UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION

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FALL MEETING

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TUESDAY,
NOVEMBER 15, 2005

The meeting was called to order at 9:00 a.m., South Building Cafeteria Conference Room, United States Department of Agriculture, 14th and Independence Ave., S.W., Washington, D.C., Barbara Masters, Chair, presiding.

PRESENT:

BARBARA MASTERS	Food Safety and Inspection Service
GLADYS BAYSE	Spelman College
DAVID CARPENTER	Southern Illinois University School of Medicine
JAMES DENTON	University of Arkansas
KEVIN ELFERING	Minnesota Department of Agriculture
SANDRA ESKIN	Public Policy Consultant
MIKE FINNEGAN	Montana Department of Livestock
MICHAEL GOVRO	Oregon Department of Agriculture

ANDREA GRONDAHL	North Dakota Department of Agriculture
JOSEPH J. HARRIS	Southwest Meat Association
JILL HOLLINGSWORTH	Food Marketing Institute
MICHAEL KOWALCYK	Safe Tables Our Priority
CHARLES LINK	Cargill Value Added Meats
CATHERINE LOGUE	North Dakota State University
MARK SCHAD	Schad Meats, Inc.

ALSO PRESENT:

MARY CUTSHALL (SIPO)	Director
PHIL DERFLER Administrator (OPED)	Associate
DAN ENGELJOHN Administrator (OPED)	Assistant
BRYCE QUICK Administrator (FSIS)	Deputy
RICHARD RAYMOND Food Safety	Undersecretary for
ROBERT TYNAN (SIPO)	Deputy Director

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

8:56 a.m.

MEMBER TYNAN: Good morning. Welcome to our Fall Session of the National Advisory Committee for Meat and Poultry Inspection. I'm Robert Tynan. I'm the Deputy Director with the Strategic Initiatives Partnerships and Outreach staff, and I have the pleasure of moderating the meeting for today.

I want to personally thank everyone for taking the time out of their busy schedules to come and participate in this meeting. I know, in some cases, you've traveled great distances. And Catherine assured me that it was a good thing because it's snowing in North Dakota, and it hasn't quite gotten Minneapolis yet, I guess. No? Okay.

We'll be using this room for the entire meeting, so we'll be doing our plenary session, as well as our breakout sessions here. And we have an interesting agenda today. We've got a single issue as the focus, and we'll talk a little bit more about that in a few minutes. We're going to use two subcommittees, and we'll go into a little bit more of

the details of the logistics in a few minutes.

Because of the time constraints, I think I've made it a little bit difficult for Dr. Raymond to do his presentation. But knowing his experience, I'm sure he will make up for my problem with our microphones.

But let me introduce to you our Undersecretary for Food Safety, Dr. Richard Raymond. Dr. Raymond was appointed Undersecretary of Agriculture for Food Safety on July 18th, 2005. He's responsible for overseeing the policies and programs of the Food Safety and Inspection Service, and he chairs the U.S. Codex Steering Committee, which provides guidance to the U.S. delegation to the Codex Alimentarious Commission.

Dr. Raymond has extensive experience in developing and implementing policies and programs designed to improve public health. And in the interest of time, there's more, but I think I'm going to leave it at that for right now. Dr. Raymond?

MEMBER RAYMOND: Thank you, Robert. And we do apologize for the delay, but that may be bonus

for you because I have a 9:30 I have to get to, so that does shorten things up a little bit. I'll just talk fast. But I do want to assure you that the half hour won't come out of the public comment time. The half hour might come out of lunch or it might come out of dinner, but the public comment time will not be jeopardized at this meeting.

So good morning to the Committee and to the members of the public and FSIS who are here to listen and to participate in this meeting. I bring you, on behalf of Secretary Mike Johans, a welcome to the city of Washington, D.C. Your work here today is going to be very important and your work tomorrow on the agenda that we set for FSIS in the next three years to try to build a more robust risk-based system. I'll make sure you heard that: we want to build a more robust risk-based system. We are not here to build a risk-based system. We are already in one. We want to make it more robust. I think it can have a profound impact on the future of food safety in the United States, and we need your help.

NACMPI has been providing the USDA with

advice and recommendations regarding meat and poultry inspection programs for nearly 25 years now. But in the eyes of some, from what I have heard in my first few months here, the urgency and the necessity of NACMPI's missions has declined somewhat in recent years. They say it's because the issues that you have been asked to comment on have often not been politically charged. And today I think that's going to change.

I do not want to just serve as a caretaker of an already good system. I didn't leave the comfort of Nebraska where I have lived all my life and the comfort of a job being that state's chief medical officer that I felt very comfortable in that position for seven years, I did not leave all of that to come here and just be a caretaker. And I don't believe that Secretary Johans left Nebraska as governor either to be a caretaker of a good department. We both want to push the envelope in food safety and public health.

And I am here to issue this challenge today. I want you to push that food safety envelope and I want you to get outside that NACMPI box that

you've been in for the last three or four years, and I want you to provide me and the agency with sound advice on a number of critical questions that we have delivered to you in the issue paper concerning a risk-based system that can greater protect the public's health.

But before we go to the future, let's take a quick look at the past. I think that's very important. We all know that we can save lives from science-based policies. And as we move closer to the 100-year anniversary of the Federal Meat Inspection Act, we're able to show just how much progress we have made.

This slide, and it might be small from the back of the room, but these two slides, this first one is the number of recalls issued from 1997 to 2004. This is the amount of recall, the poundage. And as you'll see, we top almost 120 recalls in 2002, and we're down to a little over 40 in 2004. We did over 60 million pounds of meat and poultry products recalled in 2002. We're less than 3 million pounds in 2003 - 2004. That's very impressive. That's hard

work to get there. That's working with industry, the consumers, the scientists, and the agency, and our inspectors, educating our inspectors in how to do their job better. That was a team effort that did not come easy.

Now, some naysayers will say, "Well, if you're not recalling product, maybe you're not doing a good job of policing it. Maybe more people are getting sick because you're not recalling." I will tell you that I didn't come here to recall chicken tenders and hamburger and sausage because, by the time we get to the recall, we've got people that are sick. That's why we know we have a bad product. I came here to keep people from getting sick because that was my life as a physician.

Now, so we're going to use another way to look at what we've done in the last four, five, six years. Besides recall product, we do regulatory samples. This is E. coli. You see the dramatic decrease in the number of positive regulatory samples coming out of the industry. The same is for Listeria. Listeria will show the same dramatic continual drop

year after year after year after year of product sampling.

And, again, naysayers are going to say, "Well, if you don't sample as much product, you're not going to get as many positives." But what we're really here for today and tomorrow and the agency for their careers is to make sure that people don't get sick. So let's look at the CDC's data of human borne illness from food contamination.

The E. coli rates have dropped 42 percent since the baseline that CDC established from '96 to '98, an average of those three years. This is a sister agency, a different department. This is not us. We have no control. When they produce this data, it is not from a regulatory agency or from a marketing agency. This is the agency concerned with public health.

The data for E. coli, slightly less than one per hundred thousand people who now get sick with E. coli is below the Healthy People of 2010 goals established by Health and Human Services, not by us. These are not our goals. It's Health and Human

Services' goal of less than one people per hundred thousand get sick by the year 2010. We've reached it in 2005. That's huge.

You'll see the same decline for Listeria, I believe. Listeria monocytogenes will show you a 40-percent decline since the baseline. That number right there is a teeny-tiny hundredth of a point away from Healthy People of 2010 goals and objectives.

We'll take a look at campylobacter. You'll see a 31-percent decline. Again, campylobacter is almost there where we need to be by 2010 for the Healthy People goal. And then, lastly, for yersinia, you'll see the same drop from the baseline into here.

Those are dramatic numbers. But there's still work to be done. We should be proud of this, but we can't rest on our laurels. I know we can do more. We need the capabilities offered by this enhanced, more robust risk-based system to get there, however; but we can make improvements that will be just as impressive as these. But it does include the ability to anticipate and quickly respond to food safety challenges before they negatively impact public

health, as I already stated. This is vital. We have limited resources, and we must use them more effectively and efficiently that we can, and we need your help to guide us in how to use our resources.

Our current system, while very strong, was based in the world as we knew it in 1906 with the Federal Meat Inspection Act. I'm not sure that that 99-year-old act is totally geared for the 21st Century, however.

I was talking to Denny Greeny last week. He's the District Manager for Iowa and Nebraska, and I asked Denny to help me out and give me a visual because I know that part of the country so well. I asked him to give me an example of how plant inspectors might spend a normal day going from a small plant to a small plant to a small plant in a state that's not very heavily populated, as opposed to maybe if you have three or four plants in New York City you may spend a little bit of time working plant to plant. But in Nebraska, you get out into the hither lands, you spend a lot of time on the road.

So he gave me an example here on this map

we'll show you, and there were many, but this is the one I just happened to pick. There we go, there we go. This is Nebraska. This is the turf that I know. And this plant inspector starts his day out in Kearney, and he has three plants that he's responsible for. He has to go 50 miles down to Franklin. Then he has to go 13 miles up to Gibbon. Then he has to go 65 miles down to Beaver City, and then he drives back home in Kearney.

Now, on a good day without wind and ice and snow and blizzards and things like that, that's a little over two hours of road time that we pay for out of an eight-hour workday. That's what we needed to do in 1906. I'm not sure in 2005 if that is the best use of that person's time. With telecommunications and televideo, we can surely get more plant time for that individual and multiple individuals in examples just like this.

If that person spent less time on the windshield and got outside the box and outside that routine, I think he could take a look, for instance, what if that plant is having some problems with

Listeria. Maybe that person could spend some time with plant management and go over the compliance guidelines of FSIS, review the plant records, even conduct some environmental sampling, if that was appropriate. These are activities that are directly related to food safety. Driving down the roads of Nebraska are not necessarily directly related to food safety.

Another example: that same inspector, probably when he's down here in Franklin and Beaver City, when he does hook his or her computer up to put in the data, he's probably on a dial-up, and you all know how painful that is. We're talking about wasted time. Now, that isn't your issue. Our issue is to get DSL out there wherever we can get it, but that gives these inspectors more time to do what they're paid to do, rather than sitting there watching a painful dial-up come up.

This is what I mean by FSIS needs to use its resources more effectively and efficiently to improve public safety. And I don't know, nor does FSIS know, exactly what those specifics are and how

we're going to streamline this system. And that's where, again, we're asking you for your help for these two days.

I want to take a look at the next slide, Robert. I know this isn't going to work out in the back of the room, but it's an effort to impress upon everyone in the room today that we are not moving towards a risk-based system but a more robust risk-based system. We started out with HACCP down here. I'm sorry that you can't read it. It's a dark slide with dark letters. But maybe the first step towards risk-based was a HACCP system. And I do believe, when you look at HACCP and you look at those results of the decline in foodborne illness, this was the first risk-based effort that we made that FSIS has produced tremendous results with cooperation of all of our partners, including industry.

We set up HIMP five years ago. We went to Listeria risk assessments two years ago. We're finalizing the final rule on Listeria, which is risk-based also. I don't have a name for step four or step five or step six because I don't know what those are

going to be. That's why I want your help. I don't know if step six is the final step and that's the most robust system we have. Maybe there's seven or maybe there's eight steps. But you need to help us, you need to help us get there. We need to determine together what these steps are.

And I want to talk about that just a little bit now with the next slide. I want to use the analogy of a three-legged stool, and I think this is critical to what we're trying to get as a system. A stool won't stand unless it has three legs. Now, there's an open stool with one leg, but you got to sit on it while you milk the cow to make it stand. As soon as you stand up, it falls over.

So we're going to talk about a concept of a three-legged stool here, and I think it's important to spend just about five minutes on this. This is really natural for people to have concerns when we're talking about change, especially if we're talking about significant change. It's not always comfortable. But I want to try to clear up some misperceptions and the concerns by addressing these

issues openly, transparently, and publicly. I've been directed very clearly by my secretary to do just that, and that's how I intend to carry through this process. It must be as inclusive as possible. We need to increase our communication, our cooperation, and our collaboration with all of the involved entities.

And at the risk of leaving someone out, I want to start talking about the three legs. So let's go to the next slide, Robert. I'm kind of a visual person. It helps me, at least. I don't know if it helps you.

One of these legs is going to be the employees of the Food Safety Inspection System. The next leg we're building is going to be the industry. We can't make these kind of changes without the support of the industry and our employees. And the third leg is going to be the consumers, the public, the American public and also the international public that we export our product to.

Without one of those legs, I don't care which one you remove, next slide, it falls over and you don't have risk-based system that you're building.

It will take all three to build a state-of-the-art food safety and public health system.

So the three legs, what do we have for those three groups? And you've got to, again, forgive me if we exclude a group. We can be inclusive, but we don't need eight legs. But everybody is going to be involved in this, but these, I believe, are the three players that must be walking down this road with us, not necessarily hand-in-hand, not necessarily with unanimous agreement, but one of those three major legs says we're not with you, it isn't going anywhere, and we haven't done anything to improve food safety.

So for our employees, I think a risk-based system provides them the opportunity to focus more of their workday towards activities that will directly impact food safety and public health and be less bureaucratic. I understand it will require a large investment in employees to ensure they have the training and the skills that they need to be successful and consistent in a robust risk-based environment, but it is an investment that I know will continue to provide food safety dividends well into

the future. And if they succeed, then we all succeed.

I think that increased training and a wider range of opportunities to make a real difference in public health will also open up new avenues for career enhancement for our employees. And I hope that leads to improved job satisfaction, which ultimately leads to retention of valuable employees, and also aids recruitment of employees to fill empty spots.

It's important to have a dialogue with our employees as we move down this road. They need to be very confident, and their concerns need to be heard, and we need to answer them openly and honestly. And I've said it many times, and I'm going to say it again today, and I'll say it again and again: this is not about making reductions to our workforce, this is not about saving dollars, this is not about reducing our budget. This risk-based system that we're trying to build is about finding a way to produce a safer product that benefits every consumer by maximizing the effective use of our workforce, period.

Any employee that's in FSIS today that wants to continue work with FSIS will have the

opportunity for career enhancement under this system. This is not about reducing the workforce.

For the consumers, what do they get out of this? Well, first of all, I think we need to improve the public's confidence in our food safety system as we work to build this more robust risk-based system. We must have safe products from all plants of all sizes, no matter what they produce.

Those numbers you saw, that 42-percent drop in E. coli, that was a tremendous effort by the industry. Some made a bigger effort than others, and we need to help those who have been unable to make the same equal effort. We have a small plant, Mr. Schad, I believe, Schad, eight employees. You know, that's a small plant. But if you eat, and I'm not sure what Schad's Meats produces, I'm going to go out on a limb, but if Mr. Schad produces hamburger and you eat a hamburger tonight, you shouldn't care whether it came from a small plant or it came from a huge plant. They should all have HACCP systems and other efforts to make that product safe. We need to bring all of them together. So I'm glad to have small plants

represented on this committee, so we can hear their concerns also.

I realize it's a little more difficult for some plants than others, based on resources. But our experiences with HACCP and with the Listeria monocytogenes survey that we did and the interim final rule and now the final rule that we're writing, they show me that we can use sound science to mitigate risk. And the graphs show that we have done that.

As a physician, I also understand that that simple statistical decline doesn't really express the human toll that those illnesses can occur. So when I say I'm really proud that 42-percent fewer people will get sick this year from E. coli than got sick in 1998, that's good. But if I'm the one that gets sick, that's 100 percent for me. Don't tell me about statistics. When I'm sick, I'm sick. And I'm going to blame somebody, and it's going to probably be FSIS because you didn't do a good job. So I'm trying to figure out how to get that 42 percent to continue going down the right direction because it is 100 percent for those that are sick.

And I want to assure the consumers also in the room and that will be looking at this speech maybe later and on the committees we're going to challenge you to form that we will not make changes that do not result in a safer product. We're not making changes just to make changes. Change is uncomfortable, and it's not worth the effort if we're just going to continue the flat line on the product safety. The changes will only be made based on science that we know will produce results, not just on the graphs of recalls, not just on the graphs of sampling, but also, most importantly, on the graphs that show human illness as a result of foodborne illness.

Now, for the industry, we obviously need them to work with us. They've been good partners in improving those results we've already seen. Their cooperation is key in implementing an enhanced or more robust risk-based system.

Under an optimal system, which I hope we can get there, the type and intensity of inspections at an establishment will be based on performance and the product they produce and the process they use to

produce that product. I believe that a plant that has a spotless food safety record, science-based policies whose effectiveness has been validated and is in full compliance with FSIS' regulations should benefit from that track record. Our goal is to anticipate problems and correct them before regulatory enforcement action is ever needed. I've said before, but I'm interested in preventing and not reacting to a problem.

These changes that we're talking about will require the bar for the plants be raised even higher than they already are. But I am confident that industry will rise to meet this challenge. They've expressed strong interest in working with us on a risk-based, more robust risk-based inspection system. This change will allow FSIS to better focus, once again, its inspection efforts on the product, the process, and the establishments that are most likely to pose a public health risk.

Now, in closing, as I said earlier, we know from our past experience that we can improve food safety and we can improve our protection of the public's health by relying on sound science and by

working with industry, consumers, and our employees to more effectively mitigate risk. We also know that we cannot move forward unless all of our food safety partners are communicating, cooperating, and collaborating with us to make this enhanced risk-based system a reality.

There's still a lot of unknowns, and that's where your work here today and tomorrow on critical questions concerning risk-based systems is so vitally important. In particular, I want to challenge you to describe the ideal working group that you feel can best assist FSIS and me and the Office of Food Safety in approaching the next steps that are needed to enhance our risk-based system through an open, transparent, inclusive process.

Now, I've got some questions for you. Is it this committee that meets twice a year? I honestly don't think so. I don't think you can come here to Washington, D.C. two days every six months and move something forward. Is it a subcommittee of this committee? Possibly. But I know a lot of you have volunteered to serve on this committee two days twice

a year. To ask you to come to Washington, D.C. for two days once a month may be a burden you simply cannot bear because you have another life, and I understand that. But that's a decision we ask you to consider and ponder today.

Would it be a subcommittee? Would it be a separate new committee? If it is, we have some rules, some statutes that we have to work with. We can't do it overnight. There are some limitations on advisory committees, but I promise to you, I commit to you that, if that is the recommendation of this committee, I will do everything possible to expedite that process and form a separate advisory committee. And if that's what you recommend, you tell me how often should it meet? Who should be on it? How many people? Don't give me a committee of a hundred people. We'll get nothing done. Is it eight, is it twelve, is it twenty? And who should be on the committee? You tell me.

Let's just take an example. Let's say 12 is a nice number. You can get a lot of work done with 12. Is it four representatives from the public, is it

four representatives from the industry, and is it four representatives from FSIS employees? Or do we need our state inspection programs? Should they be represented? I mean, you tell me the makeup, but you make sure that it is something that we can live with, it's something we can defend. If it is four people from the industry, how does the industry decide which four groups come? If it's four people from the public, how does that consumer advocacy group get together and decide who's represented?

I look at it as the U.S. Senate. There's only 100 people there making laws. But they're responsible to 300 million people. We can't have every single entity on this committee, or we'll never get it done. You tell me what the committee looks like. You tell me how often they meet. That's a challenge, I know.

And the last thing and maybe most importantly, whatever you advise to me, whether it's this committee, a subcommittee, a new committee, a working group, whatever, who chairs it? My ego doesn't say I have to chair it. Dr. Masters' ego

doesn't say she has to chair it. If there would be more confidence in the three-legged stool that we have an outside person without a dog in this fight chair it, fine. Tell me that. We'll figure out who that person, who that entity, what that organization might be.

We might take some ownership in the final product, I don't take ownership of the committee. It will be some kind of a working group, advisory committee that can listen to people who have knowledge, people who work in plants, people who produce the product, people who are scientists that have studied this issue for years and years and years. I need the help. That's my commitment to you. That's my biggest challenge for you today is tell me how to do this. I want to move forward. I want to do it fairly rapidly.

So I ask you don't focus on what's worked in the past, don't focus on the last 99 years. We've done good work. We've done great work. Let's focus on the future. This is a really, I think this is a crucial test for this committee, and I'm confident

that you're going to pass this test. But we have to begin work on enhancing our risk-based system so that we can meet the food safety challenges of the next 100 years, and some of them we don't know what those challenges will be yet. We know we've got issues. Some of them are very open to us, and we need your help to address them.

The state of public health is constantly evolving. We can't afford the risk of not evolving along with it. Robert, if you've give me the next slide, I'm going to wrap up here in just a second.

In 1900, at the turn of the century, the average life expectancy of an American was 45 years of age. It is now 75 years of age, and the biggest reason for that is getting control over infectious diseases. In 1900, nine out of the ten top causes of death were infectious diseases. They included things like diphtheria, for which we have a vaccine; tuberculosis, which we have medication. They included things like dysentery, interiditis, typhoid, and cholera. Things were brought about by crowded living conditions, unsanitary sewage, bad water, bad food.

Now, in this job, I'm going to say safe food is the biggest reason that life expectancy went from 45 to 75. Last year, I said it was public health and immunization. It just depends what hat you wear. So now we're going to say it's safe food.

In the year 2000, when the life expectancy was 75 years of age, nine of the ten leading causes of death were illnesses brought about lifestyle primarily: diabetes, lung cancer, emphysema, heart attacks, strokes, HIV/AIDS. The infectious diseases got under control in the last century because of sanitation, water, food, antibiotics, and immunizations primarily, and some better healthcare services.

So the Centers for Disease Control was formed to get a handle around infectious diseases. They have added something to their name. It's now the Centers for Disease Control and Prevention because the Centers for Disease Control's biggest efforts now are based on educating people about diet, exercise, don't smoke, wear seatbelts, etcetera.

We need to change FSIS. It is a new

century. And we are doing some of those things. We are trying to educate the public on safe food preparation and handling. For instance, you know, it used to be regulation of the plants, and that was it. And God help you when the food got home if you didn't prepare it correctly. We've gotten into that education mode. We've got some resources that would help us do that. But right now, they're spending two to three hours a day driving around the roads in Nebraska.

You tell us how we move into the next century. And because, I'll finish up here, because I bring this point up because while things have changed, things haven't changed. You're here for one reason. I'm here for one reason. FSIS employees are here for one reason today. The public that's sitting out there is here for one reason today. And that's to help save lives. This is our most important asset, and that's what we're here for today.

So I ask you to help us figure out the next steps into this new century. I know you can do it. I'll look forward to your reports. I'm going to

try to spend as much time with you in the next few days as I can. I definitely will be here for the committee this afternoon, but I've got a couple of commitments this morning that I've got to get to. I apologize for eating and running. I wish you good luck for your deliberations. I hope the challenges will be met and accepted. It's a new world.

So, once again, thank you for coming to D.C. Thank you for the audience. We will allow you time for participation today. I promise you that. Thanks.

(Applause.)

MEMBER TYNAN: Thank you very much, Dr. Raymond. Next on our agenda, I'd like to introduce the Administrator of the Food Safety and Inspection Service, my boss, Dr. Barbara Masters.

CHAIRPERSON MASTERS: Thank you, Robert. And we appreciate Dr. Raymond's remarks and also his challenges. On behalf of FSIS, I want to welcome you also to this important public meeting. As always, I'm encouraged by the dedication and enthusiasm that brought all of you to this meeting, and we look

forward to a productive forum.

We joked a little bit about getting your rolls and your coffee this morning because we recognize that what brings you here is your dedication and enthusiasm, and we appreciate the work and the challenges that you're going to take on in the next two days.

I realize more than ever the challenges that are confronting all of us, and I remain committed to protecting public health and making sound public policy decisions at the national level. I'm very glad to be here at this two-day meeting because it provides me an opportunity to get to know you a little better, but it also gives us a chance to build on the three areas that Dr. Raymond finished with, and that's communication, cooperation, and collaboration. All of these elements are essential as we move forward to improve food safety and also to further protect public health.

That's why I'm really excited to hear your ideas and to get your recommendations that you might have to improve food safety. This committee's work

and recommendations are vital to our success as an agency and, above all, to protect consumers. Your suggestions and your feedback are critical, and I think we have been taking your suggestions very seriously as we shape our policy positions.

We will be providing you updates on our issues that we've had in the last couple of meetings, and we'll be going through the briefing papers on recent topics. There's time on the agenda for you to get those briefings and also to ask questions that you might have on those briefing papers. And so I think you'll see that we've been taking your feedback very seriously, and I think we've made a lot of progress on recent agenda items.

However, I think there is a new flavor and a new tone for this particular meeting. We have a very focused agenda, and the next two days are very important to us as we move forward in the direction of further protecting public health, and that is by talking about furthering our steps in risk-based inspection.

We are seeking input from this committee

on two specific areas, and that is information on data and on risk-based inspection. And those are the two areas that we're going to be asking for your consideration on in the two subcommittees. And again, I think the information was in your package of materials.

Robert has put up a slide. I think it's really important to recognize, and I think Dr. Raymond did a good job of talking about -- wrong one. It's okay. I think Dr. Raymond did a really good job talking about the dramatic steps that we've been taking moving towards full implementation of risk-based system. He provided the analogy of the three-legged stool with each leg representing consumers, our employees, and the industry, respectively. And each of those legs are vital so the tool doesn't collapse, so that we have our risk-based system.

We in the agency see ourselves as building the infrastructure to support -- keep trying, Robert. We see ourselves building the infrastructure to support the Office of Food Safety's three-legged stool so that it can hold up that three-legged stool.

And what we're trying to do is to give you a different depiction to demonstrate how we can work together to provide that infrastructure to support the same three groups that Dr. Raymond was talking about, which is the industry, our personnel, and the consumers. And in this slide, if you look at the foundation and moving towards that full implementation of a risk-based system that Dr. Raymond mentioned, he also talked about the steps moving towards that full implementation, looking at the full implementation of HACCP. We talked about HIMP, risk-based Listeria testing, and not knowing what those next steps are towards full implementation of a risk-based system.

But we recognize before we can talk about those steps that we really need to conceptually understand the risk-based infrastructure, and that's what we're going to be talking about over the next few days. We felt we needed to focus on the bigger picture, the end goal of a fully-implemented risk-based system. We see that as our roof. As you see in this slide, we wanted to give you that picture because we believe to get that public health protection that

we needed your advice and guidance on getting that infrastructure, what kind of protection we might get from that roof.

So later this morning, Mr. Phil Derfler is going to walk you through the concepts of this infrastructure because what we really see in giving us that infrastructure is the work and the role of our inspection personnel and data as it pertains to our risk-based inspection system.

And so we're going to be getting your advice and guidance on putting those pieces together. And so Phil will be walking you through some very detailed questions and getting your input on the data, the public health data, and the kind of things our inspection personnel might do to help us raise that roof.

You can also see here, if you move to the next slide, that we go to the same three groups that Dr. Raymond talked about. And he started getting into this a little bit. We, as an agency, recognize our role and responsibility in working with the regulated industry and ensuring that all establishments have

well-designed and implemented effective food safety systems as we further move into a full risk-based inspection system. And we've begun doing and re-energizing our outreach efforts with the small and very small plants, and we're looking at how we can continue our significant outreach efforts in the coming year.

And when we look at our FSIS personnel in that pillar, we have done a lot of work in the area of training, and Dr. Raymond talked about that, and the role for our FSIS inspection personnel to collect, assess, and respond to public health data in a way that they can proactively look at that data. They need to be able to collect, assess, and respond to that data in a way that they can be proactive. And further, in a fully-developed public health risk-based model, we need to be able to go back and have that assurance function to be assured that whatever changes we make they have been the right kind of situation to verify whether or not we've corrected the situation with what we did when we made the policy changes that we've put in place when we collected, assess, and

respond.

So those are the kinds of things we're looking at and the kind of questions we'll be asking you as we go through the subcommittee. Because, again, under an optimal risk-based system, the type and intensity of inspection activity we'd be looking at would be determined by an analytical process that allows our inspectors to foresee problems. Again, we want to be proactive, so they can focus their efforts at plants and at processes that pose the most public health risk.

But most importantly, to get to this point, what we recognize as an agency is that we will need either new or, at least at the very minimum, updated public health data systems that allow us to collect, assess, and respond to that public health data. So you see that on the bottom step there. That is the rock-solid foundation for us is to have the right data that we can look at to be proactive. So raising the roof and having that solid public health data system, which is why we're going to be talking to you a lot today about data.

And our consumer pillar. Again, each and every one of us here are consumers, and we want to have confidence in the food supply that we're eating. And we recognize that any step that we take forward has to ensure further protection of public health and that we need to be moving forward, as Dr. Raymond said, receiving input from all of our stakeholders every step along the way and that we need to work with all of our food safety partners to ensure that every one recognizes the goals and expectation of the system that we're working on.

So Robert, if you could go back to my previous slide. I just want to reiterate that we are interested in receiving your input and discussing the broad-range concepts of risk-based inspection, as you see at the top of the slide. Again, raising the roof. And also, our public health data systems that form the very bottom of the foundation.

We know that everyone understands that, as Dr. Raymond said, the three-legged stool is important, that we need to have support from the regulated industry and our personnel and consumers as we move

forward. And I know everyone sitting out there has a vested interested in the steps, and it's very easy to want to jump right to those steps.

But in particular, for those steps that we don't even know what's on them, the question mark steps, those are the ones in particular everyone wants to run up and say, "But what about this? What about that?" We recognize this is the first of many public forum where we'll be discussing this. And in fact, Dr. Raymond challenged this subcommittee to give us ideas about how we can have more public forum. And we believe it will be very likely we, as an agency, will probably have public meetings on the steps.

But we felt it important, before we got to the steps, to get advice from this subcommittee on the infrastructure to support those steps so that we had a solid foundation in place to even get to those steps because if we don't have a solid foundation, likely those steps will lead to nowhere. And so we wanted to make sure that we asked the right questions before we even started focusing on some of the steps, particularly these unknown steps.

So I know many of you are anxious to work on the steps, but we'd ask you to indulge with us on the roof. When you build a house, you've got to put the roof on before you can start hanging the drywall and putting the paint and the furnishings. So help us build the infrastructure before we get to the steps, which is where many people want to get to is those steps.

So we really would ask you to help us think more broadly about the decisions that we need on data and our inspection personnel, which is what we really want to get through today. And I think you'll understand that when Mr. Derfler walks you through. We have some very detailed questions that we have for our subcommittees.

We'd also ask you to think in your subcommittees even down to the level. If you're deliberating and you're talking, we'd even welcome your thoughts on the definition of risk as it relates to product, process, and plants. And I think that was one of your questions. If you get into that kind of discussion and you have thoughts, we'd welcome that

kind of input from our subcommittees.

If you're deliberating and you don't have a question there but you have thoughts and say, "I wonder why they didn't come up with this question, but we think it would be good feedback to the agency on inspection or on data," please provide that information to us. We want the most solid foundation that we can have because the more solid our foundation the more likely we are to build an infrastructure that will allow us to protect food safety and further protect public health.

Please recognize we think we came up with some good questions, but we want all of your feedback as it relates to these areas, and we recognize that this is not the only time we'll be talking about this topic. It's the first time that we're going to be presenting it, but I will remind you we did talk to this committee about risk-based Listeria testing and on data and on training and outreach because we recognize many of those are building blocks, but now we want to get to the heart of the infrastructure and we'll be back to the steps in the future at many

public forum, and we look forward to the deliberations because I suspect this will be a very energetic topic.

But again, if you think of something that we didn't think of, it's not that we didn't want to talk about it. We welcome your input on all of those areas. So we look forward to your input, and we'll look forward to the deliberations. And we'll also look forward to, again, hearing from the public and your comment on these areas.

Before I conclude, we have a new person on our committee for the first time today. We'd like to give her a certificate. Dr. Andrea Grondahl, and your certificate reads, "With appreciation for accepting the call to serve the nation and the U.S. Department of Agriculture as a member of the National Advisory Committee of Meat and Poultry Inspection." So when you hear us joke about your doing this for your coffee and doughnuts, we do appreciate the hard work that you're going to do over the next few days and the next couple of years. So thank you very much.

(Applause.)

CHAIRPERSON MASTERS: And that thank you

goes to all of the committee because we recognize the next couple of days are going to be a very energetic and lively day, so thanks to all of the committee.

MEMBER TYNAN: Good morning again. We're going to go through the portion of the agenda called a charge to the committee. And I know we've been through the charge so many times, but bear with me.

But what I'd like to do, though, before we do that is something in the interest of time when Dr. Raymond was here we did not do is perhaps go around the table and just introduce ourselves one more time so that we know who we are, and the young lady that is doing the transcription will also know who we are, as well.

So I'm going to start with myself. I'm Robert Tynan. Again, I'm the Deputy Director of the Strategic Initiatives Partnerships and Outreach Staff, and I'm going to reach down here and ask Mr. Quick.

MEMBER QUICK: Hi. I'm Bryce Quick, the Deputy Administrator for FSIS.

CHAIRPERSON MASTERS: I'm Barb Masters, Administrator, FSIS.

MEMBER FINNEGAN: Mike Finnegan, Montana Department of Livestock.

MEMBER HARRIS: Joe Harris with Southwest Meat Association.

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

MEMBER BAYSE: Gladys Bayse, Spelman College in Atlanta.

MEMBER SCHAD: Mark Schad with Schad Meats in Cincinnati, Ohio.

MEMBER LINK: Charles Link. I'm with Cargill Value Added Meats, Wichita, Kansas.

MEMBER LOGUE: Catherine Logue, North Dakota State University.

MEMBER ESKIN: Sandra Eskin. I'm an attorney and public policy consultant, and I do work for a number of public interest groups on food safety issues.

MEMBER KOWALCYK: Michael Kowalcyk. I'm with Safe Tables Our Priority.

MEMBER CARPENTER: David Carpenter, Southern Illinois University School of Medicine in

Springfield, Illinois.

MEMBER HOLLINGSWORTH: Jill Hollingsworth, the Food Marketing Institute.

MEMBER GRONDAHL: Andrea Grondahl, North Dakota Department of Agriculture.

MEMBER DENTON: James Denton, University of Arkansas.

MEMBER ELFERING: Kevin Elfering, and I'm the Director of Dairy, Food, Meat, Poultry, Egg, and Feed Inspection with the Minnesota Department of Agriculture.

MEMBER TYNAN: Your acronym is longer than mine.

MEMBER ELFERING: Yes, and we don't even use an acronym. See if you can spell something with it.

MEMBER TYNAN: Let me walk through the agenda very briefly, so that we all know what we're going to be doing for the next few days. We obviously have gone through our welcome and some of our opening remarks, but the charge to the committee is now we're going to do, after we get through this portion, we're

going to do a little bit of an update on the issues from the previous meeting. That will be followed -- so I'll give you a brief summary. You can ask some questions on any of those issues, if you have any. And then we'll go into the briefing papers, which are probably updates on things from previous meetings or issues that we wanted to bring to your attention.

In fact, I believe in front of you you probably have the legislative update, and you can take a look at that. I believe Lisa Picard is in the back of the room, so if there are any questions regarding the legislative update, you have an opportunity to take a look at that, we can get those questions answered for you, as well.

At 10:15, we're scheduled to take a break, and we'll probably be back pretty much on track time-wise. And then we're going to get into the issue for the meeting. And you'll notice that we only have one major issue, which is risk-based inspection system, and that's been the theme so far in the two opening remarks, and that's what we're going to be doing for the rest of the day.

We'll have two subgroups that are working. Mr. Kowalcyk is going to be chairing one, and Dr. Carpenter will be chairing the other. And we're going to divide the questions up, and we can talk about that as we get a little bit closer to it. So we're going to assign the questions a little bit differently this time and ask you to do the work a little bit in a different format than we have in previous meetings. And I think it will be an enjoyable activity and get us through some very detailed questions.

Let's first look at the rules of order, finally known as Robert's Rules. They're under tab 14, and I'll just walk you through them very quickly. We did these probably 18 months ago, maybe as much as two years ago, and we did these for the purposes of making sure that we had an efficient and effective meeting, that things went smoothly all the way through. So let me read through the Rules of Order.

Obviously, the FSIS Administrator is the Chair that's the conducting the meeting and has delegated to me the opportunity to sort of moderate the proceedings. All the questions, requests to speak

have to be addressed to the Chair. People must be recognized by the Chair before speaking. So that's, obviously, there are going to be a lot of questions on this particular issue. We want to try to make it a more considered way of responding to that.

And if I could ask, I don't know if you did it at the last meeting, but as you have questions, if you could take your tent cards, sort of stand them up on their side, and then I'll know you have a question, and we'll find some way, in an organized fashion, to get around and get everybody's questions answered.

Presentations of the issue paper are going to be followed by some short question and answer periods. In the interest of time, some of the questions and comments maybe would have to be limited somewhat in length. It will be more in terms of clarification. Longer comments we may want to save for the public comment period, but that will be up to Dr. Masters to decide for timing purposes.

Any materials that anybody has that they wanted to display, you need to check in with us before

you put those out on the table for the public meeting. So they have to be approved first.

Committee members are expected to attend the plenary sessions of the meetings and the subcommittee meetings to which they are assigned. So the committee meetings who don't attend a presentation of a particular issue, in this case you can't avoid it I guess, participating in the subcommittee meetings, you'd have to be in your own subcommittee in order to participate in the discussion on Wednesday morning. That's in order to be fair to everybody that is working on the different aspects of the issue.

The subcommittee chairs designated by the Chair, and, as I mentioned, Dr. Carpenter and Mr. Kowalcyk are going to be the chairs for our subcommittees, they have the authority to control a meeting. Members of the public that want to attend either of the subcommittee meetings may do so, and it will be up to the Chairperson to decide how much input the public can have in those deliberations.

And last but not least, the Rules of Order are subject to review. So if at any time some of

those are too onerous, I don't think they are, but if you think they are we can talk a little bit about them; or if there are some other rules that would be helpful to make the committee run more smoothly, that will be great. We can talk about those, as well.

Any questions so far? Maybe we can talk a little bit about the updates from the previous session, and they're under tabs two, nine, and ten. I beg your pardon. I think it's -- I apologize. It's four, nine, and ten.

So the first one has to do with an update on risk-based sampling. And is Dr. Engeljohn here? Okay. Just briefly, this was an issue that was brought up with the committee in June. It has to do with Listeria monocytogenes and ready-to-eat meat and poultry products. FSIS has completed a test phase of the surface testing program in 14 plants between July and September of 2005, and that's in anticipation of a nationwide implementation. So the program is going to test for Listeria monocytogenes on food contact and non-food contact surfaces.

So this was targeted toward high-risk

operations. I think they found that food contact surfaces would be positive for Listeria monocytogenes when the product itself tested negative.

There's also considerable differences in the degree of validation provided by the different plants, and the results of this are going to be incorporated into a new compliance guideline.

Last but not least, FSIS is assessing how to incorporate more of these issues identified by the Advisory Committee into the risk-based verification testing/sampling structure. So most of that is incorporated right into your issue paper, your update.

Do we have any questions on that particular update? Mr. Link?

MEMBER LINK: Charles Link with Cargill. It's kind of loud. Yes, I've got some questions about the sampling program and data collection I guess. And I think it fits into this discussion. I know that FSIS is out doing some data collection on Listeria in plants and are going out. There's a draft that's being utilized to gather information, as well.

Talking to colleagues, I guess, that have

gone through some of this, I guess some of the questions that have come up is on the survey I guess FSIS is not allowed to discuss with the plant. I guess the inspector in charge is supposed to gather all the information. And in some cases, there's areas to answer the questions yes, no, or I'm not sure.

When they're doing the testing, it's kind of a week-long test. I guess we're going in and doing a lot of product testing and contact surface testing for Listeria monocytogenes. And in doing that, it creates quite a bit of, I'll call it painful for lack of a better word, simply because if we're doing week-long testing, we're doing week-long holding of everything we produce in that plant, which is pretty detrimental to the business. So we've got to find a place to put product. Customers are not very happy with us because we can't ship the product. And then we've got surveys where we're not real sure we're getting all the answers and not sure we're coming up with a good conclusion when we're leaving the plant after they've done the survey and done the food safety assessment, I guess, if you want to call it that.

So I'm just curious as to how that's working, if there's maybe some ways to make it a little bit better. I know it's quite painful, and I don't want to speak for small plants, but I can't imagine some of these small plants being able to go through a week of this and hold product and not get it on the market and maintain their customer base in the process. So I'm just looking for some comment on how that's going and if there's way we can make the system maybe even better.

MEMBER ENGELJOHN: This is Dan Engeljohn with FSIS. On the document that you're talking about, that's what we call a checklist, and it's what we're using as an instrument to gather more specific information about the degree of validation that is used as the foundation for the food safety system. So its intention was to ask the types of questions that would help discern whether or not the validation is supported by actual data or it's supported by computer modeling or other research that may not be directly related to the implementation that occurs in the plant.

And so that was one way that the agency could also take that feedback, put it into our risk-based program to target operations that don't have real data or really strong justifications for their food safety system to be targeted at a higher rate than those that do not. So the issue was to have an instrument. We did make that instrument available to the public earlier in October, in which we asked for comments. That was through the constituent update. I will say we did not get many comments until just this past week, actually, from an individual from the industry associations. But we really were looking for public comment on how to make that instrument a better tool.

We found it be extremely beneficial to our food safety assessment team, the EIAO that went into the plant in particular, because it helped direct them to look at the appropriate types of questions to help discern whether or not the data is there to support the system.

The issue about sharing the information with the plant, we have made it clear there are two

issues to deal with. One is we would have to seek OMB approval if we were to do a survey of the establishment and have them answer the questions. Our intention, however, was to have our employees use that instrument to better understand the food safety system's rationale.

And so the intention, though, and as we've directed our employees, is at the completion of the survey, of the checklist is to share that information with the plant. And this would be the perfect opportunity in the exit meeting to go over what they found. The plant certainly can provide at that time any clarifications or their rationale for why they think the answers were not appropriately assigned to the checklist, and that interaction could occur. So if that didn't happen, we certainly would follow-up to make sure that it does.

Our intention is to include that checklist as part of all the future food safety assessments that occur because we do find it to be a very valuable tool. We'll find ways to make sure that that gets shared with the plant. Our goal would be that that

plant actually has that tool and has the data already available for the food safety team to review before they get there so that time isn't taken aside from that.

In terms of the length of the food safety assessment, the food safety assessment that occurs is not simply for the Listeria program. When our team goes in and conducts the food safety assessment, they're looking at the entire food safety system. And so depending on the complications of that system, it may take longer. And we do recognize that it's taking a week, in some cases two weeks. The testing component to it does not take any longer than what the usual testing does when we take a product sample, or at least that's the intention of the program. We're certainly evaluating all those components to see how they work in the pilot so that, when we go nationwide, we can have that under control. Our goal also is to give the plant advanced notice of when we're coming in to take that particular assessment, so that there would be the opportunity to hold the product and to make arrangements with the marketing of the product.

MEMBER TYNAN: Dr. Hollingsworth, you had a question?

MEMBER HOLLINGSWORTH: I did. And, actually, Dan addressed a portion of it, but when I read this update I was a bit confused, partly because our first report to the FSIS on this was back in June and, with my memory, that's a lifetime ago. But I was confused about the status report versus what I recalled we proposed to the agency, which was looking at validation in small and very small plants. But when I read the status, what I wasn't clear on is the testing phase for contact surfaces done in 14 small and very small plants, was that test focused on finding better ways to deal with unique risks at small and very small plants? There almost seemed to be a disconnect there, so maybe I've misunderstood that.

Also, under the status in the bullets, there was one that says as a consequence of the new risk-based program, and that just seemed to drop out of the blue. I wasn't sure what new risk-based program was being referenced here in these bullets. So it might have been my misunderstanding of this

update, but the status report seemed to disconnect with the background and what I believed this committee had spoken to the agency about.

MEMBER ENGELJOHN: This is Dan Engeljohn to follow-up. As you pointed out, Dr. Hollingsworth, the work of the Advisory Committee in the June meeting was to provide us information about how to better address risks related to small and very small plants. And I think, in general, the response was that the small and very small plants are not unique in the issues that they deal with and that risk-based should cover all aspects of the operation.

What we have reported here is how we currently have constructed our Listeria risk-based program, and part of the 14-plant study was to look at small and very small plants included within the 14 plants. So there was, amongst the 14 plants, large, small, and very small plants. And our job now is to look through that data to see what unique opportunities afforded themselves in that particular risk-based program.

The new risk-based program is the addition

of FSA, the food safety assessments, the checklists, and conducting the food product contact surface test and the environmental tests. So that's the new aspects that were added there.

So we have our Listeria program, which we had designed. We took a pilot in 14 plants for assessing that to see how we need to make modifications. The recommendations from this committee from June then will be incorporated into the future design of both the Listeria risk-based program and the E. coli program. So we have the Listeria one ongoing right now, but the information provided by the committee will help supplement how we modify it in the future.

MEMBER TYNAN: Mr. Link?

MEMBER LINK: Charles Link. Just a real quick follow-up. During the exit interview, I guess, or the exit meeting, that would be an opportunity then for us to discuss any of the questions that we disagree with, answers I guess, and maybe to clear it up at that point. So I guess my fear is I don't want to go away from this not sure where the plant sits. So

when it's over and done, as we're moving forward, we know where we are relative to the risk assessment.

MEMBER ENGELJOHN: It is our goal to ensure that before the team leaves the plant after conducting a food safety assessment that the plant will have a very clear understanding of the responses that have been put together. Those would be shared. And to some extent, there would not necessarily be consensus there, but at least if there is disagreement, we need to be sure that we know that.

But we do want to give the plant to opportunity to provide us feedback, so we will make an effort to ensure that that does occur. This is intended to be an educational tool, to some extent, to provide the plant with the perspective that the agency has about validation in particular, but for the establishment itself to come back and provide information that we may have missed in the conduct of that food safety assessment.

MEMBER TYNAN: Ms. Eskin?

MEMBER ESKIN: Sandra Eskin. Mr. Engeljohn, again in that test phase, you identified

there were 14 plants of varying sizes. How were those plants picked, and is there any assurance that, in some ways, it's representative of the whole set of plants?

MEMBER ENGELJOHN: Thanks for the question. The 14 plants represent -- first, there were intended to be 15 plants, but we only did 14 because the 15th plant was in a district which was affected that same week that we were to conduct the food safety assessment as the hurricanes came through.

Our goal in what we call this, basically, a pilot phase was to test at least one plant in each of the 15 districts. And the plants were selected by a process in which, through the survey information that the plants are required to provide to FSIS on an annual basis identifying what's produced, how much is produced, and how effective their programs are at controlling Listeria, that was information that helped provide some basic discernment as to which plants in each district present the highest risk. And then from that list of plants, the district manager had the opportunity to decide which plants in that district

would best be able to send in an FSA team.

And so we identified to the district managers the high-risk operations within those plants, giving them some guidance to ensure that we got a cross-section of small, very small, and large. And the intention really was to ensure that the EIAO, these are our inspection force personnel who are trained and are able to do a more in-depth analysis of food safety systems. They're the ones that go in and conduct these food safety assessments, so it became one issue of where could one be conducted, how quickly could we get a team in there, and who had not had one in the relatively recent past.

So there were a number of factors that went in there, and it really was to get each district in tune with how to conduct this, not necessarily to get a true sampling of all the plants because we will, in fact, be operating this program nationwide. It really was to ensure that each district had an understanding of how we wanted this conducted, particularly with the new aspects of Listeria verification testing.

MEMBER TYNAN: Mr. Schad?

MEMBER SCHAD: Yes, Mark Schad, Schad Meats. Dr. Engeljohn, I guess I still, in my mind, I'm a little confused. The district manager decided what would be a high-risk operation; is that correct?

MEMBER ENGELJOHN: No. We, here in the headquarters office, have access to plants' performance information. We have access to the information that's supplied on an annual basis by the establishment. By regulation the plants are required to provide specific information that helps us discern what are high-risk operations and what are high-risk products. And with that information, then we here in headquarters directed the districts with a list of plants that fell into the highest-risk category versus a medium risk versus lowest risk. So we gave each district a listing of the highest-risk operations.

MEMBER SCHAD: That risk was based on compliance or that was based on -- this is really the product, correct?

MEMBER ENGELJOHN: Yes. The risk was based, in part, on what products are produced. We

know from our risk assessment that deli meats and hot dog products present the greatest risk for human illness associated with the products that we regulate, so those categories fell into the high risk. If they produced the alternative three product, which would be those products without a post-lethality treatment or a antimicrobial growth inhibitor, that fell into high risk. If they produced a high volume of product, that also contributed to one of the factors.

Other things fell into the algorithm, such as performance history. Has there been positives in the past? Has there been performance related to problems in the plant in the past. Those things factored in, but it truly was the high-risk products and high-risk operations.

MEMBER TYNAN: Mr. Kowalcyk?

MEMBER KOWALCYK: Michael Kowalcyk with Safe Tables Our Priority. You mentioned in the update that testing for E. coli will occur in the spring of '06. Could you provide any additional update as to where the agency is in the stage of setting that program up?

MEMBER ENGELJOHN: Yes. The agency is at a crossroads in terms of moving forward with our 0157 program. As you know, last year we put forward our directives on changes into the system in terms of what products are sampled and started that process before the high prevalent season began.

You should expect that this year the first step in this process will be part of our baseline study, which is going to occur, in which we are beginning to test trim for the first time. The baseline study is designed to get a nationwide prevalence associated with the particular product that we're sampling, but that also represents a step forward with our risk-based program because it will be testing trim, in addition to ground beef. So that's the first step in this risk-based program.

We don't yet have specific information about who produces the various types of trim and who has a number of suppliers to them. The factors that we believe may have an impact on risk, and some of those factors are what your subcommittee in June identified. We will begin the process of trying to

glean from the plants who's producing what, how much they're producing, and what controls they have in place for an effective program. And that will contribute to our decision-making.

But we don't yet have that information. We haven't begun the process of gathering that from our inspection employees first. And as we move through the process and identify what risk factors matter the most with regards to risk in E. coli 0157h7, we do intend to pursue getting OMB approval to get other information that would come from the establishments themselves. But our first step will be to start the baseline study, which will include trim, and that we count as part of our risk-based program. And then from there, we'll start moving into other operations that present higher risk, as we have the information available to us. It will be a multi-step process.

MEMBER TYNAN: Dr. Hollingsworth, you have another question?

MEMBER HOLLINGSWORTH: Yes. Jill Hollingsworth, FMI. Dan, do you already have a

protocol written for the E. coli testing plan, or will one be made publicly available as far as what samples you're taking and where and how many and all that kind of information?

MEMBER ENGELJOHN: The only information available at this time on the 0157 program is through the FSIS notice that we issued that announces the beginning of the trim baseline study, so that's what's available right now.

CHAIRPERSON MASTERS: We can make the FSIS notice on the trim baseline available. We can get copies of that brought down. As Dan said, that's the first step in moving in that direction, and we're a long way from moving beyond that as an agency. So we can get copies of that brought down.

MEMBER ENGELJOHN: If I can, Dr. Hollingsworth, just to follow-up, are you asking what is the protocol behind the statistical basis of the program? Is that what you're asking for?

MEMBER HOLLINGSWORTH: Yes, more what is the plan for how many samples over how long a period a time. What is the baseline design on this? I

understand it's not ready yet. I understand that that's not ready yet. My question then was will that type of protocol be available in the future?

MEMBER ENGELJOHN: Yes. I think in the interest of transparency, we certainly intend to do everything we can to make as much information available as much as possible. I will say that much of the design of the program was, in fact, made available to the National Advisory Committee for Microbiological for Foods, in which they commented on the design of the program. So that protocol has been previously made available. I'm not sure if it still is, but we will, we certainly will intend to make that available.

MEMBER TYNAN: Are there other questions on this update? Maybe we'll move on to the next one. Thank you, Dr. Engeljohn. The next issue from the June meeting has to do with applying a market inspection to product tested for an adulterant. And FSIS considered the advice of the committee, and the agency met with industry about this particular issue.

As a result, a group of industry trade

associations drafted guidance for establishments on holding products when the agency samples. I think one of the recommendations was that FSIS refrain from issuing their own guidelines and instead review the industry guidelines instead.

The industry finalized its guidelines and the agency found no objection to their issuance. The industry has issued its guidance, and the agency is working with the industry to disseminate those guidelines. I have Mr. Gioglio here, who is the resident expert on the guidelines, and I'll ask him maybe to come up, if there are any questions from the group. Ms. Eskin? One question always leads to another one.

MEMBER ESKIN: Sandra Eskin. At the very end of the briefing paper, it indicates that FSIS is working with the industry to plan an evaluation of the guideline's effectiveness. Have you thought about how that will be accomplished, sort of what timeframe after a certain period of time, and what factors you're looking at?

MR. GIOGLIO: Right. That's really in the

preliminary stages right now, actually. That will be handled by OPEER, our office of -- I'm going to forget want the acronym stands for now. But OPEER, part of that is evaluation.

CHAIRPERSON MASTERS: Program Evaluation, Enforcement, and Review.

MR. GIOGLIO: Thank you, Dr. Masters. And OPEER will be handling the evaluation part. Certainly, we'll be looking at the number of recalls for when we sample, continuing to trend down. But there may be a number of other factors that we will be looking at there.

CHAIRPERSON MASTERS: We want to know if plants are holding product. That would be another thing we'd be looking for, Sandra. This is Barb Masters.

MEMBER TYNAN: Are there other questions on the test and hold? Dr. Hollingsworth?

MEMBER HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. Is there any information collected or recorded as to when a plant tests product, holds it, it's found to be positive, and

subsequently they destroy it; therefore, there's not a recall? But is there any monitoring or tracking of that information to determine whether or not -- because I'm not sure that you can just use recalls. I mean, I'm very, very happy that the recalls are going down, but I'm not sure that can always be used as a sole determinant as to whether or not effective programs are in place for the reduction of pathogens, if, in fact, products are being held and then destroyed, which I think is certainly the better option, but is there any record-keeping for that or do we have any statistics on it?

MR. GIOGLIO: Not specifically, but that may be one of the factors as we're planning that evaluation that we may want to look at. Thank you.

MEMBER TYNAN: Other questions on test and hold? Going once. Okay, thank you, Charlie.

MR. GIOGLIO: Thank you.

MEMBER TYNAN: Okay. The third issue from the meeting in June has to do with increasing industry awareness about new technology staff cooperative agreements. And I think, based on the

recommendations, the new technology staff has begun posting the results of their cooperative agreements to our web site. FSIS has posted, actually, nine, according to the issue paper very easily understood summaries of the work done under cooperative agreements. So for those of you who are challenged in your reading, these should be very helpful to you. They're easily understood.

The new technology staff is in the process of sending out a letter to state agriculture departments, county extension agents, trade associations, and others to make them aware of the posting to the web site and the availability of these materials. FSIS has also established an information resource list that provides a brief summary describing some of the new technologies that it's received and reviewed. We have Dr. Syed here.

Are there any questions regarding this update before we ask Dr. Syed to get some exercise? There being none, we'll allow Dr. Syed to relax again and enjoy the meeting.

With that, those are the updates from the

June meeting. We also have a variety of briefing papers in your notebook that we could go through maybe one at a time. And if there are any questions, we'll try and get them answered either by people in the audience or at a later date if we don't have anybody here representing that particular group.

Let me see if I can get to my list. We'll go through them in an orderly way. We talked about the risk-based sampling, the data acquisition, state reviews. Were there any questions on the state review paper? I beg your pardon. The data acquisition under tab five will be the first one. Were there any questions on that particular briefing paper? Ms. Eskin?

MEMBER ESKIN: In the update in the discussion session, you mention that one company has offered to provide FSIS with data and then several others have signaled willingness. Any sort of timetable about when we'll get from this initial stage to the next stage? And, you know, while it's great that these particular plants are willing to do that, that's a pretty small number. So is there any

activity to try to increase that number?

MEMBER TYNAN: We have Dr. Altekruse here, who will try and answer that question.

DR. ALTEKRUSE: Hi.

MEMBER ESKIN: Hi.

DR. ALTEKRUSE: That's a great question. And as my update indicates really, we haven't made a tremendous amount of progress in developing a pilot project. That's somewhat my responsibility because this summer we were planning to move forward with that, and the conversations didn't occur because people were traveling and that sort of thing. So it's not that that particular conversation is off the agenda. It's just been moving at a slow pace. But it is very timely for us to discuss this issue.

And as you point out, one pilot project really isn't what we're looking for here. We want to go to a much more sort of aggregate approach, and I think that's what Dr. Masters and Dr. Raymond have discussed this morning. It's the issue of data sharing and the issue of providing information that can help FSIS to anticipate hazards and to allocate

resources appropriately.

And for example, if the inspector in Nebraska had data coming in from multiple plants that told him which ones were doing very, very well, which ones had identified something but had initiated an activity in response to that, and then which plant maybe isn't even collecting the data. You know, some decisions could be made by the inspector, and, at the district level, they could say, "Well, we've got six plants that fit this profile." And at that headquarters level, some decisions could be made.

So that's really where we want to get. If you will, something like a stock market. You know, aggregate information which tells us what's doing well and what isn't doing well. And the challenge is that different plants, we're already aware of this, different companies use different approaches. And so the question is what meets the, you know, the level of identifying process control in an establishment to the satisfaction of FSIS?

So really stepping back from the individual plants for one second, and we will move

forward with this, I think the real challenge here is a three-step process. One is to hear from companies what it is that they're doing that's working. The second is to have them provide data to FSIS on these very focused issues that FSIS can make some judgment about the comparability of their system for food safety. And then, third, incorporate that into thinking about how to allocate resources effectively.

So, yes, we're making baby steps right now, but that's the direction that we want to go. And we discussed at previous meetings that there are considerations at every step along the way of that, including incentives for companies to participate in this type of program, assurances about their confidentiality as they present information on food safety systems that they're using, and, third, the quality of the data that they're receiving.

So this is, it was recommended at the November 2004 meeting that we bring this up at all subsequent meetings and receive, you know, updates on where we are because it was perceived that this wasn't something that was going to be done overnight. So I

bring it back to you for your attention at this meeting.

MEMBER ESKIN: Can I just ask a follow-up there? So, again, moving forward, to date, again, you acknowledge your own, perhaps, dissatisfaction with where you are right now. Does the agency, do you have any sort of plan moving forward about how you'd like to get more data?

DR. ALTEKRUSE: Well, we know that different companies are using different approaches. Perhaps that's the question that we're asking of the committee today is how to present this so that there is broad participation. And that's really, that is the heart of the issue where we are right now.

MEMBER ESKIN: So, again, is it safe to say that you all haven't come up, at this point, with a system approach where you could hopefully get more participation? You haven't come up with anything?

CHAIRPERSON MASTERS: This is Barb Masters, and I think where you're at, Sandra, is it is safe to say we don't have a broad approach to collect systematic data from the industry. And I think you'll

see when Mr. Derfler goes through his presentation that he refers back to this issue paper to say that we still believe this is the right kind of data to help us make decisions, but we don't have all the answers in this area yet.

MEMBER ESKIN: And I guess the only follow-up comment is, obviously, since you haven't been able to figure out a way to get this data and maybe we all can help in that process, it does raise the overarching issue is how do you get data short of compelling it to be submitted.

MEMBER TYNAN: Thank you. Dr. Carpenter, I think you had your tent card up next.

MEMBER CARPENTER: Okay. David Carpenter. Yes, thank you. Do you have any research or are the data sufficient to come up with an indicator organism that is going to be predictive of a pathogenic carcass?

DR. ALTEKRUSE: I think the question you've raised is really right at the heart of how do you anticipate hazards and allocate resources. And I think the answer is that there are, there is no one

way to do it. Different companies approach it differently. Some use indicator organisms. Depending on the product, it may be that they use generic E. coli or aerobic plate counts, or it may be that they use total plate counts, depending on the actual product.

I'm aware that there are other companies that are using molecular-based approaches to evaluate whether they're seeing an uptick in gene expression that is typically equated with pathogens. Some companies actually use pathogen testing.

So there are a variety of different Approaches, and that's part of the challenge is how does FSIS evaluate the different approaches that different companies are using to make a determination that they meet some level of safety control.

MEMBER TYNAN: Dr. Logue, and then I'll come back to you, Mr. Kowalcyk.

MEMBER LOGUE: Catherine Logue, North Dakota State. My question is pretty simple. In the recommendations, we asked you to look at other sources of data, such as academia and consumer groups, and I'm

just curious as to how far down those roads you've managed to meet.

DR. ALTEKRUSE: Well, I mentioned the molecular approach, and that is an approach that, actually, several academicians have presented that they are using on a consultant-type basis with companies. So, yes, we have looked at that.

In terms of consumer groups and that sort of thing, I mean, I think that it's important to hear about data that companies, excuse me, that public interest groups might be able to bring to this discussion. But at this, standing on my feet right now or whatever I'm doing right now, I struggle to think of a particular example of that. But I would appreciate hearing about that.

MEMBER TYNAN: See, and you thought it was a simple question. Mr. Kowalcyk?

MEMBER KOWALCYK: Michael Kowalcyk from Safe Tables Our Priority. On that subcommittee in November, there was much discussion about administration of the data and data quality. There was a lot of concern on the committee about the

integrity of the data and how it's administered, and I'd like to know if you have an update as to what steps the agency is taking as far as putting an infrastructure around that. Has any communications taken place with researchers in academia, as well as in industry?

DR. ALTEKRUSE: I can address the second question more directly than the first. In one of the discussions that I've had about a pilot study, and I promise to, at the next meeting, to have more progress to report on that particular component. There's been a great deal of discussion about design and, you know, transmission of the data and ensuring that we have a clean data set and that sort of thing. So on the pilot project, that's a very large consideration that's going on.

In terms of the general issue, I'm aware that the Office of the Chief Information Officer and really all program areas within FSIS are paying a great deal of attention to this, and I believe that it's a subject that will be addressed in more detail during the committee meeting. But I'm really not able

to speak directly to that from my own position.

MEMBER TYNAN: Other questions? There being none, let's move on to the next paper. Thank you, Dr. Altekruse; I appreciate that. The next update has to do with state reviews. Were there any questions related to state reviews? Okay. Moving right along, how about outreach -- I apologize. Let's go back. Mr. Finnegan.

MEMBER FINNEGAN: Yes. Mike Finnegan, Montana. Going through the state reviews, when the review team picks a state, how much time do they give them? One month, two months before they have a review?

MEMBER TYNAN: Dr. Roth, could you address that? Very slick, Don. You said to me this morning you were just here to listen. Yes, why don't you come up here so you'd be on a mike.

MR. SMART: There we go. Is this working?

MEMBER TYNAN: Yes. The music will start in just a minute.

MR. SMART: Okay. We have a comprehensive study review manual that dictates how we handle all

the business related to review. And the question was how much advanced notice do the states get. A minimum of 60 days, and we're approaching that mark, I believe, next week on the next four. But I have it on good authority that today or tomorrow, tomorrow, that we're going to jumpstart that by a week because of the Thanksgiving holiday and notify the next four states, which that round will start the last week of January.

MEMBER TYNAN: Okay. Thank you, Don. Are there any other questions regarding the state reviews? There being none, thank you, Don. You have to turn in your microphone.

The next issue under tab number seven has to do with training and outreach. Were there any questions regarding the training and outreach update? Mr. Govro.

MEMBER GOVRO: Mike Govro with the Oregon Department of Agriculture. The briefing paper describes a number of things that you've done, and it appears that you've adopted some of the recommendations that the committee has made over the past several years. We appreciate that. I wonder if

you have, if the agency has quantified the number of or percentage of people it's reaching through things like the web cast and that sort of thing to see how effective or how you're actually reaching people.

MEMBER TYNAN: Dr. Kelly, Ms. Cutshall, did you want to address that?

MS. CUTSHALL: We're tag-teaming you all this morning. I can speak for OPAEO and SIPO, and also I'd like to welcome the committee. Unfortunately, I was not here when you arrived this morning, so I'd like to welcome you this morning.

In OPAEO and SIPO, we've done a number of things to begin to quantify who we've reached. We're keeping extensive records on our registration for web casts, for workshops. We're also looking at the number of hits to our web sites and the things that we're reaching there. We're keeping track of the numbers of our materials that we have distributed, both written, CDs, and any of the other materials. So we're in the process of keeping a very close track of what we're doing.

We're keeping a close track on the number

of students from industry that are attending our sponsored classes, and we've also done work with our cooperative agreement management program to make sure that, in our reporting out in the projects that we fund, that we're getting good numbers back on who we're reaching, where we're reaching them, and the numbers that we're reaching.

DR. KELLY: And just to add to that, in terms of the Center for Learning, which provides the workforce training and then shares that information with SIPO, any type of follow-up requests, for example after the workshops have been held, if people who were not able to attend request materials and that request goes through Center for Learning, we do track that information. We track the number of CDs sent out, the number of state employees who are attending our training programs, and so forth. So, yes, we do.

MS. CUTSHALL: I'd just like to add one thing to what Dr. Kelly has said. One of the things that we've also done, and I think this was a committee recommendation maybe a couple of years back on training and outreach is that the Office of Public

Affairs Education and Outreach and the Center for Learning and the Tech Service Center work more closely together. And CFL and SIPO have done a number of projects this year. We've been very cooperative. We're working to make sure that the training that CFL is putting together for our folks is also included in the training that we're putting out for industry, as well.

MEMBER GOVRO: Just a follow-up on that. Are you pleased with the numbers you're getting as you quantify, and can you share those with us or do you have those?

MS. CUTSHALL: I can't give you all the exact numbers. I can give you some examples. The Food Defense Workshops, we've distributed over 10,000 workbooks, CDs, materials on the directives at a minimum, and that's outside of just the workshops we've been having. The series of workshops and web casts up to a total of a thousand or more participants. An average web cast will probably have 150 participants via web for single web casts.

I think we've distributed, through our

random materials, and please don't hold me to this exact number, but we've distributed over 15,000 copies of the different materials that we have this year. So we think we're making good progress.

CHAIRPERSON MASTERS: And I would just add to that, this is Barb Masters, we started our Food Defense Workshops face-to-face and doing some of the joint web casts, and what we found through our feedback is that people are being better served through the web casts. And we actually modified an approach to go to weekdays web casts, and we actually heard the feedback through the sessions and modified our approach. We had about 40 people showing up face-to-face and 150 to 200 people showing up for the web cast. So midstream we modified our approach and went to more web casts. People said weekends aren't working, do them during the week, make them web casts; and so we modified midstream and did more web casts and tried to reach folks when they're available and got increased registration. And so we've been trying to use that feedback to modify even midstream.

MEMBER TYNAN: Ms. Eskin?

MEMBER ESKIN: Sandra Eskin. I think Dr. Masters just answered part of my questions, but I'd like to know, again, you've mentioned the quantitative tracking of how your programs and various other, web casts, whatever, what kind of response you're getting. But, again, is there any sort of formal assessment, any sort of feedback that you're getting from participants as far as the content of the programs, again in a sort of a systematic way, whether it's a questionnaire they fill out when they finish a program or you contact them and get their input?

DR. KELLY: With regard to the CDs, on every CD that's sent out, there is an evaluation that can be answered electronically and sent to web sites, and we tabulate those results. We pay close attention to the feedback that we get, and that's just a routine part of the way we normally do business. You know, we always welcome input, and we're always interested in getting ideas about how we can do better.

MEMBER TYNAN: Mr. Schad? Oh, I'm sorry, hold on just a minute.

MS. CUTSHALL: I just wanted to add to

that, Sandra. We also have instituted a method of working with having an evaluation filled out by each student that participates with a university in our class. The universities provide that back to us. We look at the feedback. Whenever we do a workshop or a web cast, we also have evaluation forms that we're now handing out and looking at the feedback that we're getting. We also use some of the four where we go out to listening sessions with small or very small plants to get some anecdotal feedback. So we're working to institutionalize that, as well.

MEMBER TYNAN: Mr. Schad?

MEMBER SCHAD: Excuse me. On your recent food defense web cast, you had in the morning and one in the afternoon. Did you notice any difference regarding small and very small plants, which was most listened to?

MS. CUTSHALL: The last two that Mr. Schad refers to were mainly targeted to try and reach out to the state folks because we had had some feedback from the folks in the states that they hadn't had adequate opportunity. We had a real mix of participants across

the board. I'd say that we tended to have, overall, judging from all the web casts, more small plants at our Saturday sessions. But we tended to have more of, if we had a weekday session, we tended to have more people in the morning, even from the West Coast, which was rather surprising to us.

MEMBER TYNAN: And I should also mention, and I think Ms. Cutshall was going to mention probably, we're going to be doing on December 9th, actually, the first fully Spanish language web cast for food defense programs. So we're trying to reach out to some of our under-served constituents who, perhaps, might not benefit from the English language version. So we'll be doing that on December 9th. The time is to be determined. Mr. Finnegan?

MEMBER FINNEGAN: Yes. Mike Finnegan. Is the training heading more towards CD-ROMs, web casts, and less classrooms? And what are the results of that?

DR. KELLY: In terms of our workforce training, we are always probably going to have a distribution of different types of training, depending

on the type of subject that we're introducing and the type of things that people will be doing as a result of that training. For example, I think in terms of things such as introducing new policies for FSIS, if that policy builds on an existing policy, that's when we may choose to use electronic training because it's fairly targeted, fairly focused type of topic. And I know for industry, in some cases, we use workshops because that policy may be fairly new, and people need the chance to ask questions and interact.

So we vary that depending on the needs that we perceive of the audience. We've got a wide variety of kinds of things, and we're constantly offering some new and different approaches, such as web casts this year were something new that we had offered, even to the workforce. We had not done that. So we have a variety of those kinds of things.

MEMBER TYNAN: Okay. Mr. Kowalcyk?

MEMBER KOWALCYK: Michael Kowalcyk from Safe Tables Our Priority. You mentioned in your discussion that a focus group was conducted, as well as in your answers talking about feedback through the

CD-based training, as well as the evaluation at the end of the workshops. Could you share with us some specific findings that the agency has learned based on those evaluations? Where are there perceived knowledge gaps out there, and what is the agency doing to address those?

MS. CUTSHALL: I'll be honest, I don't think we were asking some of the specific questions about where do you feel the knowledge gaps are in general. But one of the things that we and SIPO are doing this year is taking a look, Robert mentioned the Spanish-language web casts, we're taking a look at finding out the demographics of the workforce, not just our workforce but industry's workforce, because we've concentrated for a very long time on specifically saying small and very small plants, but we find that even outside of small and very small plants, that within the larger industry there's a population of employees that would also require the same information that would assist them in their knowledge and their expertise to be able to more fully perform their jobs, understanding the science and the

risk base behind what they're doing.

So we've been looking at doing a number of studies and information fact-finding. As you've heard from other people, without OMB approval we can't do a full-fledged survey, but being OPAEO we've tried to be very creative, and we intend to continue to be creative to gather exactly the kind of information that you're talking about so that, as Carlise said, we can become increasingly more targeted and more effective in what we do.

DR. KELLY: And in terms of just looking at workforce issues, for each type of training we get feedback specific to that type of training, so the answer would be quite varied. We do take that information. We use it as input to improve our efforts for the future.

For example, just yesterday I got some feedback from a third-party evaluation that was done by the program evaluation improvement staff on some baseline microbiological baseline training that we did for our employees, and one of the things that we found in that was they need more help. Because it was

electronically-based training, they need more help in just learning how to operate and use the CD. It wasn't that much feedback about the training itself. They said once they got the CD running, they learned what they needed to know on how to collect the samples and so forth.

So a lot of our feedback is very specific. Nevertheless, you know, we're constantly looking at it and updating and making changes based on that.

MEMBER KOWALCYK: Thank you. I agree that's important feedback, although it seems very trivial when the agency is talking about going beyond with risk-based inspection. I mean, to me, that's a key issue is making sure that it can be implemented, whatever comes out of this, that it can be implemented effectively.

MEMBER TYNAN: Could I make a suggestion at this point? If we don't have anymore questions on the -- I'm sorry. Mr. Elfering, how could I forget you?

MEMBER ELFERING: Kevin Elfering. For your processing inspectors especially, are there any

academic credentials that you require?

DR. KELLY: What we have referred to traditionally as the processing inspector we now have as the job title Consumer Safety Inspector. Those individuals are required to have 30 hours of some type of biological sciences training that are college-related credit. So it's not a degree per se, but, in many cases for employees, that may be, for example, their junior and senior year in college, or for a person who has a lot of work experience, they may be earning those college credit hours not necessarily associated with a college degree but, at the same time, while they're working. It's still, nevertheless, junior and senior-level type biological sciences training.

CHAIRPERSON MASTERS: Carlise has actually described to you our EIAO, our consumer safety officer. Our processing inspectors are required to take as a training, as a condition of employment, our food safety regulatory essentials, and so we have now made for them training as a condition of employment to pass our food safety regulatory essentials.

MEMBER TYNAN: Okay. Before anybody puts their card up, I'm going to suggest that we take the break that is now long overdue. I want to remind you that, while we've got a different room, we've got a larger room. We knew you liked the air conditioning so much the last time, we left it exactly the same. So we've brought fans. This is not for later use during a ping-pong event. But at any rate, let's take a break. Ten minutes, please, if we could. We're a little bit behind time, so I have twenty minutes of. If we could get back together at ten minutes till. Thank you.

(Whereupon, the foregoing matter went off the record at 10:42 a.m. and went back on the record at 10:57 a.m.)

MEMBER TYNAN: For those of you in the public area, where you're seated, I want you to know that we recognize that you're probably warm back there, as well. We're trying to get more fans. It's an old technology, but it seems to work. Again, in the interest of time, we have a couple of more briefing papers, but if the committee has no

objection, what I think we'll do is we'll defer the rest of the briefing papers until maybe first thing in the morning. So we'll do that, so that we can get on to the substance of the meeting, which has to do with risk-based inspection. I didn't realize that when we got into the briefing papers that there would be quite that many questions. They were all good questions and certainly ones that we needed to address. But, again, in the interest of time, what I'd like to do is shift to the main emphasis of the meeting, which is to talk about risk-based systems. And I have Mr. Phil Derfler here, who is our Assistant Administrator for the Office of Policy, Program, and Employee Development.

MEMBER DERFLER: Good morning, everybody. Today I want to talk and present conceptual blueprint, to use an architectural analogy, a blueprint for how FSIS foresees proceeding to improve its system for ensuring the safety of meat and poultry products by making it more risk-based. We want to use our resources as effectively and efficiently as possible, and that means, we think, making risk one of the major factors we look at in deciding how we're going to

expend our resources.

What I will do is present our current thinking on the issues that we will need to address in enhancing our use of risk. In presenting this conceptual framework, I'm going to on the chart that you all got in your book. In this chart, I've tried to break FSIS' food safety system into its component parts, and we've converted the chart into a series of slides that can be seen as I'm talking.

As I go along, what I do intend to do is ask a series of specific questions on how to design our verification activities so that the activities will achieve their purpose and questions on what data we need to ensure that the ongoing assessment of risks that we will be relying on to guide our activities is as well informed as possible.

I also want to issue a bit of a caveat. In order to give you as good a picture of FSIS' vision of a more risk-based system or approach as possible, in the chart I drew and in the slides you'll see, I've drawn a fairly sharp contrast between traditional inspection and how FSIS is doing inspection in its

other risk-based activities at this time.

Obviously, real life is not that clean. The agency has not hesitated to employ risk-based methods if we decided and thought that they were in the interest of the public. As Dr. Raymond talked about, we already have a lot of risk-based activities, and so I just wanted to make that clear so that nobody is confused as I go along.

Next slide, please. The first thing is purpose of inspection. FSIS' move to a risk-based system grows, in large part, out of the agency's desire to anticipate problems. HACCP supports this desire, as you heard from Dr. Raymond and Dr. Masters this morning. In HACCP, the plant does a hazard analysis. This analysis allows it to identify problems that are reasonably likely to occur in its process. It also identifies the points in the process where it is critical to exercise control to ensure that a particular hazard does not occur. The plant monitors that critical control point to ensure that control is maintained.

FSIS' role is to verify that

establishments do what they are charged with doing under the HACCP regulations, including validating the effectiveness of their controls. Significantly, FSIS performs its inspection in every meat and poultry plant in the country, or most, aside from those inspected by the state, so I'm talking figuratively. That means that in becoming more risk-based, FSIS can capture and analyze data across plants and look to see whether there are any patterns of breakdowns, findings, or even hints that presage major problems. If there are, we want to be able to focus our inspection personnel on those types of findings so that they will be able to act in anticipation of a problem and not wait until it occurs.

And so we ask you, members of the committee, what information should we be capturing to make it more likely that we will be able to identify the indicators of an emerging problem? Are you aware of any such indicators?

Some of you are from big companies. What factors do you use to anticipate problems in your plants? Some of you are from trade associations.

What advice do you give your members in this regard? Some of you are from small businesses. What do you use? And some of you are from academia. Are you aware of research that has been done or is underway to address these kinds of issues? And some of you are from consumer groups. Are there questions that your group asks when it's looking for signs of problems in its own operation, just in doing its day-to-day business? Are you aware of questions that we should be asking in a plant environment?

Next slide. Next aspect of inspection that I want to talk about is deployment of our resources. Traditionally, FSIS has deployed its resources both in domestic plants and in import facilities based on the amount of work there is to be done. How many carcasses can be inspected in an hour? How many processing plants can be visited by a consumer safety inspector in an eight-hour shift? How much product can be inspected in an import house during the course of a shift?

As we move to risk-based inspection, however, these questions and considerations become

more complex. When we talk about risk, we begin to embrace the notion that it may not be appropriate to treat all plants the same way at any particular point in time. Some plants may require a lot of inspection resources and scrutiny because the risk that they present is considered to be high. And some plants may require less scrutiny because the risk that they present is considered low.

Moreover, a plant can go from presenting what is considered to be high risk to presenting low risk and vice versa. So how do we assess how much resources to apply to a particular establishment on any given day?

Here are four factors. On the slide, there's four factors that we have identified for making this assessment. The first factor is the hazards presented by a species/process combination. That is by a product. The goal of our inspection system, as I have said, is to prevent the hazards associated with the product from occurring. Thus, it makes sense to start with an assessment of the hazards presented by a particular establishment, given the

products that it produces.

There are two dimensions to hazards: the hazards associated with the species that is used in making the product and the hazards that are associated with the process that the plant uses to produce the product. Obviously, some species present more hazards than others and some processes present more hazards than others. Raw ground beef is likely to present greater hazards than cooked canned ham. Our premise is that the greater the hazards a species/process presents, the greater the resources that FSIS will need to assign to verify that the hazards are not realized.

Two other factors that we've identified are, first, a consideration of how likely it is that a hazard will occur in the plant; and second, how significant the effects will be if the hazard does occur. These two factors present the very essence of risk. The more likely it is that a hazard will be realized, the higher the risk. The greater the potential harm to human health is a hazard is realized the greater the risk. Our view is that the greater

the risk, the more important it is that we intensify our scrutiny to prevent the risk from being realized.

The final factor that we consider to be relevant in deciding how to assign our resources is an ongoing assessment of what is going on in the plant. We have people in the plant critically appraising every carcass or visiting every shift. If the inspections these personnel perform are appropriately designed, they will provide an ongoing insight into what is going on in the plant and into whether there are any significant problems developing. If the agency takes advantage of these insights, it will be able to shift its resources when it feels that there is as reason to believe that a problem is developing.

Thus, based on the consideration of hazards, the likelihood that the hazards will be realized, the significance of the effects of the hazards if they're realized, and an ongoing assessment of the things that are going on in a plant, we will be able to more effectively and efficiently assign our resources.

We ask the inspection group to consider

the following questions: what do you think of the four factors we've highlighted? Are they the appropriate elements for a risk-based approach? Do you disagree with any of the factors? Are there other factors that we should be considering? And do you have any other suggestions?

Next slide, please. As for the data group, we ask you to consider what data we should be collecting and analyzing to accomplish our goals. We believe that the data we need to assess the risk presented in a particular plant which to decide how much resources to assign to the plant are the types of data that are listed on this slide. Data on the risk presented by the types of product a plant produces, data on the significance of those risks. What kinds of harm can be produced if the risks are realized? Data on the particular plant's performance history and data on the approximate volume the plant produces of each of its products, where production volume is essentially a proxy for the scope of the public health concern if the hazard is realized. The more product you produce, the greater the risk if it gets out in

commerce.

What do you think of this list? Are there other types of data that we should be factoring in? What sources of data can the agency look to besides its own data? And what other comments do you have on this issue?

Next slide, please. The third aspect of designing a modified inspection system is to arrive at the general principals that will drive the work to be done by inspection personnel. Traditionally, the basic design for FSIS' use of its inspectors has been fairly simple. Under HACCP, 70 percent of the inspectors' activities focus on food safety matters, and 30 percent focus on protections other than food safety. For example, they spend 30 percent of their time looking at formulation issues, economic adulteration, adherence to food standards, and the like.

In a risk-based system, we foresee a much more flexible allocation of the inspector's time. This does not mean the inspectors would devote more of their time to other consumer protection activities,

although, on occasion, that might be necessary. Rather, while some portion of their time would continue to be spent on these tasks, which need to be a part of inspection, we would try to free up our inspectors to spend as much time as they need to fully explore their inspectional findings that relate to food safety.

We intend to guide the inspectors through the use of decision criteria. What do we mean by decision criteria? If you're familiar with the agency's directive 5000.1, which we issued in 2003, you know that we tried to our inspection personnel with a thought process. Rather than telling the inspectors exactly what to do, we gave them a set of questions to consider as they perform each verification activity. We have followed this approach in other directives, as well.

In decision criteria, we intend to build on the basic questions with a series of "if then" questions, questions to help an inspector through an investigation. These decision criteria would help the inspection personnel to analyze the situation in a

plant and decide what to do based on that analysis.

For example, decision criteria would lead a consumer safety inspector from performing routine verification activities that cover a whole process to focusing his or her attention on a particular aspect of the plant's process where the plant seems to have been having less and less control over a period of time.

We ask the inspection group for their views on this approach to the design of risk-based inspection. Do you believe that there are additional ways to guide inspectors as they perform their activities? Are you aware of better ways to do so? If you are aware of better ways to approach this aspect of inspection, it would be most helpful if you cited the evidence that supports that the approach that you're suggesting will be useful to FSIS. What evidence is there that the approach will be effective?

Next slide. As for the data group, we would ask that you identify the types of data that you think are most appropriate to use to assess plant performance. What types of data are most useful in

identifying a situation that FSIS personnel should keep under surveillance? Also, what types of data do you think would be most relevant and useful in developing the decision criteria that we're talking about implementing? Are you aware of where we could find or how we could develop this type of data? Are you aware of where this type of data is available?

Next slide. We've talked, I've talked about what FSIS is trying to do in risk-based inspection, how we should deploy our resources, and how we should allocate inspectors' time. Now I want to turn to the design of the agency's specific inspection activities and how to make them risk-based.

We think that this translates into the question what verification activities by inspectors will be most effective in finding problems. In a modified inspection system, given the emphasis on risk, we want to focus on those aspects of a plant's process where loss of control is most likely to occur. We also want to focus on those aspects of a plant's process where a loss of control would have the most serious public health consequences. These are the

points in the process where the agency's inspection and verification activities are most critical.

FSIS wants to focus on those points in the process where its efforts can have the greatest impact. We believe that we can identify the points in the process on which to focus from several types of inspection activities. First, through the use of performance standards to measure process control. Evidence of a loss of control would indicate a problem in the process and the nature of the problem should help to locate where in the process the problem is occurring or at least narrow our inspection focus.

For example, we've used the results of our salmonella testing of ready-to-eat product as evidence of adequate lethality. When we found positives, we have focused our verification activities on whether the lethality that the plant is trying to deliver is adequate and whether it is being effectively delivered.

A second means that we would use is intensified verification sampling. We've started doing intensified verification sampling for Listeria.

We focused our sampling on those processes and points in the process where loss of control seems most likely. For Listeria, this has meant focusing on alternative two and alternative three operations, as Dr. Engeljohn discussed. We plan to expand risk-based intensified verification to sampling to include E. coli 0157h7, salmonella, and other pathogens.

A third means of identifying a loss of control would be analyzing consumer complaints and other information from outside the plant, such as illness investigation data. We believe that we can use our analysis of consumer complaints and the extra plant data to guide us to plants whose process may be out of control. Based on our analysis of the data, we will identify the points in the process in which to focus our verification activities.

And fourth, something that we already do and we will continue to do is use our EIAOs to assess the design of HACCP plants. Based on their assessments, EIAOs identify the points in a plant's process where a problem seems most likely to occur. Working together, the EIAO and the in-plant team

develop a verification plan that the in-plant inspection team uses to guide and focus its verification activities.

We would like the inspection group to consider the approaches to designing inspection activities that I have discussed. Are there additional activities that you would suggest that FSIS incorporate into its risk-based inspection activities? Why would these activities be helpful?

Next slide. For the data group, are there sources of data, besides the agency's own sampling data, that we could use in identifying problems that either are or are likely to be developing? At the last Advisory Committee meeting, you identified factors that the agency could use to identify plants that have emerging problems. Given what I've just laid out, are there types of data that you think we should be looking at to help identify the points in a plant's process where the plant is losing control and that, thus, should be the focus of the agency's verification activities? What data would be most useful to help the agency to develop performance

standards or would support the development of other types of mechanisms that accomplish the things that I've outlined?

Next slide, please. How should the system based on risk respond to the inspectional findings? Traditionally, evidence of non-compliance has had little impact on the intensity of the agency's inspection. While the agency certainly documents the non-compliance and takes enforcement action when it is justified, where the non-compliance suggests an emerging problem but results only in a non-compliance report and not a notice of intended enforcement, the agency has not really modified its verification activities to account for this finding.

Moreover, the agency really does not have a way of capturing a situation in which a problem seems to be developing but nothing that rises to the level of justifying a non-compliance record has occurred. This would change in a risk-based system. We would still respond to non-compliance. However, we would want to design our system so that evidence of good control would mean less intense inspection and

evidence that a plant lacks control or is losing control would mean more intense inspection. We will be more assertive in assessing plant performance and responding accordingly. We also will be transparent and consistent in that there will be a clear connection between plant performance and the agency's actions, and the agency's actions will be consistent across plants.

FSIS intends to provide less intense inspection in response to evidence of good control for a couple of reasons. First, this approach provides an incentive for plants to exercise control. There have been numerous instances where this kind of incentive has proven to be very effective. Listeria is a situation in which the agency, in its interim final rule, calibrated its verification based on the intensity of the plant's activities. And as a result, plants have taken steps to exercise more control, moving from alternative three to alternative two and alternative two to alternative one.

Second, it is an approach that is most consistent with efficient use of our resources.

Obviously, it makes little sense to spend a lot of time day-after-day on a plant that is clean, sanitary, and exercising excellent controls. This type of approach is necessary to free up the resources, particularly the people, that we may need to provide more intensified scrutiny to plants that are not maintaining control.

In addition to moving inspection personnel around, there are several other ways we can respond when there's a loss of control or evidence that a plant is losing control of its process. First, we can design our decision criteria to lead our inspection personnel to intensify their verification activities in this type of situation. We can intensify sampling in the plant. We can target the plant for an EIAO visit, or we can, in appropriate circumstances, institute enforcement action. Thus, the agency would design its actions to respond to an emerging problem and calibrate its response based on the nature of its findings.

To the inspection group, I ask what do you think of the general approach that I've outlined? Are

there other ways that we should consider responding to inspection findings, particularly evidence that the establishment is losing control of its process?

Next slide, please. As for the data group, we believe that data on the results of our inspections and of our sampling needs to be available to our inspection personnel as quickly as possible. We also recognize that we need to provide our inspection personnel with tools to analyze the data so that they will recognize good control or loss of control and order their inspection activities accordingly.

Are there any suggestions that you would have for us in how inspection personnel can best use data in deciding what inspection activities they will perform on a day-to-day basis? Are there any particular types of plant data that they should be looking at that would be useful to enhance their understanding of what is going on in the plant.

Next slide. Now, responding to an emergency problem is the sixth aspect of inspection that I want to discuss. The point of this aspect of

inspection is the ability of inspection personnel to respond when they find evidence that there is a problem. The traditional system is not designed to have inspectors make a judgment about an emerging problem, other than non-compliance. The goal of the modified risk-based system would be to arm our inspection personnel with the flexibility, data, responsibility, and training that they need to recognize that there is a problem and to call it to the attention of the plant before it rises to a level of non-compliance and before it results in a product that may be unsafe entering commerce.

I'm not saying that we would be absolving the plant of its responsibility to identify and respond to problems. Quite the contrary. We would certainly expect it to do so. But we also believe that our inspection personnel should not stand passively by and watch a problem develop.

In the Con Agra recall situation, for example, there were clues in the plant's testing data that there was a problem. And our inspection personnel should have been responding to those data

well in advance of the development of the serious problems that required a recall.

So I ask the inspection group how can our inspection personnel be most effective when there is evidence that a problem exists? Obviously, we can issue an NR or even an NOIE, but are there other things that we can do to help plants understand the significance of a problem and, thus, increase the likelihood that the plant will respond constructively, rather than just providing a minimal response?

Next slide. To the data group, I ask what data will enable inspection personnel and the district analysts and the others who support them to identify a plant trend that signifies a potentially significant problem? What parameters should the agency look at in identifying a developing plant or public health concern.

Next slide. Food defense is becoming an increasing agency focus. Under the current system, inspection personnel devote a specified amount of time to food defense activities. Although we use vulnerability assessments to target our efforts, there

is no mechanism to modify the amount of time that inspection personnel spend on food defense on an ongoing basis. A change occurs in the amount of time that they spend only if the nation's security situation changes. For example, if there's a change from yellow to orange.

We believe that we should enhance our use of risk as a driver of food defense activities by inspection personnel, just as we intend to enhance the risk-based orientation of how we do other aspects of food inspection. Thus, we're looking to design our food defense procedures based on the actual situation in a plant, as well as on the national situation. For example, a plant with a well-developed food defense plan would likely require less scrutiny than a plant that did not have a plan.

To the inspection group I ask what suggestions do you have for how we can most effectively enhance our use of risk in designing our food defense activities? To the data group -- next slide, I'm sorry. To the data group, do you have any suggestions about how the agency can factor the

results of its defense verification activities into its approach to food defense? What factors, besides an establishment's planning, are important?

Next slide. Finally, I turn to product and commerce. Although product and commerce is not the subject of inspection, it is subject to FSIS' jurisdiction. Hence, products are subject to examination and sampling and the conditions under which they are held are subject to agency scrutiny. Since the Pathogen Reduction HACCP Rule was published in 1996, FSIS had made clear that it wants to implement a strategy that would ensure that meat and poultry are safe from farm to table. Thus, we intend to factor risk in designing our out-of-plant activities.

Traditionally, that has not typically been the case. The agency has generally relied on random visits to warehouses, distribution centers, and retail stores to determine whether meat and poultry products are being held under unsanitary conditions that would render them adulterated.

As I've said, we intend to change this

approach. We foresee that our modified approach will involve using the findings that our inspection personnel make, the results of the sampling that we do, and other information to determine whether a particular facility or type of retail activity presents a heightened risk of causing problems and, thus, should be the focus of a heightened level of scrutiny.

For example, if the evidence shows that deli meat and poultry products sliced at retail present a higher risk of causing listeriosis than products sliced and packaged at federal plants, this aspect of retail activity could well receive heightened scrutiny from FSIS personnel.

To the inspection group, we ask that you consider this approach. Does it make sense? Are there other factors that we should consider?

Next slide. And to the data group, I point out the fact that, to affect this approach, we would need data on the types of conditions that create risks for products in commerce and data on the conditions in particular facilities that handle

products. While the latter type of data should be available from the work our inspectors do, we ask the data group where we can get data on the risks presented in commerce. What other types of data should we collect or seek to obtain that would guide this aspect of our out-of-plant activity?

Next slide. This, essentially, concludes my presentation. Now is the general question that we ask the inspection group. How would the success of RBIS be measured? Are there other ideas or recommendations that the committee might offer FSIS in designing and implementing a risk-based system? What inspection criteria would be appropriate in designing? That's the general question. I've tried to put some more specific questions to you as I've gone along.

Next slide. The same with the data group. These are the questions that are at the end of the briefing paper, the general questions that we would ask you to consider, along with the more specific ones that I've posed. So that's what I have to say. Thank you for your time and attention.

CHAIRPERSON MASTERS: This is Barb, and I

think I should make it clear that, hopefully, that will help you understand when we said this morning we wanted to build our roof and get the general infrastructure in place before we started going back to the steps. And Phil will be available this afternoon, as will several of our senior managers, as we go back through the charts and to the subcommittees as you work through these questions to say, "What were those specific questions Phil was asking us?" But we want as much detail from the subcommittees, and it's not so much the specific questions Phil was asking you but to really walk through those sections question-by-question-by question as a subcommittee and to give us as much thought and ideas as you have on each of those subsections as a subcommittee, to give us your ideas, are we headed in the right direction, do you have other ideas, and to really get into the specifics on those subsections, if you're on the inspection group or the data group, on ideas you would have for improvement, different direction, or other ideas as you move through that as we build the infrastructure, not on who's going to do this or did you have a

particular person in mind, but really on the infrastructure is where we really are looking for ideas. Let's take the questions.

MEMBER TYNAN: I think we can take a few questions right now. I'm sure there are some. I'm going to start with Mr. Elfering on the left, and we'll go around.

MEMBER ELFERING: Kevin Elfering. I think one of the biggest challenges that we're really going to have to look at is something that the Undersecretary talked about is, first of all, trying to define what is a risk. For example, to me, BSE is not a food safety risk, but to many people it is and to the public it's going to be a big risk. And a lot of these things are fed by the media. Another perfect example is avian influenza right now.

So what are we going to be looking at for risk? What are going to be true risks or what are perceived risks, and how do we really define that? That's the first question.

I have another question for you, and we don't hear a lot about HIMP anymore. Is it still

being used, and how many plants are actually operating under HIMP?

MEMBER DERFLER: Okay. I just will answer, the answer to your first question, I think we asked for your advice about what's risk. In my presentation, I did try to touch on the two traditional definitions of risk. How likely is it to happen and how significant is it if it does happen? So I guess one would say for BSE, given the catastrophic occurrence, that's the reason why some people would consider it to be a risk.

As far as HIMP, yes, it goes on. What I tried to do was step back and talk generally across slaughter and processing. I tried to talk conceptually in a way that we didn't talk about either one specifically, although both generally. Obviously, where we go from HIMP will be part of our consideration that we decide how we go forward with a risk-based system.

CHAIRPERSON MASTERS: And I would just add to that we see that as one of the steps on how we might move forward with one of the steps, and we would

have a very transparent process as we move forward and get back to the steps. But we wanted to talk more specifically about building the infrastructure before we got into that. But we would value your thoughts on how we might define risk related to product, process, and to plans.

MEMBER TYNAN: Dr. Hollingsworth?

MEMBER HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. Actually, my question is more for Robert on the mechanics. I know earlier in your introduction you had said we were doing this a little different than in the past. I'm not clear. Are the two subcommittees going to work together as one and be in one group and answer the questions side-by-side? Or are we actually breaking out to do the questions? It seems to me the way Phil has presented them, we almost can't work as two separate subcommittees. And in looking at the questions under tab three, if, in fact, these are the whole body of questions we're to be answering, I'm having a hard time breaking them out. So I didn't know if the difference that you had mentioned in the mechanics was

us working as one committee and answering the questions in total.

CHAIRPERSON MASTERS: The intent was to have two subcommittees, one on the role of the inspector and one on data, to answer questions about those areas. And when you come back as a committee as a whole tomorrow, that's where we had hoped to get more information and to charge you and, if you have time, to deliberate the question that Dr. Raymond charged you with this morning, which is question number five, your advice on how we might get a sounding board, for lack of a better word, on how we might have a group that would provide us additional advice on moving forward and furthering our approach on risk-based inspection that we were going to ask you to provide us as a whole committee.

If you have time to talk about that as a subcommittee, that's great; but we were going to bring that back to the whole committee in the morning. But we were looking at having you break into the two subcommittees, one on inspection and one in the role of data, to talk about the questions, basically one

and two. And, obviously, you're not going to avoid the question of defining risk for product, process, and plant in your subcommittees and any additional comments you had as a subcommittee. And we would see you answering question number five as a whole committee tomorrow. Does that help?

MEMBER HOLLINGSWORTH: It certainly helps. I would almost like to question the group and to see if, in fact, we think that would be the most effective way. I don't know. It just seems to me they're so integrated, I'm having a hard time separating them. But maybe the others have a clearer indication on how we do them separate.

MEMBER TYNAN: Ms. Eskin?

MEMBER ESKIN: I want to just start by following up on Jill's point. My reaction in reading over the questions before today was exactly the same, is that they're so interrelated and this is the first time that this group is going to be addressing this very important issue that it's a small enough group, with good facilitation, we should be able to have a good conversation. I'm concerned we're going to spend

a lot of time duplicating.

But I did want to step back. I wanted to start by commending the agency for bringing this issue to us. I know we have complained in the past about having to deal with very, very specific issues, not broader conceptual issues. This is the other extreme, I think. So I do want to commend you. However, I feel like we're being brought in in the middle of a conversation, and I guess here's some of the threshold issues that I would like to discuss, to have your reaction to, because I think it's important for all of us to understand where this is coming from.

One of those issues to me, which is threshold, is how does this fit in with the existing statutes? The statutes and traditional interpretation by the agency, the department, the courts, say a certain thing about inspection. And I, for one, and I think everyone also would like to know what's the official interpretation? Because then that sort of begs other questions.

If, in our discussions, we feel like this is what needs to happen to make a risk-based

inspection work, we may come to the conclusion that a change in the law is necessary. If you look at all of the discussions about risk-based inspection by the GAO, by the National Academy of Sciences, that's one of the questions in only the infrastructure issue. Thinking outside the box, and I know we won't be able to think that outside the box, it raises the issues about the whole food safety system beyond FSIS. But even just looking at meat and poultry inspection, that's a discussion I think that needs to be had in order for us to understand it.

And second, I would like to sort of understand how your office, Phil, how we got to these questions. In other words, what did you all look at? There's lots of stuff out there. Are there other plans that have been presented to you by groups to date? Because I think that helps us understand where you're coming from in this particular document you've given us. That's a long question. Sorry.

CHAIRPERSON MASTERS: This is Barb Masters, and I'll take the first part of the question. Obviously, the statutes, as you indicate, Sandra,

require daily inspection and carcass-by-carcass inspection.

MEMBER ESKIN: That's right.

CHAIRPERSON MASTERS: And at this point, I think what Phil presenting you is presented under the auspice of the existing act, and we would ask the committee to provide us recommendations. And if your recommendation is that we look at anything outside the act, I think you should say, "Here's what you, as an agency, should consider within the existing act," and if you have recommendation for us to look beyond that, I think it would be appropriate for the --

MEMBER ESKIN: When you say beyond, do you mean amending the statute?

CHAIRPERSON MASTERS: Yes. I think it would be appropriate for this committee to provide that kind of advice to the agency. At this point, the agency is looking at what we can do within our existing authorities. I think it would be okay for this committee to provide advice to say you should consider things beyond your existing authorities.

MEMBER ESKIN: Okay. But, again, on that

issue, you said it is the agency's position that what's being presented to us is within your current authority, and I'd like a little explanation about how you all reconcile the statutory language, existing interpretations, and what you're presenting.

MEMBER DERFLER: If I could, I would just say the most useful thing that you could give us is your response to how we would do it under the current situation. And under the current situation, I don't think we've presented anything, I presented anything that would be inconsistent with the act as we're currently interpreting it. None of the questions, none of the description of how we use our resources. I mean, we look at how we would use our resources under our current authority, and we believe that everything, I believe that everything I said is consistent with the act as it is currently written.

MEMBER ESKIN: Excuse me. It's your view that what you've presented is not inconsistent with carcass-by-carcass --

MEMBER DERFLER: Right. Yes, yes.

MEMBER ESKIN: -- because you do.

MEMBER DERFLER: Yes, I believe that. As far as your other question, I mean nobody has particularly presented anything to us. I mean, we obviously had discussions. You've had discussions as a group on various issues about risk before this. There is an industry risk-based coalition that has come in and talked. But, basically, our group and the thinking that we've presented, we felt it would be inappropriate for us to just say how do we do it? I mean, so we did try and do some thinking, but we're at the early stages of our thinking, and so our questions are as many as, you know, foreseeable answers. And so that's the reason why we're here: because we want to get your input so we can go forward at the beginning of the process.

MEMBER ESKIN: You said an industry coalition came in to discuss it. Did they present any sort of a plan or any sort of a document that --

MEMBER DERFLER: They presented a document, yes.

MEMBER ESKIN: Because that would be useful to look at, obviously, in looking at this.

MEMBER TYNAN: Mr. Govro?

MEMBER GOVRO: Mike Govro, Oregon Department of Agriculture. Sandra asked my question. I would like to reiterate I think that's a very important question. There seems to be a huge difference in the way resources are allocated between FDA and USDA with regard to the number of products looked at, the amount of money spent doing that, as well as the inspection strategy of full-time inspection versus much less than that. And so my question really had to do with how much freedom do we have to think outside the box and how willing the agency is to pursue the recommendations that we come up with. I think that's a critical point.

MEMBER DERFLER: It would just be most helpful if you focused on how we do inspections. That's really what we need help on.

MEMBER GOVRO: I understand. My comment has to do with number eight: attention to product and commerce. And it's been mentioned a couple of times that USDA wants to look at product in retail, and you used the word increased scrutiny, and I don't really

know what exactly that means in terms of inspections, sampling, or enforcement. But I would encourage the agency to first look to leveraging resources with states that are already doing work in retail. We have the food code. Most states and/or localities look at retail and are trained to do that. We're in those places. And coming from an agency that does that work, I would suggest that it's difficult for establishments to deal with more than one agency that comes in and deals with the regulatory issue. It's much easier to deliver a clean, consistent message when only one agency is delivering that message.

And I would suggest maybe you look at the arrangement that FDA has with states to perform contract inspections. I've seen the forms that USDA inspectors use when they go into custom facilities, which we also do. They're looking at very much the same types of things that we look at. We easily could perform those for you, both in customer establishments and in retail and warehouses.

MEMBER DERFLER: Okay. I would just make three points in response. First of all, I wasn't

giving an answer. I was just pointing to a problem. Second of all, we have recently entered into an MOU with the conference in food protection. We're very aware of it. We're very involved with it. And the third one -- I'm sorry. If I think of it, I'll tell you, but I lost the third point. Sorry.

MEMBER TYNAN: While he's thinking, we're going to go onto Mr. Finnegan, if that's all right, Mr. Govro.

MEMBER FINNEGAN: Mike Finnegan. I just want to say that I like the idea of risk-based inspection --

MEMBER DERFLER: I'm sorry. I remember my third point.

MEMBER FINNEGAN: Go ahead.

MEMBER DERFLER: And that is, I mean, part of our focus here is FDA's risk assessment where they said that the problems that presented risk and significantly more risk were deli meats at retail and hot dogs. And so, you know, we have to be conscious of risk. That's what this is all about.

MEMBER FINNEGAN: Like I said, I like the

thought process of the risk-based inspection. Number one, that's what HACCP is all about. And two, the CSIs would be less robotic where you have one certain task to perform and that's it. And I think one of the keys, and question six talks about training, are you talking about different type of training or FSRE training? Or would the 5000.1 directive cover it all?

MEMBER DERFLER: No. We think we'd have to build on FSRE, but we've tried to design FSRE to be a foundation training, and so we would build on it from there.

MEMBER TYNAN: Mr. Finnegan, are you okay with that? Okay. Then I'm going to go over to Mr. Elfering.

MEMBER ELFERING: Kevin Elfering. I think it's imperative because looking at the Undersecretary's presentation, it looked like daily inspection is something that would probably be included, not having daily inspection. And if the interpretation is all that is required is the agency intending to change or at least request the act be changed so that you don't have to do daily inspection?

Or is it something that can go either way? Is the interpretation, can it go either way that you can start not having daily inspection of processing plants?

CHAIRPERSON MASTERS: This is Barb Masters. And I think that where we're at as an agency is we are looking at, what we put forward is working within the realm of the Federal Meat Inspection Act. I think what Dr. Raymond was saying to you this committee is to provide feedback to us. And if it's the advice of this committee, we want you to think outside of the box and give us your suggestions and we would ask you to consider options, including if you believe it's appropriate to go beyond that. And that would come from the political office, such as the office of food safety. So we would welcome you and ask you to not be constrained by Federal Meat Inspection Act. What you're seeing here, from an agency perspective, is inclusive of the Federal Meat Inspection Act. And so if you believe it's appropriate to go beyond that, I would ask you to think out of the box and to make those kind of

recommendations and give that advice to us.

MEMBER TYNAN: Dr. Denton?

MEMBER DENTON: Thank you, Robert and Barb and Phil. I guess my initial comment would be that I really do appreciate the attempt here to move toward a risk-based inspection system as defined by our language that we use with regard to risk-based inspection.

I have two points that I want to address, and the first one goes back to what Jill and Sandra were saying. And as I read this document before I got here today, those first two questions that you have posed for this committee are almost identically worded questions. One is what are the inspection criteria for designing and implementing? And number two is what are the data needs that would be appropriate in designing and implementing risk-based inspection?

Now, in my mind, I'm linking those two. It's going to be very difficult for us to think about this. I think we need to think in terms of what the criteria are. It goes back to what Barb said earlier about building the roof for the house. We need to

decide up-front what criteria we're dealing with before we spend very much effort in looking at what our data needs are to satisfy those inspection criteria. So in that context, I agree with what Jill and Sandra are saying.

The second thing, and it struck me as I was sitting here, despite the fact that we are now using the term risk-based inspection system, I would submit to you that even as we go back and look at the original act, the mechanism that was put in place for bird-by-bird inspection was designed to deal with risk associated with animal health issues and sanitary issues in the slaughter plant.

Now, what we have done in adopting HACCP and moving to a more science-based system is we've simply substituted the terms human health risks for risks associated with the animal health that was, I guess, governed to a certain extent by bird-by-bird or animal-by-animal, carcass-by-carcass inspection. But we're still dealing with human health issues and sanitary issues within that environment.

Now, what I'm saying, I don't know if

moving to a risk-based inspection system, like what's been presented here, is outside of what the original intent of the act was. I do know that that phraseology of carcass-by-carcass inspection has always presented a hurdle to us, but I submit to you that we're simply moving our attention from animal health risk as they impact humans to human health organisms that impact the human health side of it, and sanitation has been implicit in both of those systems.

MEMBER TYNAN: Thank you, Dr. Denton.

Mr. Kowalcyk?

MEMBER KOWALCYK: Michael Kowalcyk from Safe Tables Our Priority. Again, to follow-up Dr. Denton's point and the point several people have brought up with the statutory requirements, one phrase here in this deck that concerns me is the phrase "less intense inspection." How are we to interpret that? Is that to mean that the minimum is what's called for in the current statute? How is less intense defined?

MEMBER DERFLER: I think that's part of the art of what we're trying to get at. I mean, by going to a risk-based system, we would design

inspection to cover a range of situations. And there would be, we would be looking at what are the minimum things that we need to be sure of in order to ensure that sanitary conditions are being maintained and healthful and safe product is being produced. But I don't know the answer now. I think that's the process that we're embarked on.

MEMBER KOWALCYK: But is it safe to assume that that minimum would be what's called for in the statute?

CHAIRPERSON MASTERS: Michael, again, this is Barb. I think when we wrote the document, we wrote it under the premise of the current statute, meaning daily, and we're suggesting to this advisory committee if you're advice is that you would recommend something, that we would consider something less than that. We are open to you thinking very out of the box and providing us feedback, but we'd ask you to give us your thoughts as to why, what criteria to consider, and those sorts of things, if you make those kind of recommendations to us as an agency.

MEMBER KOWALCYK: Okay. And I have one

more question. I think it goes into the inputs to this presentation. Has any input been given by any of the state inspection agencies? I know in talking with Kevin Elfering down at the end that Minnesota does some interesting things, as do other states. I was just wondering if any input was given by various states.

CHAIRPERSON MASTERS: Actually, this is Barb Masters, and I spoke to the National Association of State Meat Inspectors, and they asked that they not be forgotten in this process and that they will be very concerned as to how they're able to be brought forward and be able to comply on an equal to and brought forward. So Mr. Elfering and I agreed to bring their issues forward at this meeting since it was the first time that it's been brought forward in a transparent process. So Mr. Elfering agreed to wear that hat at this meeting.

MEMBER TYNAN: And a bit hat it is. Ms. Eskin?

MEMBER ESKIN: Sandra Eskin. Just a couple of follow-up points. One, again, back to the

law. Sorry. I'm a lawyer. That's what I was trained to think about. But, again, you said you're operating under the assumption that what you presented to us would fit within the current authority. Has there been any official memo or any sort of analysis done by your office, Phil, or the general counsel's office that looks at the parameters of a risk-based system in the context of the existing statutory authority?

MEMBER DERFLER: I would say the answer is no, we don't have a legal analysis from the Office of General Counsel. But I would say, as we do our thinking, we're exquisitely aware of the question that you're raising. It's not like throwing darts at a wall and taking stuff out, but we really do pay attention to the issue. But we believe that we can come within the requirements of the act and do this.

MEMBER ESKIN: The other follow-up question I had, I mentioned these others you're well aware of, reports done by GAO or NAS on the inspection system. When I went to the FSIS web site and typed in risk-based inspection for a search, I got a document. It's a report to Congress from 2001. I know it was a

different, it was probably a different -- no, it was this administration. Sorry. And it was a report to Congress on risk-based inspection, and in this document it referenced a system which it called the inspector optimization system and also mentioned that FSIS, at this time, in March 2001 was exploring with the Research Triangle Institute and Texas A&M University the development of a system. Again, that was the term that was used at the time. Did anything happen with that? Was research ever undertaken? Is there a report, for that matter? Again, is there any thing else that's been done through outside consultants that would help us as we move forward in this?

CHAIRPERSON MASTERS: We will check into that and get back to you after lunch.

MEMBER DERFLER: The only thing I would say is, in the course of doing this, I went back to a talk that Bill Smith gave and I gave in, I think 2000 called Next Steps, and what's really surprising and encouraging about it is what we're saying is very consistent with what we said then.

CHAIRPERSON MASTERS: Before we break for lunch, I would ask, we've heard a lot of folks indicate that it might be better to have the committee work as a whole rather than to break into two. So I would ask the committee to, by a raise of cards, if you would prefer to work as a group of one rather than two. So a group of one. Group of one? Okay, group of two? Did you count?

MEMBER GOVRO: Excuse me. Mike Govro. Could I offer one other suggestion?

CHAIRPERSON MASTERS: Sure.

MEMBER GOVRO: My only concern with having one single group is that it is a pretty large group. I do agree that questions are kind of intermixed. I'm wondering if two groups might approach all of the questions separately.

CHAIRPERSON MASTERS: All right. How about two groups approaching all of the questions and getting a lot of input that way?

MEMBER ESKIN: Can I amend that or just consider it?

CHAIRPERSON MASTERS: Sure.

MEMBER ESKIN: I think that would be fine. My concern is we're not going to be able to get to all of the inspection questions and the data questions, and not that the data questions aren't important but, to me, I think we have to address the inspection piece of it first, whether it's just in this meeting and we have to hold off on data because I think that, as I said, that's going to follow whatever the inspection issues.

CHAIRPERSON MASTERS: Michael, you have a thought.

MEMBER KOWALCYK: I would have to follow-up with Michael's comment that this is a very large group to process through these very weighty questions. However, based on the presentations today and based on how the briefing papers were positioned, I think I'm still a little unclear as to what the agency expects in terms of a deliverable from the subcommittee. So I don't know. Maybe after lunch, if you folks can what are the key things you want from the subcommittees because there is a lot here. They're all very important issues. I would just like

some clarification on that in my mind because, as people have said, the risk-based inspection criteria and the data, they become intertwined very easily.

CHAIRPERSON MASTERS: Okay. Jill?

MEMBER HOLLINGSWORTH: Jill Hollingsworth, FMI. I think Michael's point is good. Maybe we can wait until a little bit later in the day and reassess the group because there's not a clear position going one way or the other, and maybe later in the day we'll feel differently about it. I also think the other Michael's idea of having both of us look at it might be interesting to see if two groups working on the same issue come out with similar conclusions. The downside, you're right, is we probably can't get to all of it as much as we'd like to in-depth.

But my personal feeling is it's going to be very hard to answer the data questions if we don't know what the risk system is even going to look like. The data information that one subcommittee brings forward may not be relevant to proposals for how to proceed with a risk inspection system. So I'm certainly willing to wait and vote again and see if we

feel differently later.

CHAIRPERSON MASTERS: Okay. After lunch, we will come back. We'll try to more narrowly define what we're looking for from the group. But as you go to lunch, I will let you know the most important thing we're looking for is your advice, your ideas, your suggestions as we move forward. And, again, I would agree the roof, the infrastructure is more important. We believe the data will drive what we do, but if you're suggesting that need to know what our inspectors are doing so we can get to that data, then we'll certainly be open to those suggestions. So we'll come back to this issue after lunch because we want you all to give us the most information we can, and you can tell us how to best to do that.

So I'll let Robert give us our rules for where we're going next.

MEMBER TYNAN: Well, I think our next rules is we're going to break for lunch. But after lunch, at 1:00, that should be timely, at 1:00 we will do the public comment period. We normally do that before we break, but we're going to have lunch. We'll

come back and do the public comment, and then we'll talk a little bit with the subcommittees, their charge, and get them working.

So if we could, we can break for lunch and be back here at 1:00.

(Whereupon, the foregoing matter went off the record at 12:03 p.m. and went back on the record at 1:09 p.m.)

MEMBER TYNAN: What I'd like to do now is go to the public comment period. So one o'clock, I think, on the agenda we had the public comment period, and after we complete that, then we'll go back and talk with the subcommittees a little bit more about how they're going to address the questions this afternoon and how they are going to move forward for the remainder of today and tomorrow.

I omitted, and I apologize, to mention to you that for those folks that had public comment if they could sign up out at the table out there. So some people got that word without my help. Some did not.

So what we're going to do is I'm going to

proceed through this list. If you didn't sign up, no problem. We'll catch you at the end, but I think the first presenter is going to be Craig Henry from the FPA, and the committee has some comments that Dr. Henry has submitted to the docket office, and will be the basis for his remarks now.

So Dr. Henry.

DR. HENRY: Thank you, Robert. We appreciate it.

Food Products Association really appreciates the efforts that the agency has taken to hold this meeting and to put this very important subject before the National Advisory Committee on Meat and Poultry Inspection.

As Robert said, you have copies of this, but for those in the audience who do not, I would like to just take a moment in the essence of time and read these comments to you verbatim, if you will.

The Food Products Association commends FSIS and USDA officials for placing this important issue on the agenda of the National Advisory Committee on Meat and Poultry Inspection. FPA is a founding

participant in the Risk Base Inspection Coalition, which is a broad based industry coalition composed of ten associations whose members represent the vast majority of the meat and poultry products produced in the United States.

The RBI Coalition supports risk based inspection as a means to enhance food safety. FPA and the coalition believe that it is proper for FSIS to focus the allocation of inspection resources based upon risk. We believe that raising this issue with the Advisory Committee is a very positive step toward an open and transparent process that will engage all stakeholders to achieve the ultimate goal of enhanced food safety by properly focusing the obviously limited inspection resources, as well as industry resources, on the most significant food safety issues.

As the committee deliberates on this most important issue, we encourage consideration of some of the following tenets that we believe to be critical to the success of this effort. Public health protection and enhancement is paramount. The process must be open, transparent, and all inclusive. The

availability and sharing of appropriate good data will be important.

A risk based inspection effort needs to focus both on risk based allocation of sampling and testing efforts, as well as risk based allocation of inspection resources. The agency has made significant strides in the former, that is, risk-based sampling of ready to eat products. Progress on the latter though has not been measurable to date.

Measures of success will include some of the following: reduction in product recalls for food safety reasons, better compliance with food safety requirements along with fewer enforcement actions for significant food safety issues, reduction in food borne illness outbreaks and sporadic cases to the extent we are able to measure them.

Risk factors relevant to risk based allocation of inspection resources include the following: compliance history of the establishment, nature of the product, nature and reliability of the food safety controls.

In addition, certain other risk factors

could be important for specific establishments. For example, production volume can be of significance, but it must be considered in conjunction with other key risk factors, such as the reliability of food safety controls which influence the likelihood of unsafe product being produced and shipped.

In our opinion, large volume alone must not preclude a firm from consideration for a lesser level of inspectional oversight. Other considerations such as seasonal or regional factors may also be significant in certain situations.

In regard to the next steps moving forward in this process, the Food Products Association suggests the first step in the process is to define the key elements of a risk based inspection program for meat and poultry products. The industry urges FSIS to conduct a public stakeholders meeting no later than the first quarter of next year to openly discuss the key components necessary for allocation of inspection resources based upon risk. This should be more inclusive than the Advisory Committee.

Following a thorough discussion of the

desired outcome of the effort, task force or working groups representative of all stakeholders and with requisite expertise should be assigned to further elucidate the subcomponents of the primary risk factors. For efficiency and effectiveness, the task forces may need to communicate by conference call/E-mail rather than awaiting opportunities to meet face to face.

In conclusion, again, we commend USDA for starting a process that once successfully implemented will benefit FSIS, the industry, and most importantly, the consumer as it focuses everyone's efforts on the areas with the greatest potential for positive impact on public health.

Thank you very much.

MEMBER TYNAN: Thank you, Dr. Henry.

I think the next person that signed up is Skip Seward from the American Meat Institute.

Is it Dr. Seward?

DR. SEWARD: Yes, thank you.

MEMBER TYNAN: Okay.

DR. SEWARD: Good afternoon everyone. My

name is Skip Seward. I'm with the American Meat Institute.

And I support everything that Craig said, of course, as part of the coalition. We joined the coalition in acknowledgement in this initial step into a more collaborative process for developing risk based inspection and appreciate this opportunity to participate. Whatever criteria, whether it's a hazard control coefficient or some other descriptor is used to establish relative risk for an establishment, the key is to use the appropriate measures to compute the criteria.

AMI also has submitted specific comments on such measures to the Food Safety and Inspection Service, and we hope the committee will take the time to review these inputs.

One point not to be lost is that whatever criteria or measures are used to assess risk for risk based inspection, they should be linked by scientific data to their public health consequences, and these linkages need to be strengthened as noted by Dr. Masters this morning.

We would also like the committee to consider several other issues relating to risk based inspection. First, the confidentiality of establishment specific risk rankings.

Two, what measures are going to be used to define the efficacy of risk based inspection by FSIS, industry and the consumers.

And how does one manage misunderstandings and disagreements for continuous improvement of the process, and equally important, how does FSIS risk based inspection program integrate into a national risk based system that involves food service, retail, restaurant, FDA regulated foods, and even production sectors as suggested by Phil Derfler and others this morning.

To focus resources based on existing regulatory structure may not optimize improvements in public health.

So AMI welcomes the opportunity to participate in committees and task forces as suggested by Dr. Raymond in his remarks earlier today.

Thank you very much.

MEMBER TYNAN: Thank you very much.

We also have Andrea Brown. Is Ms. Brown available?

And, Ms. Brown, you're with the American Association of Meat Processors?

MS. BROWN: Yes, yes.

MEMBER TYNAN: Okay. Thank you.

MS. BROWN: The American Association of Meat Processors and its members share the common goals with FSIS to improve food safety and reduce the risks to public health. We believe that risk based inspection when based on criteria that adequately and accurately reflect risk is a logical step in allocating resources to further improve food safety and decrease public health hazards.

Key to successful risk based inspection are getting the right criteria for assessing the risk, sharing relevant data amongst the stakeholders, and having clear links between food-borne illness and specific products.

Cooperation and transparency are also very important to accomplishing the successful development

and implementation of risk-based inspection. One of the greatest challenges related to this type of inspection is defining the criteria used to assess and measure risk associated with FSI's inspected establishments. The criteria should be linked using scientific data to the public health consequence.

It can be recognized that these types of linkages are often difficult to substantiate because of the limitations in food attribution data, insufficient or nonexistent data sharing protocols, inadequate knowledge regarding the extent to which inspection issues relate to food safety, and the tremendous variety amongst the federally inspected plants in terms of size, production volume, types of products, formulations, technologies used, and so forth.

AAMP challenges the National Advisory Committee on Meat and Poultry Inspection to analyze the risk based inspection system and develop functional, realistic, and scientifically based criteria for establishing risk.

Thank you.

MEMBER TYNAN: I have on my list Doug Scott. Is Mr. Scott or Dr. Scott in the audience?

MR. SCOTT: Yes, sir.

MEMBER TYNAN: Were you planning on making a comment, sir? No? But if you have one, you could.

MR. SCOTT: (Speaking from an unmiked location.)

MEMBER TYNAN: Okay. Thank you. So far, but it isn't over yet.

Okay. We have Tony Corbo, Corbo. Sorry, Tony.

MR. CORBO: I'm Tony Corbo, and let me get this out of my way. Today is my last day at Public Citizen. Tomorrow the staff that has been working on food and water issues will be forming a new organization called Food and Water Watch. So to avoid confusion I'll just identify myself as being with Food and Water Watch today.

I appreciated all of the comments and all of the references to construction. I come from a long line of family members in construction. I used to help my dad and my uncles building houses, and I'm

happy to report that those houses that I worked on 35, 40 years ago are still standing.

I had problems with the steps that were identified as being sort of the building blocks to where we're going with this whole discussion on risk based inspection. You've had legal problems with the implementation of HSIP. HEMP had legal problems. This particular committee in previous incarnations had two meetings to discuss HEMP. They were very contentious meetings. There hasn't been any further discussion of the HEMP program. I'm glad to Mr. Elfering raised it again today, but there really hasn't been a thorough discussion of how effective that program has been.

Public Citizen did file a FOIA request for data on that system because there hasn't been a thorough public discussion for at least a couple of years on the system. So I think before we put moves on things, we had better take a look at the foundation because I think you have problems.

And so I think that you have made reference that there's going to be transparency in the

discussion of HEMP and other issues, and I implore you to have those discussions before you get into an elaborate discussion of the roof.

The other thing is I just couldn't let the reference to got to have a recall go by because the agency knew in February 2002 that there were problems at that facility. They evidenced themselves in Milestead (phonetic) and Montana, and the agency sat on its hands until you had a major problem.

So in all deference to Phil Derfler, you guys knew.

So thank you very much.

MEMBER TYNAN: Thank you, Mr. Corbo.

And the last person that has signed in to do comments if Felicia Nestor, the Food Safety Consultant.

Ms. Nestor.

MS. NESTOR: Hi. I'm a food safety consultant working with Public Citizen now. I used to be with Government Accountability Project, and I wanted to address a couple of the issues.

First, I just wanted to talk about the

transparency. You know, it's one thing to say that you're going to be transparent, and its' another thing to actually be honest and transparent, and I wanted to follow up on what Tony was just saying about what I would consider the misrepresentation of the Con Agra incident.

Phil Derfler said today that the inspectors in the plant had the data to take action on but they just didn't do it, and I think Dr. Murano at the time blamed the front line inspectors.

I spoke to front line personnel in that plant, and the Con Agra, the OIG Con Agra report makes clear that the inspectors in that plant repeatedly told their supervisors that there were company E. coli tests that were positive, and they wanted to follow up, and repeatedly they were told not to do that.

So in the interest of good faith and transparency, I would appreciate it and I think most people would appreciate if you don't misrepresent the history that people don't necessarily have access to.

The second thing I want to take issue with is just raise a question. Phil Derfler was talking

about incentives and what role incentives can play in getting companies to create improved food safety systems, and he was talking about the incentive of less inspection in a plant and gave the example of listeria.

If you look at the example of E. coli 015787 testing though, I think it provides an example of the other possibility which is that when you say you're going to do less inspection, that things are actually going to get worse.

In 1999, the agency instituted 10,010.1, I think, Revision 1 or was it Revision 2, which gave exemptions for companies that did their own E. coli H7 testing. Unlike disease statistics for listeria and I think possibly salmonella, the CDC NMWR statistics for food borne illness did not go down with E. coli 015787.

So we had at least three years where this incentive could have created a decrease in food borne illness, and it doesn't look like it did. Now, I don't know how directly connected these things are, but I think it is extremely coincidental that if you

plot month by month the CDC MNWR statistics, you see an immediate and steady drop as soon as the summer of 2002 came about when the agency announced that not only was it going to then test all ground beef producing plants for H7, but it was also going to be keeping a supplier database.

So that the agency increased the accountability for these plants and immediately the H7 numbers went down. Again, I'm not a scientist. I don't know that it was directly connected. I think there is a good reason to look and see if it is connected, and I'm very concerned that when you say you're considering lessening an inspection in a plant, once the plant proves itself, what's to prevent that plant from getting sloppy as soon as you pull those inspectors out and as soon as they know that the inspectors aren't going to be back for however many weeks or months it will be before they're seen again?

And I know that, Barb, you said that the agency is conceiving of risk based inspection, in terms of the current statutory framework, which would require daily inspection, but many of us in this room

know that there is not daily inspection in many plants, and that inspectors on patrol assignments in many plants do at best a drive-by.

The 70 percent food safety inspection tasks versus the 30 percent other consumer protection tasks doesn't play out in a plant where an inspector comes in for ten minutes.

The third thing I wanted to say is I don't know why the inspectors are not at this table and why they've never been at this table. You know, it seems a little silly that you're asking this table full of people that have expertise in so many other issues how inspection is going to work and what inspection methodologies are going to be the most productive when most people at this table if you gave them a test in HSIP inspection, how it's functioning today, would not be able to pass it and through no fault of their own.

None of us out here are experts in HSIP inspection, and I think if you're going to be test driving some mew methodologies or reordering priorities in terms of how you're going to do inspection, it would be beneficial to have at least a

check-in with the people on the front lines that have been doing this on a daily basis, some of them for over 20 years.

And what I want to say to support that is in 2000, when I was at Government Accountability Project, I did a survey with the inspectors, published it with GAP and Public Citizen published it. It was the inspectors that had worked on HSIP for the first year and a half of its implementation.

And at the time the inspectors were sometimes calling HSIP. "Hardly anyone comprehends current policy." There was a list of things, a list of options. "What prevents you from carrying out your food safety responsibilities the most?"

I got a surprising answer. I never thought the inspectors would have said this, but what they said was confusion between FSIS personnel was the most -- it was the biggest impediment to them, not even confusion between the industry and FSIS, but between FSIS personnel themselves.

You know, we published the inspector saying this in the year 2000 from surveys done in

1999. The OIG and GAO reviews later went on to say exactly that, that people within the same district couldn't explain the regulations similarly.

And finally I want to go back to this is my last comment on transparency again. I was in this room in 1995 when we were discussing HSIP, and the agency was announcing, you know, its new, latest science based program, HSIP, and they talked about doing Salmonella testing, and we talked about doing daily Salmonella testing; that Salmonella testing would be done in plants. Performance standards would be used as a gauge to see whether the plants had process control.

I did an analysis of the Salmonella statistics in 2001 for the years 1998 through October 2001, and what I found really surprised a lot of consumers. A test in a ground beef plant, a sample set in a ground beef plant should have taken at most two and a half months of daily testing, and in eight of the large plants, the beginning of one sample set, from the beginning of one sample set to the beginning of the second sample set was two and a half years in

many plants.

In a number of plants, they failed the Salmonella test early on in the test, and the agency took no action until later on. One of these plants failed the salmonella test five times over.

So the consumers came out of this meeting room fully supporting HSIP based on the representations made by USDA, and all I can say is as you go into the process of risk based inspection, I just hope that your transparency, you know, is a little more honest than the transparency that this agency was using in 1995.

MEMBER TYNAN: Thank you, Ms. Nestor.

Are there any other comments from the public that would like to make them at this time?

Yes, sir. If you could come up and identify yourself and your organization.

MR. WALGROCK: I'm sorry. I didn't see the sheet. Chris Walgrock (phonetic), Consumer Federation of America.

I said a couple of quick little things. I understand this is the beginning of a dialogue and

process on risk based inspection, but I would encourage FSIS to expand this dialogue beyond this Advisory Committee, beyond five minute public comments, you know, in the middle of the thing after lunch when we're all lethargic, and make a wider public discussion about this.

This is a very important topic. We're changing the inspection system for food and safety, and it deserves a public debate on it. So I would encourage you to go beyond what you've started right now.

Second, just on the data that the Advisory Committee has been charged to look at and collect and suggest, in the end the data that FSIS ends up using, I hope that they're very transparent about what that data is, what it actually measures, and where that data is coming from, as well as that the data is very, very useful to our purposes here.

You know, if we're coming into this system with bad data and bad information, we're going to end up with a bad inspection system, and to that point this risk based inspection system that we're looking

at cannot be -- and this may be stating the obvious -- but it cannot be as good as what we currently have. If we're going to go to all of this trouble, if we're going to design this new system, it has to be better than what we currently have.

So thank you.

MEMBER TYNAN: Thank you.

Are there any other comments from the audience?

(No response.)

MEMBER TYNAN: Okay. Well, what we'll do at this particular point is go back to the agenda and talk a little bit more about the subcommittees and how we're going to approach our work for the remainder of the day.

I do appreciate all of the comments from the public. We'll have another comment period tomorrow. So if there are some other things that come up and you want to mention them at that time, we'll have some time allocated on the agenda for that.

So with that I'm going to return it to Dr. Masters to talk a little bit about the subcommittee

process.

CHAIRPERSON MASTERS: Very quickly I'll let you know what appeared in front of you over lunch. We did give you FSIS Notice 73-05. That was issued on November 10th. For those of you in the public that are interested in that notice, it's our notice on collecting baseline samples for raw ground beef components, and so that's available on our Website that we put out for our committee members that was discussed. So that's in front of you.

Then Ms. Eskin asked about she had looked on the Website and there was a report to Congress on risk based inspection from 2001. So we put that out for everybody so that everybody could catch up with Sandra who did her homework, and it talked about inspector optimization system, and apparently that was an earlier look at moving forward and risk based approach.

And some of my colleagues shared with me that that was an earlier attempt in looking at our hazard coefficient, where we actually did an expert elicitation, and we looked at risk as associated with

products and process from an expert elicitation. That was talked about in a public meeting that we did in 2001, and the only published document associated with that is our fulfilling the vision document that Dr. Murano did, the first one, where she talks about the HC and the HCC and kind of did a map, a scattergram, where she visioned where you might look at plants and products based on their risk.

So there is a scattergram in this document that we've put out for you. So you should have gotten a copy.

PARTICIPANT: Excuse me. This is not Dr. Murano's? this is a new one?

CHAIRPERSON MASTERS: This is Dr. Murano's vision document. So that was something that Dr. Murano had put out there.

Dr. Raymond has challenged our agency to step back and so we see that as one of our steps in moving forward, but it is one of those steps that we're needing guidance from this committee on as to whether or not before we can even fill in those steps we don't believe we have the right data. So we're not

down to those steps.

So that was kind of the initiative at the time, and we don't want to get down into those steps until we get a lot more information. So it was that initiative, and this was the public document that came out of it.

And I think as you heard some of the public comments, people have heard of that. People are aware. I think some of the trade association comments came, too. If you're going to rank plants or talk about plants, make sure you have the right data, and that's, I think, where they're coming from as previous conversations that were out there in the vision documents.

And so I think it is useful to have this as background material, but that is not something that the agency is currently glomed to or stuck to. We are looking at, starting again, hearing from this committee and rebuilding from information that's being provided from this committee as far as what you would guide us in looking at products, plants, processes, and moving forward as our building block, again.

I think the general concept is something that we still would agree on, but again, this is the only published document that came out of that process, if that's helpful.

Phil, in his infinite wisdom, went and typed the questions that he had asked of the inspection when he was going through his chart. He typed the inspection, and he went back to type the ones for data. So he should be back shortly because he said it would take about 20 minutes. So while we were getting our public comment, which was very helpful. Thanks to all of you that shared that with us.

So he's bringing that back because he thought it might be helpful to have those in writing, as you all hopefully deliberated over lunch how you want to best move forward, the specific questions that he had kind of charged you with.

So that, again, they were a little bit more detailed than the five questions we had put to you, but I think the more specific thing that we were hoping to get from the subcommittee's committee is all

of the thoughts that you have relative to data and inspection as we move forward.

So I think was just trying to give you probing questions relative to the chart, but he thought it might be helpful to do that. So he went to get the other probing type questions that he had asked you as he walked through the chart. So we have that for you.

And for the public, if you don't have it yet, those of you who are hanging with us that want to listen to the deliberations, we did get copies of the chart that we do break up that you can listen in and have the chart in front of you. We want to make it as participative as we can so that you can listen in and see the chart as we talk through this. So hang with us as we make our decisions here. We do want you to be able to listen in and hear what's going on.

So thoughts from the subcommittee. I'll turn it to you all and see where you got over lunch.

We had two and a half options on the table before we left. Dr. Hollingsworth.

MEMBER HOLLINGSWORTH: One of the things

that I was looking at in talking to some people with over lunch, and that is I think that the reality is the agency, the industry, everybody has been looking at some variation of risk based inspection probably since the late '80s, and I even went back. I found a computer upstairs that someone let me use, and I went back and found all of these NAS studies, the purple book, the white book, those of us who were here then.

You know, the basis of a risk based approach to poultry inspection; the basis of using risk for a better food safety program. I mean, there's attempts to do this, and many attempts have taken place over the years, and I think that some of these old studies and other attempts that have been made are things that the agency and this group should even consider.

But I guess my initial concern today is I'm looking at these questions in the magnitude of this issue in thinking is it realistic to think what couldn't be done in 20 years we're going to accomplish in four hours. We're good, but I don't think we're quite that good.

With that in mind, when I looked over the five questions, I guess the one that seemed to me maybe the most from my perspective important for us to address is the one that Dr. Raymond laid out, and that is Question No. 5. How does the industry go forward?

I think for us to provide anything really in depth or meaningful to build that roof is beyond expectations for a group of this size in such a short amount of time, but I do think this group would be very capable of looking at what would be our best advice to the agency on how to go forward and where to go from here.

So I would like to just throw that out to the group as it seems to me even if we want to break out into the subcommittee's slated to tackle Questions 1 and 2, I would like to see maybe us work together at least on answering Question No. 5.

And the fact that Dr. Raymond brought that one out to seems also the one that he was indicating was most important to him.

CHAIRPERSON MASTERS: Ms. Eskin.

MEMBER ESKIN: I agree totally with what

Jill just said, and I was going to make the same suggestion, that we look at Question 5 now and see how much we can address those procedural issues and then take it from there.

CHAIRPERSON MASTERS: Other thoughts?

(No response.)

CHAIRPERSON MASTERS: So I'm hearing some thoughts about answering Question No. 5, which is providing advice on how we can get more input collectively on moving forward, Dr. Raymond, I wrote down even some more specifics. The ideal working group, would it be this committee, a subcommittee of this committee, a separate committee; how often they would meet, the number of people, who they would be; state, FSIS, industry consumers, House elected, who chairs, outside because he was speaking freely, as he often does, even outside of the actual written question, and providing us some advice on that question as a whole committee, and then breaking into your subcommittees to tackle as much as you could on the other questions because from an agency perspective, in addition to this question, any thought

you're able to provide us on the actual chart and any advice you might be willing to give us on the actual chart in moving forward, anything that you gave us would be very useful and helpful to us because I don't disagree with Dr. Hollingsworth.

Obviously there's been much work done, but any advice and thoughts that you had, even if you picked one or two sections of the chart as a subcommittee, if your chair said, you know, "These two questions would be two we thought we could provide some helpful guidance to the agency," would be very helpful in moving forward, I think, just to get started.

I don't think anybody walked in anticipating that you would say, "Here's the eight questions and here's our answers to the eight questions. Whew, that was done. Move on."

I think we just wanted to get something out there and get your ideas, as many as we could, moving forward.

So if you guys want to take a vote, is everybody working as a whole committee on Question No.

5 to start and then breaking into your subcommittees and tackling as much as you can as a subcommittee on your inspection issue and your data issue and getting as much work as you can accomplish in those areas and tackling those however your chairs guide you through the work?

David and Michael, are you up for that challenge?

Sounds good. David and Michael, I'd ask you to co-chair then for this section. Are you guys willing to do that? Okay.

MEMBER TYNAN: Could I suggest that we do a five-minute break so that we can get some people in here who are better typists than I am and maybe some flip charts in here to help facilitate the process?

So if we want to take I'm reluctant to say ten minutes because then it's usually 15, so if we say five, will that be ten?

(Laughter.)

MEMBER TYNAN: Okay. So I have quarter of. So if we could get back together maybe five minutes to the hour.

(Whereupon, the foregoing matter went off the record at 1:45 p.m. and went back on the record at 2:03 p.m.)

MEMBER KOWALCYK: This is Michael Kowalcyk.

I guess starting with Question 5 we'll look at each aspect because we're charged with looking at from an inspection perspective, and we're also charged with looking at it from a data perspective.

So David and I discussed earlier that we would kind of split responsibilities where we will handle each question, what inspection issues need to be addressed and then data issues if that's okay with the full committee.

For the sake of time we may want to try the tent card if we get off track. I'd like to keep us on track as best as we can in the sake of time and getting some good work done.

So with that, 5(a) or five, the question is: if the agency were to form an ongoing working group to look into risk, what recommendations would the committee have on (a) who should compose of the

group?

And I guess I'll open it up with comment and starting with Mr. Elfering was first with the tent card on the end.

MEMBER ELFERING: I think one of the things that we should probably identify is I think everybody who has a stake in this: consumers, industry, academia. I mean really everybody who has some part in the meat and poultry industry.

So I think we need to limit the number of people. I think that's important, but you need to have someone there from inspection as well. I think that from an inspection standpoint, from a state inspection standpoint, from consumers, the industry and academia.

MEMBER TYNAN: All groups represented, including inspectors.

MEMBER DENTON: I guess that would include industry, consumers, agency. Would we also want to include state agencies as well?

MEMBER TYNAN: And industry. So those are the major categories.

MEMBER DENTON: That could be.

MEMBER TYNAN: I'm sorry. My handwriting is not good. Can you all read it or do I need to write larger?

MEMBER KOWALCYK: Dr. Denton, do you have anything you'd like to add or, Mr. Elfering, are you finished?

MEMBER DENTON: Just to add a couple of things, I agree with what Kevin said about the regulatory component having representation from FSIS as well as our state inspection agency. Industry, and as we look at each one of these major categories, I think there are several ways that you can look at those.

In the industry component, I think we have the more traditional, large, small and very small representation as far as the size of the organization. We also have a way of looking at it across commodities, beef, pork and poultry.

The consumer groups obviously have a keen interest in this. As I look at the, and I chose to call it "scientific community," there's several groups

that could fall into that, some of which are part of academia. Part of them come from the agricultural research service, and from various backgrounds in animal health, food science, and public health.

I think that as we look at the scientific part of this, there are three or four different groups that would have a very important --

MEMBER TYNAN: So how would I capture that, Jim?

MEMBER DENTON: I would cal lit scientific community, and within that we have the academic research. We have the ARS or government research, as well as public health component in research.

MEMBER TYNAN: So we have academic research, government research, and public health research.

MEMBER DENTON: Yes.

MEMBER TYNAN: Now I know you can't read that. Trust me.

MEMBER DENTON: But that's only one way of looking at it. I mean, there's obviously lots of other ways that we could cut across that, but just

thinking in general terms.

MEMBER KOWALCYK: Okay. Thank you.

sure.

MEMBER LOGUE: Hi. This is Catherine Logue.

Could I just add to Dr. Denton's point? Among the academics and the scientific what might actually be worth including here is other agencies that also do risk. I mean, FDA do this and other sister agencies. So maybe that should be included, and you don't just limit it to FSIS.

MEMBER KOWALCYK: CDC comes to mind as well.

MEMBER LOGUE: CDC, yeah.

MEMBER KOWALCYK: Dr. Harris.

MEMBER HARRIS: This is Joe Harris.

I hate to be disagreeable with some of the points that have already been made, but apparently being disagreeable is frowned upon here. And I don't disagree with the thought process. I'm thinking that this particular group has just mushroomed into a really large, unwieldy thing with that many if you're

going to be inclusive of all of that, and I think inclusive is imperative.

But I do think that the bulk of this working group needs to be focused on the three legs of the stool that Dr. Raymond talked about, and I think that as a working group then could solicit specific input from so many of these outside entities, such as the CDC, to provide data to them or that type of input where the core working group might be a little more of a smaller group, if you will, and then solicit input on specific questions of interest to that group from, you know, the various other entities that are listed there.

MEMBER KOWALCYK: Okay. I think that's a valid point because you want to get something done through the working group. I do think though that having these groups out there listed, I mean, they would become a valuable resource and maybe we would go down the lines of these working groups would have to be done in a public forum so that academics who are interested in that type of research state inspection agencies that are interested in what's going on and

maybe they can lend some support.

Certainly, I don't want to speak for other people on the committee, but for myself to get something done if you get beyond a certain amount of people, it gets very intractable. So that's a good point.

Mr. Govro.

MEMBER GOVRO: Mike Govro.

I agree about the size of the group, although I do need to say it may go without saying, but I think FSIS should be represented in some fashion, at the very least as a resource as it functions in our subcommittee type groups to be there to answer questions and let us know when we're astray somewhere.

MEMBER ESKIN: Sandra Eskin.

There's one approach that probably could easily reflect everything that's been said, and that would be to go to a group like the National Academy of Sciences, which has a long track record in not only doing reports on food safety but all aspects of public health. They have in recent years done a report on

regulation of dietary supplements, child obesity. It's all different panels, but the organization would be the umbrella there.

And my understanding, again, of how it works is they do put together a committee, and then part of the process is a series of public hearings in which all of the interests like those reflected there have input, but it's this group of experts, this expert panel, that would come up with the recommendations.

Again, they've been used -- the National Academy of Sciences has been used time and again, and there are certain advantages. Again, they're independent. They're not representing any particular interest. They're not representing the agency, and I think that's something we should consider recommending.

MEMBER KOWALCYK: Okay. Dr. Hollingsworth.

MEMBER HOLLINGSWORTH: Jill Hollingsworth, FMI.

I'm more, I think, along the same lines as

Sandra is mentioning, and that is to have an oversight group, for lack of a better name right now, that's charged with seeking out and getting input from all of these different stakeholders because even I'm looking at that list and you could probably even add to that list. I mean, you need professional risk assessors. If you're going to talk about risk based inspection, you need people who really understand the concepts of risk.

And maybe under FSIS that was the intent that Michael had, but you need policy makers. The inspectors who carry out the policy are a valuable resource in this, but then you also need the policy makers.

I also think you probably need lawyers or regulatory experts or legal experts. So I think there's a lot of different input that needs to somehow be consolidated, and I would envision that as there being a third party that has no stake in the outcome that pulls together all of these groups and gets their input, either, you know, in small breakout sessions or on panels or however they organize it, and then they

consolidate all of that information.

And I think the idea of NAS is certainly a strong one to consider. I agree with Sandra they have a long history of doing this, and they also have the ability because a lot of people just like being on NAS committees, to probably get a lot of participation.

People show up when the NAS asks you to come and be on a panel. They can certainly pull in some of probably the country's best risk assessors and public health experts to participate on those kinds of panels, unlike if it was just a government group or even an FSIS group. You might not be able to tap into that kind of expertise.

MEMBER KOWALCYK: Okay. Thank you.

Anybody else on the committee who would like to add comments? Mr. Govro.

MEMBER GOVRO: Yeah, I just want to echo what's been said here. I think there would be some advantages to having a third party, people who were professionals at doing this, with no disrespect intended to this committee. We're all pretty much otherwise employed, and I'm not sure we would have the

time to give this as much attention as it would need.

MEMBER KOWALCYK: Okay. What we can do is we can talk more about -- we've got a lot up here. The issue was brought up about the size of the group. There are a lot of different stakeholder groups that would be involved. It seems like we're in general agreement that inclusiveness if very important.

Do we want to talk about the more details on how this should be composed or do we want to go on and talk about how this should be composed for handling the data issues that may come up under risk based inspection?

Dr. Harris.

MEMBER HARRIS: I guess I want to touch, before we completely leave that. It does sound to me like there was some consensus around the table that a disinterested third party to guide the process or to facilitate the process is the route to go, but I wanted to get a little more specific.

Do we recommend that the agency identify that entity or how is that entity going to be identified? I mean, I have no idea if the National

Academy of Science has an interest in doing this. And there may very well be other entities that might, you know, be appropriate for that.

So is our recommendation then that the agency find and identify that entity or are we going to recommend which entity it is?

CHAIRPERSON MASTERS: And this is Bar Masters.

I can at least share with you we've had some preliminary conversations with the National Academies, and that is something I'm in the process that Ms. Eskin described as something that I believe is very similar to a description they provided to the agency as a process that they do put together panels. We would contract with them.

That is, we have talked about using them for a couple of other processes that we've looked at. So we haven't specifically approached them on this topic, but we have talked to them on some other processes, and so it is through a contract process that you can work with them to get a panel put together, and so we've had some briefings by them, and

so we have been in contact with them in the last couple of months on some other areas that we're looking to gain some advice from them.

So I think that is something if this committee wanted to pursue that. Just to make you aware, that is something that I think is a viable option that this committee could recommend.

MEMBER TYNAN: Ms. Eskin.

MEMBER ESKIN: Obviously, I guess the other question is does FSIS currently have the resources. Again, saying that the NAS is to do the study and then having the resources to have them do it is two different things.

How does that work? Do we have to go back, or if we recommend that you all get a third party like NAS to do this, you need to ask for funds?

CHAIRPERSON MASTERS: I think at this point, I think we're going to have to look at the options that come out of this and then look at our resources and make those determinations.

So I think that I don't think we're prepared at this point to commit to it. We'd have to

see the kind of cost and that sort of thing to make those determinations.

MEMBER ESKIN: Right.

CHAIRPERSON MASTERS: Again, we were looking at a different situation at the time we were talking to NAS, and it's not something that's not expensive. It is a very expensive process.

MEMBER ESKIN: No, it is.

CHAIRPERSON MASTERS: But this is obviously a very -- this is something we're very committed to doing and so I think it's something that we would take very seriously if this was the advice that came from this committee.

MEMBER ESKIN: And often what has happened in other contexts is in legislation at NAS is sometimes specifically designated. You should do a study, contract with the NAS, and here's the line on it. Here's the money that you can do.

I just wanted to respond, Mike, to your question about sort of the substance of it the committee should look at. My sense would be if we went down this road with a third party basically

running it, they would look at all aspects of the issue of risk based inspection.

You know, we've discussed these two pieces of it, the data collection and then the inspection kind of process, but it would be every issue that is raised under this umbrella concept.

MEMBER KOWALCYK: I think also one thing I'd like to add is whatever the composition of the group is, there should be equal representation among the stakeholder groups.

There are further questions down talking about frequency and where they should meet. Obviously, I feel that these meetings should be public. I think the input that this committee gets from the public is very important, and I'm sure for something as significant that affects everybody involved, public input is of the utmost importance.

MEMBER TYNAN: I guess the question becomes is this the alternative that you're proposing. So were there other options, assuming we didn't have resources, to be able to proceed or is this the best and the choice?

MEMBER KOWALCYK: I guess I'd ask the committee does anybody have any additions or is anybody uncomfortable with representation of stakeholders for those issues?

MEMBER ESKIN: May I?

I guess I just wanted to clarify exactly, you know, again what we're at least thinking of right now, and clearly if it were a NAS type process -- Dr. Masters, correct me if I'm wrong -- generally the actual committee that they put together is anywhere from 13 to 15 people, and those people represent some range of expertise.

And through the deliberations, which I don't know if there is a common length of those, if it's a year, if that's common or longer, they have a series of public hearings, and it's at those hearings that all of the stakeholders would be heard from. But they wouldn't necessarily be members. That's the NAS model, which again, that's one option to put forward.

MEMBER KOWALCYK: I would agree that -- Dr. Harris, did you have some comments? Sorry.

MEMBER HARRIS: Actually along those same

lines that Sandra was just addressing, in going back to your comment, equal representation from all stakeholders. Well, we identified a pretty lengthy list of all stakeholders over there, and if you're going to have a committee of manageable size, you're looking at probably no more than one individual from each of those entities as far as the group goes. So I wanted to comment and define what you meant when you said equal representation from all stakeholders because I would contend that one representative couldn't probably represent all of the consumer views. One representative probably couldn't represent inspectors' views, and I know one representative probably couldn't represent all of the industry views.

So, you know, I agree with your concept. I just wanted to a little more clearly define that, and along with what Sandra was saying, you're going to have to have a core group then that facilitates getting all of that input from everywhere else, and maybe that is something we leave up to whatever third party we arrive at. Maybe that third party assemble the group and we give them some criteria on, as you

say, equal representation and give them a little flexibility on how they carry out their mission.

MEMBER KOWALCYK: Okay, and then the NAS model would allow for public participation. So you could get that opportunity for representation.

Dr. Hollingsworth.

MEMBER HOLLINGSWORTH: I was basically going to follow up. Sorry. Jill Hollingsworth.

Following up on that, my general understanding and even having worked with some past NAS commissions and committees, you would not have this group equally represented on the NAS committee. In fact, the NAS committee would probably be much more heavier leaning towards academicians, risk assessors, people of that nature.

What they do then is they determine how do they get sufficient and equal input from all of the stakeholders. So their job is really to assemble the groups, identify the groups. Certainly they would go to others like, for example, to FSIS and say, "How can we get representation from your work force?"

So they would go and ask for advice, but

I've been on NAS panels that have met with NAS committees, and the panels can be as many as 20 people, and you all get an opportunity to make a presentation on the issue or share your input, and then if they have questions, they can even come back to you later or ask you to revisit them and answer questions that they might have.

So I think it's really up to the NAS committee to work through the mechanics of how do we make sure all the stakeholders are represented. How do we get their input?

The committee itself is usually not the stakeholder group.

MEMBER KOWALCYK: So the alternative would be a third party led community similar to an NAS panel, and they would elicit input from the various stakeholders that are interested in risk based inspection; is that correct?

Mark.

MEMBER SCHAD: I just want to be sure I understand these concepts. Dr. Hollingsworth, your recommendation, your suggestion or your idea here is

leaving it up to a third party to compose the make-up of this group?

MEMBER HOLLINGSWORTH: The third party is not a representative group of all the stakeholders. The third party's job is to solicit all of the stakeholders' input, consolidate it, and then develop the series of recommendations from that input. So they serve as more a team of facilitators to get all of the input and then to assess all of that information.

MEMBER SCHAD: Well, let me say this. I'm all for a third party facilitator because I think that would be good. I'm just concerned about I think the make-up of the group ought to be consumers and industry and inspection, and I don't want to get away from that, leaving it up to a third party of the composition.

MEMBER HOLLINGSWORTH: Yes, I see your point. I guess where I'm concerned with that is how do you put together a -- when I say "disinterested," not that they're disinterested, but an unbiased sort of have nothing to gain or lose kind of third party

whose job it is not to pass judgment that one group's argument is more compelling than another, but rather to just take all of the information and assimilate it.

My other concern -- and that's not to say -- I mean, the NAS usually within their own body, they make the decision as to who is on the committee itself. They may choose to say, you know, "We need an industry person," or, "we need a consumer," but they're not constrained by having one of every representative on the committee. What they are told is get equal and adequate input from everybody.

MEMBER KOWALCYK: Sandy, do you have a comment?

MEMBER ESKIN: I was just going to agree with what Jill just said, and I would just say, Mark, that again, NAS is well respected. Again, we keep pointing to this, and they have a certain process they use, and again, the most important thing to focus on is obviously who is the third party, who composes their committee, but again, how broad those panels are.

So I guess I'm confident that they would

hear from all the interested parties and take to heart all the recommendations that are made. You know, if you do look, I'm just looking at the two food inspection related reports that they've done over the last 20 years, and it is primarily, it looks like, academicians who make up the committee, but again, they're well versed in the substance, and obviously many of them also have worked with industry.

So I would defer to that third party because I think the process they have developed has worked, and we'll all be in there, all of the interested parties, making sure that our positions are heard by them.

MEMBER SCHAD: Well, let me just say, again, the concept of the third party, I think, is a very good one. I just am concerned. I'm speaking for industry. You know that, that whatever rules or whatever system comes up with, it's up to industry to make it happen.

So I just have to be sure that this is going to be something that we can work with, with all due respect for all parties interested.

MEMBER KOWALCYK: That is a good point because ultimately the program is only as good as how it's implemented when it's all said and done. I do think though, reflecting on this morning's meeting and the discussion, how this discussion has evolved and going from including everybody to really getting down to key experts in the area of not just risk management, but also with respect to food safety, because ultimately the goal of this is to make the food supply even safer.

I think having that expertise on this type of an impartial panel would be very important because this morning we spoke about legal ramifications, operational issues because this is changing the way the agency conducts its business with its inspection personnel, and there's many areas that are affected by this.

So maybe having it run by an expert panel with public input may be a very good way to go initially to guide the agency along its way.

Dr. Harris.

MEMBER HARRIS: It would seem to me that

in following the model that we've kind of been discussing we would wind up with a set of recommendations from this third party that then would go forward through a series of public input and debate, if you will, or whatever, to determine, you know, the ultimate how it's going to be implemented.

And my second comment is I'm beginning to come to terms with why this has been lingering for 20-plus years without being done. This thing has got tentacles out every different direction, and it's really going to be hard to get arms around it.

MEMBER KOWALCYK: Dr. Hollingsworth.

MEMBER HOLLINGSWORTH: Jill Hollingsworth.

I do think there's one part of this that, you know, although I see a lot of the good, I mean, everything has a down side, I guess, and what I see as the one concern particularly from my perspective on this is that the NAS reports do tend to be recommendations. They tend to be a little more broad brush. They don't include "so here's a great idea. Now, how do you implement it?"

And I think that one of the things that

maybe we should task ourselves with or at least tell the agency this is only half of the recommendation; it's one thing to have an NAS committee look at the issue and identify ways to maybe approach it from risk based, the kind of factors and determinants that need to be considered, but then there needs to almost be Phase 2, and that is now how do you turn that into reality. How do you turn that into a program that can be implemented?

To go back to your point, Joe, I think part of the reason these studies have been around for ten, 20 years is they're a great set of recommendations and they never go anywhere. There are some things in that risk based inspection program that probably the technology exists to do today and they still haven't been done because it's always kind of that next step.

And that's the hardest part. It's one thing to come up with the idea. It's another thing to use them and implement them, and I think that maybe as a group what we need to think about, too, is if we went down this road to come up with a plan, then what

happens Phase 2. How does it get implemented? How does it get turned into an inspection program or an FSIS program?

MEMBER KOWALCYK: So, Jill, are you thinking somewhere along the lines for this committee where it would be incumbent on them to provide recommendations that are actionable, not just 10,000 foot view of how it should be, although that's important to guide something this significant, but really actionable steps that the agency would need to take?

MEMBER HOLLINGSWORTH: Well, I think it would be nice if they could do that. I'm not sure that that's often within the scope of what the NAS sees itself as doing. Maybe, you know, I don't know. I haven't given this thought. Just off the top of my head, but maybe we need to say that this report, this set of recommendations then needs to come back to this committee to determine now what happens to it. What happens to it next?

I think the worst thing that will happen is if we have another great NAS report that gets put

on the shelf and everyone says it's great, but nothing changes.

And it would be nice if the NAS could do that, but I personally don't know that they can. They're academicians. They're going to come up with the ideas, not the implementation component.

MEMBER KOWALCYK: Sandy.

MEMBER ESKIN: Sandra Eskin.

Another option would be -- one is obviously as you just said, Jill, to bring the recommendations back to this committee. Two would be to have FSIS make a commitment -- I put that in quotes -- to respond to the recommendations within a certain period of time, whether that means with a proposal to change rules or policies, but some sort of a commitment from the agency itself to respond officially to those recommendations, one option being official action, and obviously other options as well.

MEMBER KOWALCYK: Dr. Denton.

MEMBER DENTON: You would think that after this many years that I would learn not to do these things because every time I open my mouth I usually

get me in trouble, but in thinking about this, and I can't disagree with anything anyone has said with regard to how to go about this, but to me it seems like if we want to have the focus that we expect to have coming out of anything that the National Academy does because it will work just exactly like Jill has said, they will take the charge that they're given, but they're within the limits of their scientific expertise. They'll come back and make beautiful recommendations, but unless there is some guidance that comes from this agency that ties a pretty tight bow on what we ask them for, we are apt to not get back something that we can actually take and move forward with.

So we're talking about possibly -- and it comes to the question that Dr. Raymond asked this morning. Should it be a subset of this committee or should it be the entire committee that looks at this? But there's got to be something with regard to oversight that comes from the committee and the agency working together so that we define what we expect the outcome to be with regard to what we're asking the

National Academy to do.

Now, whether that's a subset of this committee or whether it falls back on the entire committee, I have not got a clear picture of that, but I think unless we do provide some fairly strict boundaries with regard to where they're going and what we hope to get out of this, that we will probably wind up with another one of these marvelous studies that fits on a shelf, and we will not have fulfilled what the request was from our Under Secretary with regard to moving forward with a risk based inspection system.

I think I see the goal, but I for sure do not see the road that we need to go down yet. That being said, I'll hush.

MEMBER KOWALCYK: Mr. Govro.

MEMBER GOVRO: Mike Govro.

I'd like to build a little bit on what Jim just said there and add to it with something that's been bothering me a little bit as we've addressed this question, and that is, you know, what question are we going to ask of this group. What question are we being asked?

And I'm a little bit uncomfortable with the wording in the question, "form an ongoing group to look into risk." And that's a little bit vague to me.

Getting back to some of the text here in the discussion, I'd point out a couple of things. Let's see. I may have to work backwards.

Well, let me see. I may have to work backwards.

FSIS recognizes that under our traditional approach to inspection we have not fully followed the core functions of the public health model: assessment, policy development, and assurance.

I guess my question for FSIS would be in what areas do you think you've fallen short, and perhaps by identifying those things we could go more closely to the question of what it is you want to know.

You've said FSIS must collect and assess our data. That's the assessment part, and there's, let's see, something back here. Recognizing that it needs to collect different data, and again, I would ask: what is it that you think you don't have?

And then respond, policy development, and I would see that would be something that would come out of this discussion, and then conduct assurance to verify that -- well, I guess that's the third step that follows later.

So I'm sort of with Jim. I think we need to define the questions that we're asking perhaps a little bit more concisely.

CHAIRPERSON MASTERS: This is Barb Masters.

And I would say that we don't know all of the questions we would ask this committee, and I would have to agree with Dr. Denton. I think that we would appreciate help in defining that, but I think we're looking at perhaps a series of questions we would ask, whatever this group became, using them as a sounding board as we move forward and looking at further steps into risk based inspection, which would have been a better question here.

And saying that we have not fully followed the public health model, I would say where the agency sees ourself falling short is probably most on the

assurance function. We have not most fully used our peer staff, which is the staff that goes out and looks at what we're doing as an agency to assure that our policies are effective, that our inspection is effective, and that was a group that we put in place about three years ago now to follow up on ourselves; that when we put a new policy out, was it the right policy? Are folks implementing it effectively?

And so it's our assurance function that we believe needs to be more robustly implemented, and that's the piece that we're looking at to be more robust with.

Collecting the right data, that's why we have a lot of questions for you. We recognize that there's a lot more data we could be looking at to be more proactive. Right now we have a data system that allows us to look at data that exist today. We believe there's a lot more data that we could look at if we want to be more proactive in looking at data so that we can assess that data.

I think Phil asked a series of questions in his data questions that instead of being an agency

that reacts to data, as Dr. Raymond says, "I don't want to recall product when people have become sick. I want to know when data are starting to trend out. I want to find problems before they happen."

We believe there might be ways to get at that data. How can we work with the public health community? How can we work with states? As you even suggested, how can we work with local public health communities to get our arms around some of that data, to be more proactive?

But certainly when we say we haven't followed the public health model to the most robust means, we believe it's the assurance function that we need to build up as an agency most closely to assure anything that we put in place is effective.

MEMBER KOWALCYK: Okay. Any other comments?

I think we've touched even on whether or not it should be a subcommittee of this committee and the size a little bit in people's comments. We've spent quite some time on at least for the inspection side. I don't know if we want to talk a little bit

about the data side of who should compose of a group that would make recommendations for how FSIS should manage and collect data.

I don't know if anybody has any objections, but it seems that the two go hand in hand. So maybe we can address that as well and then come back with a tighter recommendation. We have a lot of good ideas here and there's a lot of issues that people have raised. I think this is important information.

So I'll pass it to David to lead that discussion momentarily. If anybody has any objections or want to add to this, that's fine.

(No response.)

MEMBER KOWALCYK: Okay.

MEMBER CARPENTER: Well, I think what Dr. Masters just said is a good segue to what we're going to talk about in terms of data. You could interpret that your policy development is realistically going to have to be in a state of flux because the data, your assessment portion, is always being updated, and you're saying, "We're not sure we have all the right

data."

And until you get whatever is determined to be needed as a minimum, that assurance function is not going to come together in a really significant way until those first two functions in public health, as Michael brought up, are definitely in place.

If you look at data, and as we consider that question, and the question that's imposed to us about where does the agency obtain data or is it appropriate, I've got to believe that when you pursue what went wrong in recalls, you've got to get a pile of data.

If we had intervened here and applied a proper intervention here, that probably would not have happened. That's going to be a good source of data.

If you forget about the inspection function that Michael just discussed and just look at the data that we ought to get our arms around, I've got to believe the suggestion from the public a while ago about the inspectors saying we ought to be on the data committee, and I think Phil Derfler said, you know, what we're looking for in data are the emerging

issues, emerging trends.

And inspectors have to be in the position to say, well, we see this or that or second generation HSIP is or is not working. You know, the data from associations or members of associations like food marketing or Southwest Meat Institute or the meat processors, it's got to be brought to the fore.

And are any of those data available to the agency? I mean, where does the agency get data now? Can you share that with us? Do you have to bribe the manufacturers to share that with you?

CHAIRPERSON MASTERS: And when your data group gets together, we do have somebody prepared to give a more general data briefing, but, no, at the in-plant level, all of our inspection personnel have their daily inspection findings that they have electronically. They have all of the regulatory, the FSIS laboratory data. They have that particular plant's laboratory data that's available to them, that that plant is conducting their own laboratory testing. All of that laboratory data is available to them so they have access to that laboratory data for that

particular plant.

They have access to information from agency, salmonella data for that particular plant. So basically they have all of the information for the plant for which they are doing inspection at the in-plant level.

A supervisor would have information for that plant as well as plants on all of the plants that they supervise. And then the district would keep more information than that.

The supervisor would also have access to consumer complaints for a particular plant that might have come in against a particular plant so that they would have access to that kind of information if a consumer had had a problem.

So they have access to all of the findings, FSIS findings as well as plant findings for that particular plant that are available to them.

MEMBER CARPENTER: So when you consider the data, you know, in the recall investigation the agency had got to be -- I mean, correct me if I'm wrong -- has to be in the position to say, "We know

this was one of the most significant factors that led to the adulteration that then resulted in the recall, and if we had paid more attention to it or the plant or the supervisor, you could have rectified that."

You may not have those data. I mean, if you don't, you know, correct me. If you do, then that ought to represent a focus on what should be incorporated in an inspection protocol. Yes, no?

CHAIRPERSON MASTERS: Where Dr. Carpenter is coming from, he's saying on a particular recall, we would have information. Let's say a product was recalled because it was not -- it's a ready to eat product and when we went to do the recall, we found that that product was not fully cooked, for example, and that might be why we're recalling it.

So we know for that product it was not fully cooked. What we don't currently have and what we have found with our databases is that they are stovepiped, and so that is why we're saying we are having to build a public health data infrastructure.

So the agency has found we're having a difficult time getting our -- we have laboratory in

one stovepipe data. We have inspection findings in another stovepipe. We have information on enforcement actions in another stovepipe, and so we agree with you. We have a lot of good information as an agency, but where we are having a difficult time is trying to get all of that data to talk to one another.

So we are trying to build that infrastructure to try to get all of that information pulled out of some of those databases because we do believe that public health data is what will build the foundation.

But we also believe if we know undercooked product is a cause of a recall, that's not the cause of all recalls, but that may help other plants learn from that one plant's mistake. So we are trying to get some lessons learned from some of those instances because we believe that is good information to share, particularly in our outreach that we do for small and very small plants, for example.

So we have begun to do some of that lessons learned in our validation materials, for example, where we've done food safety assessments, but

we've manually had to go back and take information from our food safety assessments to do some compliance guidelines, for example, for ready to eat plants.

So we are as an agency, when I say we're building that public health data infrastructure, and we believe that is the key to a lot of our public health decisions; that's some of the work that we're having to do as an agency, is to actually -- when I said we needed new data systems or, at best, updated data systems, we as an agency recognize that's going to be the key to building any risk based inspection system that we move towards.

MEMBER CARPENTER: Okay. Michael.

MEMBER KOWALCYK: This is Michael Kowalcyk.

I think the follow-up with that and back to the focus to Question 5 as far as the working group, it seems that addressing data issues and over the past couple of years there have been issue with interpretation of data, whatnot, that comes out of the agency that has raised questions in the public's mind; having the committee, maybe a sister committee of the

risk based inspection committee, maybe their prime focus should be on how all of the sources of data, FSIS can use to do its job, how they can be integrated together to meet that goal.

Because one of the concerns I have for risk based inspection model is you're basing it on data. A lot of people agree with that approach. However, it's only as good as the data will allow, and the integrity of that data and how the data is collected, if that's going to drive agency's policy for inspection, maybe this committee or maybe committees is one way to describe it, but a working group that would have experts in the area of managing data systems and to actually do a thorough review of all the data FSIS has accumulated over the years and how the agency has used it to guide its actions over the years; to do an overview and say, "Okay. What have we learned over the time since HSIP has been implemented?" let's say, and how that can be improved upon that would facilitate a risk based inspection process.

So maybe the focus of that working group

could be more experts in those areas. Again, I'm risking going down the road of the NAS discussion where it comes through with a good recommendation and then it can't be applied. So that's just, you know, something I think we ought to think about. I don't know.

MEMBER KOWALCYK: Any other inputs? Dr. Hollingsworth, yes.

MEMBER HOLLINGSWORTH: Just some random thoughts on the whole concept of data, I guess. One is that I think that -- and perhaps this would come more out of the study if the NAS, in fact, looked at the whole concept of risk based approaches, is that I think there's a lot of technology out there that has not been utilized that would give the agency new and different types of data to make different decisions, and we've heard about technologies. I mean, ways to quickly screen carcasses and products, ways to use videocameras and infrareds and all kinds of technologies that are out there that I think everyone tends to think, oh, that's too pie in the sky and it will never be applicable.

But I think a lot of those technologies, in fact -- I was recently down at Georgia Tech, and they were showing some of the technologies that they've developed, and it's incredible, and they're ready to use. I mean, these aren't pie in the sky research projects.

So I think that one of the things the agency needs to look at is other ways of getting data, not just doing micro swabs and testing. I think there's a lot of other kinds of technologies to give the agency good data.

That's one point. Another point, I think, is the idea of, Dr. Masters, you mentioned stovepipe. I also think that in some ways the agency may want to look at their analytical capability and how can they do more with analyzing the data that they have.

I would be fascinated even now to see analysis of let's just say all the 015787 information you have on recalls: size of facility, type of product, time of year, what was involved in the process. There's so much, I think, that can be learned from the data and the information that's

there, but I think the analysis just doesn't take place. So I think there's a lot more that can be done with analytical applications to the data that exists.

And I guess my third point, which might be a little controversial, but I believe that there's this thinking that the industry has some miracle set of data, and if everyone just got their hands on it, everything would go away and be better.

I don't think that data exists, and sometimes when even listening to poor Sean I felt bad because he was trying to talk about how they're going to get this data, but I'm not sure that magic data bullet exists, and I think that we need to be realistic about are there, in fact, sources of data that would really, really make a difference, and if we just could have our hands on it, I don't know.

It would seem to me if the industry, for example, knew a way to treat a carcass or treat ground beef and all the problems would go away, then they would tell you. I don't think they have that information.

So I guess I tend to back off this kick of

how do we get this information that the industry has that they're not sharing with us because they know so much and they have all of this information? I think if they did, they'd be more than willing to use it, put it into effect. They certainly have the capability of getting the analysis, getting research done, and if they had the answers, I think they'd share them. That's just my point of view.

MEMBER CARPENTER: Dr. Harris.

MEMBER HARRIS: Well, in response to Jill's last point there, I would agree wholeheartedly with it. And, in fact, as Dr. Masters pointed out a few minutes ago, as of this moment, today, if a company has micro data upon which they're basing food safety decisions, the agency has access to that data today.

MEMBER CARPENTER: Would you expand upon that? Do you mean they would modify a process or put into a protocol?

MEMBER HARRIS: I'm saying that if they are basing any of their food safety decision, companies have to support all of their decision making

process within the regulatory framework of their food safety systems. If they are relying on their micro data for any of those decisions, that data is available to the agency today to look at.

Okay. Dr. Masters I think will correct me if I get too far off base on that one, but I think I stated it correctly.

MEMBER CARPENTER: Okay. Thank you.

Kevin, yes.

MEMBER ELFERING: Just one question for Dr. Masters. The salmonellas and E. colis that you're getting positive, they're all being molecular subtyped?

CHAIRPERSON MASTERS: Don't want to step too far out either, but I'm being told, yes, that they are.

MEMBER ELFERING: An how about the data that you get from industry if they find a listeria positive? Are they doing anything with molecular subtyping? Do they, first of all?

CHAIRPERSON MASTERS: That varies. Some companies are doing more with their laboratory

findings than others.

MEMBER ELFERING: And then everything gets posted on pulsenet for the FSIS, is all posted on pulsenet?

CHAIRPERSON MASTERS: Everything that FSIS does is posted on pulsenet. That is correct, yes.

MEMBER ELFERING: Now, we do molecular subtyping as well. Would that be of any value at all if there would be any other programs that would do the same thing?

CHAIRPERSON MASTERS: Absolutely, yes.

MEMBER TYNAN: Everyone is looking over at me. I'm not sure why.d

MEMBER KOWALCYK: Joe, do you have another question, comment? Okay.

This is Michael Kowalcyk again.

I think with respect to data and the question we've been charged with as far as forming an ongoing working group, it seems to me that we're in general agreement that a working group would be valuable to tackle risk based inspection going forward and possibly creating two groups, one that would deal

with the actual mechanics of how it would work, in other words, operationally how it would be carried out, legally what the ramifications are, and then the data side because it would be data driven.

Another group that I would argue should be experts in the field of data analysis, statisticians, operations research experts, to understand how these disparate sources of data would come together to make this system work.

As a consumer that's a concern I would have. Is the agency with all good intentions to enforce some regulations based on data that is in some way flawed is always a concern. So maybe there would be two working groups that would come out of this, and then they would provide their recommendations, too. I don't know. Maybe this committee, may be NACMCF, on how to go forward with this, and obviously with public input as well for that committee.

MEMBER TYNAN: Could I stop for just a second? Maybe I have misunderstood what you were saying, but when we first started our conversation, my recollection of the consensus of the group was that

there was a third party, somebody like the National Academy of Sciences, that would become a steering committee. So please correct me if I misunderstood.

CHAIRPERSON MASTERS: No, that's correct.

MEMBER TYNAN: And then they would be sort of a steering committee, and that steering committee from the National Academy of Sciences would then go out and serve to do some of the things that I think you had a concern, that there was adequate representation. So somehow through their scientific process, that they would assure the consumers, the health organizations, federal agencies, academicians, state government, would all be involved.

So I thought I heard you saying that the third party was a larger, independent, objective group. Are we still tracking together?

MEMBER KOWALCYK: Yes. I guess I'm just expanding on it and saying maybe there should be a separate group that would focus primarily on the data issues.

No, it would be one group?

MEMBER TYNAN: Yeah, well, maybe Dr. Logue

or, Sandra, did you want to?

MEMBER LOGUE: No, my understanding was that we were looking at the third party taking care of the committee, and then whatever input they had into it. I think creating another committee is another layer. It's going to turn into an onion, and we're going to be peeling layers forever. We don't want to do that. We want to make this almost as simple and straightforward as we can.

So let's go back to the point of focus, which was a third party and a committee, and whatever they sought for that committee.

MEMBER TYNAN: And when I heard the second part, the other committee -- please correct me if I'm wrong -- that second committee, if there was one, was where Jill was talking about having that implementation fixed; after the National Academy of Science presents its recommendations, that somehow those are going to be broad brush, and so they aren't going to have the implementation issues that we need to have as an agency in order to move forward.

So I think the thinking was -- correct me

again if I'm wrong -- but that we would have this second phase that would bring those recommendations back to this committee or to the agency and somehow we would go forward and try and respond in some manner with a plan on how we would implement the recommendations.

Is that a fair statement?

CHAIRPERSON MASTERS: The only thing I would add to that is I heard Dr. Denton, at the risk of speaking out, say that he believed that a subset of this committee might want to provide oversight with the agency, defining what we might expect the outcome to be, to make sure that we charged the NAS very carefully, and that's where I think Mr. Kowalcyk's concerns could be brought in and that the agency, as well as I heard Mr. Kowalcyk say we have particular concerns when it comes to data, where we're obtaining that data, the quality of data, and those sorts of things, and that's where I believe you might be able to say to this committee that we have particular interest around the data, and you could very carefully make sure that you asked those questions to make sure

that if you were charging the NAS that you made sure that you asked those questions in a way to make sure that your concerns were addressed, and I think that that might get to some of your issues, Michael.

If I'm hearing you correctly, you have issues around data. Certainly agency is putting the data question on the table because we have issues around the data question, and so I think I heard James say that this committee could certainly help frame the questions asked of the NAS, and I think that may get at some of the questions you were raising.

MEMBER KOWALCYK: Yes. Yes, I think that does.

CHAIRPERSON MASTERS: Mine as well.

MEMBER LINK: May I muddy the waters a little bit more? Is that okay?

MEMBER TYNAN: Please do.

MEMBER LINK: Listening to the general discussion, it's my understanding there's business consulting groups out there besides NAS that might be able to get into this and maybe get to the heart of what we're trying to get to and actually look at our

current system, look at the proposed system, look at the data we've got, look at the data we should have, kind of assess, make the recommendations and even to the point of how do you implement so that we don't have to necessarily come back here and try to figure out now how do we take that big, thick book there and figure out how to implement all of these recommendations.

A couple of names have come out. Exponent is one. Booz Allen Hamilton, I guess, was another group that's probably worked with the agency, worked with the industry to do this very type of thing.

So we want to be careful when we're NAS. That may be the right way to go; that may not be the right way to go. There may be some other instead of because they may be able to take it to the next step of implementation and actually be people that are more familiar with our business, with agency policy, and things of that sort than NAS would be.

MEMBER KOWALCYK: Dr. Harris.

MEMBER HARRIS: Maybe it's a question from me to some of the rest of you guys. NAS has been

really tossed around a bunch, and maybe I'm going to kind of go along with Charles for a second. Do we have any real life examples of NAS reports that have culminated in sound policy?

Of specific interest might be within the realm of meat and poultry inspections since that's what we're talking about.

I guess I'm a little skeptical because my experience with NAS reports is that they are very good bookshelf material, not so good in practical implementation kinds of reports, and I know that has sort of been touched on, but I do think we need to be open minded about there may be other entities that are better equipped for what we're talking about asking for.

MEMBER TYNAN: Dr. Hollingsworth.

MEMBER HOLLINGSWORTH: I would agree, and I for one, although started out with NAS, I'm not necessarily wedded to just them, and I guess I was the one who pointed out that if you use NAS, you probably do have to have a second phase because of the nature of the way they look.

And like I said, there's good and bad with them. On the one hand, they have a tremendous amount of credibility. They will certainly be seen as not influenced or biased by anyone. So on that side they're good.

On the other side, you're right. I don't think they get down into the real business part of it. How do you use this information?

I think we should look at all different models. In fact, I was sitting here trying to think of some other groups, and, Charles, you've named some good ones. I appreciate it because I wasn't thinking of them.

I even thought about, well, what about a university or a university consortium. I mean, I think there are other ways of looking at who could do that body of work. I think NAS is one good recommendation, but certainly they have ups and downs, and I think maybe we should consider what would be the better option for a group. Should it be a purely scientific body like NAS or should it be someone who can focus on business and other aspects of it and

deliver us maybe a more practical approach as opposed to a pure scientific set of recommendations?

So I think it's a good idea to throw those others out.

MEMBER LINK: I think part of it may be time line. I mean, we've got years and then, you know, we go one way and if we don't, we go a different. So I guess it depends on how quickly we want to turn the system.

MEMBER HOLLINGSWORTH: Probably by the time we get a NAS report none of us will be on this committee anyway.

(Laughter.)

MEMBER HOLLINGSWORTH: We'll leave it to someone else to have to deal with.

CHAIRPERSON MASTERS: This is Barb Masters.

I should just add when we talked to NAS, that was one of the issues I raised with them. What is the time line? And through the contracting process you can provide specifications of when you want your work back, although most of the work is accomplished

over the course of nine to 12 months in working with them because they do expect because of risk assessments and those sorts of things nine to 12 month time frames.

MEMBER ESKIN: Dr. Masters -- this is Sandra Eskin -- if we were to come back to you and say FSIS contract with a third party, is there a process you have to go through? Do you put out a proposal and then all of these proposals come back in and then you all determine which contract?

I mean, I guess the other question would be can we say to you if we wanted to designate a particular entity?

CHAIRPERSON MASTERS: This is Barb Masters.

If you said to us and your advice was to go with the National Academies and that's what the advice that we chose to act on, I believe we could work directly with the National Academies because of who they are.

If you said to work with a private entity, then I believe we'd have to look at working through

the contracting process, and we might have to go out for bids, depending on how we proceeded through the work process because of private entity, yes.

MEMBER TYNAN: Not to take back over again, but we have a pause. Is there more discussion that we need to do on this phase of Question No. 5 or have we sort of beaten the horse to death and then kicked it?

Dr. Hollingsworth, did you want to answer that question?

MEMBER HOLLINGSWORTH: No, but I did have one other thing. I didn't know if we'd get around to it, and maybe it's not directly under Item No. 5, but I guess even looking at the chart one of the things that struck me is I'm not sure that anywhere I have seen what is the objective. What are we trying to do and why?

I keep hearing we're going to risk based inspection, and my question is: and that is because why? Is there a current system not working?

Actually I'm not sure I would totally agree with some of the comments about this has nothing

to do with money or resources. I think it does. I think realistically if what we're saying is as time goes on under the current system the agency will be less and less able to achieve their goal of assuring safe food, then the resources is an issue and I think it should be addressed.

So I guess I would say that or I would like to have an answer to the question of it sounds great to say you want a risk based inspection system, and my question would be why. What is your goal? What are you trying to get? Is your intention that food is not as safe as it could be and, therefore, a new system is needed to make it safer?

If that's the issue, then I'm not sure that just saying with blinders on we must have risk based inspection. What we need is a way then to make the food safer, if that's the intent.

Let me logically tell you it is, but I've never seen that stated anywhere, and I think we need to be careful that we don't go into we need risk based inspection for the sake of risk based inspection, and somebody else had mentioned this.

If, in fact, when we're all said and done we've got the exact same degree of public health, the exact same degree of protection, other than maybe saving resources, what was the point?

So I think that goal and those objectives need to be clear.

MEMBER TYNAN: Dr. Hollingsworth, your question was very timely because it just so happens that Dr. Raymond just sat down. Maybe he would like to speak to that question.

MEMBER RAYMOND: Actually I've been in the back. Sometimes you hear more when you just stand back and listen, and my style is to jump in too often so until this time. I felt I really had to jump in on this one.

The CDC will tell you that 13 people will die today from food borne illness in the United States of America, 13 people. Now, if that's good enough to maintain status quo, then I'll just go back to Nebraska.

To me 13 people, one of those might be me tomorrow. That's too much of a risk that I don't want

to take. We spend millions and gazillions of dollars on mad cow and nobody has ever contacted mad cow in this country from eating beef. We spend another gazillion dollars on avian influenza, and no one in this country has ever contacted avian influenza.

You know, we aren't going to get any of that money to get those 14 deaths down to ten deaths. We just aren't going to get more money for food safety inspection service. This country has a huge deficit.

We have to take what we have, and we have to put it where it will do the most good because I'm not satisfied with status quo.

As I said when I gave my opening remarks, I didn't come here to caretake a very good system. I'm not saying this is a bad system. You saw my numbers. You saw what has happened in the last five, six years. We've made tremendous progress, but people still die from food borne illness.

Now, try to use a couple of examples that might help. If we had 100 state patrolmen and we put 50 of them on every mile on Highway 395 over in

Virginia and we put another one every mile on Highway 50 and we put another one on every mile on Highway 50 that went to outside the Beltway, a lot of people are going to die on 395 because we don't have enough patrolmen because they're out there in the western part of Virginia where there aren't near as many people driving.

That is not a good use of the resources. We should put a patrolman every ten miles out there and put one every tenth of a mile on the Beltway, and that's what I'm talking about, is realigning the chairs on the Titanic so that we find out where the risk is.

Now, I know 395 is the risk and I know a rural highway is not. I'm smart enough to figure that out. I don't know what the risk of eating ground poultry is compared to the risk of eating ground turkey compared to what the risk of eating something from Mr. Schad's plant is compared to, you know, someone else's plant. I don't know that to a science. I have an idea on some of the products, but that isn't how we assess our inspectors necessarily.

Sometimes it's how many chickens are going down the line, and sometimes it's how many pounds of produce, but it isn't based necessarily on risk, although we're getting better.

So it's kind of like realigning where your law enforcement are. It's where is the risk the greatest. We look at where the most accidents are, and you look at where the most deaths are, and you try to realign your resources, and that's part of it.

Now, another issue is, and maybe I use motor vehicles too much, but if I'm going home tonight and I'm going five miles over the speed limit, I'll get a ticket and rightfully so, and they'll give me a little fine and tomorrow I'll still drive.

But if I'm driving home tonight on 395 30 miles over the speed limit intoxicated, that's a high risk driver putting the public's health at risk, and I should be taken off of that road.

And that's what I want to find out, is where the high risk products are, where the high risk plants are, what we can do to better educate the public to help protect themselves, all of those

issues. Where can we put workers best?

And I'm not -- I've heard comments today about you want to move them from Texas to Maine. I'm talking about maybe moving some off the line and onto the floor. I'm talking about maybe moving some off the floor and into the paper work. I'm talking about, you know, lots of different issues that I don't know where we'll move them. We're not talking about turning the system upside down and moving everybody away and taking them out of plants.

But does this plant need 30 inspectors and this plant need one inspector one hour a day? I don't know. That's where I'm coming from.

It is not about saving money in my mind's eye. It is not about decreasing FTEs. It is about making the best use of those that we have. I mean most states don't get more state patrolmen if their motor vehicle deaths go up. The state patrol commander is assigned to rearrange where the state patrolmen are at, and they do that very easily.

It's more difficult for us to do that, and we want to do it very openly, very transparent. I

appreciated listening to the comments about National Academies of Science and so forth, and I'll just not even comment on those things. We'll wait and see what the committee report is, but that's certainly one avenue that I had not thought of. So I really do appreciate that discussion. It's another way to perhaps get this done.

So I've learned a lot sitting back there today. Thank you for letting me respond.

MEMBER TYNAN: How are we with Question No. 5? Do we have -- have we discussed it enough or are there some other major points that we may have overlooked?

(No response.)

MEMBER TYNAN: Well, I took some notes, and I'll put them up on the wall for everybody to kind of look at and consider some more. I think LaVonne is typing up a quick report. So hopefully we'll have that for you later on this evening before you go so that we can come to some consensus on at least Question No. 5.

Could I suggest, given that we've been

sitting here for a while, it is a bit warm? So why don't we take maybe a ten-minute break? Could we get back at 3:30? Is that a 15-minute break?

All right. I can't count either.

(Whereupon, the foregoing matter went off the record at 3:17 p.m. and went back on the record at 3:41 p.m.)

MEMBER TYNAN: Dr. Masters is all right. Besides being a great administrator, she can figure out the microphones.

We're going to have two subgroups, one to look at inspection, one to look at data. And so the way we're going to do this is Group No. 1 is going to Room 0161, and the reason we're going to do that is because we have a time limit in the cafeteria of five o'clock.

We had no idea that we would be getting to this point this late. So we have a time limit in the cafeteria. So we're going to another conference room, 0161. So the inspection issues, and I believe that was going to be Mr. Kowalcyk was going to handle the inspection issues.

Mary Cutshall is going to be the facilitator of that group. Dan Engeljohn is going to be the technical person, and Dr. Masters as well, until perhaps around 5:15 or 5:30. She has another commitment.

And then Bea from our staff will be the transcriber, and so that's where that group will go, and I think there's a series of questions. The group has those? Okay.

And then subgroup number two is going to deal with the data issues. I'm going to facilitate that. I think Mr. Derfler and Mr. Paul Lisano (phonetic) are going to join for the technical aspects of it.

LaVonne will be our transcriber and take copious notes on all of the good things we say, and then we're going to do that in Room 327E, which is over in the administration building and the Witten Building, which is across on the other side.

So if we could reconvene at those locations, that would be great. You can work to whatever time you need to work. We'll check in in the

morning. If you need some additional time to fashion a report, we'll work with you then, and hopefully we'll have a report on Question No. 5 for you to consider as well.

Here in the morning, please.

CHAIRPERSON MASTERS: Just to remind the groups, what I have shared with the chairman is that if you will look at the chart that we've given you and the questions, we recognize as Dr. Hollingsworth so eloquently said that there's been work on this topic for many years, and we know we're fortunate to get your good insights and information.

So if you look at these questions and look at the chart, any advice and information you provide to us is valuable and appreciated. So even if you don't get through all eight sections of the chart, any sections of the chart that you get through and answer these probing type questions for us would be valued and appreciated advice and guidance to the agency.

So the more that you can get through obviously we appreciate, but even if you get really thoughtful advice and insight into two or three of

those subsections, that would be very valued and appreciated insight to the agency.

(Whereupon, at 3:44 p.m., the Advisory Committee meeting was adjourned, to reconvene Wednesday, November 16, 2005.)