research Service looking at a lot of biotech. We have a marketing regulatory program that is

looking at organic foods, okay? Those are two programs that have a certain tension, okay? There is the department's structure to reconcile, if you will, different points of view on the agricultural industry within the department.

DR. WOTEKI: Nancy, the issue of -- from a public policy standpoint, the organizational structure of the department, its roles and responsibilities, whether a reorganization is going to be responsive to public concerns about potential conflicts of interests such as you outlined, and then frequently concerns about the regulatory programs within the Department of Agriculture -- issues like that would be ones that the secretary's office, my office would be concerned about. And we seek opinion from the office of the general counsel in helping to decide whether indeed there is a conflict of interest and then how to deal with it.

So John's office, as he said, is really focused on the individual aspects under the laws that govern the executive branch and questions of ethics in conflict of interest. But we would really look to the general counsel's office to provide us with advice about how to proceed. And

we frequently do on those kinds of issues.

John, I might ask a question. I take from your comments that an advisory committee like this, you expect the members -- we expect the members to be biased. We wouldn't have asked you to become members of the committee if you did not have a base of experience and be representative of a point of view. And your office doesn't necessarily get involved in review of what are individual members' financial disclosures because they are not considered to be special governmental employees.

MR. SURINA: That's right. They are not SGEs, as the acronym we all -- have everybody's acronyms. No. The narrow interest of the members here, quite frankly, is presumed. And that's a benefit, so long as it is representative and across the board, and so long as the deliberations are in public. I think advisory committees throughout government are built on that structure, so that we can get some unfiltered input from your various points of view.

MS. HANIGAN: Katie Hanigan, with Farmland. As a committee member, if we are approached and asked to speak at

a public forum on behalf of this committee, how is that to be handled?

MR. SURINA: I think careful disclosure is appropriate also. I think you probably should say that you are on this committee. But you should say who you are representing on this committee, that representing the committee generally, I think, is the obligation of Dr. Woteki and Tom Billy.

But I think most of our audiences are pretty savvy. If they know who you are with and what committee you are on, they can make that very small leap to say what angle you might be presenting on the committee, which is not to say there is anything wrong with that. It is just a matter of full disclosure.

MR. BILLY: Any other questions? Thank you very much. I appreciated that. Okay. We're heading towards our first break. But before we do, I want to work through the agenda, make a few comments about the agenda, and then ask the committee members if there are other items or issues that they would like to raise. We can talk about that and see how we might fit those in.

If you'll turn to the agenda, you'll see that as we have done in the last several meetings, we are going to get a briefing on the National Advisory Committee's recent meeting -- that's the National Advisory Committee on Microbiological Criteria for Foods. Then we are going to shift to some of issue updates. And these are particular issues that the committee has expressed an interest in. And we want to bring you up to date in terms of new developments.

If you look at tab 4 in your notebook, you'll find that we have listed here all of the recommendations that the committee has made recently and identified the actions taken, the state of followup on those recommendations, and also identified a contact person. And we continually update this, so I wanted to call your attention to the variety of things that the committee has recommended in the past and where it stands.

So we're focusing in particular on several items that the committee has indicated they would like to address more specifically.

Then we are going to shift into a series of issues

that the agency has identified. These are areas where the agency has views or ideas about how it can do a better job or solve a problem that has been identified and wishes to get advice and counsel from this committee. And we'll cover those agency issues then through the afternoon.

Then tonight, we have the subcommittee meetings. In this instance, I wanted to cal your attention to tab 3. And you'll see on tab 3 the membership of the three committees, the three subcommittees, the subcommittee on inspection methods chaired by Katie Hanigan, the subcommittee on intergovernmental roles and coordination chaired by Dan LaFontaine, and then the subcommittee on resource allocation chaired by Carol Tucker Foreman. Lee Jan is going to chair the committee on Carol's behalf tonight because of a conflict.

So those are the makeup of the committees. We have two new members. And we tentatively put you into one of the subcommittees. But we sort of have a rule that committee members can choose which of the subcommittees they would like to participate in. But at the same time, we try to keep an appropriate balance of membership in the

committees.

So if any of the committee members have a desire to change their subcommittee, they should let me or Mike know, and we'll try to accommodate your interest. But we think that this provides a good distribution of the membership of the full committee in doing the specific work at the subcommittee level.

We should also be aware, particularly for the new members, that even if you -- since the meetings occur simultaneously, nothing is lost because the product of the discussion results of the subcommittee are then presented the next morning, tomorrow morning, to the full committee. So you have an opportunity to hear what was discussed and to provide input at that time as appropriate.

The Thursday -- oh, then at the end of this afternoon, we have a period for public comment. We encourage members of the public to provide input and comment. We welcome that. You need to notify the secretary to the committee of your interest, and then we will schedule those that wish to speak during that time.

On Thursday, we will hear the reports of the

subcommittees during the morning. And then in the afternoon, we have a series of agency briefings that again are in one sense kind of new developments or new items that we want to bring to the committee's attention and provide you information that could eventually turn into a matter that the committee would deal with in some depth over the next several meetings.

And then we'll talk about remaining issues, and get a sense from the committee members of what you'd like to see on the next agenda, and then a public comment period and wrapup of this meeting.

So that's the general plan for the agenda, and I'd like to open it up for any comments from the committee members. Carol?

MS. TUCKER-FOREMAN: Yea, Carol Tucker Foreman with Consumer Federation of America. Nancy and Caroline and I would like to request that we put on the agenda, either today or tomorrow morning preferably, a discussion of noncompliance reports. GAP has collected and evaluated data on the first three quarters of 1998 in ours, and there is really very distressing information there -- 1,752 NRs at

Lundy Packing in Clinton, North Carolina, 224 of those HAACP violations, 545 sanitation; 1,419 NRs at Tysons in Dardanell, Arkansas, 574 sanitation, 198 HAACP; and just to let you know that even the higher authority doesn't help here, 234 at the Empire Kosher Poultry in Middletown, Pennsylvania.

In many of these cases, no enforcement action has been taken. So it was my understanding that the HAACP system was established so that companies would take actions to prevent a situation in which NRs would be filed. Are NRs appropriate for this kind of system? How can you have these companies operating without any enforcement action when they have that many NRs on file against them? It really undermines our assurance that this system will work the way that we all want it to.

So we would like to request that we have some time and that it be done in such a way that we not end up with people having to squeeze out the door to go chase airplanes before we have the discussion.

MR. BILLY: I think it would be appropriate and important that we have the right people here to talk about

NRs and how they are dealt with. And we currently have both Mark Mina and John McCutcheon scheduled to be here tomorrow afternoon during the 1:00 to 4:00 period. Perhaps -- you said preferably the morning, but we could put it as the first item in that afternoon session.

MS. TUCKER-FOREMAN: Okay. That's fine. I just don't want to be in a situation where people, if they have to leave early, miss it. So if we could do that, I would appreciate it.

MR. BILLY: Okay. Katie?

MS. HANIGAN: I will be leaving tomorrow because of a conflict at home after the first break, and would like to hear the NR discussion. I'm sorry to do that to the committee, but something did come up at home.

MR. BILLY: At the first break in the afternoon?

MS. HANIGAN: No, morning break.

MR. BILLY: Okay. Maybe we could do it first thing in the morning then?

MS. TUCKER-FOREMAN: Is it possible that we can start prior to 8:30 in the morning and put it on 8:00 in the morning? Is that a problem?

MS. SMITH-DeWAAL: I can't be here at 8:00. I just -- I can't, sorry.

MS. TUCKER-FOREMAN: Well, if it has to be in the afternoon, it does.

MR. BILLY: Other ideas from the committee? Rosemary?

MS. MUCKLOW: Tom, I would -- I'm not at all familiar with that problem. I would just ask could you also provide us the records on how many of those NRs are under appeal, or how many were appealed? My experience -- did you have that, Carol?

MS. TUCKER-FOREMAN: No, I don't, but I'd sure like to know it.

MS. MUCKLOW: Yeah. My experience has been, or my staff's experience is that quite often there will be repetitive NRs, the same thing over and over again that really should never have been raised in the first instance. And so those numbers are very frightening, and we need to be concerned about it. And Carol is right to raise it. But I think we need to get some sense of proportion because sometimes you'll get a repetitive NR that didn't have merit

the first time. And if you have it repeated many, many times, it distorts the picture.

So I think it would be very helpful to know the data. And I don't know, if Carol doesn't have it, we may have to go to your records just to correct that problem.

MR. BILLY: I'm not sure what is possible by tomorrow. But the later we do it tomorrow, the better chance we having more information. So it is a tradeoff, in other words. I don't -- I just flat don't know whether we would have that kind of additional information.

MS. MUCKLOW: I understand. I just wanted to put the thing in perspective.

MR. BILLY: Other comments? Yeah, Caroline.

MS. SMITH-DeWAAL: Just to further put it in perspective -- and I don't think what I am going to be asking for will be that hard to get since we can get it off the Internet fairly easily. I think it would be helpful to see also recall actions that were linked to plants that are on -- that we have NR information on for last year. And particularly, I am concerned about the Belmar (phonetic) situation, where there were numerous inspector reports about

condensation leaking onto the product line. There were sanitation problems documented in the plant. And yet contaminated food product managed to get out of that plant.

So I think the recall information from 1998, where we have the NR information, would also be helpful because it would document where in fact contaminated food was leaving a plant following inspector evaluations of that product and certification of the product.

MR. BILLY: Any other suggestions?

MS. MUCKLOW: One other suggestion or request I would like to make, one of the documents that I have come to love over the years is the annual report of the secretary to the Congress on the program. And that has not been filed for the last couple of years, and I wonder if you could give us an update and tell us when that might be expected because it would be -- it provides very useful data and information. I can't imagine why the Congress hasn't been screaming for it, but I'm -- it's now several years in arrears, and I'd just like to know when we are going to see the last two versions.

MS. TUCKER-FOREMAN: Is that one of those that OMB

cut out because -- to reduce the paperwork?

MR. BILLY: No.

MS. MUCKLOW: I don't think so.

(Laughter)

MR. BILLY: Chris Church will be speaking later in his class. He can shed some light on where we stand on that. Getting back to the NRs then, given what has been said, my judgment would be to put it into the afternoon session as the first order of business, tomorrow afternoon. And we'll try to have the additional information of what is possible by that time.

MS. TUCKER-FOREMAN: Thank you.

MR. BILLY: Dan?

MR. LaFONTAINE: One additional topic. When the final rule was published in 1996, there were performance standards for various commodities, carcasses or raw ground products. At that time, it did not contain a performance standard for pork sausage. Subsequently, approximately a year or two later, there was some type of a notice or interim -- some type of a notice for a performance standard. Subsequently, it was withdrawn for some technical or legal

reasons.

My question -- or my suggestion is if we could get a five minute status report of where that is, because that is a major raw ground product that is out there in limbo. I feel eventually that we are going to see it, but we all need to know where it is at and when we can expect it.

MR. BILLY: Okay. I'll fit that in some time. I'll see if a particular person will give an update on that. Lee?

MR. JAN: One thing, too, that I would -- that same person, if we could give them another two to three minutes to tell us about the performance standard for generic E. coli testing that plants are required to do but that have no standard. And I have heard from some of the FSIS people that give us information that they don't see that that -- that there is a standard, a very liberal standard. We have been promising them for several years, so it is hard to see is that going to happen. And if there is not going to be a performance standard, maybe we ought to go without it.

MR. BILLY: In this instance, you're talking about

for animals?

MR. JAN: Livestock.

MR. BILLY: Livestock, where there currently isn't established numbers.

MS. JONES: Sponge-testing for carcasses.

MR. BILLY: Okay. Same thing, we'll add it in and include that as well. Other -- Rosemary?

MS. MUCKLOW: Tom, I hate to wear the microphone out. But over on the recommendations, there is the provision that FSIS should assess the health risk exemptions and seek legal authority for performance standards and site inspection resources. A paper is to be prepared. I hesitate because it may be tucked in this document somewhere. Is it, or is that something we're looking at in the future? A task force paper. When in the future will it come to us?

MR. BILLY: Okay. Phil will be here tomorrow afternoon when he talks about he E. coli white paper and plan. And I'll have him address that as well.

MS. GREEN: Tom? I think that is one of the agenda items.

MR. BILLY: Is it? Okay.

MS. GREEN: Rosemary, you are asking about the resource functions? Am I right?

MS. MUCKLOW: Yeah, the one under tab 4 on the second page, the last one on the second page. It talks about future R&D.

MS. GREEN: Right. Tab No. 7 on page --

MS. MUCKLOW: It had a different set of descriptions.

MS. GREEN: Yeah.

MS. MUCKLOW: That's the response? Okay.

MR. BILLY: That will be talked about first thing this afternoon. Any other suggestions? Okay. Let's adopt that in the agenda with those modifications. And let's take -- we are going to take about a 30-minute break. But we have a couple of announcements.

MR. MICCHELLI: What I would like to do is invite the two new members to have their picture taken with Dr. Woteki if Dr. Woteki has a few moments at break. That would be swell. Thank you. And anyone else that missed getting their picture taken, we do have a certificate that

it is anonymous that you can fold and get your picture taken. If you missed your chance at the last meeting, then you are more than welcome to join us at break. Thank you.

MR. BILLY: Let's be back at quarter to 11:00.

(Recess)

MR. BILLY: There has been a request made by several members of the committee of Carol Foreman. When she raised the issue of the NRs, she cited some numbers and read from a report or something. And so they have requested that information that she was using be made available to the committee before the discussion tomorrow afternoon. I have spoken to Carol, and she has agreed to do that, and will be making the information available to us shortly, and then we'll make it -- we'll copy it and provide it to all of the committee members.

Also relevant to that is our quarterly enforcement report. And we have copies of that that we will also make available because it addresses the issue of where we have taken action against plants and which plants. And I would suggest that committee members may want to look at that as well. And that would be made available to you shortly as

well.

And then, Collette, I understand you wanted to raise a point related to this?

MS. SCHULTZ-KASTER: Thank you. Just one more thing on the GAP report, if possible, relative to the HAACP and the sanitation NRs. We would like to know the trend indicators associated with those NRs and also specifically the time frame of those NRs. I think Carol mentioned the first three quarters of '98. Did you mean '98 or '99?

MS. TUCKER-FOREMAN: '98.

MS. SCHULTZ-KASTER: Of '98, okay. So the time frame in those three quarters in which those were received by the plants.

MS. MUCKLOW: Tom, while we're getting paper from the South Building, is there any potential that we could get the month's -- the more recent report on salmonella? The one that we have all seen several times over now is through July. We are all pretty interested in August and September at least, if not October, since October was just last week. But August and September would be very useful.

MR. BILLY: Yeah. I'll check. I am pretty

confident that it wouldn't be available that quickly. The time lag from getting the data through the lab system and doing the analysis on it is about a two-month time lag. I'll check and see what might be --

MS. MUCKLOW: Yeah. August and September are months we are very really interested in. Plus some of us have called a request in for the basic raw data, but we haven't seen that yet either.

MR. BILLY: Okay. One other announcement is that the hotel has informed us that they are going to be testing the fire alarm system over the course of the day. And they have informed us that we do not have to leave, although we may be a little annoyed. And if there is a real fire, someone will come and tell us that it is actually real.

(Laughter)

MS. MUCKLOW: Is that before the flames engulf us?

MR. BILLY: All I can say is use your best judgment when you hear the alarm. I think I am going to stay.

The next item is the update on the recent meeting of the National Advisory Committee on Microbiological

Criteria for Foods. This report is going to be given to you by Dr. Karen Hulebak. And Karen is relatively new to the agency. She has been with us a little over six months. She is our chief scientist. And I have asked her at the outset to say a little bit about herself because this is the first time she has presented information to the committee.

Karen?

DR. HULEBAK: Thanks, Tom. Good morning to all of you. Pleased to meet you. I am sorry I missed your last meeting. I was called away for a family emergency. I'm happy to be here today.

A little bit about myself. I think I was -- one of the reasons I was brought in by FSIS from FDA was to bring diversity into the staff. My Ph.D. is in toxicology from The Johns Hopkins University. I'm quickly learning microbiology. Prior to coming to FSIS, I was at the Food and Drug Administration in the commissioner's office, where I had the food safety desk, focusing more on the contamination issues rather than labeling and nutrition, as Caroline well knows.

I have also worked in the private sector in

consulting at a company called Environ Corporation. And I was for slightly over six years the deputy director of the Board on Environmental Studies and Toxicology at the National Research Council, the operating arm of the National Academy of Sciences.

As Tom said, I came to FSIS about six -- a little over six months ago. And one of the first requests that was made of my time was that I take over as executive secretary of the micro committee. That has been a real pleasure. The micro committee, as I'm sure you all know, is a really committed and hardworking group of people, and they have demonstrated that abundantly in the two meetings I have spent with them.

I'd like to tell you about what happened at our last meeting, the micro committee's last meeting, which was just this last September, the 21st through the 24th. The major focus at that meeting was (1) barehand contact with ready-to-eat foods, and (2) updates on the status of two risk assessments, on Listeria monocytogenes and Vibrio parahaemolyticus.

The barehand contact issue was brought to the

micro committee by FDA after last year's conference on food protection, which considered the food code provisions on barehand contact and essentially concluded that those provisions in Section 2-201 were too restrictive. FDA asked the committee to defer a final decision on that question and said that it would bring the matter to the micro committee to consider unresolved scientific issues regarding barehand contact with our ready-to-eat foods.

So in September, the committee reviewed the data that document the various ways that we can interdict the transmission of person to food, fecal to oral transmission with ready-to-eat foods. These include handwashing, air-drying of hands versus towel-drying, the effect of gloves worn by food workers, cross-contamination issues, and consideration of the effect of prohibiting or excluding ill or infected workers from food preparation, especially contact with ready-to-eat foods.

And the committee concluded and recommended that the primary prevention strategy in this area ought to be the exclusion of ill or infected workers from ready-to-eat food contact, also, number two, that proper handwashing by food

workers is essential because clearly even asymptomatic workers can transmit, can be shedding infective agents and transmit to food or food contact surfaces, and that, third, we should strive to minimize barehand contact with ready-to-eat foods, in combination with the above -- with the first two recommendations that I mentioned.

But, the committee concluded, the available scientific evidence is insufficient in itself to support a blanket prohibition of barehand contact with ready-to-eat foods.

Now I'll next describe to you the status presentation that the committee heard from the risk assessment teams that are preparing risk assessments for Listeria monocytogenes and for Vibrio parahaemolyticus. For the listeria risk assessment, the primary focus of discussion at this meeting was on the exposure assessment section of the risk assessment model and on the hazard assessment section. The exposure assessment section is really focused on grappling with the issue of listeria present in foods, consumption patterns of various foods, and how those consumption patterns can be modeled. Again, the

primary focus here is on ready-to-eat foods.

The committee's concerns, reviewing what the team had presented, was -- and they suggested that the team consider how to improve the way they deal with these issues. Number one was a concern about the use by the team of prevalence data that are more than five years old. And the sense -- the reason for that is that the committee had a general sense that sanitation in the food industry has improved more recently and that to use data that are from ten years ago may not accurately enough reflect the current day situation.

They also suggested that some of the food categories that the risk assessment team is using need to be split. For example, they need to split home- and restaurant-cooked ground meats data from those instead of lumping them, that they need to separate as much as possible long versus short shelf life deli meats, and they need to treat undercooked chicken as a separate category from all chicken.

Finally, they suggested that the team think long and hard about using generic listeria to represent Listeria

monocytogenes in the model. Again, the team is grappling with a paucity of data and risk assessment, just like in any such exercise. Sometimes extrapolations have to be made. But that was one that the committee expressed concern about.

Now regarding the hazard assessment, the main challenge for the team has been a lack of outbreak investigation on dose and attack rate. An additional limitation has been that the experimental data most typically available used nonoral dosing regimes, in other words, interperitoneal injection oftentimes. And they acknowledged this can present some significant problems when you try to extrapolate to human disease.

The team acknowledged the limitations in the present risk assessment. And they did say that this current undertaking is probably the first in what is going to be a series of risk assessments on various aspects of listeriosis. The team proposes to present -- plans to present the final iteration of this risk assessment to FDA management by the end of this year.

Now the vibrio risk assessment was also presented. And, of course, this risk assessment focuses not on a meat

product, but on oysters. The risk assessment, as constructed by the team, has three segments which they call harvest, postharvest, and the so-called public health segment, which by standard terminology is really the dose response part of the risk assessment. I'll just recall for you the classical common risk assessment terminology is, of the four stages of risk assessment, hazard identification, exposure assessment, dose response, and risk characterization.

In food pathogen risk assessment, sometimes other terms are used. In particular, I hear this term, public health segment. It often seems to refer to the dose response investigation and modeling.

In the vibrio risk assessment, the harvest segment is attempting to develop models for each region/season combination because there are differences in climatic and harvest practices in various regions. And they want to try to make the models reflect those differences as much as they can. The goal overall of the segment is to identify parameters that contribute to the likelihood that shellfish in a particular region, a growing area, are going to contain

virulent strains of Vibrio parahaemolyticus.

In the postharvest segment, they describe their attempts to simulate effects of typical industry practices in transportation, in handling and processing, in distribution, in storage, and in retail, and how those will affect vibrio populations in oysters, again in various regions and seasons.

In the so-called public health segment, the focus is on modeling or developing models to reflect the relationship between consumed dose of vibrio and disease response in the consumer, in other words, the number of pathogens at the time of consumption and the probability of illness occurrence, and also illness types and severity of illness at different doses.

The final two items that I would like to discuss with you that were considered by the committee -- these three items I have just discussed took up probably 80 percent of the committee's time at the last meeting. But there are two others that I would like to mention, and one is to give you an update on where the micro committee and the agency overall is on the hazard guide for very small

plants.

Now the micro committee worked long and hard for several years to produce a guide that would be actually useful to small plant operators. And it appears that they have been successful. At this last meeting, the committee accepted the guide that the committee -- the committee as a whole accepted the hazard guide that the subcommittee had produced and acknowledged that it will remain in draft as a sort of living document. If significant changes are suggested for the document and thought to be a good idea, and a change is made to the draft, a judgment will be made about whether that change is sufficient to bring it back to the full committee. But the committee acknowledged that the guide needs to remain a living document.

The agency has accepted the guide as its own -- as its own, and will be and is distributing it to small plants now, acknowledging the help that the agency has received from the micro committee. I have heard also that at least in some early reviews, small plant operators are actually finding it useful, which is very nice to hear.

A final note I wanted to mention, where the

committee stands with campylobacter performance standards. At your last meeting, I believe it was, you recommended that the micro committee consider options for campylobacter performance standard or other alternative approaches that would achieve the same public health goal.

In the committee's, the micro committee's, May meeting, they considered the available data long and hard and came to the conclusion that there were not sufficient data at that time to render a judgment about the appropriateness of developing performance standards or developing alternative approaches to achieve the same goal. They encouraged the agency to continue gathering data through the two mechanisms that are in place, the chicken monitoring program for campylobacter that was begun in October '98, and the nationwide young chicken campylobacter baseline data collection that began in January of this year. And the committee said we will revisit this issue in about a year. So they intend to have a look at the data on campylobacter during this coming summer.

I should also note to you that the agency has established a docket committee to begin consideration of

what options might be for development of performance standards or for development of alternatives to achieve the same public health goal. I note that in your tab two, you have a copy of an update memo that went to the micro committee to bring them up to date on the data collection for campylobacter as of September.

I have some other news from the micro committee of a more general nature, and one is that Maury Potter, formerly of CDC, most recently of the director of FDA's Food Safety Initiative Program, and vice chair of the micro committee for one glorious meeting, has had to step down. He has left FDA to go to ILSI, International Life Sciences Institute, which is a big blow for the micro committee, and I'm sure is a big blow for FDA, too. FDA has not yet decided upon who will be his replacement.

Janice Oliver will serve as vice chair of the micro committee at our upcoming meeting in December. There is a possibility that the person who has been brought in to replace Maury, Dr. Susan Alpert, an M.D., Ph.D. pediatrician with a background in infectious disease and I think an undergraduate degree in microbiology, could maybe

do that job. But she is really -- she has been at FDA for one day -- as of -- or two days as of today. So I think the decision hasn't been made yet whether she will actually fill that role.

The December meeting then is going to be December 8, 9, and 10. The major topics at that meeting are going to be (1) a request by FDA of the micro committee to consider the unresolved scientific issues that are challenging the agency as it attempts to implement HAACP for fresh juices. The micro committee will also hear a comprehensive briefing and be given an opportunity to critique FSIS' ongoing risk assessment for E. coli 015687.

Now as a final note, I serve on a search committee, on the search committee for the executive director of the new presidentially created Joint Institute for Food Safety Research. I think in your tab 2, you also have a copy of a position announcement and description of what this position entails. I can tell you that the food safety agencies and departments with responsibility for food safety, who are engaged in search for this executive director, are seeking a topnotch scientist, someone who is

visionary, someone who has strong demonstrated leadership strengths, because you can imagine herding -- it is like herding cats to get agencies together to agree on budget priorities, especially for research.

So leadership skill is certainly the major characteristic. Clearly also national scientific visibility will be important, knowledge of food safety science and research would clearly be a desirable feature. This executive director would have the opportunity to shape food safety research budgets in the next two years, and even shape the direction of food safety research. It is a two-year appointment, by the way. And we are seeking to fill it as early in 2000 as possible.

So please consider the information in your book. If there is any other question that you have, please call me. I'll be happy to talk to you and give you -- I actually have, or will have shortly, an updated formal position announcement. Talk to your colleagues, think about folks who might be qualified, who might be interested.

That sums up what I had to talk to you about, and I'll be happy to answer any questions.

MR. BILLY: Okay. Questions? Katie.

MS. HANIGAN: Location of the December meeting, please.

DR. HULEBAK: It is going to be in Washington. And I can't recall the hotel right at the moment, but I can get that for you easily.

MS. HANIGAN: Thank you.

MR. BILLY: Caroline?

DR. HULEBAK: Caroline.

MS. SMITH-DeWAAL: I was hoping Katie would ask this question. I have two questions. One is that it is my recollection that we asked them to talk about options, not to necessarily come up with a performance standard.

DR. HULEBAK: Correct.

MS. SMITH-DeWAAL: But to talk about options. And I guess I am disappointed that the committee didn't come back with more options. I mean, we all know we need more data. That is -- it doesn't take a room full of food safety scientists to tell us that. But I thought we asked for things that they could have given us more of an analysis. And I guess I am disappointed that they didn't take that

request more seriously.

DR. HULEBAK: Well, I think they did take it seriously, and they did struggle with not only just the idea of performance standards, but they did spend some time talking about what options might be. Now it is true they didn't settle on a set of what options might be. But they did give it hard conversation and hard discussion and debate. And I will carry your sense back to them.

MS. SMITH-DeWAAL: Okay. I mean, my understanding from people in the room is that they got off on a big policy discussion and weren't -- I mean, you know, you can -- options is not like a hard and fast thing. They could throw back some options, and we could respond to them. I don't know if anyone else wants to weigh in. I have something else.

MS. HANIGAN: Can I just comment on that? Caroline, I don't disagree with your position on that. And I had placed a call to Mike in September, basically asking what happened at the micro committee meeting. I think it was when I received my first packet of information for this meeting and saw that there was basically no update from that

committee back to our committee. So I was concerned as well because at one time we talked about having a conference call between the last meeting and this meeting just to address -- so I was concerned that when I received my first packet of information, there was no correspondence on it at all.

MR. BILLY: Nancy.

MS. DONLEY: I was in Chicago. That particular meeting was held in Chicago, and I did attend that particular session of the micro committee meetings. And what Karen says is just true. They did discuss at points some options, but I came away from the meeting that that was kind of more or less as an okay, and very little amount of time was spent on that. And frankly, it had really gotten into a policy discussion meeting.

That was the first time I had attended a micro committee meeting just as a part of the public audience. And it really made me stop and think of what -- of maybe we need to assess what we send out to other committees as far as asking them for input, or maybe we have to be very, very, very specific what it is we want to get back from them because it really did develop into a policy meeting. And

frankly, it was should we have performance standards for campylobacter. But the whole discussion generated around should there be any performance standards at all. And if so, we don't -- and that particular committee came away saying we don't want -- if we set it for campylobacter, the next thing is going to be for listeria, and then on and on and on and on.

So I do think that we have to be careful this committee of what it is we send other committees and be very specific about what we want back.

MR. BILLY: Caroline.

MS. SMITH-DeWAAL: And then just to follow up, and then I'll move on to my other question. I'm just troubled that -- I mean, we are supposed to be the policy committee. And I always -- I guess Rosemary brainwashed me to think of them as the scientists and the scientific committee. You once referred to them as the secretary's scientists, and I think I objected. But, you know, I am disappointed. Options is, you know -- you don't need -- we didn't ask for a standard. We didn't ask for something where there had to be complete consensus necessarily.

We wanted a list of options. And I'm just very disappointed. And I think Nancy is right, that we need to be much more cautious about taking issues and trying to send them off to the scientists because they'll just digress, apparently.

My other question goes more to -- and maybe Tom could help out in responding to this as well. I don't -- you know, maybe -- I have done a lot of work in risk assessments, and I know what the theory is, and I know how they have developed in terms of chemical risk assessments versus micro risk assessments. I guess I am really troubled when we have an issue like Listeria monocytogenes, when we have 21 people dead, 100 illnesses from a single food source. What do we need to assess with a deadly pathogen in the food supply?

The risk assessment was done, in my mind. Why do we need to spend a huge amount of time going over what we already know, that a pathogen in a product, even it is intended to be cooked, like hotdogs, can kill people. And so what are we waiting for for the department to take more stringent action, even a proposed regulation perhaps, to

deal with Listeria monocytogenes?

We sat through the meeting on the listeria risk assessment. And the questions are very large, and the holes are very big. And I'm not confident that they are going to come out with anything that is going to be terribly to the department in moving forward, and where we all know we need to go with Listeria monocytogenes in terms of a system to enforce what we already have, which is a zero tolerance performance standard.

So I'm wondering what we're expecting to get out of this risk assessment. And is there a way to get what we need rather than waiting for them to -- what sounds like to take years to fill in all of the data gaps. The public can't wait. And as we sit here -- you know, Carol has been quoted and, you know, Nancy and I, I know, are very concerned that we could have another outbreak tomorrow. And I don't want to sit around and wait. I'd like to see the department take -- and I understand the steps you have already taken, and we're glad you took them, and rulemaking does take a long time. But we would like to see a proposed rule coming out of the department soon to address Listeria

monocytogenes.

MR. BILLY: Let me say something in terms of the role that risk assessments play. And I think we have mentioned this before. The USDA Reorganization Act of 1994, among other things, requires us by law to conduct a risk assessment and provide that risk assessment as part of proposing rulemaking. And so one of the steps we have to take to establish a performance standard, or whatever, is to have a risk assessment that identifies clearly the risk, it quantifies the risk, and allows us to look at alternative options for mitigating the risk.

And so given that requirement now, there is a staff in the secretary's office that reviews risk assessments to ensure they meet the requirements of the law as part of forwarding rulemaking proposals through the department, to OMB, and then to publish.

So there is also a requirement, a formal requirement, both by law and by executive order, that we do a cost-benefit analysis. And the cost-benefit analysis has to be tied to the risk assessment and the options that it presents. So that is now a formal part of the rulemaking

process. It is important for that reason that we move forward and complete these efforts as quickly as we can.

We share your concern that we take appropriate action to deal with pathogens like listeria or campylobacter. And so that should be clear by the priorities we have set in terms of the work that is underway. But it is in that context that we are using the micro committee to look at, as an example, in December, the E. coli 015787 risk assessment model for ground beef, and getting their input as well as separate peer review of that model, as part of the process to reassess our policy. And you'll hear more about that tomorrow afternoon.

But that's the context or the environment in which we are working to address these pathogens. I don't know if you wanted to add anything from the committee's point of view? Then I have a suggestion about where we go from here. Carol?

MS. TUCKER-FOREMAN: This is a case -- I'm a strong supporter of risk assessment. The CDC figures estimate of the 2,300 and I think 19 cases of listeria -- of listeriosis, that 500 people died. I think that constitutes

an emergency. When added to the fact that these diseases, these illnesses, come from products -- and I'm sorry I didn't bring my bag with me today. I went shopping at Safeway. I bought cooked ham, cooked. I do think that implies ready-to-eat. And it says "good if used by," and it had a date three weeks later or four weeks later. And then it has a seal on it that says, "Inspected and approved, United States Department of Agriculture."

And none of those things are true. That product -- they are true. But they imply that the product is safe to eat. And the product is not safe to eat if you are a pregnant woman. And frankly, brochures are not enough. I think that you have an emergency situation, and that perhaps it is time to go to the department and say we think that the emergency provisions of the law kick in with regard to these special groups, and we would like to have labeling on the package as an interim step until the risk assessment is completed, and we can find ways to diminish the problem because right now it is clear you cannot address the problem. So at least, for goodness sakes, tell people that this product, despite the fact that it says "cooked" and

"good if used by" and "inspected by," that if you are pregnant, you shouldn't eat that cooked ham until you cook it again.

And it was on turkey, sliced turkey. It was, you know, the same thing. I have got seven different packages that I carry around in my little plastic bag now. And we are misleading people. There is a precedent for this. The department did it with safe handling labels on certain raw meat and poultry products at an earlier time. And I think it is time to take this as an interim step now with so-called ready-to-eat products.

MR. BILLY: We have an item a little later in this session before lunch, hopefully, on the update on listeria. And I think what I would like to do is capture your thought and come back to it at that time. One sense I am getting from the committee -- and I'd like to suggest that perhaps we send another letter to the national micro committee that reiterates our desire to receive input from them in terms of the options that are available to deal with campylobacter in light of information that is available now, including in the options the approach of a performance standard, and express

in an appropriate way concern about, you know, more progress and advice from the committee to this point, something along that line.

MS. SMITH-DeWAAL: Perhaps they can take it up in their December meeting.

MR. BILLY: Jim and then Collette.

DR. DENTON: I had a comment about that very issue, in thinking about what Karen has told us and what Keith said. I think that if we expect something back with regard to well-reasoned and very clearly thought-through options other than the performance standards, that we probably dropped the ball here as a committee by not being able to convey that obstacle with that particular group in order to communicate that to them, because I'm not certain that they really grasped what we were talking about in outlining other options.

Now coming from the scientific community, I suspect what they were faced with is looking at trying to determine that they can establish performance standards for campylobacter and recognizing that they have a real shortfall in information to establish those correctly, that

they were, I guess, diverted from the possibility of looking at other options than the campylobacter.

They are scientists. They are driven by data and numbers. So when we start looking at other types of options, we are probably going to be in the same situation of having to have some basis in scientific information to come to a reasonable alternative option to the performance standard.

Now with regard to the issue of the listeria situation and with regard to the campylobacter situation, I kind of disagree with much of the conversation that I have heard this morning at the table. I think we are comparing apples and oranges. In one case, we are trying to establish performance standards on raw product. In another one, we are dealing very clearly with a cooked product. Those are very, very different situations that we have to contend with. I think they are appropriate to be addressing those sorts of issues. But I do think that we need to be very clear in our thinking with regard to getting into that because we are talking about two very, very different products with a raw product and precooked product.

MR. BILLY: Okay. Collette?

MS. SCHULTZ-KASTER: I that think Dr. Denton summed up most of this, but I would like some clarification, possibly from Caroline or from the group, on what options are we looking for. I understand that, you know, if there were to be a performance standard, how -- as Dr. Denton said, how the committee will approach it, because they will think of it as scientists, and they won't be prepared to set it. And if in a situation relative to a performance standard -- what other options are we looking for, things other than a performance standard? And then we need to clarify that in order to present that for them because otherwise they will come at that from a very different approach than we would.

MR. BILLY: Okay. Caroline.

MS. SMITH-DeWAAL: And I am reading right from tab 4, the very last entry, request the NACMCF to evaluate the options for defining a campylobacter performance standard, e.g., quantitative versus qualitative. So we gave them some examples -- I think we were quite specific -- and alternatives to a campylobacter performance standard. So we

were asking for both. We were asking for how would they set the standard, and also were there alternatives.

I don't know whether a letter is the right approach. And perhaps at the subcommittee meeting, we might spend five minutes on this and make a recommendation on your suggestion, because maybe we need to come back and outline our own options and give our options to the department rather than waiting for some other committee to do that. Or maybe we should wait, but we would like them to pick it up in December because we feel like they dropped the ball this time. So maybe as a subcommittee, we could spend five minutes on that at the beginning of our meeting tonight.

On the listeria risk assessment, I would just like to come back or wrap up. I'm not sure that risk assessment ever contemplated what we're dealing with with the ready-to-eat meat products and the outbreaks that we have had. I think the risk assessment -- and correct me if I'm wrong, but it may have been started in advance of that. It is dealing with a much broader group of food products, both FDA-regulated products and USDA. And it is asking questions about, well, do people get sick from frozen ice cream if it

has got listeria versus ready-to-eat meat products.

Well, we know the answer on ready-to-eat meat products. So maybe the risk assessment you need is not the one that they are conducting. And maybe you need to think about something that is more tailored to what you need to get your regulation moving.

MR. BILLY: I can add a little more information in that regard. It is in fact the case that the risk assessment model that FDA is taking the lead on, but we are a partner with them in this process, is a generic model that looks at all foods. And in developing that generic model, they are doing some very important groundwork in terms of determining how a more specific model for listeria in ready-to-eat meat and poultry products ought to be designed. And it has been our intent right along to take the work that is being done generically and then tailor it to our specific approach for meat and poultry products.

That is a plan that is in place. And as soon as we get some of these important issues and advice from the micro committee which was provided and Karen outlined, all of that helps us then move forward as an agency in terms of our

products that we will be focusing on. So that is in fact our intent, to tailor a specific risk assessment to ready-to-eat meat and poultry products.

MS. SMITH-DeWAAL: And when would we expect that to start? I am very concerned, Tom, that what we are seeing is you guys tied up in knots dealing with a very crucial public health issue. And we can't sit back. So I'm wondering when can we expect that risk assessment, when can we expect you -- we cannot wait for this committee. I sat there, and they really -- I'm not confident that what they are going to come out with is going to help you be where you need to go.

So if you could think about, maybe at your -- when we talk about listeria, think about the urgency here because I am not comfortable waiting.

MR. BILLY: Rosemary.

MS. MUCKLOW: My first knowledge of Listeria monocytogenes was the ugly cheese outbreak in Los Angeles, the soft Mexican cheese product in 1985. And my learning curve on that was that when it hits, it hits big. And that was certainly a very dramatic event and caught everybody's

attention. Unfortunately, one of the more recent outbreaks was again that it hit big. And those numbers are always very frightening to people.

I listened very carefully to Carol and her shopping experiment. I hope she has eaten the products, and that she is watching that "keep refrigerated" statement on those little packages, or that it is the packages and not the product with the packages?

MS. SMITH-DeWAAL: It grows.

MS. MUCKLOW: Mm?

MS. SMITH-DeWAAL: It doesn't matter if she refrigerated it. It grows in the refrigerator.

MS. MUCKLOW: I understand that, Caroline.

MS. SMITH-DeWAAL: She should freeze it.

MS. MUCKLOW: I hope she is not walking around with the meat in the bag, just the packages.

One of the questions that I would like to ask a little bit about on this subject is the -- as I would understand it -- and I don't have perfect knowledge on this, but I figure we have got people at this table that can enlighten us, including you, Mr. Billy, in your products

role. As I would understand it, there is an international standard that is not zero tolerance for Listeria monocytogenes, and we work on a zero tolerance basis in this country.

How do we balance that when it comes to the equivalence of imported products? Do we only take ready-to-eat products from other countries that meet our zero tolerance standard for Listeria monocytogenes in meat products? Can you give us any balance on that one?

MR. BILLY: Sure. I'm unaware of any international standards for listeria. There are national standards in various countries around the world for various types of ready-to-eat products. Some countries have zero tolerance, and others have established a tolerance that is based on classifying a category of products into minimal risk, moderate risk, and high risk, and then determining the listeria control measures that are in place to deal with preventing or minimizing the presence of the listeria in those categories or classified areas of products.

Canada is an example that has -- a country that has such a system that ranges from zero for high-risk

products to, I think, something on the order of 100 organisms per unit -- and I don't know the unit -- for more moderate-risk products. But it also is based on the practices and the control measures that they have in place. So it is not a -- there is no uniform approach. There are problems with listeria all around the world. That is increasingly recognized.

And it is for that reason that the United States has led the effort to convince the World Health Organization, one of the sponsoring organizations for the products commission, to establish a third expert panel of microbiologists and other experts that would be in a position to do international risk assessment and recommend appropriate international standards for pathogens like listeria. And that is -- that recommendation from Codex to its parent organization has recently been reinforced by a conference that was held by FAO and WHO in Australia a few weeks ago with a very strong recommendation coming out of that conference that WHO follow up on this and establish this new international expert body as soon as possible and support the work of the Codex committees that wish to move

forward to develop international standards along the lines that you have mentioned.

Mike and then Jim.

MR. MAMMINGA: Listening to this discussion, we just had our United States Animal Health Association annual meeting and our state directors meeting a few weeks ago, and at our last committee meeting, we speak an awful lot about risk assessment/risk analysis. And I got some very good lessons in that. And I think as Dr. Denton indicated a little bit ago, we have a little bit of apples and oranges here because from what I have learned about scientific risk assessment and analysis, it is a methodical discipline process that lives on data and numbers and takes time to project its findings as far as a risk analysis.

What my friends here from the consumer groups are talking about is another kind of risk analysis. It is the kind of risk analysis that says that if rocks are falling off the building, I had better get away from this building. And they are illustrating examples of numbers from CDC and other sources that say there is this many people, and there are this many people sick and dying. And they are doing a

risk analysis based on what they see and what they know to be a fact and what they are able to study.

It doesn't necessarily mean that that data will help solve or fix the problem, like you hope that a scientific risk analysis will do. But they are saying let's address a problem, and that's a little different kind of risk analysis. And in that respect, while the micro committee and other scientists may deliver us some very good answers in time, I think we ought to recognize we are doing a little different kind of risk analysis when we talk along these ways. And that might be more the kind of thing that policy people do.

And I think it is important for me to keep that -- to keep those two different concepts apart in my mind because there are just so many things that you can do scientifically in a day or two, and then there are those sorts of things that you have to discuss crossing all of your constituents, as you like to say, the industry, the consumers, the government, the academia, to come up with what the industry people I hope feel is reasonable and can be substantiated in some reasonable fashion if you don't

have the scientific data in front of you.

So in that respect, I think I'd let the micro committee work. They are the scientists, and they can do that. The policy people are going to have to put all of these thoughts together that are expressed here and determine what is reasonable on a short-term basis to address the horrors that we hope do not happen from our part in producing food. Just a thought.

MR. BILLY: Thanks, Mike. Jim.

DR. DENTON: To follow up on Caroline's comment a while ago about the major issue with Listeria monocytogenes being one that grows with refrigeration temperatures, I'm reminded of some of the philosophical discussions that we get into among scientists. Believe it or not, we can get engaged in philosophical discussions. But I believe -- and there are several people that happen to think the same way -- that Listeria monocytogenes is a problem of our own creation.

If we think back about the development of the food industry in this country and the fact that we have relied so heavily on refrigeration and cold storage to control the

earlier pathogens that were of concern, particularly the enterics, what we have done is we have established an environment throughout the marketing system that is refrigeration driven. And what we have done is we have created an environment in which a very normal soil organism, which listeria is, because it has the ability to grow at refrigeration, can permeate that system just a bit.

Now what we'll have to do is take a real hard look at how we get that particular organism back out of that system if we continue to rely on the refrigerated system in our marketing process. But I believe that refrigeration created this one.

MR. BILLY: Carol.

MS. TUCKER-FOREMAN: I know it seems we're doing the listeria update now, whether it was on the agenda or not. I appreciate all of those comments, and I -- what we want is sound science. We want to base government action on sound science. But we also -- the decision about policy issues uses science. It frequently doesn't give us all of the answers that we need. And the policy process frequently cannot -- there is never a final answer in science, right?

We try to get to the point where you can take a step based on science. But I'm not sure that it is appropriate to say to the public we can't act on this problem because the scientists, for good reasons of scientific method, can't move as fast as we want them to move.

I don't think it is acceptable to say as a policy matter we can't do anything. I think that in the case of meat and poultry products, wherein you have all of the circumstances I described before, cooked, use by, inspected by, that we have an obligation to act more quickly based on the best information that we have now. And I am probably going to propose that the committee take a position in that regard. And maybe it is time for us to say to the regulatory officials in the department this has some counterweights to your argument that we have to proceed along the lines of regulatory reform, that is, that the department is making some promises and the industry is making some promises that amount to misleading labeling.

MR. BILLY: Okay. I want to -- let me say two or three things. One is it is my sense that Katie's committee on inspection methods will look at this issue in terms of

what we ask the micro committee to do and consider either another letter to the committee or some work on the part of the subcommittee in developing some options or ideas of its own or both. And that sounds like a good way to progress to that area, particularly as it relates to listeria -- or excuse me, to campylobacter.

With regard to listeria, there is in your packet, on page 5, a sort of compilation of materials that we wanted to share with you that is a followup to the actions that the agency has taken since the large outbreak that occurred about this time a year ago. And it summarizes not only the regulatory actions that were taken, but also the consumer education information efforts and other actions as well.

In here, you'll find an action plan that lays out both the immediate or near-term actions as well as the longer term actions that we are -- we have embarked on. It is clear to us that our request to the industry to reassess their HAACP plans has been followed up on. We have done a review of that. You'll find in here in this packet the instructions, the request, the formal request that went to the industry and the audit procedures that our inspectors

followed in verifying that in fact that has been done.

Having said that, you know, we're currently involved in a recall situation that is associated with hotdogs. We have had a number of other similar recalls in the intervening months involving various kinds of ready-to-eat products that we regulated. And based on that, it is the intent of the agency to, shortly after the first of the year, to prepare a white paper and use that white paper as the basis for a public meeting that we will hold to review the situation, learn from our experiences over the last year, and to lay out some options in terms of further actions that the agency should consider, and get wide public input into that process.

It will include consideration of emergency actions as well as more formal actions, as we just discussed here a few minutes ago. So we -- that is our intent. And I think that the committee should take that into account in the context of the work that you are planning to do this evening and perhaps at future meetings as well. I'm not going to go through all of this material. I urge you to look through it, particularly those of you on the subcommittee, and

factor it into your discussion.

Are there --

MS. MUCKLOW: Tom?

MR. BILLY: Yes, Rosemary?

MS. MUCKLOW: I don't want to belabor this subject a lot longer. But I would just like to reassure all of the people around this table that the industry has not slept through the listeria crisis this year. And in fact, there are organizations sitting here in the audience today, along with others represented here at the table, who have responded to this concern because we like to sell meat products over and over. And when people have a bad eating experience, they don't come back to that product.

We developed and, as you know, submitted to you and have made available for free some guidelines to help people help the industry in the smaller firms and any firm address this issue, and hopefully work towards a very powerful reduction of this ugly microorganism which can continue to grow under refrigeration. It is a matter of great concern to the industry. And we appreciate and have worked with the agency to this end.

MR. BILLY: Caroline?

MS. SMITH-DeWAAL: Thank you for giving me one more opportunity to put my thoughts on the record before we leave this topic. I just -- I continue to be troubled by the fact that in the guidance material to the industry, you recommend both environmental testing and end product testing for listeria. In the NFPA documents to the industry, where they are setting out their own guidelines for the National Food Processors Association put together by a number of very distinguished scientists and experts on this, they recommend environmental testing and also discuss the need for product testing.

In your instructions to your employees, you say that there is no requirement for microbial testing. The bottom line is -- and you only require a reassessment in the event that there is a history of positive result for Listeria monocytogenes product samples, either from the establishment or from FSIS testing. This is very inconsistent messages. We're telling the industry, do the right thing, sample. But you're only enforcing a system if they have had positive samples. And if I were in the

industry, I'd like at this and say, hey, if I haven't had a positive result, I'm not starting to sample now because I don't have to take any action until I have an actual positive in my product.

So we really need to look at the hurdles we are actually putting out in front of the industry. I think the only way we are going to get the industry to test their products and their plans for Listeria monocytogenes is if they are mandated to do it by the government. And we have written nice letters to the secretary. We have asked for -- the CSPA will be petitioning the department for an emergency rulemaking in December to require the industry to test their products and their plants for listeria.

But I wish we didn't have to do that. I wish we were confident that the agency would do the right thing.

MR. BILLY: Katie.

MS. HANIGAN: Can I make just one comment? And I know you want to move on, okay? As a company that moved our environmental and product testing into our HAACP programs because of the reassessment, I think when we meet in January, the agency has to come up with how does it fit in

to record review prior to shipping. And I know Farmland spoke to you folks before -- you know, about that subject before. It does not fit into the current definitions, and it is very difficult. And ours are CCPs in our models. And we have had a lot of discussions with inspectors at our plants on that not fitting into the definitions given in the original rule.

MR. BILLY: And this is in part tied to the time it takes to get your test results back.

MS. HANIGAN: Yes.

MR. BILLY: Related to when you do the final checking and ship the product. I understand. Other comments?

MS. SCHULTZ-KASTER: Just quickly to build on Katie's point. Then it needs to be recognized that what Caroline is saying, that testing is not occurring, that that is not true. That is company by company on a hazard basis, per the HAACP type approach to do that testing on end product. And there are numerous companies in the industry that are doing that type of testing. So we need to be careful as we apply standards or regulations that these are

properly building on the information that we have and what can be done.

MR. BILLY: Nancy?

MS. DONLEY: Really, just one question. Are we revisiting this topic later, or is this it? Are we finished with it, or do you intend to go back to it in its normally scheduled time?

MR. BILLY: This is it.

(Laughter)

MS. DONLEY: I then would just like to make one addition to -- actually, it kind of builds on what Caroline had said before. And the reason I ask is I'd dig it out in my briefcase if I had it, but it -- and please bear with me if my numbers aren't exactly correct here. But in the case with the Belmar plants, that they had their environmental testing started out by showing 25-percent positive rates. It jumped up to 96-percent positive for the environmental testing for listeria. And product continued to ship.

There is something wrong with this system if a company knows that they have a problem like that and can legally continue to ship product out to the consuming

public. And it is a problem that is in dire need of fixing immediately.

MR. BILLY: Dan?

MR. LaFONTAINE: I'm certainly no authority on Belmar, but I believe that was -- those percentages related to psychotropic organisms, not necessarily listeria. So we're talking about the same type of cold-loving organisms. But I don't believe it was all listeria. It was rather psychotropic, just to clarify that.

MR. BILLY: Any other comments? Okay. All right. So, thank you, and we may be sending you back to the micro committee with a further message.

MS. HULEBAK: Thank you, Tom.

MR. BILLY: Thank you. All right. We are bumping against -- up against noon. My suggestion is we go ahead with one more of these issue updates, and have it be the second one, the interstate shipment of state-inspected product because I think we can do that fairly quickly. Sorry, Mike Grasso.

(Laughter)

MR. BILLY: I guess Chris Church will lead this

discussion and provide you with sort of a status report on this project that his committee has worked so hard on. Chris?

MR. CHURCH: Right. Good morning. While it is being passed out, I wanted to address something Rosemary brought up earlier, and that is the report to Congress. I, like you, share your concern on getting a copy of the report to Congress because it is one of the things I always keep within arm's length on my desk because it is so valuable as a resource tool because it has just got the numbers for everything. You know, it answers half of the questions that come into the office. Unfortunately, I don't have a recent one.

Well, I have good news and bad news. The good news is that the report is on its way to the printer and will be on the Internet within two weeks. Now the bad news is that is last year's report.

(Laughter)

MR. CHURCH: On the other front, on the report that is due this year, I do know where that one is because it is on my desk. We have gathered all of the information

for the report and, like I say, it is somewhere in my office. But someone in my desk should be reviewing that and then moving it further through clearance. And I hope to get it out there as soon as possible because I want it.

MS. MUCKLOW: So '97 should be available --

MR. CHURCH: Let's see. The report was due last year, which covers the year '97. It will be on the Internet within two weeks.

MS. MUCKLOW: Okay.

MR. CHURCH: And it will be printed there. I don't know how long that takes.

MS. MUCKLOW: FY98 is under review.

MR. CHURCH: That is correct.

MS. MUCKLOW: I would remind you the law says that FY99 is to be delivered to the Congress by next April.

MR. CHURCH: One of the other things I keep within arm's reach is the --

MS. MUCKLOW: Law.

MR. CHURCH: Federal Meat Inspection Act. Yes, so --

(Laughter)

MS. MUCKLOW: Thank you, Chris. I am very pleased to hear that it has finally cracked through.

MR. CHURCH: All right. Now turning to interstate shipment, up until about yesterday, I was feeling a little bit like a pregnant elephant. As many of you know, we have been working on interstate shipment, the concept and the legislation, for about two years. Well, finally, the baby elephant has been delivered. As I just passed out, yesterday evening we delivered the actual language of the Clinton administration's bill to allow for interstate shipment of state-inspected product to the Congress.

So over the past couple of months, I have talked to many of you and groups you are associated with about the concept that was developed largely with the help of this particular body. The committee was just an excellent resource and sounding board for getting all the views on interstate shipment. So over the past two years, with your help, we have been able to develop a consensus concept on what it would take to achieve interstate shipment of state-inspected product.

So I thank you very much for that. What we have

is a consensus bill. Over the past couple of months, I have talked to many, many congressional staff people about this, and we are optimistic about having it introduced. It is particularly getting a good reception in the Senate, where they very much understand the concept of consensus. So if the consensus holds together, I think there is a very optimistic future for interstate shipment of state-inspected product.

I'll just take two minutes -- I know there are some new members here and perhaps some members in the audience who are not entirely familiar with what the concept is. But let me just take two minutes to talk about what I think will cover about 99 percent of the bill. The core of the bill is that we would move to a seamless national inspection system where state-inspected plants would be required to meet federal statutes and federal regulations. This is a move from the former equal to requirements of the states.

In essence, there is really no change as far as food safety is concerned. But there will be a change in wording. And the states, if they are using state -- rather

the federal statutes and regulations -- will be eligible to put the federal seal of inspection on state-inspected product. This is in addition to the fact that they will be able to continue to use the state seal. So product coming out of state plants would be unique in that it would have a federal seal of inspection and also eligible for a state seal of inspection.

With the federal seal of inspection, that product can now move, move in interstate commerce. It will be eligible for export. It will be eligible to enter into other federal facilities for further processing.

The other provision of the bill that I want to talk about in general is with this new system, there will be additional review of the state programs. It was discussed here. We are talking about doing comprehensive reviews of the state programs every year so that American consumers and our trade partners have full confidence in the seamless national inspection system. We'll be coming back to you again when we are designing the comprehensive reviews.

In the legislation that is attached, it is stated that those comprehensive reviews will be designed in

consultation with all stakeholders. So we will be asking all parties. As you can imagine, we will have a public meeting asking for comments on what is necessary for the reviews. We have had some interesting suggestions from the states already when I have been talking to them, that they would like to be included on the reviews. When there are reviews being done of other states, it might be important to include state representation on those reviews. So we will be open to all suggestions on that.

I want to emphasize that the bill is designed to ensure the integrity and identity of the state programs. We feel very strongly about supporting the state programs. We think they are uniquely qualified to work with particularly the very small plants that they have developed the expertise in working with. We very much want to support that concept continuing.

One of the things we are suggesting in the bill is up till now the federal government has reimbursed the states for up to 50 percent of the state program. In the language that you have, we are proposing that we would reimburse the states up to 60 percent. So we would like to see that

authorized and funded.

So that is the core of the bill. As I say, the baby elephant has been delivered, but we now have got to have it baptized and confirmed. We have to have it introduced in Congress and passed by Congress. And I think if the consensus holds together, there are very good prospects for that. And I hope everyone continues to support the concept that we put together and now delivered to the Congress. Amen.

(Laughter)

MR. CHURCH: Lee.

MR. JAN: Chris, you talked to us in San Diego about this and indicated that if there were any changes or any provisions, that the consensus would start to fall apart and there would be a not a consensus or support, and therefore the bill would not make it, in your opinion. While we have the group together, I would like to at least hear how the mark, the federal mark of inspection, which we have already heard today the consumers do not have confidence in, is an important part of this bill. Why not recognize the state mark of inspection as an official mark?

This whole concept started with removing or repealing the prohibition against interstate shipment. This bill is still not doing that. This bill is now saying that we knew all along, at least the state programs, that the state programs are equal to, and now we are calling part of, or seamless, part of the seamless system. But we asked for to recognize the state seal or state mark of inspection as being equal to and therefore allowed to move in interstate commerce. And it would seem to me -- and I would like to see that this bill be changed or modified.

And there will be hearings, and we need testimony or whatever it is, whatever the processes are, that the state seal be the official mark of inspection for state-inspected products and be eligible for the USDA mark of inspection if it is necessary. And the reasons that you indicated it would be necessary would be for international commerce. And if a product is going to national commerce, if a federal plant is receiving the product and doesn't want to try to keep it segregated, which there shouldn't be no cause for that -- but whatever reason a state -- a federal seal is required, then they could put that on as well.

But the problem by -- one of the problems of requiring a federal mark of inspection, now you are imposing an additional cost to state plants or state-inspected plants that have no desire for shipping in interstate commerce. And it seems to me that this mark of inspection, just reversing two words, making it which one is optional, as for additional, should not lose the consensus.

I'd like to see what the other committee members feel.

MR. BILLY: Now before I recognize Carol Foreman, your opening about the consuming public's not having confidence in the mark is contradicted by a survey that I just recently saw the results of and will be made available through the White House later this month. Quite the opposite is true. There is wide confidence in the inspection mark. So there are -- you know, all the committee members and others can express their views about that. But I just didn't want to leave the thought that there is not confidence in marks. Carol?

MS. TUCKER-FOREMAN: In fact, you misunderstood me, Lee. I'm not suggesting that consumers don't have

confidence in the seal. In fact, my concern is with regard to the ready-to-eat products that they see the seal and they do have confidence in it, and then in that case I think it is an appropriate confidence. So it is not -- I think people see that seal. I'm glad to know there are going to be some data that back that up. I think for -- since -- for the 30 years or so that we have had the most recent act of account, that people have looked for that, and they do understand it. It is my concern when a product doesn't warrant that level of confidence. And I really think this is good for everyone.

There are a lot of different interests at stake here. I have proposed year after year after year moving state-inspected meat in interstate commerce because there wasn't an assurance. There was no completely acknowledged level that defined "equal to," and I think that it is great that we move now, that we have got one, that we have a standard that can be written down on paper and is within the eye of the beholder. And I know that everybody is going to want to go up to the Hill and have it read exactly the way they would like for it to read.

And I just caution people. I think this is a very fragile alliance, and we will -- if you decide that you can't live with this, then very quickly we'll decide we can't live with it either.

MR. BILLY: Other comments? Terri.

MR. BURKHARDT: Well, I would echo Lee's issue on the use of the legend. Initially, in the earlier on versions, it was state product with a state legend moving in interstate commerce. Then some of the international issues came up, which really the state programs and the state products are not interested in export. We just want to go across the river, you know. So that particular issue -- and that state inspection legend means a lot to the people that work in those programs. That is our identity.

Plus, I think in the case of any particular type of trace-back, it would be much easier to trace product with a state legend on it than a particular federal legend on it. So I would echo -- if we can allow -- that the primary mark of inspection be the state legend on those product. It has some unique marketing aspects as well. So -- and the additional cost. And there is no change in safety.

MS. TUCKER-FOREMAN: I don't know. You all are getting something you have wanted here. For as long as the law has let you move state-inspected meat in interstate commerce, you are getting what you want. And if you start fooling around with it, I promise you, Consumer Federation of America and Center for Science in the Public Interest and STOP will be on the Hill opposing allowing moving state-inspected meat in interstate commerce.

Now you may be able to beat us. But do you want to?

MR. BURKHARDT: It is not even a safety issue.

MR. BILLY: Okay. Rosemary and then Dan.

MS. MUCKLOW: Clearly, Carol's words need to be considered very carefully by my state friends. I was going to see if I could be a broker here. From my perspective, and I have not presented this to my board of directors or discussed it with the other industry organizations, but it would seem to me that the issue for export trade is that our international partners look to the USDA, not to the state of Texas, for those assurances. So if a firm wanted to be in that international trade, I understand that you would need

the federal mark of inspection on that product.

However, if they just want to ship across the river, I have a hunch that I would be quite comfortable with the state inspection program and maybe make the federal mark an optional mark for the individual state-inspected plant to add. And probably once they have added it, they can't ever take it away. Over time, you might find that both marks would be on -- I think it is a bit confusing to consumers to have two marks on the product.

I would offer that as something, and maybe when we all go eat lunch and people talk with each other, maybe that is an idea that could grow in their sandwich.

(Laughter)

MR. BILLY: Dan, our final comment on this.

MR. LaFONTAINE: To let you know that among the state programs, we have some honest disagreements. And on this one, I happen to disagree with my colleagues. I don't think -- I think it is a nonissue. I think if we have the federal mark of inspection, and you also put the state, yeah, there will be some growing pains as far as some new labels and whatever, but that is a temporary blip.

And to add a positive note to it, we are a coastal state in South Carolina. And we have -- as most states do, we have international ports of entry and exit, such as Charleston, and we have cruise ships calling and you name it. And I can see, even though we may not even know it is happening, or it is not happening now but I can see it happen very easily, that these products will find their way into the international marketplace just because of the international travel that occurs today, both in sea and in air. And so I think it would alleviate a lot of international concerns to have that kind of mark.

So my bottom line is on this particular point, I don't see it to be a problem.

MS. MUCKLOW: One other brokerage thought, Tom, might be that maybe the state mark is a hexagon, I think, still. Maybe the hexagon -- is that right?

(Simultaneous discussion)

MS. MUCKLOW: Pardon?

MR. BURKHARDT: Most states, it is the shape of the state.

MS. MUCKLOW: Okay. Maybe it could be surrounded

by a ring, which is the traditional federal mark of inspection, and some additional wording placed in it. I mean, maybe there could be a blender there of some kind. I think Dan is probably right, it is not really a huge issue. But there is a states' rights issue that is probably very important to some of these states to maintain that identity.

MR. BILLY: Okay. Well, I'm really pleased that it has moved to the Hill. I think that now it is incumbent on us to send certainly the administration plan to support this legislation and support enactment of this legislation. So there is not a lot of time left, obviously, in this current session. So I think the most likely situation is that it will be dealt with in specific terms the next session after the first of the year.

I'd like to break now for lunch. It is about 12:15, so I'd like everyone back at 1:15. Thank you.

(Whereupon, at 12:15 p.m., a luncheon recess was taken.)

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

(1:17 p.m.)

MR. BILLY: I'd like to move on. Two or three of the committee members asked about the session we just had on interstate shipment. And what I have encouraged is for people to talk during the breaks so everybody understands the different perspectives that were shared before lunch. But I would prefer not to go back to talking about that issue. There are clearly different views, and I'd just encourage people to talk this evening or during the breaks so you understand the different points of view.

I'd like to move on to the inspection-based, inspection models project, the HAACP-based inspection models project. And Mike Grasso from the agency is our project leader overseeing this work. And this is to provide you an update on the project to where we stand and some of the recent developments and where we are headed. So at this time, I'd like to turn it over to Mike to provide you with that information.

MR. GRASSO: Thank you. I think in your handout books, you have received some excellent information. And I

would just like to take you through that information. This is the most recent background that we have, and that is several pages. And then we have our initial performance standards for a broiler plant. That is the second document. And one thing of information that you need to know is that the ten-bird sample sets that appear on the first page of our activities within the plant, and specifically where it talks about a 60-bird sample set, that is specific to Goldkist (phonetic), so that is not for all broiler plants. That is the sample size that Goldkist has chosen. So we have identified the numbers as it relates to performance standards over a 60-bird sample set.

MR. BILLY: Okay. Mike, you're on tab 5, is that right?

MR. GRASSO: Correct.

MR. BILLY: At the beginning there. And there is the backgrounder, and then what you're just talking about is just behind the backgrounder?

MR. GRASSO: Correct, the performance standards. It says final draft.

MR. BILLY: Final drafted dated 9-29-99.

MR. GRASSO: Correct.

MR. BILLY: Has everyone found them?

MR. GRASSO: And also, following that is there is a good example of what occurs in a plant as far as the side-by-side traditional inspection activities and activities within the models plant. If you flip the page, it gives you a good example of the enhanced responsibilities that the plant has today, and also FSIS responsibilities, a nice little map showing you where most of the plants are located, and then an actual listing of the plants that have volunteered. The last document is a HAACP inspection model pilot document that we use at site visits when we go to the plants before the startup of baseline data collection.

I'd like to talk about a few things. Currently today, we have approximately 30 plants that have volunteered to participate in the project. We have broiler plants, swine plants, and changing plants. Of these plants, we have baseline data collection for 16 broiler plants completed. And if you don't know what baseline is, I'd like to just explain that to you. The agency, to measure the accomplishments of the existing system, goes into a plant

and takes baseline data. We take 600 microsamples, 300 for generic E. coli, and 300 for salmonella over a 30-day period of time. We also, over a 25-day period of time select 2,000 carcasses, approximately 80 carcasses a day.

So that baseline data collection has enabled us to establish performance standards in a broiler plant. So that second document in Section 5, that is how we got those numbers. It is based upon the data collection in those plants.

Currently today, we have completed 16 broiler plants, baseline data collection, two swine plants, and one turkey. We have -- we are lining four more turkey plants, and also three more swine plants. In fact, next week we will be on an initial site visit and baseline startup for another turkey plant.

The models phase -- the models phase is actually where a change occurs from the way we did it in the past with the new activities. And we have three plants that are actually in the models phase as I speak today. We have Goldkist, which is a broiler plant, and also Hatfields, which is a swine plant, and Quality Pork, which is a swine

plant.

In livestock plants, there are three steps in the models phase. There are two antemortem steps that they have to be successful in first before they go to the postmortem activity, where the change takes place for FSIS inspection personnel in the plant. Hatfield is scheduled to take over postmortem activities on November 14, and Quality Pork is scheduled to take over postmortem the following week. The broiler plant has -- this is their fourth week that they have taken on the postmortem activities.

Each plant that goes into the models phase goes through what we call a transition period where have a technical consultant that is assigned to the establishment to work with the establishment, and also the IIC in the plant to make sure that things are running smoothly in the plant. Once the plant goes into the models phase, the transition part, we will target a 51-sample set for salmonella on the day that they start the models activities.

We have in January and February probably another eight to ten plants that will be coming in on the models phase. Some of the plants are holding up because of the

holidays, for Thanksgiving and Christmas and New Years. So we should have a lot of plants starting. Two that are scheduled is Choctaw and also Kagel's (phonetic), the first two to go in January.

A little update on training activities, because that seems to be of interest to a lot of people. And there are different types of training that are providing. Number one, slaughter training for industry. We have provided so far three classes in College Station for industry to actually receive the slaughter training that FSIS personnel receive. As of this date, we have close to 80 people that have participated from industry in those slaughter classes. We have another class scheduled on November 15, and another one January 25.

So we have solicited all of the models plants if they want to send their people to these sessions, either train the people that are going to do the work, or most plants opt to do train the trainer, and then those people come back and train the personnel within the plant.

In addition to that, industry had requested to receive what we call oversight and verification training,

and also statistical process control. Oversight and verification activities are what we will do in the plant when they are in the models phase. And we actually concluded a session last week where we had close to 30 people from industry who actually received the oversight and verification training that is given to our management people. And also Dr. Shira (phonetic) from Clemson University came in and actually taught them SPC on how to establish a statistical process control plan within the plant. Our people, our management people, receive the same type of statistical process control training, but on how to audit a program as opposed to how to set one up.

We have trained -- as far as our management people, we have trained 125 managers, and we have two more training classes coming up on 12-6 and January 25. When I talk about management people, I am talking about the IIC, the magfed (phonetic), the relief fed (phonetic), safety supervisor, people from the district, all of the management people that are involved with the models plants as it relates to startup.

In addition to that, we have inspector training,

the inplant inspection personnel. We have had six plants completely trained, and we have two more scheduled for November and December. That is the Tyson Plant and the Kagel's plant. Those inspection personnel receive three weeks of training. Two weeks is actual HAACP training, and one week is oversight and verification training.

So the oversight activity is for the slaughter operation -- wants to work. We have to have an inspector in an oversight position observing the carcasses as they are being slaughtered. In addition to that, we have verification activities, such as in a broiler plant, a current plant for food safety performs two zero tolerance checks per line per shift. In the models plant, it is six times per line per shift.

So that gives you a quick update as to where we are as far as how many volunteer plants we have, exactly where we are with baseline data collection to establish the performance standards, exactly where we are with the models phase and the training. And this week, we have just developed the performance standards for the two swine plants that will be coming in on 11-14.

MR. BILLY: Questions? Lee?

MR. JAN: I'm happy to hear that we are providing the training. That was a concern that I had. I still have a concern that there is no training requirement. Or at least my understanding is training is up to the plant whether they want to send somebody or not. If they choose not to have the training, they are not required to have anybody with any specific training in any one of the postmortem procedures or ability to identify. And with that, it concerns me that FSIS has made the statement that this is a plant responsibility, to determine what tasks are necessary to protect the public health, when they were asked about whether industry has concise plans or not.

So you are purchasing -- why not have any specific plan, and it is up to you to decide what is appropriate for food safety. And I am still having a problem with it, that we are going to allow industry -- the concept -- I think the concept is good. But I think that industry should be required to have a person that is trained and qualified to make those decisions. If they are going to make the calls, they need to be qualified. And I am talking about, you

know, some qualification in diseases and how they affect people.

So that's my concern.

MR. GRASSO: Well, I think the agency's position is that we have set the performance standards, and the establishment needs to meet them. If they don't call it right, they are not going to last too long as we perform our verification activities. They will fail. So --

MR. JAN: I have got a question about the publication activities then. To make an appropriate and accurate diagnosis about a disease condition, we need to look at more than just the carcass. You can't look at a carcass after eliminating any of the lesions that may be there, or the internal organs, for that matter. Is there a provision that you can -- that verification will allow the inspector, the veterinarian, to make the oversight or verification has the ability to look at all of the organs related to that animal without saying now look at this one and it would be treated differently.

MR. GRASSO: Well, the IIC within the plant is the final say on those decisions.

MR. JAN: Well, my question is what is going to be available for the verification task in ways that work, or what is the inspector, or the IIC, going to be able to look at to verify that the conditions are being appropriately culled or segregated, whatever the term, be taken out of production, if they are only looking at a carcass, where those identifying lesions may be gone.

MR. GRASSO: Well, one of the big activities in the models plant, both between the IIC veterinarian and also the inspection personnel, is what we call "correlation." It is extremely important. In our ten-bird sample set that we perform, those ten-bird sample sets for OCPs are for correlation purposes. We need to be on the same plant -- the same page with the plant on how you score defects, okay, because when they are doing activities within the plant, they need to be scoring them the right way because in this plant, the 60-bird sample set, we have established the performance standard there. So they need to be calling them the same way FSIS will be calling them so that it would -- you would have a good, true performance activity.

MR. JAN: So my understanding --

MR. GRASSO: There is correlation going on between the IIC and the plant personnel as it relates to veterinarian activities, and there is also correlation going on between the plant personnel and the inspection personnel as it relates to OCP and zero tolerance.

MR. JAN: So am I understanding correctly that the verification would actually be done simultaneous with the plants making their activities?

MR. GRASSO: It doesn't have to be 100 percent of the time. When a verification activity occurs, that is how we measure their performance.

MR. JAN: Oh, I understand, not 100 percent of the time, but say the selection is two carcasses an hour, or whatever it wants to be. They would follow that carcass all the way through to verify that it is being done the way that they should be dissecting. How will that meet verification?

MR. GRASSO: I think it is -- there are several different ways of doing verification within the plant. One type of verification is of paperwork that the plant records. Another type of verification within the plant is the actual owner-directed activity that occurs. And another type of

verification would be submitting samples for micro testing. But I think the verification that you are talking about is an ongoing activity that IICs have a chance to evaluate the system within the plant.

MS. STOLFA: Hi. I'm Pat Stolfa. As I understand your question, it is most relevant in livestock. It is a less critical question in poultry establishments. And there is a requirement that the plant maintains the identification of the carcasses and its parts until such time as a decision can be made and we have an opportunity to verify it. This hasn't come up in livestock plants because we are going through a slower approach in livestock establishments, and we have just started taking over some of the antemortem things that they haven't done previously. But maintaining the identity of the carcass and its parts is a requirement in livestock establishments.

MR. BILLY: Okay. Dan?

MR. LaFONTAINE: First, a general statement. Personally, I have in public supported this whole concept of an alternate inspection system. I still do. And also, one of my other hats with the AVUMAY (phonetic) is the chairman

of this food safety committee. The AVUMAY also supports that.

There is one area that we have -- we, myself personally and the organizations I represent -- have quite a bit of concern about that I think needs more digging into, for the lack of a better word. In the other consumer protection number one category of other animal -- or of animal diseases -- some of those diseases -- and I'll just give you some examples, airsacculitis, enteritis, tuberculosis, nephritis, pericarditis, pneumonia. Those are normally localized infectious diseases.

But what happens in the animal, is when you challenge an animal with a localized pneumonia or nephritis, even though he may not have a systemic disease or a toxemia or a septicemia -- let's just take the bird. If it is a latent carrier, that is, it is carrying salmonella or campylobacter in its gut, but it in a latent manner where it is really not shedding them, but you challenge an animal with an infectious disease, the literature will show you that they immediately start -- not immediately, but they soon start to shed significant numbers of organisms, the

salmonella, the Campylobacter cinaedi. And this is not just birds, but also livestock.

The point I am leading up to is, to say that some of these diseases are under other consumer protections, is misleading. We have a continuum -- you have probably heard me say this before -- where many of these conditions are actually very rapidly -- many of these animals, birds or livestock, very rapidly are heavysetters of the pathogens we are concerned about. So what I am asking or suggesting as we get into this rulemaking is that we look at that one category. And it may be that some of those need to be in the food safety arena, which is what we are really concerned about, as opposed to other consumer protection.

So I'll just leave it at that. I'm not asking for any comment or change at this point. But it needs to be given a hard look.

I have a question. The concept paper talks about the goal of a final rule by the fall of 2000, a year from now. What is the -- can someone give me the grand plan as far as --

DR. WOTEKI: I think the plan is to have a

proposal by fall of 2000, with a final rule the following summer.

MR. LaFONTAINE: No. It says final rule 2000.

DR. WOTEKI: In the fall?

MR. LaFONTAINE: It may not be your intent, but it does say final rule.

DR. WOTEKI: Okay. Well, we no longer think we can meet that goal.

(Laughter)

MR. LaFONTAINE: I do read the fine print.

DR. WOTEKI: No, no. I'm glad you did. And we did -- that was our ambition at one point. But at this point, I think we think either late summer or early fall of next year would be a proposal.

MR. LaFONTAINE: Okay. Well, I still have the same question then. What is your game plan as far as public meetings leading up to the proposed rule? Give us a feel for the grand plan between now and the summer of 2001.

MS. STOLFA: I think that we are anticipating a public meeting early in the year 2000 to report on experience to date in the plans where some change has

occurred. We don't generally -- we don't generally more than one public meeting at a time. We sort of get a feel for when those are necessary.

We are actually going to try and push the proposal as fast as we can. I doubt that we will be completed with the rulemaking by the fall of the year 2000. But we believe we are in a position to propose. We have collected all of the baseline data that is going to form the basis of the performance standard. We have made what amounts to a policy decision that is relatively consistent with other policy decisions the agency has made regarding performance standards as to where that performance standard should be set. And so we are -- you know, we have all of the items necessary for the framework of the proposal.

What we don't have is experience as to whether or not companies can meet the performance standard. But to some extent, whether they can meet it or not wouldn't be highly relevant to our determination about how it should be set. And so, you know, we have the pieces for that. We wouldn't be able to predict all of the impacts and those other kinds of things that we need to do when we propose a

regulation. But I believe that we have the significant pieces of it.

MR. LaFONTAINE: Just a follow-on comment. I think it is obvious why I am asking because all along, FSIS has committed to being transparent. And so the issue I just brought up needs to be looked at in a transparent manner. And then, of course, the data that is gathered, baseline and pilot, needs to be open and transparent so that we can have the scientist take a hard look at it and say are the conclusions you have drawn based on good science. And that's the next thing I'm looking for.

MR. BILLY: Yeah. We would, I expect, in the end have several additional public meetings as part of this process. But the one we are focused on now is the one after the first of the year to share our experience to date. As we gain that experience, then we will make some judgments about whether we will have another one like that even before we're at the stage where we have completed the data sets, and perhaps have some kind of meetings, perhaps different kinds of meetings, one for scientists and one for all of the rest of us.

So in terms of dealing with all of the data, the thousands of results that we'll have to work with, and allowing people to get comfortable with that data and understand it, all leading up to the rulemaking process. So and then even during that, if appropriate, we will hold public meetings as well. So we are very open to that. It is just that we are going in a sort of a stepwise manner.

MR. LaFONTAINE: I realize it is a very complex and difficult path you're on. It is just that, you know, it has been approximately a year since the last public meeting that was in December of last year. So those of us who have a keen interest in this -- all of us do, I believe -- we're anxious to have a chance to speak up on it.

MR. BILLY: Thanks. Cheryl?

MS. HALL: Yes. Cheryl Hall, from Zacky Farms. I had a few questions, too. I wondered, did we say that then the rough data from the baseline studies would be available?

MS. STOLFA: The baseline data has all been collected. We don't have a report that summarizes all of the baseline data yet on young chickens, for instance, where we have collected all of the data. We would anticipate

assembling a report that was somewhat comparable to the report we gave before on partial data that we gave at last year's December meeting. We would have a report that reflected all of the data from the young chicken plants. And I think that should be ready for a meeting after the first of the year. I don't think there is any difficulty with that. Then we would also be able to explain how we went from the baseline data to the performance standard. So that would all be part of that public meeting.

MS. HALL: And that will include the study you did on the condemned birds and the birds -- and the criteria? There are going to be results here for setting standards?

MS. STOLFA: Yes.

MS. HALL: We talked about the training that is being done in College Station. And up to this point, it has been free. Is it going to continue to be free for people that are going into the models program?

MR. GRASSO: Free? We don't know that word.

(Laughter)

MR. GRASSO: It's $600.

MS. HALL: $600?

MR. GRASSO: Not a company, per person, and you have to pay your own expenses there.

MS. HALL: Okay. Is there any provision for someone to go to companies that are going into the models phase to help them at the plant level? In other words, do you send people out other than just verification types?

MR. GRASSO: We actually assign a technical consultant to a plant that goes into the models phase on day one. So that person actually is in the plant working with plant management and the IIC, what we call the transition phase. As you are performing new activities within the plant, so are we, and we want to work with both sides. It is kind of like a dry run, make sure everything is going right. And if something can't be resolved at the local level, then either the IIC or the plant calls me, and then we resolve it.

MS. HALL: Okay. So my understanding is then that other than that type of assistance, there isn't any training required or provided for people in the plant by USDA FSIS.

MR. GRASSO: We'll provide the slaughter training if you choose to go. And we'll assist you in your rewrite

of your HAACP plan as it relates to the slaughter portion. And we'll assist you with your write-up on the process control plan. So we'll provide you feedback on those two documents. You could either do that coming into Washington, or we'll set up a series of conference calls to provide you with that feedback.

MS. HALL: Okay.

MR. GRASSO: And that -- we just completed last week the data from the 15 plants. So Friday, I think, was the last day.

MS. HALL: It is my understanding that you expect plants that have, say, four slaughter lines --

MR. GRASSO: All or nothing.

MS. HALL: All or nothing. So all of it goes in at once.

MR. GRASSO: Correct.

MS. HALL: You realize this may be chaos.

MR. GRASSO: It hasn't been. I get a daily report from the technical consultant at Goldkist, and things are going surprisingly well. They have four lines.

MS. HALL: Four lines?

MR. BILLY: I think our concern was that it would be chaos if we did it partially. There are two many different systems that way.

MS. HALL: One last question, please. On this -- the standards, when the verification is done by FSIS, will the plant be able to correlate at that time to see where they are having failures or what kind of things are going on?

MR. GRASSO: On the first page of that document, where it talks about the ten-bird sample set, those are -- for OCPs, those are twice per shift per line. And those are true correlation samples. When we're doing them, you can be right there with us with what we find, sharing that experience, correlating that experience. And if you look to the second page, that is Goldkist's sampling plant. So that is what they are choosing to take, 30 birds per hour to come up with a 60-bird sample set. And then we have adjusted the performance standards for those 60 birds.

So whatever you choose as a company to sample -- let's say you wanted to do 40 or you wanted to do 80. We would adjust the numbers based upon your sample set. And on

the 30-bird sample set that Goldkist is doing, their people review the birds. We do like a verification activity looking at how they are doing it. And we certainly do some correlation on those 30-bird sample sets.

MS. HALL: Thank you.

MR. BILLY: Nancy, did you have --

MS. DONLEY: Thank you. Yeah, a couple of questions. On the performance standards that have been developed, are they just based on the data that was collected from the volunteer plants?

MR. GRASSO: The performance standards that you see in the document are based on nine broiler plants at that time. And we have taken the 75-percent percentile, which is a position between the seventh and eighth plant.

MS. DONLEY: Okay. And as more plants join the project, do those performance standards change?

MR. GRASSO: We have established for Goldkist those performance standards. But as Pat said, we have just completed data collection for 15 plants. So that would be the performance standards that the agency would move forward with rulemaking. That would be the performance standards

that we will provide feedback to Goldkist now, and also any broiler plant that comes in the models phase, we will use data from the 15th for the performance standards.

MR. BILLY: So there may have to be some adjustments.

MR. GRASSO: Just for Goldkist.

MR. BILLY: Now that I think about it, we had to get started someplace, so we used the largest data set we had to start. And now that will be refined as we go forward.

MR. GRASSO: And the change isn't significant because it is relatively the same in most categories. It has gone up a little bit, I believe, on one or two categories, and it has gone down, I think, on one category. I don't have that document in front of me. But it is relatively the same.

MS. DONLEY: If we have the top 16 plants in the country that are participating in this, and we get -- I am concerned with the proportion of plants, the information of that data that it is going to be comprising a performance standard. And in the case of pork now, we have two plants.

So is it just two plants for pork that is determining the performance standard?

MR. GRASSO: Well, I think what you have to do is take a look at the 300 large HAACP plants that came in on January of 1998. And there was a little over 100 broiler plants, but a very, very small number of pure turkey plants, and the swine plant. So we're looking further on down the road to use a number in excess of five on the swine and above five on the turkey.

MS. DONLEY: Okay. And just one other thing is I noted that as each plant comes in, that you are starting a salmonella testing --

MR. GRASSO: Fifty-one sample set.

MS. DONLEY: -- per sample set.

MR. GRASSO: From day one.

MS. DONLEY: On day one. If during this time that they have whatever the number of positives is until a failure, are you going to be -- are you going to be administering this sample set as FSIS does now and does not inform the plant until the end of the sample set, even if they fail the first -- I am going to use -- throw a number

out.

MR. GRASSO: It is 13. If they would get --

MS. DONLEY: Thirteen?

MR. GRASSO: -- 13 in a 51-sample set.

MR. BILLY: For broilers.

MR. GRASSO: Correct.

MS. DONLEY: So if on days -- I'm going to give the worst case scenario -- days 1 through 13, the plant has failed the salmonella testing portion, the plant will continue to operate through the 51-sample set without any notification from FSIS that obviously there is a problem.

DR. WOTEKI: No. In those situations, our district manager will inform the plant of the problem.

MS. DONLEY: That happens now in the current system?

DR. WOTEKI: Yes.

MS. DONLEY: Okay.

DR. WOTEKI: It is a verbal notification.

MS. DONLEY: And what then does the plant have to do?

DR. WOTEKI: Well, the plant then has the

opportunity to fix the problem. We don't see any reason to -- we think it would obviously be inappropriate to wait for the entire sample set to be completed, although we do complete the sample set, before the plant knows it has a problem. And so our district managers will let them know they have a problem.

MS. DONLEY: Okay. And then just one other comment on this time frame that I'm hearing to have a public meeting in the beginning of the year, I -- 51 sample set, that is, you know, roughly nearly two months down the line. We're practically into the first of the year just to complete a single sample set for one plant. I'm just wondering how much valuable information will we have at that point. I don't think that I would feel myself very comfortable in coming -- drawing any conclusions from such a small, small amount of data.

MR. BILLY: Yeah. I don't think that, as Pat explained it, it is not to draw conclusions. It is to just share the data and help people understand what it is. We are a ways off from drawing conclusions, you know. We are working towards a rulemaking. So -- but we think it is real

important, as Dan is implying in his questions, that we maintain transparency in this whole process, that people are continually updated on the progress that is being made and the data that is coming in. It is going to be a huge set of data that we're working with. And, you know, I think progress reports will help people understand it and enable them to manage working with the data and then their thoughts about what it means, that kind of thing.

MR. GRASSO: Now, also, so that you understand, is that baseline, we did the 600 samples of E. coli and salmonella. We did the 2,000 carcasses. Now we start the models phase, the transition phase. That 51-sample set is just an extra activity. RTI, the contractor, is going to come back in on the models phase and duplicate in the models phase what they did in the baseline. So they are going to take another 600 samples. They are going to take a look at 2,000 carcasses again. And that is how we measured them, whether they have met the performance standards for OCPs, and they have to be within the regulatory requirements for the micro sampling.

So it is not just the 51. There is going to be

another 600.

MR. BILLY: And that's for every plant.

MR. GRASSO: Every plant.

MR. BILLY: So it is an enormous amount of data that is going to be coming in. Carol

MS. TUCKER-FOREMAN: Yeah, thank you. I know I'm dumb, but I have got a couple of questions that I think you have answered several times before. But I need them answered again. Why is ingesta an OCP instead of a food safety contamination?

MS. STOLFA: That's the status of that particular defect under current regulations.

MR. BILLY: In cultures.

MS. STOLFA: In cultures.

MS. TUCKER-FOREMAN: Why is it that way under current regulations?

MS. STOLFA: Well, we have come up close to and looked at the question of whether or not it should have a different status. And I don't believe we can find a sufficient basis to justify its classification as a food safety problem in poultry.

MS. TUCKER-FOREMAN: Pat, what have you done to -- what kind of studies have you done to assure me that it is not a food safety problem?

MS. STOLFA: We haven't done the studies, although other people have done the studies. And we have reviewed the studies with great interest and great care. And we haven't published anything yet, but we came, I believe -- and Dan is here, so Dan can jump up if I am saying something wrong here. We have not found a basis for changing that into a food safety defect.

MS. TUCKER-FOREMAN: It just doesn't have salmonella and campylobacter in high concentrations?

MS. STOLFA: The studies that have been done don't substantiate a sufficient pathogen problem associated with ingesta to support our classifying it under the regulations.

MS. TUCKER-FOREMAN: Could we maybe get copies? I'd certainly like to have a copy of what the difference is, the amount of salmonella and other pathogens in fecal material as opposed to that in ingesta.

MS. STOLFA: We do have a Federal Register document that is winding its way through the clearance

process which has all of that information in it.

MS. TUCKER-FOREMAN: Okay.

MS. STOLFA: And that will be publicly available as fast as we can get it printed.

MS. TUCKER-FOREMAN: Fine. That's good enough. I have got one other. Over on page 4, when you say inspectors may be assigned to perform oversight inspection at any point in the slaughter process -- let's play like I'm an inspector, and I see the bird go by with obvious fecal matter on it, and the plant is not doing anything about it. Do I just let it go on by?

MR. GRASSO: Well, there a couple of things that the inspector could do. They still have the regulatory requirements that they have today. So if the belt needs to be stopped, we certainly can still do that. In addition to that, the inspectors in the plant are set up via walkie talkies, so to speak. And the oversight inspector can communicate to the IIC that something is occurring upstream that is unacceptable, and they could request an immediate verification activity.

MS. TUCKER-FOREMAN: So if I saw this one bird go

by with poop on it, I would stop -- I can radio the IIC, or I can stop the line to get that bird right then. I don't have to wait until it gets down the line, I don't have to wait for the ten-bird sampling, right there and take action.

MR. GRASSO: Well, I would like to -- you know, I would like to see the establishment have an opportunity based on what is occurring, that their control plan takes care of the defect.

MS. TUCKER-FOREMAN: How many steps down the line do I have to follow the bird waiting for the plant to do something? You know, if I saw it coming along here out of the eviscerators, say, and I notice that it is just continuing down the line, can I follow it down the line?

MR. GRASSO: As an oversight inspector?

MS. TUCKER-FOREMAN: Mm-hmm.

MR. GRASSO: Basically, the oversight inspectors have ability to move at different points of the line. But where we like to be in oversight is after the plant is performing some sort of control activity. So they perform it, and then we observe it right after that.

MS. TUCKER-FOREMAN: Where --

MS. STOLFA: We give people the same kind of guidance that we do on your HAACP, and that is we encourage people to permit the company's control system to play out.

MS. TUCKER-FOREMAN: Okay. Where is the first -- I'm sorry. Where is the first critical control point after the eviscerator?

MR. GRASSO: Each plant submits a -- could be submitting a different plan. So then --

MS. TUCKER-FOREMAN: Where is it in Guntersville?

MR. GRASSO: I'd have to go look at the plan.

MS. TUCKER-FOREMAN: Where is the one we are doing now, the Goldkist?

MR. GRASSO: Goldkist.

MS. STOLFA: Right. We don't have the HAACP plans memorized, so we can't tell you for sure. It is likely that someone will have a CCP after final wash or in that vicinity.

MS. TUCKER-FOREMAN: Well, are we going to let the poop go into the wash?

MS. STOLFA: The final wash is like an inside/outside bird washer. We're not talking about the

chill.

MS. TUCKER-FOREMAN: Okay.

MS. STOLFA: The checkpoint where we do our ten-bird check and where we do the checks for fecal contamination is after final wash and before the birds enter the chiller. I would bet there is a CCP in that vicinity. So the company would have an opportunity to carry out its control activity. And then we would take our verification samples at that point.

MS. TUCKER-FOREMAN: If I saw --

MS. STOLFA: But I want to be clear. You could stop the line for one bird. There is nothing that takes that authority away. It is not something that we encourage because we don't think that -- we don't think that that permits the plant to take its responsibility for controlling the process.

MS. TUCKER-FOREMAN: But if it passes through the final -- if it gets to the final wash, and there are ten of them in a row getting to the final wash past the CCP, then you would assume the oversight inspector would be there. He couldn't do it on one, but you would assume if he saw ten in

a row --

MS. STOLFA: There is going to be one or more verifications taken in rapid succession if that is happening. And I say, I am quite certain that we perform the verification activity at that point because that is where we check for zero.

MS. TUCKER-FOREMAN: But is somebody going to stop the first bird if the company doesn't?

MS. STOLFA: I suppose that depends on did the oversight inspector see it and notify, and did we take the verification sample fast enough. It is our intention that that would happen.

MS. TUCKER-FOREMAN: But I am saying he saw it. I just -- I want to be assured that it is not okay for birds to go by if the company is not performing its checks the way it should, if the CCP isn't making it.

MS. STOLFA: No, it is not okay. But I would expect that it would initially get noticed by the oversight inspector. And the way we would confirm it would be through a series of verification inspections.

MS. TUCKER-FOREMAN: Okay. Thank you.

MR. BILLY: Go ahead. But then we need to move on.

MS. DONLEY: On that same point, though, where I get confused is because it is one -- either the verification is a very limited sampling program that if it is spotted at one point on the line, chances are really very slim that it will be part of the ten-bird verification.

DR. WOTEKI: No. I think what Pat -- I was going to say, what Pat is saying is that when the oversight inspector sees something, one of his options is to call for an immediate verification. I see birds coming down the line that shouldn't be coming down the line. You need to do a -- don't wait till, you know, the next time you plan to do a verification check. Do one right now as those birds are hitting that station. And if you pick up nothing, look again in two minutes, look again in five minutes. So the ten-bird sampling is very flexible. There is both what our verification people schedule throughout the day. But there is also -- there is something going -- I don't like the look of what is coming down the line right now. There is too many misses.

There is, you know -- so that is what gives you the assurance that the sighting by the oversight inspector is quite likely, highly, highly likely, to be caught at verification.

MS. DONLEY: Can the oversight inspector say, hey, Mr. Plant Employee, you missed this, and say something should get done right away?

MR. STOLFA: The oversight inspector communicates with the IIC, who does most of the communicating with the plant. There is nothing that would necessarily prohibit that from happening. Again, it is sort of a question of whether or not that is the most efficient use of the oversight inspector's time. But I want to sort of reiterate what Maggie said. There is no limit on the number of verification samples. These may be ten-bird samples, but the IIC can order as many of them as he thinks are necessary.

MS. TUCKER-FOREMAN: I think that it is probably not sufficiently clear in the documentation that we have. I think the backgrounder is really good. Each time I go through it, I understand it better. But I think that

probably isn't sufficiently stated there. And since it is going to be a while before most of us get to see the plant operating with one of the models, it might be useful if you could do a mockup, a cartoon of what it would look -- what a model might look like.

MR. GRASSO: Actually, if you go back to the December public meeting, it actually had a document that depicted activities in a traditional plant today and also a mockup of a models plant, where the plant would be doing some CCBs and the activities of FSIS inspection personnel.

MS. TUCKER-FOREMAN: Is that something besides the columns that we have here?

MR. GRASSO: Yes. It was a side by side.

MS. STOLFA: It was a diagram.

MR. GRASSO: A diagram.

MS. TUCKER-FOREMAN: The diagram. But it might be useful, you know, to just keep reproducing that diagram because there are those of us who have a hard time keeping it in our heads.

MR. GRASSO: Well, I think the clear message here is that the six per shift per line is the minimum random

verification activities that it does. And there is no limit on unscheduled verifications that could have been done.

MR. BILLY: And what is interesting is that because of the shift of responsibilities, it frees our people up to do many, many more focusing on what I think are the high priorities, which is, in your example, fecal contamination. So I'd be interested to know how well it is working in Goldkist. What is your sense from the first two or three weeks?

MR. GRASSO: The reports that we are getting from Dr. Benson, that it is actually going very well. And also remember that Goldkist is taking 60 -- 30 samples every hour. So they are taking 60 samples, a 60-sample set. So they have to meet the performance standards for that 60-bird sample set. And if they don't, if they go above the maximum limit, which was the ninth position of the nine plants, then that is where the potential impact on the product occurs.

MS. TUCKER-FOREMAN: Thank you.

MR. GRASSO: I mean, you are talking about a lot of sampling that the plant is doing.

MS. TUCKER-FOREMAN: No. You helped me. Just

sometimes I have to get this repeated a lot of times.

MR. GRASSO: The next plant that would come on is Hawaii.

(Laughter)

FEMALE SPEAKER: You're taking the committee over there?

MR. GRASSO: No.

MR. BILLY: No.

MR. GRASSO: Just Carol. Not Caroline, Carol.

(Laughter)

MR. BILLY: I'm going to move on. I think we have had a good discussion. It is clear that it is real important that we continue to have dialogue with the public and share some of the earlier information as well as the new data, and we'll do that. And I would suggest that it is worthwhile to keep this item on the agenda for this committee so that at our next meeting, we will be enriched by a lot more data. Maybe we can schedule more time to focus on this project.

Okay. So now I would like to move to the afternoon agenda. And --

(Laughter)

MR. BILLY: The first item is going to be presented by Charles Edwards, and it deals with an idea that we have regarding reinforcing the food code by adopting key food safety provisions in that code as federal performance standards. And I'll turn it over to Charles to sort of introduce the idea and explain it. And then we can have a good discussion on it.

MR. EDWARDS: I'm Charles Edwards. And sitting here beside me is Dr. Dan Lazenby (phonetic). I have asked Dr. Lazenby to join me because he has been instrumentally involved in developing this idea, and I think that he can contribute considerably to the discussion that is going to follow.

Several meetings ago, I believe the committee was briefed on the food code from people from FDA. And one of the key reasons for doing that was to emphasize the importance that the food code plays in establishing food safety throughout the farm-to-table continuum. This particular issue that we are going to be discussing here is actually a mechanism to reinforce the food code by adopting

certain key food safety provisions as federal performance standards.

As you all know, a key goal of the agency is to create a seamless food safety system that uses the resources at all levels of government. And what that means is that in order to achieve that goal, the federal, state, and local agencies need to work together in order to ensure food that is safe. And we believe that the food code is one of the means that we can use to achieve that.

Over the past several years, the agency has taken a number of steps to improve its working relationship with the state, the local government, and other public health and food safety agencies, and to strengthen the federal -- not the federal, but the state inspection systems. And we have also sought to improve food safety as the food moves -- or as meat and poultry specifically moves from the inspected plant into commerce.

One way that we believe that we can improve food safety as it moves from the plant to the consumer is through state adoption of the food code, and how best to achieve this or to encourage this goal is the purpose for bringing

this issue and what we are seeking advice on.

The Association of Food and Drug Officials, or AFDO, has suggested one approach through a resolution that requested that FSIS incorporate the food code, including standards for retail meat and poultry processing into the Code of Federal Regulations in order to facilitate adoption of uniform retail standards by the states. We believe that this stems from the belief of state officials that it would be much simpler for states and local authorities to adopt the food code if it were a part of the C.F.R.

The agency has responded that it will look into that idea, and that it will consider it, and that it will discuss the issue with FDA. However, we have come to believe that it would be extremely expensive and time consuming to put the food code into the Code of Federal Regulations, not to mention the fact that it would totally be going upstream from our effort to reduce the number of pages of regulations that we have.

Therefore, the agency is not inclined to adopt this approach. But we believe that there is a better and more efficient way to use its regulations to support state

adoption of the food code.

First of all, both the meat and the poultry inspection acts give the secretary authority to prescribe by regulations the conditions under which covered meat and poultry products are going to be stored or otherwise handled after they leave the plant in order to ensure that they are not adulterated or misbranded when they reach the consumer. And the specific sections in the acts are Section 24 of the Federal Meat Inspection Act, and Section 14A of the Poultry Products Inspection Act. And I believe you have copies of those sections.

Thus, the statutes that we operate under provide FSIS with the authority to set performance standards for handling and storage in order to ensure that products remain unadulterated and not misbranded as it moves through commerce. It is not our intention to use this authority to go back to a command and control mode, however. Rather, our intention is to set performance standards that would, for example, require not exceeding a certain level of pathogen growth during transportation and storage, or provide that there be no pathogen growth during display at retail.

A more specific example might involve the performance standard that the agency published in last February's Federal Register, which addressed certain cooked meat and poultry products. This performance standard actually established the lethality that must be achieved during processing of meat and poultry and the level of pathogen growth that must not be exceeded during the stabilization or cooling process.

Our intention was not to mandate, and is not to mandate, a step-by-step procedure that establishments must follow. In contrast, corresponding sections in the food code do in fact have very prescriptive language, down to the point of mandating specific time and temperature requirements.

What we intend to do in this strategy is to work with the FDA, who has primary responsibility for the food code, and the Association of Food and Drug Officials conference on food protection to ensure that the federal performance standard and the prescriptive requirements of the food code are consistent with one another. By that we mean that they achieve the same standard of food safety.

The food code could thus become one of the ways to meet the federal performance standard, and vice versa, with appropriate changes to the language within the food code.

It is the agency intention whenever possible to set standards that can be met by adherence to the food code. And thus we believe that states would be free to adopt the food code without fear of conflicting with federal law and with full knowledge that they have had active participation through their activities on the conference for food protection.

So in summary, the FSIS strategy is to exploit this opportunity to create a complementary, seamless food safety system in which performance standards will provide a framework within which more specific requirements can be laid out through state adherence to the food code. Through this approach we hope that we would be able to bring greater consistency and coherence to the food safety system.

And specifically, we believe that it will help to establish the national food safety standard. It will help to reduce foodborne illness by reducing the retail -- or by influencing the retail segment of the farm-to-table food

safety system. It will avoid conflicting and inconsistent federal and state systems or standards. And perhaps most importantly, it will help the states and local agencies to adopt the food code.

We brought the issue to the committee with certain specific questions at least that we would like to have you address during your discussions, the first of all being what recommendations can the committee make that will help us to improve implementation of this particular strategy. And secondly, we would like to know what problems the committee anticipates if the agency goes this route. And third, we would like your input on any advice that you can give us that we should consider as a part of our discussions with FDA and the Association of Food and Drug Officials.

That basically is what the plan is.

DR. WOTEKI: Okay. Questions? Caroline?

MS. SMITH-DeWAAL: This might be over my head, but let me try to see if I understand what you are saying. I was at the AFDO meeting. And what they are trying to do is to get the federal government to put into regulation the food code, because then it makes it easier for the states to

adopt the food code as written because they can adopt it by reference. So they can just say hereby the state of Maryland adopts C.F.R. "blank." That was their goal, to facilitate state adoption of a uniform food code for use in retail, but also in restaurants.

What you are saying is you are going to bring the food code and make sure it is consistent with already existing federal statutes or federal regulations. Is that right?

MR. EDWARDS: This will be consistent with the performance standards as we continue to develop them.

MS. SMITH-DeWAAL: The performance standards for what?

MR. EDWARDS: For processed food products primarily.

MS. SMITH-DeWAAL: Okay. So you are going to make the food code consistent with your existing regulations.

MR. EDWARDS: Right. There is another piece --

MS. SMITH-DeWAAL: How does that facilitate adoption of the food code by the states?

MR. EDWARDS: There is another way to crosswalk.

If you remember, I said that it would be consistent, vice versa, or they would interchangeable, vice versa, with appropriate changes to the food code language. What we would propose is that one of the ways that the food code could be satisfied is by cross-reference to our performance standard, which could be handled through the food code's variance process.

DR. WOTEKI: But Charles, we are talking about performance standards that we do not currently have, am I right?

MR. EDWARDS: By and large, that is correct. The only example that we have of a food code that might fit into this was the one that was published last February for certain cooked products.

MS. SMITH-DeWAAL: I'm a little concerned that AFDO is up here and you're down here, and you are saying -- and we're meeting, and we're -- I mean, this isn't responding to what AFDO is trying to do. So it might be independently a good idea to make sure your standards in the food code are consistent. But that's because the two federal agencies involved, FDA and you, together with the

Conference for Food Protection, should be putting together consistent standards. That's good, but that has nothing to do with what AFDO is trying to do, which is to get a federal regulation which then the states can adopt by reference.

So I guess I don't have a problem with what you are proposing. I just -- I think it is misleading to say that it responds at all to what AFDO is proposing.

DR. WOTEKI: Katie.

MS. HANIGAN: I have a very basic question on this whole thing. Number one, at the last meeting I requested that we receive this key information in advance. I'm going to ask for that again because here we sit trying to quickly absorb a document and understand it. So I still wish we got all of the information in advance of the meeting so it could be reviewed by us.

But anyways, on this topic, if we would adopt the food code, would we still have the current situation we have in industry now, which is in our HAACP programs, where we have referenced some of the current regulations, we have been told, well, that's fine, but how do you know they are scientifically valid. If everybody -- because we are being

told some of the current USDA regs, there is no scientific documentation behind them.

So if we all adopted the food code, is it then going to be how do you know that that is scientifically valid?

MR. EDWARDS: We're not proposing to adopt the food code.

MS. HANIGAN: And I understand that. But if the performance standards that you are going to put in place are going to be built off of the food code, how are we going to know the food code is scientifically valid?

MR. EDWARDS: I don't think we're planning to build our performance standards off of the food code. Rather, we are going to establish safe food performance standards at the federal level. The intention is to work through AFDO and the FDA to ensure that the food code is adjusted wherever necessary in order to meet those food safety performance standards.

MS. TUCKER-FOREMAN: Well, why are we not putting it into the Code of Federal Regulations, which is what AFDO requested?

MR. EDWARDS: One of the principal reasons, I believe, is simply the volume and the magnitude of that task. We would be going totally contrary to where we are intending to go in reducing federal regulations. And secondly, if we were to adopt the food code, then we would have the same problem that the people at the states now have or that the food code now has in trying to keep track of changes in the food code's regulation or requirements.

MR. JAN: I think that I would still rethink the not just going to the federal regulation or C.F.R. with the food code. You know, I understand that you want to reduce the volume and all that kind of stuff. But if you don't, then each state has to adopt it as a regulation, then enforce it. And the food code, I think, is pretty good document. And I use Texas for an example. I think it took them a year to change the food code into regulations. Most of it is verbatim, but there are some -- and it always gives you the opportunity to try to improve the language or to make it fit your hand a little, or get a better glove, maybe. So all that is going to take a little time.

And also, the process. Now, they adopted -- or

the department of health adopted that probably about a year ago, not more than a year ago. By next year, there is going to be a lot of changes. So they have got to go through this process again. And if every state has to do that, you are going to have a conglomeration, even though maybe everybody is trying to do it the same, but at different times and different time period. And if the food code can be with a federal regulation, or adopted in the federal regulations, it could be created off the food code. And when changes are made, they are made by one agency, and then each state could adopt by reference as amended.

And so as the food code is amended -- just like the federal regulations, as they are amended, we just fall right in, and we don't have to go to our boards or our legislatures to make those changes.

So it seems to me in consistency and trying to get the states all together on the same page, is that page could be kept up by the federal agency, which is a good role for them, I think. Then we could all read off that same page.

MR. EDWARDS: One of the considerations that we have is in addition to trying to have the standards the

same, but to get included in the food code the specific citation of our performance standards, thereby a state would not have to change the food code every time we changed our performance standard.

MS. MUCKLOW: Charles, I'm struggling to try to understand this. And it was pointed out to me yesterday I'm not a scientist, but a political scientist, and that is true. And so I am trying to bring my measure of politics to understanding what little knowledge I have of science here. Could you give us an example, maybe using one of the performance standards that we have had for quite awhile, for instance, cooking of roast beef? And some retailers cook roast beef, and a lot of restaurants cook roast beef.

Tell us in a simple, pragmatic manner how it is going to work using the principles you have laid out, because I don't understand this hodgepodge. I need to hear it in nice, simple stuff, from you and Dan.

MR. EDWARDS: Well, let me give it try, and Dan can help me, certainly. The performance standard that Rosemary is referring to changed our prescriptive time temperature tables in the meat inspection regulations to a

performance standard that basically said that during processing, cooked beef products have to achieve a lethality of six and a half logs of salmonella, and that during stabilization or the cooling process, that there could be no more than a one-log growth of Clostridium perfringens. I am correct? Okay. I'm not a microbiologist.

MS. MUCKLOW: You have got a star so far.

MR. EDWARDS: The food code, on the other hand, still contains specific time temperature requirements. It says that if you cook to a particular temperature, you must cook that product for a particular amount of time in order to achieve a certain level of safety. Right now, the lethality requirements that we have, and those that are reflected by the time/temperature tables in the food code, are close, but we are not certain that they are absolutely identical. Both are safe, but that isn't the question. But we believe that the food code might be based on a seven log lethality as opposed to the six and a half that our data shows is adequate.

MS. MUCKLOW: Given the lack of very specific controls such as we have in large commercial cooking

operations, that is probably a good margin.

MR. EDWARDS: Right. What we have provided as a part of our performance standard, what we call compliance guidelines, these are guidance documents as opposed to specific requirements. These are documents that our scientists have shown will achieve -- or processes that our scientists have shown will achieve the desired or required lethality. They do include time/temperature tables.

What we would propose is that the time/temperature tables in the food code in this particular example, or the time temperature tables that we have adopted in our compliance guidelines could both be used by state local authorities or retailers in order to satisfy the requirements of our performance standard.

The food code has different requirements from what our performance standard requires. What we would propose would be to change the food code relatively simply by cross-referencing the specific section in our regulations that includes our performance standard, giving the industry or retailers the option to either use the food -- to comply with the food code by using the time/temperature

requirements that are in the food code, or by seeking a variance which would allow them to continue to produce a safe product, but comply with our performance standard regulation, which would give them more latitude.

Is that any clearer?

MS. SMITH-DeWAAL: Rosemary, let me give you some examples of some other performance standards. The food code contains performance standards for restaurants in their cooking of certain high-hazard food products. For example, hamburger is supposed to be cooked, and there are some parameters, but the one we looked at was 155 degrees. In 1996, CSPI surveyed 45 state and local and county jurisdictions that inspect restaurants. And three years after the Jack in the Box outbreak, only two-thirds of these jurisdictions enforced the minimum cooking standard for hamburger that was necessary to get rid of E. coli 015787.

But the story doesn't end there. We looked at cooking standards for chicken, pork, fish, and eggs. And with the exception of chicken, only about one-third of the jurisdictions met minimum cooking standards for these high-hazard products. Chicken was the only one where about 80

percent of the jurisdictions met the food code recommendation.

The problem here is that the food code is a series of guidelines to the states. The states independently adopt these guidelines. If the state -- if the restaurants or retail outlets are inspected by a city or county instead of a state, then that city or county also has to adopt it. So it is -- what the AFDO, which is the people who have to enforce this document, is asking for is a federal regulation that they can use to inspect restaurants, retail outlets, grocery stores, nursing homes, schools. I mean, this is a very important document.

My concern -- I think it is just --

MS. MUCKLOW: Well, haven't you just made the argument for what he wants?

MS. SMITH-DeWAAL: No. What he wants to do is to take a very narrow group of regulations, one that they already have, and to apply -- and to make sure the food code is consistent with FSIS regulations. Well, sure, that's fine. But it doesn't respond to what AFDO is trying to do.

DR. WOTEKI: I think there is a misunderstanding

because the idea is -- and that's why you have this piece of of --

MS. SMITH-DeWAAL: I see it.

DR. WOTEKI: -- legislation. I think the agency's thought at this point -- and, you know, we are bringing this forward as a paper because obviously we are in early stages of thinking this -- is to promulgate food safety performance standards for the handling of meat and poultry products throughout the system.

MS. SMITH-DeWAAL: Okay. That's not clear because all he said is transportation display and one other point. He has never mentioned restaurants or cooking temperatures.

DR. WOTEKI: And to make those performance standards so that a business or a state or a local that is following the food code would meet the performance standards.

MS. SMITH-DeWAAL: But the problem is that they are not all adopting the food code, or they are not adopting the standards. So the assumption you are making is, well, if you are following the food code, then you'll by reference be following our regulations. But that doesn't address the

problem.

DR. WOTEKI: Dan.

MS. SMITH-DeWAAL: As I understand it.

DR. WOTEKI: I'm sorry. I didn't mean to cut you off. I thought you were pausing.

MS. SMITH-DeWAAL: I'll -- I want to hear what Dan has to say.

MR. LaFONTAINE: As the chairman of this subcommittee --

(Laughter)

MR. LaFONTAINE: -- I have the task tonight to address the issue. Not me only, but our subcommittee. And the way I plan on approaching it once we have had a discussion with the subcommittee, is to take the issue at hand, which is what I call standardizing the requirements between FSIS and FDA as far as performance standards -- well, standardizing the FSIS and FDA standards for the proper safe processing of meat and poultry products. And we are not addressing how to get the food code enacted by all of the states.

I'm not saying that is not important. But,

Caroline, what I am saying, that is the issue they presented us with. One of the things that has bothered me and others is the inconsistencies between USDA and FDA as far as meat and poultry products as they go through the chain. So I probably made it a little bit too narrow, but that's the way I see the topic being presented.

MS. SMITH-DeWAAL: May I just note, though, that I think Rosemary has actually made a very good point here. Part of the inconsistency is because we are dealing with different audiences. And the food code audience is frontline retail, restaurant, and people who might be right out of high school and learning how to cook a hamburger. And those people might need very specific direction, as opposed to people who are doing commercially roasting ground beef -- or roast beef, where they may have much more scientific background.

So in looking at that -- I mean, I have sat through the National Advisory Committee for Micro debates on this. I see Dan over there, and I remember him during that debate. And we're dealing with very different audiences. And you can define the issue as narrowly as you want to.

I'm just interested that, having been to the AFDO meeting and hearing what they want, that this is kind of what the feds are coming back with, because simply saying it is too long to adopt the food code doesn't satisfy me.

The states are begging the federal government to give them uniform standards. The industry, NFPA, has asked for uniform standards for food safety. And you can't do it because the reg is too long.

DR. WOTEKI: Dan.

MR. LaFONTAINE: One additional comment. I think in the deliberations this evening, in addition to looking at the performance standards, we will give due consideration to what I call safe harbors, that is, some prescriptive times and temperatures that can be used by the relatively uneducated individual, whether it be in a retail store, a restaurant, or a very small meat processor because they don't have the technical knowledge or interest -- not interest, but technical knowledge or expertise to decide for what a five-log reduction is, or seven-log. They have to have some baseline they can live with.

So I don't want to preempt what we'll come back

with. But I think that -- I'm pretty sure that will be part of our recommendation once we have discussed it.

DR. WOTEKI: I think that is very much -- that would be very helpful to the agency because one of the premises that we were working on in this is that the federal government's role is more effective as a setter of standards than as a designer of very specific -- what we have called traditionally command and control requirements for businesses. And that is really where part of the basis for this particular approach.

Rosemary, did you have --

MS. MUCKLOW: Yeah. Charles has clarified this for me. And, you know, when you talk about performance standards, even I forget how many we have. The roast beef one was one of our early ones. And I think it is very helpful to think along the lines that Charles described that to us as a vehicle to get consistency for meat and poultry products, and whether it is for cooked chicken or whatever, plus the support material that goes along with that regulatory requirement to guide those who can't judge the lethality or whatever those other complicated terms are.

Finally, I was going to say I looked up the committee membership because if Caroline had been a member of Dan's committee, I would have been out selling tickets for people to go to it.

(Laughter)

MR. LaFONTAINE: She'll be there sooner or later.

MS. SMITH-DeWAAL: I'll see you tomorrow morning.

MS. MUCKLOW: And thank you, Charles. That clarified it for me, and hopefully to my people.

DR. WOTEKI: Are there other questions or comments at this time that will inform the work of the committee and tomorrow's followup?

MR. BILLY: Okay. The next agenda issue is regulatory reform. And Dan Engeljohn is going to lead the discussion on this. There is a handout that is being provided and he will lead us through that and explain the agency's interest in this area, what we're doing, and again lay the groundwork for your advice. So, Dan.

MR. ENGELJOHN: Thank you, Tom. Good afternoon. I am Dan Engeljohn. I'm the director of the regulations, development, and analysis division within FSIS. It is my

office that is responsible for putting together the regulations, as well as the FSIS instructions to the employees for how they should do their tasks on a day-to-day basis.

I believe in your report books, under tab No. 8, you should have a summary of the regulatory reform efforts that have been underway at USDA that came out a few weeks ago in response to the sanitation rule which issued as a final regulation. Because the sanitation rule was in fact one of our major regulatory reform initiatives, at that time we decided to put together a background to summarize some of the issues. There are a couple of points I want to provide to you today for you to think about, and then certainly it would provide opportunity for this evening's discussion.

I first wanted to go through the process of what it takes to get a regulation through the system. For those of you who do not know, I think it is important to understand that there is a process, and it is calculated to be one in which all sides of the debate related to a regulation are accounted for and the cost benefits are also documented related to a regulatory initiative.

FSIS started the process back in 1985 with its regulatory reform in the process of -- in the form of a regulatory agenda, which we published in December of 1995. And in that, we made clear that it was our goal to remove burdensome and obsolete regulations, as well as to move into the direction of setting standards in the form of performance standards that define a level of safety that could be measured in the processing of products, whether it be raw or ready-to-eat.

We also had the goal of reforming our regulations so that they accommodated for the benefits that would be derived from HAACP in that there needs to be innovation in the way products are processed if in fact they need to be made safer. And many of our regulations prohibit, and in fact inhibit, the way that you process a product, simply because we have in fact defined how you have to make a product, as opposed to what the level of safety should be. And so our goal has been, with that in mind, of establishing performance standards.

I would say we have a number of standards that are out there. First, through the HAACP pathogen reduction

regulation, we issued microbiological based standards for the raw products. These related primarily to the slaughter floor in that we established levels for salmonella as well as some ground products. We also issued a final regulation on cooked roast beef and cooked poultry that Charles and Dan talked about in the previous discussion, which in fact defined the level of safety that is necessary for roast beef. And with that regulation, it defined what was to be achieved in the processing and allowed for the opportunity to innovate.

The agency also has made a commitment to provide compliance guidelines to the industry, in particular very small business, so that if they do not have the resources to redesign their systems to meet the performance standard, then we would still provide them with the how-to. And that would be something that they then could incorporate into their HAACP plan and modify if need be, but at least we would provide them with information as to how they can meet the standard. And again, the effort was to get rid of those prescriptive standards in the regulations themselves because it is difficult to change a regulation. It takes a number

of years for the most part, whereas we can modify the compliance guides as science becomes available to us, and we can incorporate them.

I would like to say that we have focused on microbiological standards. But in the handout that you should have just received, there is one in there that deals with a chemical hazard that we are going to start moving into in terms of how we look at our regulations. And I'd like to start off then -- we have gone through the regulatory process. This past year, we have had a major effort underway within FSIS in which we are in fact relooking at how we develop our regulations.

Before, we used to have concepts of where we wanted to go, we wrote the regulations, and then we justified the economic cost benefits once we developed the regulation, and then put that through the clearance process. The system has changed, mainly through the Reorganization Act of 1994, in which the department created the office of risk assessment and cost benefit analysis. With that, we now are obligated to provide an additional risk assessment for rules that are designated as economically significant,

meaning that they have an effect on the economy of $100 million or more, and then affect health, and that could be health in any way.

If a rule meets those criteria, we may have an additional burden of developing a risk assessment that is reviewed within the department before it can be issued. For the most part, most of FSIS' regulations end up being significant. Again, a significant rule can mean that it has $100 million affect on the economy, but it also may be a regulation that is deemed by OMB to be novel or in fact something that is new that is a new approach that may in fact set new precedents. And for the most part, OMB designates our regulations as at least significant.

The process that we go through in terms of developing a regulation is first to identify a need. That need may be identified through the petition process, which many of you are familiar with. It is also something that we are in fact reassessing and making more transparent as to what we expect in terms of petitions that come into the agency and how we handle them once they get to us.

But petitions are also handled by my office. We

receive them, and then we evaluate them as to whether or not there is merit. If there is merit, then obviously we would proceed with developing a docket committee that would formulate what that regulation would look like.

The work plan that we have to put together as a first step identifies what it is that we want to do and why we want to do it. And then as an additional feature, we have to identify alternatives that are considered in terms of the rulemaking activity. So we identify a number of those alternatives, and then the more important part to this is to establish the economic effects that the regulation may have. And we would do that for all of the alternatives that are identified.

That work plan then gets signed off on within the agency, and then it goes to the department, the office of budget and planning analysis. We make an initial recommendation as to whether or not the rule is not significant, significant, or economically significant. Once the department agrees with the designation that is there, it gets forwarded to the Undersecretary for Food Safety. That would be Dr. Cathy Woteki.

Once Cathy signs that rule, it becomes official agency work, and at that point, we would include it in the regulatory agenda that comes out twice a year. After it is approved tentatively by Dr. Woteki, it then gets forwarded to OMB, and OMB makes the final designation. And they can either agree with what we have put forward, or they can change it. But they become the ultimate say. And as I mentioned earlier, most every one of our regulations tends to be designated as significant.

What that means to you is that once it is developed by the agency and then goes into the legal review, the next step, if it is a significant rule or economically significant rule, is that it goes into the department for a review. There are approximately nine offices that it goes into within the department. And we -- based on past experience, we know that it is rare that any rule would make it through the department in under two months. So it is at least two months within the department, if it is in that particular designation.

Once it clears the department, then it would go to OMB. They have up to 90 days to look at it. So it is an

additional three months. So to develop a regulation as a proposal, if it is designated significant or economically significant, it takes a minimum of five months once it has cleared the agency. So that should give you an idea of how the process works. We go through that same process once the regulation has been put out for comment. We look at the comments. We then go through that same process for the final rule.

Now I provided you a listing of the regulatory reform initiatives that we had underway. Many of them are identified in the handout that you previously received. But I want to point out a few of them that have some major significance in terms of changing how we actually regulate meat and poultry.

The first has to do with our proposed rule on food and color additives. This was something that was issued back in December of 1995. It also has enormous significance in the sense that once FDA approves a food additive, our policy at the moment is that we also have to go through the process of adding that additive in our food additive table. That process takes a number of years for the most part.

But what this proposed rule would do would be to remove the necessity for FSIS to issue a separate rulemaking so that once FDA issues their findings on a food additive, it automatically can be incorporated into meat and poultry because we have a process worked out in which FSIS would review the petition that FDA is working on as part of their mission and their rule.

Next we go into the animation of a number or prior approval programs related to the equipment and to facilities and blueprints, some related to labeling, others related to partial quality-control programs. It has been a major effort by the agency to remove the agency's requirement of having to review programs that the industry develops prior to them being implemented. Because now we are establishing the standards that have to be met, we believe that it is better served to have industry identifying how they are in fact meeting the standards, as opposed to FSIS sanctioning something without actually being in-plant to review how it is working.

The final regulation on sanitation issued in October of this year goes into effect in January. And it

establishes performance standards for the general sanitation within an operating facility. It does not have specific microbiological controls, as does the performance standard reduction criteria that we have for salmonella on carcasses. But it does identify what has to be met to prevent insanitary conditions within a facility.

The one rule that we are still waiting to issue would be our final rule on rules of practice. And we do expect that to come out yet this year.

Moving on into the issue of what is planned, we have a desire to issue performance standards for all ready-to-eat products, which is something that we have tried over a number of years to issue individual regulations for fermented sausages, for example, but have not been to do so in terms of the old way that we issued regulations. So our effort underway at the moment is to issue a performance standard reg that would supersede the roast beef and cooked poultry rule that came out recently and incorporate that into an overriding performance standard reg that would deal with all not shelf stable products -- that would be the perishable ones that need to be kept refrigerated or frozen

-- all shelf stable products, such as fermented sausages or country cured hams, and then the commercially sterile products.

That would be one regulation. It is designated as economically significant. And we are developing it. The rule itself has been developed. The support is fairly well complete. The one piece of it that is not complete at the moment is a better description of the economic impact. And that is what we are working on now to finalize.

The next one deals with the performance standards for bacon. And this is the one that I wanted to talk about that does not necessarily deal with a microbiological standard. This deals with a chemical standard for nitrosamines. The agency currently has a regulation on the books that requires the agency to test bacon. This rule would remove the agency's prior approval for that, but would identify performance standards both for -- our expectation is that it would identify a performance standard for nitrosamine as well as for Clostridium botulinum.

I have mentioned here that we have the HAACP inspection models project as a performance standard

regulation that we would expect to issue yet this year. It deals with antemortem and postmortem inspection. There are a number of issues related to antemortem inspection that will not be covered in that particular proposal. But the agency certainly has a number of those items that need to come forward in separate rulemakings. So we are looking into additional antemortem/postmortem inspection regulation. But first we'll deal with the models project performance standard.

The one I think is of considerable interest to this committee relates to handling and transportation. This is one in which we issued an AMPR back in 1996. It is our intention to issue a performance standard rule that would deal with the handling and transportation of meat and poultry products once they leave an official establishment and move into commerce, into warehouses, and on their way into retail. And I'll talk a little bit -- I think we will talk about that in this evening's discussion.

But it is directly related to the next performance standard I have listed there, for the chilling of meat and poultry products. And what this relates to is that we have

existing criteria for poultry which says how quickly you have to chill down the poultry carcass. We do not have a similar type of criteria for livestock product. Our intention is to issue a performance standard that limits the growth of microorganisms on livestock as well as poultry, and then tie that standard to the handling and transportation standard, such that once the animal has been slaughtered and eviscerated, from the moment that it begins the chilling process until it arrives and is inspected throughout that time period through its shelf life, the performance standard would be applicable. So we see this as one way to get into the retail handling and storage of product once it leaves an official establishment.

That one in particular is dependent upon some research that the Agriculture Research Service is in fact doing to help supplement the modeling programs that ARS has developed for the growth of pathogens on meat or poultry products. So we have a bit more information to collect on that. We had expected that data to be available by the end of this December. It is still being worked on, but we do intend to move forward with both of those performance

standards rules yet this year, and in fact hope to have them issued by the summer.

We have our egg HAACP rule, which will take the existing egg regulations and put them into the form of HAACP regulations, as well as establish sanitary SOPs for the operation of an egg-processing plant. This would characterize the pasteurization requirements for egg products, as well as the storage and handling of that product after it has been made ready-to-eat.

We also have issues related to the grant of inspection and retail exemptions which are on the books to be evaluated. And we certainly know that we need to do some work in that area. And we have concepts together on how we want to proceed with that.

The questions that I have posed to the committee in terms of helping us relate to how best we can move forward. And first, we are looking for recommendations from this committee and how we can improve the chances of success with the approaches that we're taking with regards to performance standards for ready-to-eat products. And then the next step would be for the not ready-to-eat products.

The second question would be does the committee have additional suggestions for what the agency can do in terms of developing regulatory reform.

And then finally the one area where we have a severe lack of information that hinders our regulatory development process, and that is economic data, data that relates to the cost benefits for regulations that we are going to issue. This touches on the fact that a regulation related to health within the department for the most part should be considered to be economically significant. That is where we start the process in terms of how we look at it, which means we have to weigh the costs and the benefits of a regulation and all of the alternatives that would be considered. The agency has access to very little data related to what it costs industry to make a change in the way that they produce products, as well as the effects and the benefits that the consumer would derive from its regulations.

And so the one area where we do know that we need additional information relates to the cost benefits associated with the regulation. We have invested a great

deal of time looking into databases that potentially can provide us some of that information. But again, it is difficult to get real data. And so we certainly can characterize what kind of data needs that we have. But when we ask for data from a group of individuals, if it involves nine or more individuals, it creates a paperwork requirement that we have to get approval from OMB.

And so we have -- in addition to needing data, if we ask the question, it becomes one in which we also have to go through the rulemaking process to gather that data. And so I'm certainly open to ideas on how we can generate information that would support the quick development of regulatory initiatives. Thank you.

MR. BILLY: Rosemary.

MS. MUCKLOW: Dan, I'd like to clarify -- most people may have caught on to this, but again I'm a slow learner. And that is that when you talk about this year, you mean this fiscal year. Most of us are talking about the year ending on December. The year you are talking about ends next September. When you say you are going to do it this year, you mean your federal fiscal year.

MR. ENGELJOHN: I'm sorry, Rosemary. I probably wasn't thinking clearly when I said what I said. What I meant when I said this year would be by December --

MS. MUCKLOW: Oh, really?

MR. ENGELJOHN: -- 31, 1999.

MS. MUCKLOW: Oh, you are going to work terribly hard then.

MR. ENGELJOHN: Well, no. If there is something that I -- if I promised something this year, and you think I meant September, I'd be glad to know which ones those are. I did put some dates on there.

(Laughter)

MS. MUCKLOW: September 2010.

MR. ENGELJOHN: Well, again, there is a great burden in terms of putting together these regulations. I believe that we have gone the -- made the extra effort of identifying why we need these regulations, again through the work plan process. Part of it is it is just the burden of getting the regulation through the system. But for the final rules that we have in place that I expect to in fact move fairly quickly would be our food additives rule, our

rules of practice.

MR. BILLY: Irradiation.

MR. ENGELJOHN: Irradiation I did not include on here because I didn't put it as one of the regulatory reform initiatives. But it certainly is one that we have as a high priority, and we would expect it to issue yet this calendar year, 1999.

MS. MUCKLOW: When you talk about chilling your meat and poultry, I would remind you when the megaregs were proposed, that was an issue of enormous heated discussion about the ability of the agency to figure out how quickly the depth that the round could chill without going sour and so on. If you truly are going to go back and look at that issue, I would suggest that you somehow go out and get a lot of information from the practical industry, not just from the ARS, about chilling your carcasses because my memory of Mike Tinger (phonetic) was he loved to bombard on that issue.

And so if that will help guide you on that, don't instantly run into buzzsaws because it is a very complicated issue. And I see Gary nodding his head. And we are going

to end up with an awful lot of sour rounds, the way they proposed the ideas in the proposal on the megareg, and it got lost in the shuffle. So I would strongly recommend that you engage the industry in that issue long before you put anything out in the Federal Register.

MR. ENGELJOHN: I appreciate that, Rosemary. We do certainly have a concept in mind of where we wanted to go. I would say that it is not directly related to food safety. Obviously, we have other criteria that the agency has responsibility in terms of its statutory authority. The issue becomes one of which -- as I see it, one in which we can identify situations in which product is abused. And that is truly where I think we need to go with maintaining a criteria for product within the official establishment, as well as throughout the transportation and handling chain.

I would point out that if we were to issue a regulation that significantly changes or requires the industry to significantly change what they are doing today, that then affects the cost of implementing a rule. Of course, if we can identify the benefits associated with that, that then has one means of countering that.

But I think we have come up with some concepts that, as quickly as we are able to share that, I would like to ensure that we have that dialogue open, and that we work on that ahead of time. I'm well aware of the debate that went forward in the previous HAACP proposal. I think we are going to take from that information that we gained and build from that. And I do think that we can come up with a standard that in fact will ensure that product is not abused throughout the handling and transportation chain.

MS. MUCKLOW: I noted the problem on the transportation. It was the next one down, the chilling of meat and poultry, that I had the concern about because that will vary substantially all kinds of different reasons. And that was what really got a firestorm going.

MR. ENGELJOHN: Certainly.

MS. MUCKLOW: But I like to work with the agency, contrary to some notions around, that, you know, we really have a vested interest because we are all after the same goal.

MR. ENGELJOHN: Certainly. And if I could just make one other point on there, which relates to the

discussion earlier by Charles and Dan about performance standards in the food code. The food code does have a 41-degree requirement for entry of products into those establishments. And it is our intent to fully account for that requirement in the benefits that that 41-degree requirement has and account for that in terms of this standard because, again, it is our goal, as was pointed out earlier, that we want to make sure that the standards we establish for meat and poultry are applicable throughout all of the distribution chain, which would include retail, and that it is contained within the food code. So we certainly are taking that into account as well.

MR. BILLY: Caroline.

MS. SMITH-DeWAAL: Thank you. So I just want to be clear. Under this future regulatory reform, you are going to get all of that done by the end of the year?

MR. ENGELJOHN: Much of that has been fully developed and is in the process of either being reviewed or is in the final stages of going into the clearance process. So that's why for me the future had the limitation of December 2000 of being issued. So that is what I expect to

accomplish this beginning January of this next year.

MS. SMITH-DeWAAL: Okay. And when you said performance standards for all ready-to-eat meat and poultry, maybe you explained this, but what are we -- what pathogens are we talking about.

MR. ENGELJOHN: What we are talking about here is, as you probably well know, we actually have regulatory requirements only for cooked meat patties, cooked roast beef, and cooked poultry. Those are the only ones that we actually have regulatory, defined criteria for the safety of those ready-to-eat products. We just converted roast beef and cooked poultry into a performance standard. We did not change the cooked meat patty regulation.

But what this would do would be to address those products, as well as all of the fermented sausage products, which count as the shelf stable ones for the most part, all the country-cured ham products, which count as shelf stable, all the soups, all the canned products. Everything that we regulate in the form of meat or poultry as a ready-to-eat product would be covered by these.

MS. SMITH-DeWAAL: What about hotdogs?

MR. ENGELJOHN: Hotdogs are covered here. And just to give you an idea of how we develop a performance standard, the first thing that we did in the previous rule -- and again, we learned a great deal from that rulemaking. We began -- we issued a proposal in May of 1996, I believe. And it took us until January of 1999 to issue that as a final reg. So that was something we felt very strongly about, and it was an example of how we can convert existing regulations into performance standards.

So that, we thought, was going to be easy. All of these other products, we don't currently have regulations for. But we believe that we have identified, categorized them into definable groups, shelf stable, not shelf stable, commercially sterile. We have identified within those groups the differences that may need to be addressed in terms of target organisms. We know that the acidified fermented sausages have, or tend to favor, E. coli 015787. In the process of defining how we would come up with a performance standard, we deal with the issue of which pathogens are there in highest numbers, which pathogens are there and are hardest to kill through any type of lethality,

which ones are more virulent. And that's how we start the process.

And so in terms of -- as an example, for the shelf stable category, we would have those that are treated by heat primarily or by drying, those that are treated in one category, subcategory, those that are treated by fermentation in another category because we believe it affects the target organisms differently, and then those that are treated with salt. And so we take all those into account, and would likely have individual performance standards for each of those subcategories based on the target organism.

Now due to the discussions you had earlier today about listeria, I would point out that in the rule that we just issued on performance standards for roast beef and cooked poultry, at that time we didn't have a great deal of information on listeria. But we do know that it is generally harder to kill than is salmonella. So what we have done and will do in this next proposed rulemaking, we'll deal with the issue of the target pathogens. I can tell you that listeria is one that we are very concerned

about. We are interested in establishing a standard that addresses the product throughout its expected shelf life, not just during the time that it is in a federal establishment.

I think this would take care of part of the issue of how long that product sits in a grocery store and is safe. And so our expectation is that that standard would have to cover that product throughout the maximum shelf life that the manufacturer would expect it to take. So that would take care of any potential grow-out that would be there. And so that is the process that we would go through. Because it is a proposed rule, you would have the opportunity to comment on that.

MS. SMITH-DeWAAL: One final question. I remember a meeting back in 1995 where we talked to the agency about the fact that we -- that we had evidence from a letter from the department signed by an official in the department that there was no requirement for refrigeration of meat products during transportation. I see here handling and transportation. I assume that that rulemaking is in part to address that. Is that accurate still today, that there is

no standards? We're still waiting for this regulation to come out to put a refrigeration requirement on red meat products?

MR. ENGELJOHN: That's true. We do not have a regulatory requirement for red meat product. This standard is intended to address that.

MS. MUCKLOW: Dan, we're already kind of well down the road to a performance standard on hotdogs in the sausage regulations. Now I realize that that takes us through a kill step in the production of that product. It doesn't take it to the next step through packaging. But would you agree that the regulation you already have on the books is better than a halfway house to a performance standard for cooked sausage?

MR. ENGELJOHN: If I could point out, Rosemary, on hotdogs, as an example, we do have a standard of identity for hotdogs. But we do not have any regulatory requirements for how that product should be cooked, to what temperature or to what time. That is one of the reasons why the agency has taken on the initiative for which we as the federal government believe that we need to do is establish minimum

food safety standards. And by that, I would mean that we would define what level of safety is necessary to produce those products.

Right now, we simply have an adulteration standard. It is a ready-to-eat product. It is expected to have any pathogens on it at the time that it is consumed, whether it be consumed raw or cooked.

MS. MUCKLOW: I thought that we had a standard on that. And maybe I'm confusing it with trichina kill. But I thought we had a heat standard on both sausage and hams to make sure that we had killed -- we reached a certain temperature that would be more than adequate to deal with trichina and to make it a ready-to-eat acceptable product.

MR. ENGELJOHN: The regulations that we have on the books is, as you mentioned, our regulations on trichina. Those regulations are inadequate to deal with the pathogens such as salmonella or listeria. Trichina is more easily killed than are any of the other enteric pathogens.

MR. BILLY: Collette, last question, and then we have got to move on.

MS. SCHULTZ-KASTER: If you divide this page up

into the sections that you have, and you look at the sections of most of the regs that have been recently enacted, for example, elimination of PQC in equipment and facility prior approval, the more recent one on elimination of sanitation, that's meeting the objective of simplifying and incorporating HAACP. Then you look in Section 2, and we are going to add a reg for chilling of meat and poultry -- go back, I assume, to the kind of curves you were talking about in the megareg proposal, and add a reg associated with antemortem and postmortem.

So aren't we kind of philosophically at odds with the two approaches, where on one hand we are simplifying and incorporating more of that into a hazard analysis approach. But on the other hand, we are going back and saying you have to do chilling in this manner or an antemortem inspection in a prescribed manner?

MR. ENGELJOHN: In actuality, related to antemortem and postmortem inspection, we have some of the most complicated regulations in that particular section of the reg that we have not touched yet, we haven't even begun to look at in terms of making clear what the criterion is.

At the moment, we specify disease condition by disease condition, as opposed to specifying that we don't want diseased animals to come into the federal establishment in the first place. So I think there are better ways that we can write that.

In terms of our goal of making more clear the regulatory requirements, we still have an enormous number of regs that are in place that specify how to do something as opposed to here is the objective that you have to meet. The performance standards do not add a great deal of detail into the regulations, but they define what it is you have to meet. And that, I think, is something that is severely lacking, particularly within the ready-to-eat industry because at the moment, we have just previous policies or good manufacturing practices that have been followed, but they don't necessarily address the level of lethality that we would believe to be necessary.

So I think that we're still consistent in the sense that we are removing those that are obsolete or burdensome, but we are defining the standards that need to be met. And I don't see those two things at odds.

MR. BILLY: Okay. I am going to move us on. And I'd like to beg the committee's indulgence and do the next item, which I am told won't take very long, before we break for coffee, and that is the HAACP systems in depth verification review. This discussion will be led by Pat Stolfa and Judy Riggins. And, Pat, the floor is yours.

MS. STOLFA: Thank you, Tom. Tab 9 -- in addition, I brought one extra page today, which I think Mike is passing out to put some context on this particular document. What we are putting in front of you now is a series of questionnaires or checklists that we believe should form the basis for an in-depth review of an establish SSOP and/or HAACP system. And the reason I put this page together was to remind you that we have some tools that we now regularly use to make judgments about these systems.

The simplest one is the basic compliance checklist. That is probably the first one that an establishment encounters, and that is actually -- it focuses on the HAACP plan. It is a relatively cursory review to determine that all of the pieces are there. And it just goes right through the regulatory requirements in part 417,

and it says you have this, you have this, you have this. When inspection program personnel use that, they are not asked to make significant judgments about how good it is. Is it there? Did they sign the HAACP plan? Are there CCPs and critical limits. But that is the basic compliance checklist.

The other thing that we presently use to evaluate HAACP systems are the basic 01 and 02 procedures that inspectors follow as they look a the system. The 01 procedure, as you know, looks at an element of the system. The 02 procedure follows a lot throughout the entire process. So these two things are already in place.

What we didn't have, and what this series of checklists is designed to fulfill, we didn't have an instrumental -- a set of instruments to conduct a detailed, careful review of a company's SSOP and HAACP systems. And so that is what these checklists are about. And when I was thinking about this, I just spent a lot of time sort of thinking about how we should do this.

But we believe that when there is such an in-depth review called for, that it is important for the people

conducting the review to have two different standards in their head. They have to have a regulatory standard. That is what the companies have to meet the requirements of 416 and 417. But in addition, if we do a really good job of this, people conducting these reviews also need to have scientific and technical concepts in their heads that inform and give more detail and more insight about what is expected.

And so it was pretty easy to do the regulatory standard, you know. We just take the regulatory references out of our regulations. But then when I thought about, well, what is the best way to define the technical or scientific standard, it seemed to me that the best thing that we have right now -- this might not be the only thing -- is the micro committee's '97 paper. And the people performing these reviews, in addition to knowing the regulations, need to be familiar with and able to make judgments based on the concepts that are included in that '97 paper.

Now there may be other documents. I was thinking maybe that the -- you know, I could put the codex references

in there as another way of defining technical measures of adequacy. But I'm not sure that the codex document in fact adds a whole lot to the micro committee paper. It is probably more likely that as experience with HAACP grows, the published peer review literature will yield more specific articles that would become appropriate references that people who are performing these reviews should be familiar with and should be able to manipulate as they are making these judgments.

Now this series of questionnaires -- and I can't remember, there is maybe ten all together because we divided them up. These series of questionnaires are all divided into two parts. The first part is always a documents review. We believe that HAACP and SSOP are systems that are necessarily supported by documents, and that there are not only regulatory requirements for documents, but there are also -- it is clear if you read the scientific and technical literature that there is an expectation that documentation is an underpinning of SSOP and HAACP systems, so that part A on any one of these questionnaires is always about documents and documents only.

You can perform a documents review. Just get a pile of papers in a room and you go through them, and you look at the questions, and you find out if they are there. Part B in each questionnaire is always a system review. It always requires that you be out in the establishment looking at what is happening, what is going on within the system, what are they doing. Are they doing what they said they were going to do? Are they meeting the kinds of expectations that when you read the micro committee paper about this subject, is this the picture you get in your mind of what should be going on.

So that part B is always a systems review. It always anticipates that people performing this kind of verification activity would have access to the plant at a time that the plant is working its system. You can't do this, part B, without seeing the system in operation.

Now I will say that the way the references work in this particular document, the regulatory standards are real easy. You just go back to the regulation and you look up that section, and you read it. That is what we're looking for. The technical measure of adequacy is a little

cumbersome in this version because I had to use just a Xerox copy of the '97 paper. But now I have a reprint, so I'll convert the references from this bulky Xerox copy into the appropriate pages in the published article. And what it means is that before someone goes out and performs their review regarding the technical aspects of an SSOP, it is our expectation that the person will be familiar with these citations in the literature, that they will know this and that this will be the concept that is in their mind as they are making a judgment as to how this individual system stacks up against the technical ideal.

Now as I say, this could probably be considerably enriched. And, of course, we appreciate your suggestions on that. I think probably a good literature review would help us fix that up.

There are a couple features of this review document that I want to emphasize. It is designed to be used in multiple ways. It can be used by a team of people that might be looking at a system in detail. But the expectation is that some if not all of the members of that team would have familiarity with both the regulatory and the

technical standards, and that they would be able to apply those. And we could decide, well, we're going to do the whole -- we are going to do all ten questionnaires, all the parts. And they all apply in this establishment, and we want a total in-depth verification review conducted.

We also might say, well, we are not really interested in doing all of that. We think that the issue here focuses on critical control points or critical limits. So we are only going to use that checklist, or we would like to have a sample of plants, and we would like to look at the documentation supporting their hazard analysis. That is all we are going to look at. And so we'll just use the documentation part of the hazard analysis checklist, and we'll send a number of people out to gather that information.

This would give us an excellent way to look at a sample to look across the board and see how implementation was occurring in perhaps a class of establishments or some -- you know, some particular population that we were concerned about. But this is specifically designed to work that way, to work in total or to work in parts. And you can

break it in half by documents versus system in action. You can select one checklist. You can select three checklists, however you want to do it. You don't always have to use a team.

But I do think that you always have to have people included who are sufficiently familiar with the scientific and technical standard that they can in fact apply it. I think people are pretty familiar with our regulations, but it is the scientific and technical standard that is a new dimension.

I think those are the main things that I want to say, highlighting it. As I say, I would be particularly interested if -- I know this isn't work you can do in a subcommittee meeting, and we are not planning to close the books on this particular instrument for quite some time. I would be particularly interested in other kinds of references that would enrich the technical measures of adequacy so that we could have a number of references which we felt were appropriate and would be the kinds of bases for making judgments about the scientific and technical adequacy of a HAACP system.

And that's all I have.

MR. BILLY: Yes, Rosemary.

MS. MUCKLOW: Pat, thank you. I like surveys that give you a chance to make a positive input in response and that no, definitely yes. You know, I had a real problem with one of those early surveys where no meant yes.

MS. STOLFA: The basic compliance checklist.

MS. MUCKLOW: Yes, the basic --

MS. STOLFA: It is still like that.

MS. MUCKLOW: I still don't like that. I think it is a very bad document. So at least this one learns from that experience. When you say maybe a person or a team will go out to do this review, who will those people be, and who are you perceiving those people to be?

MS. STOLFA: Well, as I say, there are multiple ways in which this series of checklists can be used. Generally, if we would be using the full set and both parts, I would expect an interdisciplinary team made up of people from different parts of the agency, depending on what the HAACP system covered in a particular establishment. And you might have a different team makeup if you had an

establishment that did a lot of process products than you would use if you had an establishment that was principally a starter and a cut-up kind of operation.

MS. MUCKLOW: And you can --

MS. STOLFA: But -- excuse me. Let me just say one other thing. Because it also does contemplate that individuals might use particularly some portion of the checklists. And, you know, we were thinking in particular of individuals like the proposed consumer safety officers, who would have different skill levels than we currently have in the inspection.

MS. MUCKLOW: So without looking at people, literally, from the line service -- we are not looking at circuit supervisors or even district people. We're looking at probably a Washington-based team going out to do this?

MS. STOLFA: I think the tech center has a lot of people that contribute to this. It is possible. You know, sometimes the district will offer a person who will lead and manage the team, that is, keep the team going, schedule things, do all of that sort of thing. But I think between the tech center and the various experts staffs, that those

are the main places where I would expect teams to be formed from.

MS. MUCKLOW: One of the concerns I have is that many of the member firms of our organization and also of other organizations in this room have somebody designated to be responsive and responsible for the HAACP team. And while you may have a multiple disciplinary team come to a plant, it is going to be one person at that plant who is going to work with them and answer the questions. And they are only going to be able to probably deal with one page of this at a time. And so I would encourage you to think about how a plant is going to be able to be responsive.

Now in a very large plant -- go to a big IBP plant -- you may have two or three or four people able to deal with different pieces of this. But by and large, in most of the companies under HAACP, you are going to have one person in that company that is going to be dealing with whoever it is that comes to work on this. And they don't need to be literally or figuratively overcome by a barrage of federal officials. You know, they need time to work through the questions and deal with them.

So that is a matter of concern in terms of the logistics of how this works in reality. And I think it is helpful for us to be looking at this ahead of time. I didn't do my HAACP training yet. Bob Savage hasn't worked me over. So one of these days I am going to have to do it. So there is that concern per se. There may be -- and I'm sure I have some other thoughts about it, but that is all I can think of for the moment.

MS. STOLFA: The checklists are not meant to be a secret.

MS. MUCKLOW: I appreciate that.

MS. STOLFA: These should be widely available. You know, everybody gets to see it, everybody gets to know what the questions are going to be. It seems to me prudent establishments would organize their files in ways that make it easy for them to access documents that help them to rapidly, you know, answer the questions. But as I say, it is not a secret. It is not a surprise.

MS. MUCKLOW: Would the company be given some advance notice, you know, XYZ is going to come and visit you on such and such? They don't just turn up on the doorstep?

MS. RIGGINS: Let me speak to that, Rosemary. We haven't conducted routinely scheduled in-depth reviews yet. We do plan to conduct them in this fiscal year. In the limited instances where we have gone in to do a review, the district manager is really the one who is the leader, and he is making the decisions about the complement of skills that are needed for a particular plant because he in conjunction with the IIC and the inspectors in the plant understand better the processes that the plant undergoes each day.

So the district manager has been the one to basically designate the team. And for the most part, we intend to use expertise from the tech center with some additional experts from headquarters in those instances where we don't have people in the tech center. The district manager has in those instances also designated a team leader. And in those cases where there were for-cause -- and you'll notice in the document there are two types of reviews, one that is for-cause where we are in a situation where there has been a problem in the plant and we are going in to look at it for specific reasons, or for random reviews.

For those random reviews, we are not planning to notify the company ahead of time. But at the time that the review is scheduled, the district manager will contact the plant. The checklist will be made available prior to that time. And the district manager will make those arrangements with the plant manager as to who the point person in the plant should be that the team leader that the district manager designates should contact and work with on a continuing basis throughout the time that they are in the review.

MS. MUCKLOW: I know that the agency reserves the right to go visit anybody any time, even at 2:00 in the morning. But it is useful for an activity like this to make advance arrangements, just to make sure that the person who is truly the responsible person is available and is able to set aside what is not an insignificant amount of time to work on a project like this. And you know, as the industry, we would like to think we are leaving behind the gotcha game. We understand you still have that authority. But a planned effort with the industry would sit a lot better than just suddenly turning up on the doorstep, well, I don't care

who is here today, we want to see this, and we want to see that, and so on.

So I would just encourage you very strongly to see if you can make advance arrangements when you are going to take this kind of time. And this is not an insignificant effort in terms of the time commitment. It may take a week, not a day.

MR. BILLY: Other comments, questions?

MS. SMITH-DeWAAL: Are we going to continue this after the break?

MR. BILLY: No.

MS. SMITH-DeWAAL: Because I have a series of questions.

DR. WOTEKI: The subcommittee is going to continue it this evening.

MS. SMITH-DeWAAL: Yeah, I know. But I'm not on that subcommittee. In fact, I don't even know what subcommittee I'm on. This is unfortunately very important. Pat, I want to pretend I'm Carol for a minute and pretend I'm a poultry producer. I have done a hazard analysis, and I have determined there is no risk from salmonella or

campylobacter on my raw poultry products. I have no test data. I haven't run a single test in my plant. I have had no outbreaks linked to my products. And there is no government test data on my products. How will this document deal with that situation?

MS. STOLFA: Well, there is a regulatory requirement that specifically applies to -- there are a series of regulatory requirements, actually, that specifically apply to a hazard analysis. And so there is -- you know, and those are appropriately referenced at the checklist regarding the hazard analysis. And one would go through the various questions that are related to the hazard analysis. And one would apply, first of all, the regulatory requirements. And also, one would apply the technical and scientific standards that we referenced in the '97 micro.

MS. SMITH-DeWAAL: And that's very good for you. But I don't care. I am the chicken producer, and I have done my hazard analysis. Am I going to be allowed to operate with that hazard analysis?

MS. STOLFA: Well, I think that issue has actually come up. And we have been very skeptical of hazard analyses

that arrive at that conclusion. I believe that I have specifically spoken to the tech center about that issue on a number of occasions because the questions have been put to them. And they wanted to make sure they were on solid ground in their not accepting that.

MS. SMITH-DeWAAL: Okay. So you're skeptical, but I might be able to operate.

MS. STOLFA: I don't think so. I think this has not been the case. I can't think of a single instance where they have said yes.

MS. SMITH-DeWAAL: Okay. Now let me change the scenario. I produce hotdogs, and I have just done a hazard reassessment. And I decide that there is no risk from listeria in my products. I have no test data. I don't do either product or plant testing. There have been no outbreaks linked to my products, and there is no government test data on my product. Will I be allowed to continue with that hazard reassessment?

MS. STOLFA: Somebody else is probably closer to exactly the listeria standards that would apply in the reassessment than I am. So --

MS. RIGGINS: Well, I can tell you what we have done to date. In an instance -- well, and Dan can talk about the checklist if it is still here. I'm not sure if it is still here. But we did issue a directive to our inspectors which basically -- we did issue a directive to our inspectors which spells out the steps that they are to follow in evaluating a plant's reassessment.

The scenario that you gave to us, one of the conditions that you said was that there was not illness connected to the plant's product, and there were no positives. Is that what you --

MS. SMITH-DeWAAL: I don't test my products, and you have never tested my products.

MS. RIGGINS: And we have never tested the products. In that case, our inspectors are instructed to record what they find and then to record that back to the district manager for any type of disposition. But unless we have some sound data that indicates that the plant is not operating in accord with its HAACP plan, we would have no basis at that time to take any action, in the scenario that you gave to us.

Dan, do you want to speak more specifically about the steps that are in the directive. But in the site conditions that you just gave to us, there would not be a basis for us to question at that time the plant's operation.

MR. EDWARDS: Do you have a copy of the --

MS. SMITH-DeWAAL: Sitting in front of me.

MR. EDWARDS: And could you rephrase the question that you had, Caroline?

MS. SMITH-DeWAAL: Well, we have just gone through the chicken processor who claims they have done their hazard assessment. And on the same grounds, they have no problem with salmonella or campylobacter. Essentially, they have no data. The same thing with the hotdog -- well, let's make it better. Let's make it a sliced deli meat, okay, something I am not even going to cook before I eat. I have done my hazard reassessment. I have determined there is no risk from listeria from my product. And my basis is I have never run a test for listeria in my plant, so I have no positive. I have had no outbreaks or illnesses linked to my product, and the government has never run a test. And it is ready-to-eat product.

MR. EDWARDS: Okay. Well, we don't have anything in our policy that would require us to document that as a failure. The issue related to sampling is that the agency does have a sampling program that it tests ready-to-eat products. And so --

MS. SMITH-DeWAAL: It's random.

MR. EDWARDS: It's a random test.

MS. SMITH-DeWAAL: And you run about 3,500 samples a year, and you have just never tested my product.

MR. EDWARDS: The agency is in fact reassessing how it has its sampling program and what products that it targets. But with regard to --

MS. SMITH-DeWAAL: But even so, even if you have never had a negative. So I would be able to continue to produce a ready-to-eat meat product without -- I just -- I think that is a very interesting -- a very interesting scenario, and I'm not surprised how it turned out.

MR. BILLY: Well, I could draw another scenario and say that hypothetically that analysis is correct, and there are no problems. I mean, how do you deal with hypotheticals? I mean, you can hypothetically assume a lot

of things. I think the important point is to continue to make use of data information, experiences in developing a strategy that assures that the best control measures that the science and other information provide for are being applied by the industry. And at any given point in time in a continuum, you don't always have available to you all of the information that gives you the basis to establish additional requirements. You need to develop that information and use that information in an appropriate way.

I think what is important about these questionnaires and this in-depth review is that it lays the groundwork for the agency and the industry to more effectively address the quality of HAACP plans. And I think that is an important next step for our agency in terms of looking at the HAACP plans that are in place. I mean, one major hurdle was getting HAACP in place. And we have been very successful. Industry has responded very well, and it looks like we are going to have a similar experience now with the very small plants.

But that's not enough. Now it the next step is what is the quality of those HAACP plans. And as new

science and new information come forward, then your example with listeria is a good example. Then we need to have a procedure, a process, that allows us to look at the quality of plans in the face of new information, and then when it is necessary to consider in fact new requirements beyond what exist in the basic HAACP regulation, as an example.

MS. SMITH-DeWAAL: And if I could just add one more thing. I think that there are a common set of hazards associated with poultry products and with ready-to-eat meat products, and that you as part of your regulatory framework should be able to require all chicken producers to have salmonella and campylobacter on their hazard assessment -- I mean hazard analysis. We know those are likely to occur.

But similarly, I think you should have listeria on all of the hazard analyses for these ready-to-eat meat products. And the fact that somehow the agency hasn't done that, that in the directions to their employees, companies can get away with saying we just don't test, and you have never tested us, and we have never had an outbreak. So we don't have a problem. I think that's a big gap. And I hope it is one the department will correct.

MR. BILLY: Yes, Katie.

MS. HANIGAN: Pat, I think as always, you have done a good job, thought it well through. My compliments to you. I am glad to see that you are -- your group is recognizing the National Advisory Committee's document because there was much discussion at the technical meeting in Omaha as to what part this original paper played in HAACP.

Two questions I guess I have. Judy, I think I heard you say you would like to roll this out yet this fiscal year. And if that is so, my question is will there be a final on this, Pat, or are we going to work off the draft? Before you start rolling this out, are we going to get a final?

MS. RIGGINS: We're going to work off the draft. This is actually the second version of this. The bare bones we developed back during the winter and used that as a model for the in-depth reviews that we did in certain enforcement issues that we have. This is now a modification based on the experience that we gained from that set of reviews.

And we intend for this to be basically a document

that will be revised as we learn new things, as we have new experiences, as we gain new information, so that we can improve it and improve our ability to detect problems that may not be as obvious, more subtle problems that are brewing, but to also help the industry to think through the kinds of questions that it needs to ask itself as it is reassessing -- as plants are reassessing their HAACP plans, reassessing their hazard analyses, that they can have up-to-date information about the kinds of problems that we're encountering across the industry so that we can all learn from it.

If this stays -- if this is a static document, it will only, you know, remain in place, what we know today. So it is going to be a dynamic document. It is going to move with us as we gain new information.

MS. HANIGAN: Okay. And then my other question on this, using the 1997 paper, I assume you are taking the paper in its entirety, which means it includes all of the appendices and specifically appendix A, which talks about the prerequisite programs, which was much discussed at the FSIS technical meeting in Omaha. So you are taking the

paper in its entirety into consideration for the in-depth review.

MS. STOLFA: Yeah. Notice that the reference for SSOPs includes a reference to appendix A.

MS. HANIGAN: Okay. And I haven't looked at all of this. But it is not saying that appendix A, which could be all of our foundation programs, are automatically SSOPs, is it?

MS. STOLFA: No. But it is saying when you are making scientific and technical judgments about SSOPs, you ought to take into account and have in your head appendix A from this paper, which discusses those kinds of programs.

MS. HANIGAN: But not saying they have to be an SSOP.

MS. STOLFA: No.

MS. HANIGAN: They could be a company's GNP program.

MS. STOLFA: No. All the regulatory references are there. The regulatory references have to be met, but in addition, when you are making your judgment that you should be familiar with what appendix A says.

MS. HANIGAN: Okay. Thank you.

MR. BILLY: Nancy.

MS. DONLEY: Two things. Number one is how many of these do you anticipate doing on your -- not in response to a problem, but on a -- just on a regular -- a random basis.

MR. BILLY: I don't think we know the answer to that. It will start with dozens this year, then perhaps eventually be hundreds in a given year. I mean, we don't have a fixed year on that yet. We are trying to -- we are still sorting out how it is going to be done, who is going to be involved, how much time we have available to do this, proportioning out that time between for-cause reviews and then the random reviews. So it is a work in progress, figuring out how we can manage this within our -- you know, our existing workforce, if that gives you some sense of what -- how we'll start, and then we'll expand it.

MS. DONLEY: I'd also like to just kind of weigh in, too, with what Caroline was saying. And I, too, have a real problem with a plant that could say that it has a historic look at historical information only and just say,

well, we have never -- to our knowledge, we have never had a problem, so therefore there is no reason for us to consider that we are going to have a problem with something. I'm just going to remind, too, everyone that when FSIS initiated the random sampling program for E. coli 015787, industry's response was, you know, it is just not really out there -- you're looking for a needle in a haystack. But when additional sampling methodologies and better methodologies were employed, we are finding more and more and more of it.

So I just -- that kind of thinking can be very dangerous to the public's health if you just look back on historical data. Or lack of data, not even data. They had none. They are saying there is no problem because I can't support that there has ever been a problem. And they are not required to look for it.

MR. BILLY: Rosemary, you are going to have the last word on this.

MS. MUCKLOW: Okay. This becomes a very technical activity of the agency. And I would strongly encourage the agency to sit down with people who are HAACP-qualified people. I know that you didn't hear us when we asked the

joint training a number of years ago. You were not the decision maker at that time. And hopefully, we might be able to have a different decision this time. And that is that there are people sitting in this audience today, there are even some people, a few of them, around this table, who are a lot smarter at HAACP than I am.

But as you look at these questions, the complexities just overwhelm you. And I would encourage the agency to invite in some of the really qualified technical experts -- some of them will be on the micro committee, some of them are in the audience, a few of them are at the table -- and go through this so that there is a really good understanding -- the Dane Bernards, the Bob Savages, those kinds of people, so that there is a common understanding of what is acceptable and what is not acceptable because everybody is trying to meet the standard.

And you have already -- and Judy has admitted, this is a learning curve for the agency. Let's see if we can together this time rather than go off at odd purposes.

MR. BILLY: All right. We're going to break now. And I'd like to shorten that break to about 15 minutes. So

whatever you need to do during the break, do it quickly.

(Recess)

MR. BILLY: The next item is another agency issue, but also an issue that has been addressed by this committee in the past, which is extending our meat and poultry inspection program to additional species. This discussion is going to be led by Robert Post. And I think Dan is going to participate, as well as Neal Young. So I'm not sure which of you are going to -- Dan? Okay. So we have a committee member that is going to kick off this discussion. And these two --

MR. LaFONTAINE: I am going to make this painfully fast. At the last committee meeting, when this subject was discussed, one of the agreements was that the USDA/FSIS would survey -- or rather compile information from several plants on the numbers and types of nonmammal species being slaughtered under voluntary inspection. And that working through the state -- the Association of State Directors of Meat and Food Inspection, that I would ask Lee Jansel to do a similar survey for state plants.

So this information I'll present in the next few

minutes is a result of my survey. So it is just a slice of the pie. Then I'll turn the table over to our FSIS colleagues.

This information was sent out -- I have to give a little plug in here -- in advance to the committee. And it is available at the table for our guests. It is raw data. And I am not going to spend a lot of time on it. I have a summary chart here. One key difference I want to make -- or I want to mention is that in state programs, I surveyed 26 states -- that includes the 25 that are under what we call normal state inspection, but also California, because California, in addition to the program for the testing of exempt slaughterers also has some state laws that require they inspect some of the nonmammal species. So that is the reason for 26 states.

The other difference is that many of these species are under mandatory inspection in some states. And that is the reason for the three sets of charts. The key thing on this particular chart is that these are the states and species under mandatory inspection. Then you see some fairly significant numbers there. Quail are the million

birds under mandatory inspection. That is probably near California. Squab -- that's pigeons, between California and South Carolina, a half million birds.

So we feel in some ways -- my opinion -- we're ahead of the feds. We are actually requiring certain species that are offered in the commercial marketplace to be under inspection.

There are also, under voluntary inspection, a lot of animals being slaughtered on a fee-for-service basis. There are some unique issues out there that meet that situation. And I'll use my state as an example. Under voluntary inspection in South Carolina, for example, we see that there are 6-1/2 million quail slaughtered under voluntary inspection. However, the quirk is that that is paid for, even though it is voluntary, if somebody wants to do a voluntary, the state pays for it. So that is 100-percent funded by the state.

So I only bring these out, these idiosyncrasies, because that is the type of thing that is going on at the state level to cover this particular situation. And I wanted to mention -- and I don't want to insult anybody's

attention -- intelligence, but for those who don't know what a ratite is, that is ostrich, emu, and rhea, birds, large birds, originated in some cases from South Carolina -- excuse me, South --

(Laughter)

MR. LaFONTAINE: South Africa. And also, I think the emu is from Australia or New Zealand.

MR. BILLY: National bird.

MR. LaFONTAINE: So this is one more. And I have to say this is all raw data. But I guess it took a lot of effort to put it together, to collect it all from the data available. This is pulling all the mandatory and voluntary inspections together. And you take a look at the bottom line, we are talking about a significant number of animals or birds. Once again, going back to the quail, adding the various states together, it is over 7 million birds, squab, over half a million. If you label some of the mammals, thousands of different species, cervidae, and bison, et cetera.

One thing I wanted to point out -- and I don't know if anyone will give this detail, that these numbers

will not exactly match your table 20 in the USDA handout. And I believe the difference is that California was not counted in your information. So just in case anybody checks and double-checks things, that is the reason for the difference. It doesn't have a great deal of impact, although California does slaughter quite a few birds. Quail and squab, for example. So that does have some effect.

Finally a summary chart, and it's right here, of the 26 states that are in the survey, 23 are inspecting nonmammal species. In the case of five states, we are doing some voluntary and some under mandatory inspection. Eleven states only do voluntary, and in seven states, they only do mandatory.

A very interesting thing I found out as I was making the phone calls, is that this is growing little by little in voluntary or mandatory, where states, as they become aware that in their particular state is a growing industry for certain types of species, they are adding it in their program in their state laws, either as a voluntary or mandatory. So you say, well, we didn't do anything with this is '98, but there was a law just passed in '99.

They'll have to start inspecting just pieces of that. So, little by little, it has been growing based on those comments.

I just did a grand summary with my totals, over 8-1/2 million nonmammal birds were slaughtered. Obviously, the greatest numbers were quail, almost 7.7 million, and squab, a half a million, but then quite a few pheasants, especially in the state of Wisconsin, I believe, is where most of those, and California, 17,000 ratites, and some partridge. And then under mammals, by far the largest number was rabbits. And obviously, the effort, both in the plant and in the inspection, to accomplish this slaughter and inspection of the deer or bison is considerably greater than, let's say, of quail. So the numbers aren't as big, but the impact, the amount of meat that would be generated, is considerable for some of these mammals.

That's it. If there are any questions about this information, I'd be glad to answer them now or later.

MR. BILLY: Okay. Go ahead Dale.

MR. MORSE: Your survey was just states at random, or did you select ones that you knew had programs? Or do

you think the other ones you didn't survey also had a similar program that was in the survey?

MR. LaFONTAINE: Well, let me answer your question. The 25 states that have an ongoing routine that have a program that is under the FSIS umbrella, equal, two states were surveyed. I was aware that California was doing quite a few, so I asked them. Minnesota did not have a program at the end of '98, so it was a moot point. New York has a custom-exempt system. Do they do any?

MR. MORSE: That's what I was wondering. I wonder if the states that don't have a program -- there is no federal --

MR. LaFONTAINE: That comes next. In other words, I didn't ask -- I only surveyed those that are under state inspection. And my colleagues here from FSIS will present their information on what was done under federal inspection, regardless of where the state is -- the state rules, or that is, have a state program or not a state program. Does that answer your question?

MR. BILLY: I think what Dale is getting at is that were missing 24 states and the territories, right, that

are not included in these numbers, unless it is federal.

MR. MORSE: So they're included there.

MR. BILLY: Some, yeah.

MR. MORSE: So I guess the question getting down to us is like, how did you find these. Did they have to get a permit to start to set it up? I mean, there may be lots of these that may be difficult to find, like finding daycare centers.

MR. LaFONTAINE: You brought up a good point. If it is voluntary, that just means that. Technically, they can sell the product in the marketplace without any inspection. And I know in our state, we have -- and I won't mention the species because it would be inappropriate. We have a slaughterer that does a certain species and sells it in the marketplace without any inspection.

MR. JAN: If they are going to sell it in the marketplace and they don't have inspection, they need to come from a good source which would be through a USDA license.

MR. LaFONTAINE: So it depends on your state, and how the state law is written. They had a powerful

legislature that got a lot of it written in. It doesn't include it either way, that particular species.

MR. BILLY: Okay, Robert.

MR. POST: I think one of the points that we'll be making is that there definitely is a need to coordinate the state data. The data that Dan has provided is certainly helpful. And we have data from FSIS. Somehow or another, we'll get them to merge and account for all of the designated states, as well as the state-approved programs.

As was mentioned, in November of '98, the advisory committee recommended that FSIS prepare a concept paper on the issue of mandatory inspection of all animal flesh foods. And the goal of expanding the types of animal species required to be federally inspected under the USDA inspection program would be to ensure that most if not all animal flesh foods that are commercially slaughtered or processed for human consumption are federally or state inspected for safety and wholesomeness. And currently, statutory and regulatory provisions define the species of animals that are inspected by USDA under a mandatory inspection, and those that are under voluntary inspection.

In certain instances, explicit exemptions from inspection exist. States with inspection programs may also inspect the slaughter of animals and the preparation of the meat and poultry products from both amenable and nonamenable species. Under FMIA, the Federal Meat Inspection Act, and its implementing regulations, livestock and meat products are defined as being of cattle, swine, goat, horse, mule, and other equine origin.

And the Poultry Products Inspection Act is broader in its definition of poultry and defines poultry as any domesticated bird. The poultry regulations are a little bit more explicit and provide examples of domesticated birds, for example, chickens, turkeys, ducks, geese, or guineas.

At the previous advisory committee meeting, the committee recommended the application of a set of criteria for deciding the issue of what animal should be involved in mandatory inspection. And the agency has given careful consideration to the committee's recommendations. And in order to be consistent with the USDA vision of a public health risk-based seamless federal state inspection system, the agency agrees that additional species, such as ratites,

quail, and squab, should be added to those species currently under inspection.

And so a decision was made to begin the process of exploring the expansion of the definition of amenable species. And I might add that although an expansion of amenable poultry species may be possible without a legislative process through the Poultry Products Inspection Act, I think expansion of livestock species will require amending the FMIA.

There is a concept paper, and it is in tab No. 6 in your notebooks. The concept paper that was distributed at today's meeting represents the first step in the process necessary to move toward a legislative proposal to amend the Federal Meat Inspection Act to add to the list of species under mandatory inspection. And this paper presents a conceptual framework or a starting point for determining which species of animals should be added to the list of already amenable species. And the paper is intended to be a basis for further dialogue and prompts questions for which data are needed for a response.

Essentially, we have laid out the statutory and

regulatory basis for a mandatory and voluntary inspection, a public health rationale for considering additional species, a very preliminary economic assessment of the costs and benefits of adding additional species, and a set of criteria to consider in making the decision as to which species should be added to the list.

In a preliminary examination of the public health issues and implications, we reviewed the production data on species for which voluntary inspection was provided by FSIS in 1998. Those are the tables that were referred to earlier, table 1 and table 2 in this paper. This kind of data will help determine the extent of the market and the possible exposure if a public health issue associated with a particular species is identified.

In our preliminary work, we have acknowledged that the degree to which to which there is a public health need to extend mandatory inspection to exotic or nonamenable species is uncertain. However, based on literature reports such as those published by the CDC, it is reasonable to suspect that animal flesh foods in general have the potential to pose some level of risk to human health. And

therefore, strategies to prevent foodborne illness must consider all the sources of a possible contamination, and if and how an inspection process can be instituted as an effective prevention measure in reducing risk to human health.

We said that the difficulty of obtaining indisputable scientific data linking a specific nonamenable species harboring a specific pathogen responsible for causing illness should not deter FSIS from pursuing a thoughtful approach for bringing new species under mandatory inspection. Such an approach should be -- or would be precautionary, and based on a rationale that any animal used for human food is a potential source for agents that could cause foodborne illness.

But other factors also play a part in the development of a public health rationale for adding additional species, and we covered those in our paper. For example, we must consider the exposure of certain populations to nonamenable species and their products and whether the changing demographics of consumers, for example, play a part. For example, more older adults -- there are

more older adults today, and there are also -- there is also less at-home instruction about safe food handling. And perhaps that increases the risk of foodborne illness with regard to these species.

The principles that the agency should apply in determining the applicability of mandatory inspection to additional species should also consider the allocation of inspection resources based on the relative food safety risks presented by different animal flesh foods, and should be hazard based, science based, and public health based. And logistical and practical adaptations of inspection systems to unaccustomed physical attributes of nonamenable species could play a secondary role that we would have to consider, and would need to be considered if mandatory inspection is extended to additional nonamenable and exotic species.

The concept paper also presents a very preliminary assessment of the costs of mandatory inspection for additional species. Extending the coverage of mandatory inspection to additional species would entail costs for FSIS and for industry. Effects on state governments and consumers are more ambiguous. Many of the costs for FSIS

and industry are startup costs, and that would be one-time expenditures, for example, conducting baseline microbiological studies used to develop performance standards for additional species, and the development of procedures and criteria for chemical residue testing.

Continuing expenditures for FSIS would primarily be related to inspection and compliance activities. An important issue here is the transition from voluntary to mandatory inspection, and how the income relative to voluntary inspection is redistributed. More data are needed to address this issue.

The economic effects on state governments of making inspection mandatory for nonamenable species are complex, and we presented information in that regard. States that currently have state inspection programs for nonamenable species will largely be affected in terms of federal reimbursement and the ability to collect fees for inspection. Much of the agency would also face startup costs, for example, retrofitting equipment and facilities to allow the inspection of additional species and having to comply with the provisions of the pathogen reduction and

HAACP final rules.

There are also recurring costs for industry. For example, those firms under voluntary inspection now will have to be responsible for HAACP recordkeeping. Consumers also face a relatively ambiguous situation. For example, the costs of voluntary inspection are assumed to be passed on from consumers -- from producers to consumers. If the burden of paying for inspection is removed from firms, firms may be able to charge less for their products. The exact measure of these types of shifting costs are not currently known.

Having provided views on statutory and regulatory public health and economic issues, our conceptual framework goes on to provide some recommendations for criteria in determining additional species to mandatory inspection. And these criteria, though not exhaustive, will provide a clearer guide to policymakers. These criteria can be seen as a sequence of things to consider from the public health perspective.

One criterion is to determine whether the animal and its products are used as human food, and whether there

is something to gain from regulating the slaughter of animals in that circumstance. Obviously, there might be, or there is nothing to gain from regulating the slaughter of animals that are not used for food.

Another criterion is considering whether there are sufficient microbiological risks associated with nonamenable species for FSIS to mandate inspection.

A third criterion is whether there is scientific evidence linking the new species to human illness in general.

Another criterion is whether there is a sufficiency of market, in other words, whether there is a sizable market for the nonamenable species and its products. The level of production and the level of consumption relate to the potential for exposure, and this also relates to the allocation of FSIS resources.

The fifth criterion we suggest is compatibility of the species with the FSIS inspection system. An establishment with a grant of inspection must be available and near where the nonamenable species are. And the requisite number of inspection personnel must be present.

The last criterion we are recommending is the consideration of the costs, looking at the costs of mandatory inspection where social benefits outweigh social costs.

And none of these criteria we are suggesting should be used alone as evidence in favor of or in opposition to expanding mandatory inspection to additional species. We are recommending that these criteria be used collectively to determine the appropriate course of action.

Well, with that synopsis, I thought I would conclude by saying that in order to add to the species of animals required to be inspected by USDA using the criteria suggested in the concept paper, more information is needed. The agency invites input from the advisory committee on a number of things.

First, we welcome input on the approach of using the criteria we have outlined. We also want to know if the criteria we have outlined are adequate, or whether other criteria are necessary. Also, as I mentioned, a more comprehensive analysis of the costs associated with adding to the list of amenable species needs to be performed. And

as part of that effort, we need more information about the production volume and the marketing of nonamenable species and their products, and consumer purchasing habits of such products.

In many cases, these are regional products, and state programs have the information we need. And members of the advisory committee can certainly help us in this effort. Also, further consideration and analyses are needed from state inspection programs regarding the effect of adding more species to mandatory inspection and how long it would take the states to develop equal to programs. So we also look forward to any input the committee can provide on that point.

With that, I'll conclude by -- and I just will add one more comment, and that is I would like to know about that one lonely llama --

(Laughter)

MR. POST: -- that appears on the table.

MR. BILLY: Okay. So this paper, like what we have done in the past, is a first draft of a concept paper on how we might go about doing this, and some criteria to

use and other related considerations to achieve the outcome that we have established. So are there any questions about the concept paper, or are there comments that people would like to make to guide the subcommittee in considering this? Rosemary and then Lee.

MS. MUCKLOW: I have -- one of our members sent to me a copy of a draft bill that is -- I don't think it has yet been introduced by the congressman in question. But it was to amend the Poultry Products Inspection Act to include pigeons that are distributed in commerce for use in human food. And it is dated, as best I can read, about October 28th. And I understand that the aide to the congressman was going to be here today. I don't know if that lady is in the audience. Her name is Lisa Richards. Did she come or did she not?

It was Congressman Gary Condit. And I'll be glad to share this with you. And I'm impressed at their brevity. They have got it all done in two half pages, better than I can say for the agency.

MR. BILLY: But the committee hasn't dealt with it yet.

MS. MUCKLOW: What?

MR. BILLY: The committee hasn't dealt with it yet.

(Laughter)

MS. MUCKLOW: In the paper reduction world that we are busy trying to do, I think it is quite interesting. And this is pigeons, or otherwise known as squab. And these are those squab in California. And this guy would like inspections. So I'll be glad to share this with you. I don't -- it is the only copy I have, but Mike has a machine somewhere, so you can make all sorts of copies out of it if you want.

MR. BILLY: Okay. Yeah, Lee.

MR. JAN: I just had a comment regarding inspections of voluntary species. We do a lot of it, a considerable amount of it, in Texas. We do mandatory, so we do not charge a fee. And I would -- and as we move to this, obviously, we need to have some kind of assurance of safety in these products. I think state inspection programs provide that. By making it mandatory under USDA, it would probably -- and depending on how the regulation is written

-- but I would expect, based on precedent, that it would be not a full-fee basis, and I think it would be free inspection, I guess you would call it -- any inspection, free.

It doesn't necessarily mean that the bill couldn't be written that it would be on a fee basis. FSIS has been trying to -- or USDA has been trying to collect -- or collect user fees. And this would be a good way to start. So it doesn't guarantee that the inspection would not be with a user fee attached.

I think that leaving it as under state inspection, industry can work better with their individual legislatures to try to make it mandatory or not a fee basis issue. The product can go in the interstate commerce. The product can go in international commerce. And if it became mandatory under FSIS, then those -- and there is a lot of it out there that is being produced for sale, value-added products that add nitrites. And that would not be allowed under FSIS, or at least under today's inspection or production, even under voluntary, you cannot use nitrites. And it is not an FSIS ruling. It is an FDA ruling.

But in most states, it is allowed under state law, and they do allow the use of nitrites, we believe that it is a safety issue. FSI -- I mean, FDA -- to the extent that it is not a safety issue unless you are using it back when they decided it was a safety issue, or it was a health hazard they were already using in those products that somehow miraculously did not cause a safety or health issue.

So it would certainly be, if we're going to move to make it a national mandatory inspection, then I think we need get a conference with FDA and get the nitrite issue resolved before we go any further because I think that is going to be a detriment to a lot of this industry that's already established out there.

MR. BILLY: Other comments? Yeah, Dale.

MR. MORSE: Just back to the numbers again -- that we'll just fix that on numbers. How complete are you capturing the data on what is out there? Dan said 26 states surveyed, and probably -- it may not be the total list, but this one list, it looked like 37 states. I guess that is a voluntary program in the federal. And so Dan had six states that weren't listed in table 1. There are 20 states in

common and the federal list had 17 states. It covered 43 states, so at least seven states aren't listed on the list. Maybe they are in there, but mandatory. So do we have a good handle on what is completely out there that is covered by state and federal, or are there a lot of missing establishments that process these?

MR. LaFONTAINE: Let me start the answer. I think whatever is being inspected by state or federal presently is included in the data. That would be voluntary or mandatory. But it may not -- what may not be there in those seven states, or even in the states that are listed, is producers that are doing this commercially without any kind of inspection. And we'll never know that. I mean, there is no way to get that information is what I am trying to say.

So you're right. There is missing information. But I don't think we can -- there is any way to capture it.

MR. POST: And we addressed that in the paper, the custom-exempt operations and others that might go unknown, I guess, or not quantifiable. But our data is intended to represent all states that we know of where either a species, nonamenable species, are inspected under voluntary, or where

we know there is a state inspection program, they have a state inspection, and we know that they deal with nonamenable species.

Between those two tables, we meant to be complete with regard to all states. As I said, though, I will -- I prefaced the remarks that I began with. I think we need to make sure that between the data and the hard work that Dan did in getting to states with state programs that we would have to make sure these data merge and are correct.

MR. BILLY: Yeah, Dan.

MR. LaFONTAINE: I'd like to make a few general comments. I won't be in the subcommittee because I'll be in a different one that I will be chairing. I talked to some of the primary authors of the two acts, the Federal Meat Inspection act and the Poultry Products Inspection Act, who are now retired FSIS employees. And what they told me is that the species that were included in both cases were the species that were commonly being raised for commercial sale at that time. And if you look back, that's true.

In the last 30 years, ratites, bison, squab, quail have evolved as industries that are putting product into the

commercial marketplace. So I just offer that as some baseline of how we got started where we are.

The other thing as a general statement is that these mammals and these birds carry the same pathogens as the ones that are under inspection. I can guarantee that if you look at the squab and the quail -- I know that from my state, and they periodically have some flare-ups with salmonella. It is included in this paper, but the cervidae have the same problem with E. coli 015787 as our bovine species does. So I know I am making some very general statements, but the public health risk is there. There are documented outbreaks in some pretty significant journals, the AMA, for example. So that's one thought I want to leave with you.

The other thought is that it is mass confusion out there on the fact that you don't have to inspect certain products in the commercial marketplace, and you can ship them anywhere in the world, not only interstate but international, with no mark of inspection, and the next species, adjacent species, we have everything under the sun to make sure it is a safe food.

So I know I'm making general statements. But that is one reason why I am so concerned and I guess passionate about this, because I see what is going on, and it makes no sense from a public health viewpoint to let the situation continue as it is now. Thank you.

MR. BILLY: Mike.

MR. MAMMINGA: Dale, I am going to speak to you just a minute because when you look at all these tables, unless you are kind of familiar with what those of us in inspection do, it does seem rather confusing, and you could question the numbers.

The state programs, whether we inspect what we call exotics on a volunteer basis, reimbursable, or if we do it under mandatory basis, and in the states that have no state programs under federal, I think the numbers on these pages tell you how many animals are inspected, whether or not it is done on a reimbursable basis, or whether or not it is done on a mandatory basis.

The one number that we don't know is that since FSIS considers cattle, sheep, swine, goats, equines, and domestic poultry amenable, then our states also must

consider them amenable, plus we have an option to do some other ones if we would like. The fact that these animals do not have to be inspected -- for example, in Iowa, we have a federal program, we have a state program that inspects ratites. We inspect some buffalo. The federal program could inspect buffalo in Iowa, too, depending on the plants that the producers choose to use.

But there also in Iowa could be ratites and rabbits and buffalo and water buffalo slaughtered without inspection and sold for food. That's the number that you don't have, and that nobody has because there are no records to document that. These records document to you what has been inspected in these United States, whether it be under federal or state, mandatory or voluntary. So I think that number is accurate. What you don't know is what is done without inspection of any kind.

MR. BILLY: Thanks. Rosemary?

MS. MUCKLOW: Tom, could you help us at all with information about what other countries are doing? We buy a lot of game meat from Australia and New Zealand. Do they have a mandatory inspection system?

MR. BILLY: To be honest, Rosemary, I don't have a good understanding of what other countries do. I don't know if Robert has looked at that. There are some that do have more comprehensive programs that include all of the species that are commercially produced. But it might be valuable to get that type of information.

MS. MUCKLOW: It might be useful information since we peddle a lot of that stuff here. We import it and bring it in under FDA and so on.

MR. BILLY: It would be good to -- maybe FDA in fact has some data that could get us pointed in the right direction to see what --

MS. MUCKLOW: On a quick call -- I don't know if there are some Australia or New Zealand people here. We might ask them if they know.

FEMALE SPEAKER: They left.

MS. MUCKLOW: They left. Well, they must have known the question was coming.

MR. BILLY: All right. I think we have had a pretty good start on discussion on this, and I look forward to the subcommittee considering this paper and arriving at

some advice. And that pretty well wraps up the scheduled presentations. We now will shift to public comments. I think the public -- particularly those that have indicated an interest in speaking to bear with us for running a little behind schedule. I'll just read off the names as they appear on my list and ask you to come to the microphone and state your name and your affiliation, and then proceed to make your presentation.

The first name I have is Jeannie Summerhour.

MS. SUMMERHOUR: Good afternoon. I am here this afternoon on behalf of the American Indian Association. We're one segment of the ratite industry, and we're here in support of mandatory inspection for ratites.

The first issue that we have is food safety because we are beginning to see an increase in the distribution of uninspected meat. As much as we encourage our producers only to distribute inspected meat, it is happening.

Second of all, the industry wants baselines and performance standards established. In a letter to Sen. Coverdell in December of 1996, I believe the USDA said that

the end run period of voluntary inspection would allow them to gather the data needed to establish this. We are not any closer today than we were four years ago. I think that the only way we are ever going to get it is if we get mandatory inspection.

Voluntary inspection has a lot of regional discretion involved in it. We have a lot of labeling discrepancies which produce an additional burden on the grower. You get the approval of a label through FSIS, and then you have a regional compliance officer who disapproves it.

We also have issues with the nitrites and the nitrates in value-added products because we have to include 3 percent of an amenable species. Now why 3 percent makes it any safer, I honestly don't understand. But it is one of the things that we are required to do.

Lastly, we asked you to consider the position of equity, that when you start at the very beginning of the charter chain and the distribution chain, and you are being charged $38 an hour, potentially while the animal is on the kill floor, while it is being processed, while it is being

packaged, while it is being turned into sausage, you can easily increase the cost to the producer as much as $2 a pound. Take that all the way through the distribution chain, and you end up with a product that is basically nonaffordable.

It is very, very difficult to compete as an alternative meat producing industry in this arena. Thank you.

MR. BILLY: Okay. Are there any questions from the committee for the speaker?

MS. MUCKLOW: I would suggest that Bob Post can explain the 3 percent to her very easily, but later.

MS. HANIGAN: I only have one question. Again, who did you say you were with? I'm sorry.

MS. SUMMERHOUR: The American Indian Association.

MR. BILLY: Lee?

MR. JAN: I'd like to just make sure that they understand that by making it amenable, it is not going to change the FDA rule that you have to use 3-percent amenable, because FDA has already said that the exemption for use of nitrites in food only applies to those species that were

under the act in 1958 or whenever the FDA rule came out. So that making it amenable is going to continue to be a problem with nitrite unless it can be simultaneously addressed with FDA and get them off this interim issue.

MS. SUMMERHOUR: One of the considerations that was brought to my attention by Dr. Quigley, who is head of Georgia state meat inspection was that poultry products back in the 1950s did not commonly use nitrites and nitrates. Today they do. And by that, I am talking specifically -- you know, the turkey burgers, turkey hotdogs, and that kind of thing. So I think that there is the potential to work around that.

MR. BILLY: A point was made about the 3-percent rule. And you might want to just shed some light on what the requirement is so that everyone knows.

MR. POST: In order for a product to be amenable to USDA inspection, we have general criteria that are laid out in the regulations. Essentially, a product is amenable to USDA inspection when it contains more than 2-percent cooked or more than 3-percent raw meat or poultry. There is a slight difference between the meat inspection regulations

and the poultry products inspection regulations, but those are essentially the criteria we use that are outlined not only in the regulations, but in our policy book that the agency has offered. So that is where the 3 percent comes from.

Now 3 percent, adding 3 percent amenable species, does enable the plant to become amenable and therefore be covered under the definition of meat or the definition of poultry, meat food product and poultry food product. So we have allowed use of nitrite in products that contain the appropriate amount of amenable species.

The issue of nitrite, though, is more that FDA did not permit -- or does not permit the use of nitrites or nitrates on the types of meat not referenced in the Federal Meat Inspection Act. And because these exact species aren't in the FMIA, that's why they were not prior sanctioned, they were not used prior to 1958. So that is the reason there.

If we make these species mandatory, then they are included in the definition of meat, and then nitrite and nitrate, that issue is dissolved.

MR. BILLY: Thank you. The next speaker is Jill

Hollingsworth.

MS. HOLLINGSWORTH: Hello and thank you. My name is Jill Hollingsworth, and I am with the Food Marketing Institute. FMI represents the retail grocery store, supermarkets, and wholesalers in this country and internationally.

We would like to make a recommendation to both FSIS and this committee. We have noticed that the nature of the work and the scope of the issues that this committee has been dealing with recently has greatly expanded. Whereas in the past the committee focused primarily on issues that impacted meat and poultry slaughter and processing, we are now seeing this committee tackle such issues as what to do with FDA's food code, issues regarding state and local inspection activities out of the federal plants and out of the state plants in retail, restaurants, and other nontraditional, federally inspected establishments. You are dealing with transportation and handling issues, and the area that FSIS commonly refers to as in distribution.

Those of us who are in this segment of the industry are concerned about the lack of representation that

this committee has for that segment of the industry. We also feel like you are at a real disadvantage when asked to address those issues without having the expertise and knowledge that this portion of the industry could bring to the committee.

Not long ago, the Secretary of Agriculture asked that the membership of this committee be expanded so that it was more balanced to represent consumer interests in the states. We would propose that once again this committee consider its membership and also whether or not new members should be considered.

So long as this committee will be dealing with out-of-plant activities, we think that it would be relevant and helpful to have that kind of expertise and knowledge brought to the committee. FSIS has mentioned today on several of these issues that they have had discussions with groups like FDA and with AFDO. We encourage that, but we think that is not quite enough. We think that representatives from this portion of the industry should be included.

Some groups to consider would be the food

distribution industry, warehousing, transportation, freezing, wholesaling, retailing, food service, and also groups like AFDO, who we think could add a lot of information to the group. We also think that although the group now consider -- I mean now include state representatives, that there is another portion of state and local government, that portion that directly oversees retail stores and restaurants, that perhaps needs more representation on the committee.

And lastly, in keeping with the President's initiative for collaboration and cooperation between the departments, we would like to see more involvement by FDA in this committee meeting and deliberations, particularly when areas like their food code are being discussed.

We do not believe that it is appropriate or fair, not to the committee, not to FSIS or FDA, not to the industry or AFDO or the states, for this committee to be asked to address issues when they in fact do not have the expertise and knowledge that can be brought to the committee to discuss those issues. We think that all of the experts and stakeholders that will be involved in your deliberations

and the outcome should be included.

Thank you for your attention.

MR. BILLY: Thank you very much.

MR. LaFONTAINE: Mr. Billy?

MR. BILLY: Yes.

MR. LaFONTAINE: Just to make sure -- a little clarification. The states are not new additions to this. The original law said state representatives. We were at the beginning, not the newcomers. So just to make sure everybody understands that.

MR. BILLY: Okay. Thank you.

MS. SMITH-DeWAAL: Can I just --

MR. BILLY: Sure, Caroline.

MS. SMITH-DeWAAL: Jill Hollingsworth and I don't agree on much, so when we do I always want to point it out.

MS. HOLLINGSWORTH: Is it one of those days?

MS. SMITH-DeWAAL: It's -- she is absolutely right in terms of the state representatives who we have here tend to represent the department of agricultures, although I will note that in Texas, they have a single food safety agency, so they don't have that problem. But in most states, it is

different pieces of state government that actually regulate restaurants and retail than the agricultural representatives that we have here.

MR. BILLY: And we also have Dale Morse, who isn't part of Agriculture in the state of New York.

Next I have Kim Rice.

MS. RICE: It's late, so I'll make this as brief as possible. I'm Kim Rice, with the American Meat Institute. And I just want to put a couple of things on the table for the subcommittee to consider this evening when they are talking about in-depth verification. The in-depth verification process is basically an audit process. And while the two documents that were presented today take a step in the right direction, there is also a process that is missing. And I think that the subcommittee should consider the process that should be followed when the auditors take up -- or the in-depth verifiers, whatever you want to call them -- take up this activity, starting with the initial desk audit that is typically done during an audit.

And then when the team arrives or the individuals arrive at the plant, there is a face-to-face meeting before

anything takes place. This provides an opportunity for the verification team to lay out on the line what they are looking for and what they are there for. It also provides the plant or establishment the opportunity to explain how their process works, how their system works, and for the two groups to ask each other questions so that all of the right information is provided. Then the actual audit or verification would take place. And following that is a closing meeting or an exit meeting. And I think that should be included in these documents.

Also, I think that the auditors or the people doing the verification should be trained in the auditing process. There are several organizations out there that do this, and many of the large customers of my members require that they have audits done by trained auditors, and there are lots of organizations that can do that.

Just one other small -- a couple of other small things. The in-depth verification is an in-depth verification. Anything less than that should not be considered an in-depth verification. If you want to use the checksheets for other things, gathering other data, that's

fine. Don't call it an in-depth verification, though. That's a partial piece.

Reference material that Pat was asking for -- I know that when the original generic models were done, there was a lot of reference journal articles that were given to the team who put together those programs. I'm sure the HAACP alliance still has that information available. It was articles not only on HAACP but also on the specific processes that are out there and being used by the different companies. And I would also encourage the agency to keep this in-depth verification process an open process.

Judy said that this is a new process, and we are going to learn as we go along. But I would suggest that it remains open and that learning should be shared on both sides.

MR. BILLY: Very good. Thank you. Our next is Dennis Sexas.

MR. SEXAS: Yes. I'm Dennis Sexas. I'm a rancher. I raise bison in North Dakota. It is my second time here, so I'll be extremely brief. I don't want to repeat myself when I addressed you in May.

I think this young lady from the Emu Association really summed up a lot of my remarks because there are some issues here that are very important to these emerging industries. I think that in the case of food safety -- and that's what we're talking about here, that is the most important single thing that can kill an emerging industry such an emu or bison, and I am here on the part of the bison producers.

The bison industry is one of the fastest growing industries in agricultural production in the United States. It is growing at a compound growth rate of 20 to 25 percent. It has become a major factor in the Great Plains. In North Dakota, bison is the second most important livestock after only beef. It has passed pork, poultry, sheep, and all the others, and yet it is not being treated, as far as I am concerned, by FSIS as a real industry.

If you look at the numbers that were gathered, I think on table 2 there, bison numbers appear fairly small. But if you look at it in terms of meals instead of numbers of animals, it would be the most meals on the entire chart by far, probably representing 18 or 20 million meals, which

is more than 6 or 7 million quail. I usually eat a whole one at a time when I eat quail.

One of the gentlemen, I think, here on the committee mentioned that this is a local issue and should be left to the states. And that sounds fine in theory, but it really doesn't work that way in practice. States like North Dakota, which processes -- about two-thirds of all bison in the world are processed in North Dakota -- has no state inspection program. So I don't know how that would fit into that.

The last thing I really want to talk about here is the whole issue of fairness. Not only is this thing about paying for inspection versus not paying -- and that is a very serious issue. We as Americans think that the playing field ought to always be level, and it isn't in this case. It is a tremendous burden on us when we are processing the few animals we process to have to pay $100,000 a year for these farmers and producers who are already struggling for their livelihood when people down the road raising a very similar animal isn't paying. That is inherently wrong. I think it is anti-American, as far as I am concerned.

Also, the states that do have state inspection are often sharing. The federal government is paying up to 50 percent of the inspection costs of their bison, whereas states like ours that go with the voluntary program, they don't. And I think the reason for that is, apparently, from what I understand, is not all -- or some states consider bison mandatory, so they treat them and get federal subsidy. But I have been told that by some people

The other thing here, I guess, is this nitrates problem. It is so ridiculous that I can't believe that the talent I see in this committee can't grapple with this. This is crazy, to put 3 percent of beef into bison and add nitrates and call it safe, while some states are mandatory -- are making the adding of nitrates to smoked bison mandatory in the face of the FDA. The state of Wisconsin is a perfect example. I have talked to bison people that are having meat down in Wisconsin, and their state inspector insists they put nitrate on straight bison because it is unsafe not to use it. And he is right. So we have gotten ourself in a crazy situation.

I just had the Veterinary Council from the

European Union stop me here and, unfortunately, he had to leave. He handles North America, and he recognized me. He does inspect our plant. We ship a lot to Europe. And he wanted to report -- he just asked me for a report on this because they take in hundreds of thousands of pounds of our bison every year into the EU. And he nor anyone else understands why this is treated as such an orphan. And he wanted to know the response that we were getting. And he asked me about what happened in May when I was here.

I mean, this is not going unnoticed. So I hope that people take this seriously. This is a public health issue, period. Millions of meals of bison are being served and other nonamenable products. They can be uninspected. They can be unsafe. And we should not, I don't think, waste time considering all of the frivolous things that surround it. Thank you very much.

MR. BILLY: You're welcome. Any questions? Dan.

MR. LaFONTAINE: I just want to make one clarification. States cannot get 50 percent funding for nonamenable species. Now if you do it within your state, that is possible. But there is no provision for federal

funding to states for this. So just a point of clarification, no one left feeling that some federal money is being devoted to this. That is not true.

MR. BILLY: Okay. Next on the list is Kenneth Reralson (phonetic).

MR. RERALSON: My name is Kenneth Reralson, and I am also a bison rancher. I was a veterinarian by trade, but I had a herd of bison as a hobby, and I turned it into my livelihood in the early '80s, in '81, to be exact. I started raising bison in '73. In 1975, I started slaughtering them. And having that training as a veterinarian and understanding it, having taken microbiology or bacteriology and all a few times, I wanted to have inspection immediately. And so then I did. I always went to plants that had inspection. And then when they made it voluntary, I started paying, and I have been paying ever since.

I think the public perceives when they buy something, it is safe. They think everything is inspected. And being a veterinarian, I can see this, but I have not been able to convince all the bison ranchers that they

should have. So I think for the safety of the industry and the safety of food, we need to make it mandatory for everyone. Like I said, I couldn't influence everyone.

One of the large groups that buy from us bison people are the older population. They perceive it as being a healthy food. And I'm sure they are not aware that they can buy it in several states without having it inspected. And so again, I think that we need to inspect it. Dennis, who you just heard, happens to manage a plant that 350 of us bison ranchers have built. And he has got a saying, let's act, let's not have to react.

Now I heard people talking about food illness here today. What do we need to get this out of the political arena and get it into a food health thing? Do we need to have a Jack in the Box thing happen with the ostriches or the buffalo or something else? I think we really want to look at this.

Another thing, there are many cases where the bison meat is mixed, and ostrich meat and other meats, wild boar and other things, are mixed in plants with others. You know, this negates the whole thing of food inspection. If

you take an uninspected product and mix it in with an inspected product, is this still safe? I don't think so, you know. This is about as ridiculous as saying that we will inspect all cattle except white cattle, for example, and then the food industry will be safe, you know. We can't mix it.

Now let's take this beyond the plant. Let's take this into the restaurant. Now a lot of states will allow you to serve rabbit, ostrich, buffalo meat, and other meat that isn't inspected. Now I heard you talk earlier that some of this food is handled by people that don't have a lot of training in science. When they slide all them meats across that chopping block, and all that other stuff, and put it on the same type of plates and the same silverware and everything else, you don't think we have cross-contamination?

I think it is time that if we are truly involved in food safety that we have to take in -- we have to -- we are living in a changing world. People's eating habits are changing. We need to inspect all food, and we need to -- the public needs to feel -- they paid -- when they pay tax

dollars for inspection, the public, they think all food is inspected. They don't realize that they are eating some that isn't. So thank you.

MR. BILLY: Thank you. And the final speaker is Felicia Nester.

MS. NESTER: Mine is shorter than the previous speakers. I'm Felicia Nester, with Government Accountability Project. I'm not sure if there is anybody here still that could answer questions on the HAACP slaughter models. Maybe Mike Grasso left. Am I right, there is no one that can answer questions? All right. I am going to make my remarks based on assumptions. I'll explain what they are.

I wanted to talk about GAP's concerns about the OCP, the other consumer protection category in the HAACP slaughter models and the way the other consumer protection violations are treated. First, I wanted to reiterate what I heard some consumers say and what some veterinarians were saying here today, that the categorization of food safety versus other consumer protection may not be sufficiently science based. I am very concerned that FSIS went ahead

with the models when that -- and there is still a debate about whether the category is sufficiently science based.

My second concern is how the OCP violations are enforced. And here is where the assumptions come in. My understanding is that food safety violations, if the plant does not meet the performance standard for food safety, the plant is issued an NR and the inspectors tell the plant that they have to fix their process so that they are meeting the performance standard.

In contrast, my understanding of the enforcement of other consumer protections is that no NR is written -- there is no government document written that they failed the other consumer protection performance standard and that the plant only notifies -- sorry, the inspector only notifies the plant that they failed the other consumer protection performance standard. I got that from the performance standard information that was passed out when the slaughter model was initiated.

If the inspector only has to inform the plant, and there is no required action on the plant's part, my question was, well, will the plants change their process so that they

at least try to meet that performance standard. The information we get from whistleblowers in the plants is that, no, they are not doing that.

Apparently, in the Guntersville plant, from October 4 through October 28, the local union president there says -- reports that on the first shift, there were 19 OCP failures, and on the second shift, there were 42 OCP failures. That is a total of 61 OCP failures in -- it looks like maybe 20 days of processing.

When FSIS started the HAACP slaughter models, they assured consumers that all regulations would have to be met. And we took them at their word. But if FSIS is not going to enforce this in any meaningful way, it seems that FSIS has just washed their hands of abscesses, airsacculitis, sores, scabs, intestines in the product.

Some people say that quality -- this is a quality issue, it is not a food safety issue. Let's assume that the concerns this morning were completely wrong, and this is only a quality issue. Some people say that the industry is just spinning in its own soup, that, you know, they are hurting no one but themselves because the consumers will

find out. Well, if FSIS is not keeping the records, how are the consumers going to find out? I mean, this product could be ground up for baby food. It could be in chicken potpies.

I would venture a guess that the reason that consumers eat as much processed food in this country as they do is because they assume that FSIS is following the mandate of the law and ensuring the wholesomeness of the food. I don't know whether consumers would have as much confidence in processed product if they found out that FSIS had decided not to enforce these standards at all. Thank you.

MR. BILLY: Since no one is here to confirm your assumption, we'll follow up and get that information to the committee. I don't think you're correct, but we'll get to the facts and share it with the committee.

Are there any last-minute thoughts from the committee?

MS. HALL: How long for dinner?

MR. BILLY: Well, the subcommittee meetings start at 7:00. So you can take as long as you like, as long as you are there at 7:00. I'd like to thank you all for your attention, and I think we accomplished a lot today, and look

forward to tomorrow. Thank you very much.

(Whereupon, at 5:25 p.m., the meeting was adjourned.)

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Date of Hearing

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