UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOOD

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September 26, 2008
9:00 a.m.

USDA Cafeteria (Conference Room)
1400 Independence Avenue, S.W.
Washington, D.C.

CHAIR: H. SCOTT HURD, D.V.M., Ph.D.
Deputy Under Secretary for Food Safety
U.S. Department of Agriculture

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LEEANNE JACKSON, Ph.D., FDA Liaison
COL TIM STEVENSON, D.V.M., Ph.D., DoD Liaison
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I-N-D-E-X

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

(9:00 a.m.)

DR. HURD: Good morning. Everybody ready to roll? You guys look bright and chipper quite honestly.

Well, I'm Scott Hurd, and I'm pleased to welcome all of you, members and guests, to today's plenary session of the 2007-9 National Advisory Committee on Microbiological Criteria for Foods.

I'm Dr. Scott Hurd, Deputy Under Secretary for Food Safety and Co-Chair of this committee, along with Dr. Sundlof.

This is our first plenary session this year, and it's my first time presiding as Chair. I came to the Office of Food Safety in February this year, and I was pleased to learn that I'd be chairing this committee. I know many of you, and I respect your science and your contribution to food safety greatly.

NACMCF is one of the most respected and top producing federal advisory committees. Another area where NACMCF is strong is that the Committee work

has directed its application to the programs of the sponsoring agencies.

Some of the recent past projects of the Committeeinclude Guidelines for Safe Cooking of Poultry for Consumers, Safe Cooking of Seafood for Consumers, and the Analytical Utility of *Campylobacter* Methodologies. The latter *Campylobacter* project greatly assisted the recent FSIS nationwide microbiological baselines for poultry by assisting the Agency at arriving at the best methodology for detection of this organism, and I can tell you it's really important when we're out there mucking around in people's product that we're using the best available methodologies and we appreciate your input on that.

FSIS plans to report back to you regarding their progress on these baselines at a future plenary session.

Although this is my first plenary session, I've had the opportunity to roll up my sleeves and work behind the scenes with the Executive Committee. And I've seen firsthand all that goes into planning

this Committee and, in particular, the work of Gerri Ransom and Evelyne and others, and we appreciate them greatly.

The sponsoring agencies of this Committee, which are the USDA's Food Safety and Inspection Service, Department of Health and Human Services' Food and Drug Administration and the Centers for Disease Control and Prevention, the U.S. Department of Commerce's National Marine Fisheries Service, and the U.S. Department of Defense's Veterinary Service Activity have all been developing a joint charge on the control of foodborne noroviruses and the Department of Defense charge on microbiological criteria for food being purchased for troops overseas.

Much input and thought from all these sponsoring agencies goes into these charges for the committee, with the goal that a maximum food safety benefit can be achieved through this work.

It's possible that a project of higher priority may end up being brought before the Committee next, but at this time it appears that a

norovirus charge and one on microbiological criterion will be brought before the Committee next. And we expect to release these charges soon, they're not quite done. We're still cooking the charges, right? (Laughter.) You'd hate that if a prosecuting attorney said that, wouldn't you? (Laughter.)

Another thing I've been able to witness firsthand in my short time working with the Committee is that it's an extremely hardworking and dedicated group of scientists. I went over to one of the subcommittee meetings at Aerospace, and it was like the smoke was just rolling out of the rooms. I mean, people were hard at it, two different groups. I stopped in to say hi, and they said hi and just kept on working.

I've seen these subcommittees at work, and one thing that's evident is that they provide valuable guidance and recommendations to our sponsoring agencies and to stakeholders on issues around the microbiological criterion of foods. And I'd like to thank each of you for your hard work,

particularly those of you who started early in the week and stayed through the rest of this week for this plenary. I really appreciate that.

At this time, I'd like to turn the floor over to Dr. Steven Sundlof, our Vice-Chair and Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition. Dr. Sundlof.

DR. SUNDLOF: Thank you, Scott, and good morning to everyone. Again, I'd like to welcome all of the members and the guests to this plenary session.

Like Dr. Hurd, I too, joined the NACMCF Executive Committee just this year and assumed the position of Vice-Chair when I became the Director of the Center for Food Safety and Applied Nutrition. I've known about the work of NACMCF for many, many years, but as a toxicologist, I figured I'd never be able to see the actual inner workings of it. So I have this great opportunity, and I do have great appreciation for what the Committee does.

I wanted to mention that this is the 2007

through 2009 committee. So it's coming to a close next year. It includes the people sitting at the table before us and has been an extremely productive session, and I'll just mention some of the accomplishments that have been achieved during this session.

There are two final adopted reports, and these include the report, Response to the Questions Posed by the Food and Drug Administration and the National Marine Fisheries Service Regarding the Determination of Cooking Parameters for Safe Seafood for Consumers. We've got to work on shorter names. (Laughter.) And the report, Assessment of Food as a Source of Exposure to *Mycobacterium avium* subspecies p*aratuberculosis*, or MAP.

Also during the 2007 to 2009 term, which ends March 23rd, next year, two subcommittees have been very actively working and these include the subcommittee on Parameters for Inoculated Pack/Challenge Study Protocols and the subcommittee on Determination of the Most Appropriate Technologies for the FSIS to Adopt in Performing

Routine and Baseline Microbiological Analyses.

The Inoculated Pack group is developing recommendations for the appropriate criteria for inoculated pack/challenge studies to determine if a food requires time temperature control for food safety. And the New Technologies group is developing guidance and recommendations for FSIS to consider on improving laboratory and in-plant testing methods for pathogens and indicator organisms.

And both of these subcommittees have been steadily working, and each anticipates having a draft final report for consideration for adoption by early next year, and you'll hear from those folks today.

This morning we will hear progress reports from Dr. Don Zink on the Inoculated Pack subcommittee and from Dr. Uday Dessai, Chair of the New Technologies subcommittee. And I just wanted to say that I do appreciate and am aware of the long hours that the Committee members have worked on these projects, and I seriously look forward to the

updates today.

NACMCF is a very dedicated group of people and again on behalf of the executive committee and the sponsoring Agencies, I want to express appreciation and thanks for your time and willingness to share your food safety expertise.

So at this time, then, I'd like to go around and have each of the members introduce themselves, and I'll start over on this end of the table with Dr. Cliver.

DR. CLIVER: Dean Cliver, University of California, Davis, mostly. (Retired)

DR. MADDEN: Joe Madden, Neogen Corporation, Lansing, Michigan.

DR. GLASS: Kathy Glass, University of Wisconsin-Madison.

DR. BUNNING: Kelly Bunning, FDA, Center for Food Safety and Applied Nutrition.

DR. HILL: Walt Hill, formerly with FDA and FSIS, now with the Institute of Environmental Health.

MS. RUPLE: Angela Ruple, National Marine

Fisheries Service.

DR. BROOKS: Dr. Scott Brooks, Yum! Brands.

DR. ENGELJOHN: Dan Engeljohn with Food Safety and Inspection Service.

DR. WESLEY: Irene Wesley, Ag Research Service, Ames, Iowa.

DR. TAUXE: Rob Tauxe, Centers for Disease Control and Prevention.

DR. HARRIS: Linda Harris, University of California, Davis.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

MS. SCOTT: Jenny Scott, Grocery Manufacturers Association.

DR. ZINK: Don Zink, Food and Drug Administration.

DR. JAYKUS: Lee-Ann Jaykus, North Carolina State University.

DR. JAHNCKE: Mike Jahncke, Virginia Tech.

DR. KASE: Julie Kase, North Carolina State Laboratory of Public Health.

MS. KOWALCYK: Barbara Kowalcyk, Center for

Foodborne Illness, Research and Prevention.

COL STEVENSON: Tim Stevenson, DOD Veterinary Service Activity.

DR. JACKSON: LeeAnne Jackson, FDA, Center for Food Safety and Applied Nutrition, Liaison to the Executive Committee.

MS. RANSOM: Gerri Ransom, Food Safety and Inspection Service, NACMCF Executive Secretary.

DR. MBANDI: Evelyne Mbandi, Food Safety and Inspection Service.

DR. DESSAI: Uday Dessai, Food Safety Inspection Service.

DR. RASEKH: Jim Rasekh, FSIS, Food Safety and Inspection Service.

DR. CRAY: Bill, Cray, FSIS.

DR.LARSEN: Steve Larsen, National Pork Board.

MS. STOMBLER: Robin Stombler, Auburn Health Strategies.

Dr.HUFFMAN: Randall Huffman, AMI Foundation.

(Speakers away from microphone identify

themselves.)

DR. HURD: All right. Thank you, and welcome again.

At this time I'm going to turn it over to Gerri Ransom, our Executive Secretary, who will update you on some of the details. Gerri.

MS. RANSOM: Good morning, and I want to join Drs. Hurd and Sundlof in welcoming you today to our NACMCF session here, and as always, if you need any assistance, don't hesitate to come see Karen or I for that.

I want to start off with giving you a few updates on the committee. I'm happy to report that NACMCF was rechartered this year, June 5, 2008, and that gives us an active charter until June 5, 2010. So that's good news.

I want to provide some clarification for everybody regarding NACMCF membership terms. NACMCF membership terms do run for two years, and they may not necessarily run concurrent with the NACMCF charter, but current NACMCF membership runs, as we've already heard today a couple of times, runs

through March 23, 2009. So this Committee is most of the way through a two-year term, although we do have six months left, and I'll mention that NACMCF members may serve for up to three consecutive two-year terms.

Now, we have already begun work to start looking for a 2009-2011 committee. We did issue a Federal Register notice last month, soliciting nominations for membership for the 2009-2011 NACMCF term. That Federal Register notice remained open for a 30-day period and current eligible NACMCF members were able to reapply. The NACMCF Executive Committee is going to begin work in October and November to evaluate resumes that came in and make recommendations to the Secretary of Agriculture for the next Committee membership. Ultimately, the Secretary will be appointing 30 new members to serve for the next two-year term. We are targeting that a committee will be in place with little lag time after the current term expires March 23rd.

I have a quick status report update on the two adopted reports that Dr. Sundlof mentioned. The

report on the Seafood Cooking for Consumers, that did publish in the June 2008 Journal of Food Protection, and it also can be found on the FSIS website. The other document, the Assessment of Food as a Source of Exposure to *Mycobacterium avium* subspecies p*aratuberculosis*, or MAP, we're currently reformatting that report for publication in the Journal of Food Protection, and it will soon be submitted to the journal and also we'll get it up on the website for you.

Next, I wanted to mention something new this year, and that is that we have been holding some subcommittee meetings by web meeting over the internet. Both of our active NACMCF subcommittees have been successful in utilizing this technology. Both groups have found this meeting mechanism to be very beneficial. Web meetings have allowed subcommittees to meet in between in-person meetings. We've been using these meetings essentially for editing documents. We run these meetings by having one person leading on a computer and the group going through edits on documents. We are not intending

that these web meetings replace in-person meetings but instead, as I say, a way of getting in-between meetings in. Generally web meetings have run about two hours.

Meeting notices for web meetings are posted on the FSIS website, and we are giving the public access to web meetings through a computer terminal at the Aerospace Building in D.C. We are very happy about the way the web meetings have been working out, and we hope that this will help NACMCF accomplish final documents sooner.

I wanted to move on and mention a few items of protocol for today's meeting. I think we've already figured it out, but when you want to speak, press the button and you'll see a red light. The court reporter will not get your comments if you do not speak into the microphone. Also please state your name and affiliation.

For any guests wishing to make public comment, we do ask that you please register at the front desk. Each registrant will have up to 10 minutes for their remarks. I also want to point out

to our guests that there is a table out front with documents related to NACMCF. So feel free to pick those up if you're interested, and also if anyone would like to distribute materials, please see our folks at the front desk.

Okay. I just wanted to make a note regarding the next NACMCF plenary session with accompanying subcommittee meetings. We are looking at the week of March 16 through 20, 2009. I haven't heard from all of the Committee members yet, but most people have said these dates look okay. We were looking at having subcommittee meetings Monday through Thursday as we've done this week and a Friday plenary session.

One additional and final item I need to mention to you today is as soon as you're able, please fill our your travel expense sheets for your reimbursement for travel to this meeting and provide them to Karen Thomas-Sharp along with required receipts. We are at the end of our fiscal year. So it's critical that we receive your claims soon. If you have any questions on this or need assistance,

please let Karen know.

And with that, I wish you a good meeting today, and I'm going to turn the floor back to Dr. Hurd.

DR. HURD: All right. Thank you, Gerri. We'll begin by hearing from Dr. Don Zink, Chair of the subcommittee on Parameters for Inoculated Pack/Challenge Study Protocols, known as Inoculated Pack for short.

This subcommittee is nearing its completion of the work, and Don will provide us with some details.

DR. ZINK: Thank you. I'm glad she's doing that for me. My computer literacy is declining annually. I don't know why.

I'd like to begin by first of all thanking the --

DR. HURD: Don, can you bring the mike closer?

DR. ZINK: That's a little better. I'd like to begin by thanking the FSIS and FDA support staff that's helped the subcommittee with its work.

They've done an outstanding job, and actually the webinars (web meetings) that have been arranged have worked out extremely well. Any problems we've had with them have largely occurred when I had some role of responsibility over the thing (laughter), but it's been very, very helpful, and let us do a lot of good work, you know, very economically without having to have people travel here.

I want to begin by saying we had tried very hard to have this report finalized by this meeting. Several weeks ago, we realized that we simply had too many little details still outstanding. We have virtually a final draft for you, but it was just not sufficiently finished to give to the committee.

I think one of the revelations for me particularly is that we were called upon to take several specific product examples and then prove the value of what we had written using those examples.

Initially I thought, well, we'll be able to do that pretty quickly. That proved to be a difficult process, and it showed us where we had need to explain things more fully, need to change

things, to make it broadly applicable and, in order to do a good job on this, we've had to go back and make sure that we've got everything all self-consistent and tied together in the level of detail we wanted.

I should also say that I think we're going to be able to have this report to the full Committee for review and give you a good month or more to spend with the document reviewing it. That's one advantage I think of delaying issuing the final report because it will take time and some consideration to review.

It's a unique document in a way. What had been out there before in the literature on this subject fell into the category of research papers and monographs and components of larger reports like the IFT Report. I think you could probably write a textbook on this, and we knew that it was not our job to write a textbook. And early on we said, look, we're not going to try to take somebody who's a non-microbiologist and give them all of the knowledge, methods and skills in this document that

a non-microbiologist could do this.

On the other hand, we realized that part of our audience, our state and federal regulatory officials and members of industry, may not have the expertise of a microbiologist. So we've tried to strike a balance and point out in the document and in numerous places that it's critical to involve a microbiologist. And we have tried to include the elements in the report that a non-microbiologist could use to judge whether or not a study was appropriately designed and adequately reported.

Apart from that, you cannot, in the subcommittee's opinion, get away from the involvement of an expert food microbiologist.

What I'd like to do now is just briefly go through and talk about some points of the document.

By way of background, the genesis of this was primarily related to food service establishments. One of the most common areas where inoculated pack and challenge study protocols are run is in the food service area, where an establishment wishes to exempt a product from time

temperature control for safety and must prove to themselves and to regulatory agencies that pathogens do not grow in that product to any significant extent during the time period and conditions under which they wish to hold a product.

These kinds of studies are done and submitted to local and state and federal agencies virtually every day. Oftentimes, these agencies struggle with how to evaluate a study, whether or not it was adequately done, the proper organisms were used, the proper methods were used and, you know, whether or not the report is sufficiently complete. And we think this report is intended to be a guide in how to do all of that.

The subcommittee realized that undertaking this task, it was more than just food service establishments and their challenge studies that needed to be addressed. It's very common. I know those here who represent USDA and FDA will know that they often see challenge studies to prove the adequacy of a process or the lethality of a process, and shelf life studies to prove the shelf life of

perishable food. So what we have done is broadened the scope of it. It was a relatively easy thing to do if you were going to write a paper on inoculated pack and challenge study protocols to make it inclusive of those other purposes as well. And that's what we have done.

The 2005 Food Code introduced the concept of the interaction of pH and water activity in determining whether or not a food was potentially hazardous. This table is included in that Food Code and prior to that, the interaction of these variables had not been considered. Yet, we've known for years that multiple factors interact to affect the stability of a food. And the judgment was that pH and water activity are two of the most easily measured and significant interactions that can affect the microbiological stability of a food. For that reason, it was put into the 2005 Food Code.

I suppose the long term vision would be at sometime in the future, perhaps distant future, we will have good microbiological growth and survival models that are user-friendly and highly validated

and that we could eventually go beyond these two simple factors.

But one of the things we've done in the subcommittee is extend this table, if you will, beyond ranges and at a level of detail that were not originally included in that Food Code to make it more useful.

The charge to the committee, first of all, was to identify what are the appropriate criteria, and the answer to this question, one, is without doubt the bulk of the report. One of the most difficult things is how do you select the organism that you're going to use for a challenge study, and the approach the Committee has taken is using the aforementioned expanded pH and water activity table. We included a table that lists a superset of all of the microorganisms of public health significance that could conceivably survive or grow under a given set of pH and water activity conditions.

Certainly you don't have to worry about *Vibrio parahaemolyticus* in meat loaf perhaps, but nonetheless, we started out with a superset of these

microorganisms and then used, I'll call it a decision tree for lack of a better word for the moment, but then used the decision tree to show how to weed out organisms that you didn't need to worry about. Obviously if it's not a seafood item, you don't have to worry about *Vibrio parahaemolyticus* and *Vibrio vulnificus*. And if you encounter a situation where *Listeria monocytogenes* is the most heat resistant or some other organism is the most capable of growth, then you can focus your study on that organism.

So I'm very pleased with the solutions the subcommittee came up with for how to answer the difficult question of what organisms do I use and which ones do I not need to worry about.

We gave a pretty hard look at mathematical models, and there's a huge variety of models out there. Some of them are widely used and to a fair degree, user-friendly, like USDA's pathogen modeling program, widely used on the web. Another, the ComBase model and database is widely used. These are probably the most user-friendly models out

there, but they're certainly not for the amateur. And there are a great many models out there that are less user-friendly. Some of them are simply Excel spreadsheets, but we've tried to be fairly comprehensive in reviewing these models and their use and their advantages and disadvantages.

There are some excellent models out there for *Clostridium perfringens* that are probably more useful for example than the pathogen modeling program, and we try to point this out.

We discussed, of course, the limitations for applying results based on inoculated packs, and we review in a bit more detail the previous monographs and reports that have been written on inoculated pack and challenge study protocols. There are some excellent materials out there and for a variety of reasons, each of them has some limitations.

The decision tree was interesting. I guess, and I was probably the genesis for this idea, the originator of it, and I admit that because it didn't work. (Laughter.) The idea that you could

use a dichotomous decision tree to, say, ask a question and depending on the answer, it will take you down the path and the tree that would lead you ultimately to some clever experimental design for an inoculated pack or challenge study, that didn't work. Despite encouragement and best efforts, we couldn't figure out a way to adapt this to kind of a dichotomous decision tree.

Instead, what we developed is a set of questions that must be answered. So what you'll see when you review this in the examples is you'll see about a six-page list of questions, there's a lot of space between the questions that have to be asked about how a particular food is to be used and processed and stored, et cetera, packaged. And essentially if you go through this list of questions and correctly answer them, then the study design will be self-evident, we think, to someone with adequate food microbiology experience. Like I said, you can't take a certain amount of food microbiology expertise out of the equation.

The examples, they've proved a little

difficult to work through because we want one tool that will work for just about every food. And so you'll go through one example and find that you need to do something and then go back and harmonize it with the other food examples, and that's the process we're in now is really fine-tuning these examples and then going back and making changes to the body of the report to reflect what we're doing in these examples.

At any rate, I expect that with no more than a few of these webinar style meetings, we should be able to finish it out, check the validity of all of our references and hopefully have this report to you I'm thinking, what, shortly after the New Year, you know, would be a reasonable time.

And also in there, this will probably get everybody's juices going, we tried to define what level of expertise a laboratory and an individual had to have. So we also wondered whether any of us qualified. (Laughter.)

If anyone has any questions, I'll take them. Dean.

DR. CLIVER: Is there a perceived responsibility on the part of a food service organization to anticipate temperature of use when the customer walks out of the shop with the product?

DR. ZINK: Yes. We make a point of that in there.

DR. CLIVER: So that's built into the --

DR. ZINK: We ask how is this to be evaluated? Now, one of the interesting philosophical questions is, for example, we use two figures, one and a half time shelf life and one and a quarter time shelf life.

One and a half time shelf life is appropriate for short shelf life products. If you have 10-day shelf life product, you know, should it not last at least 15 days to account for potential abuse, et cetera?

If you have a longer shelf life product, such as a 10-month product, shouldn't it perhaps last at least a bit longer than 12 months, for example?

So we use those, but the question becomes

is that our fudge factor for how the consumer might store it and use it, or should you factor in how the consumer is going to handle it, how long they're going to keep it, how they're going to store it, and then apply your multiplier? And I think we're leading towards the latter.

In our questionnaire document, if you will, we asked, all right, you're going to sell this to a customer. How long is it going to be in the hands of the customer? You know, if you're talking an eight-hour shelf life, is the customer expected to handle it for two hours? That leaves us with 10 hours that it could be out of time temperature control, and shouldn't we then do a study for 1 1/2 times the 10 hours rather than 1 1/2 times the 8 hours?

DR. CLIVER: Since 1995, I've been trying to work in the land of litigation, California, and if someone walks out of the store with their leftovers and leaves it in the back window of the car --

DR. ZINK: Right.

DR. CLIVER: -- and then they get sick, they will sue the food service establishment. I don't see any way to model that.

DR. ZINK: Right. We asked for how the consumers reasonably expected to do this, and I think that while you can't model the damn fool, you have to take into account what a number of people are likely to do. Any more questions?

(No response.)

DR. ZINK: Okay. With that, Gerri.

DR. HURD: Thank you, Don. There certainly is time for any more questions, comments about that. So we can't model the damn fool, but can we model the fool? (Laughter.)

All right. Well, I think then we'll move on, unless anybody's ready for a break. We just got started.

The second report we'll hear is from Dr. Uday Dessai on the work from the Subcommittee on Determination of the Most Appropriate Technologies for the FSIS to Adopt in Performing Routine and Baseline Microbiological Analyses. So we're taking

votes for a shortened name on that one. You guys probably have already developed your handle for it.

DR. DESSAI: We fondly call it NTSC, New Technologies Subcommittee. So New Technologies is the charge.

DR. HURD: New Technologies.

DR. DESSAI: Yeah.

DR. HURD: Thank you.

DR. DESSAI: First of all, I want to get your attention to Tab 7 in your book. (Laughter.)

UNIDENTIFIED SPEAKER: There is no Tab 7.

DR. DESSAI: What's that?

UNIDENTIFIED SPEAKER: There is no Tab 7.

DR. DESSAI: Oh, 6. Tab 6. Tab 7, not quite yet.

Well, on the first page there, you see the members, and I want to really appreciate the membership of this subcommittee for all their hard work and given the nature of the charge, the title itself is a mouthful, and the content of the charge is humongous.

So to capture the charge in its entirety,

both the expanse and the depth of it, the subcommittee met several times to really digest the charge and then kind of tease it apart and see what it is that the subcommittee would really address. And the subcommittee has had meeting after meeting and has worked very, very hard.

At this point, we have kind of a draft outline, which is, I should say is generally acceptable to the subcommittee, and the content is being drafted, reorganized, and different items are being addressed by the subcommittee and the thought is that this would result in answering all the questions.

Now, we had four members who could not attend the subcommittee meeting this time, but they did submit their assignments, and we had three members from the public who attended the meeting also.

Now, I'll draw your attention to the charge, and the charge questions which is the next page. I'm not going to read all the charge questions, but the charge was generated by FSIS,

keeping in mind that there's much more we can glean using new technology from the samples that we take, whether those are regulatory samples or baseline samples.

And what is the technology that would be adequate or appropriate for FSIS to make better informed decisions which will provide data for our risk assessments? And that was the background for developing the charge.

The charge was captured in the text as well as six questions which are laid out there. The first question focuses on appropriate technologies out of the whole universe of technologies that FSIS might be able to focus on.

The second question focuses on the advantages and the disadvantages of these available technologies.

The third question focuses on what technologies can be used such that you can maybe change the sampling part of it, change the preparatory part of it for the sample, something that will be done much before you start analyzing

the sample. Is there something that could be suggested by the subcommittee out of all the technologies available which FSIS can explore so that the target is presented to a method and is amplified to a large extent?

The fourth charge was a little more specific about SNP type technology to be used in screening.

The fifth charge was about what considerations should FSIS have in selecting newer technologies.

And the last charge was about how to make the newer technologies a reality within FSIS.

So that's just a summary of all the six questions that were asked of the subcommittee or the committee. And if you look at the verbiage in those questions, each question has different dimensions to it. So what the subcommittee decided to do was basically collect a lot of information through experts. So the first few sessions, maybe four or five sessions, we had a number of experts in the field who were invited on different specialty areas.

So the subcommittee learned a lot about what is out there, what is the cutting edge technology which is available.

Then the subcommittee decided given all these technologies out there, what is doable in the near future, what is promising and what is a long shot.

After deciding that, the subcommittee began to work on the details of all the aspects, and if you look at the charge, the charge actually focuses on page 2 on the charge questions, says please consider both laboratory and in-plant users for each of the following. And like Dr. Zink said, we could probably write volumes after volumes on each one of these charges, and that's what we were leading to.

But, at this point, after so many meetings, we have condensed the content, and it's been organized in a meaningful manner into seven or eight categories that address the charge but there might be certain overlaps. For instance, one category might answer charge 1, question number 1, 2 and 3 and so on. And we're not ready to discuss that in

today's meeting, but probably by the next meeting, we will get quite there, but we will have the organizational structure and maybe summary content under each of those categories.

For having said that, let me go to the summary of what was discussed. This is a summary of what we really discussed over two days, and many folks put a lot of overtime in doing what they did.

We identified and summarized relevant methods in the context of FSIS testing, and most of the recommendations will come, keeping in mind what FSIS does and also keeping in mind what the other agencies do.

We were able to align the work more to the public health objectives and identify gaps where we need to do a little more work.

One of the strongest things that came about was developing a process rather than being prescriptive about use this method in this fashion. The subcommittee thought, providing FSIS with a process to select among the technologies, and technologies are going to be developing. There will

be newer technologies coming down the road. So a process is better than being prescriptive. So the process looks pretty good, and it's almost in a final form.

And a number of details were discussed which we will not talk about at this point, but we'll certainly talk about where we are and when we intend to conclude this charge.

The committee's term ends on 3/23 which is at the end there. So we think at the pace that we are going, we will be able to get the charge questions completed and report fully developed for the full Committee to look at before that.

Now, we are at 9/24 in person, and our recent two-day meeting was very successful, like I said, and then we will be doing that net meeting, and maybe a couple of more net meetings we haven't shown here, depending on the progress, and in person, there will be one meeting in between which is in January sometime, and then the second meeting in person which is about 3/16, 3/17, we think we will have the product almost completed then. I

think that's it for now.

DR. HURD: Okay. Thank you, Dr. Dessai. Any questions, comments? I have one. Don't leave.

Can you -- back to the slide just before the timeline if you don't mind.

DR. DESSAI: Yes.

DR. HURD: You mentioned you wanted to be sure either the technologies or the methods used were aligned with your public health objectives. Can you give us an example of what you meant and how you kind of thought through that question with an example methodology?

DR. DESSAI: Okay. Rather what I would do is we were grouped and regrouped into different pieces of this big part. So I had the group which worked the process out, and they're putting in a lot of time. So I would say either Barb or Angela, do you guys want to take this? There was a lot of discussion on food safety objectives and how to get that processed.

MS. KOWALCYK: Barbara Kowalcyk, CFI. If I understand the question correctly, basically the

subcommittee had decided that it would really be difficult to go through and outline all the possible methodologies. So we decided that it was good to come up with a process to recommend to FSIS of how they would go about adopting a new technology, and just the starting point would be what are your public health objectives and that should therefore then drive what your testing objectives would be which would then drive what the criteria for selecting methodologies would be. Does that answer your question?

DR. HURD: So, for example, if our objective is to reduce the *Salmonella* prevalence on carcasses by X percent, or even further, to meet the Healthy People 2020 Goal, that's what you mean?

MS. KOWALCYK: Well, you would go back actually to the Healthy People 2020. By the time this would be adopted, you'd be looking at the 2020 Healthy People Goals and look at that as what is your public health goal in terms of FSIS' public health goals, and then that would then drive your testing objectives and what objectives you feel

would help you meet those goals.

DR. HURD: Okay.

DR. DESSAI: I would also have Dr. Walt Hill say something about this because he's the one who got the public health objectives in the forefront of every meeting saying, "we need to tie our work to public health objectives." Dr. Hill.

DR. HILL: Thank you. Walt Hill from IEH. In order to make sure that your testing program is going to give you the kind of data that you can actually use, you have to understand fully what that data is going to be used for, and the only way you can figure that out I think is to work from the top down. What is your public health objective? What is your food safety objective? What levels of contamination are you looking for in products? Do you have a method that can detect that level of contamination? Do you have a sampling plan that can give you the statistical power that will allow you to have confidence that you've reached those particular levels?

So if you're looking for small changes,

then you need a sensitive method and you need a strong statistical plan. If you're looking for grosser changes, then perhaps you can get away with less sensitivity and a smaller sampling plan.

So these whole things are coordinated with each other, and I think that the point we wanted to emphasize was that the technology in the laboratory is not isolated from the rest of the Agency's mission. All of these things have to be coordinated together.

DR. HURD: That's excellent. That's better than the answer I was hoping for because you talked about keeping in mind the sampling plan that's going to be used as well which is very helpful. I mean, the reason I, not the reason I brought it up, but part of what occurred to me is there's a tendency to say, oh, here's a fancy new test, let's use it. And for FSIS' purposes, fancier may not always be better, and so I really appreciate that sensitivity to the objective and the context in which we're carrying out that objective. So that's very positive. Thank you.

Yes, sir.

DR. HILL: I just wanted to maybe make this a little bit simpler and emphasize a point you just made. And that is the concept, if you have a brand new hammer, everything looks like a nail. And instead of having the programs technology driven, have them public health and policy driven from the top down rather than bottom up.

DR. DESSAI: And just to add to that, while the box for public health objectives is an empty box, FSIS can decide as in when and what they should have as their objective at that point in time. So those are not drafted or decided.

However, those objectives will also depend on whether we want those objectives close to our testing or if they should be far broader. And if we make them a very high level and broad, then we have to be cognizant that at the endpoint where FSIS does not regulate, to the point of consumption, that's pretty much a black box where data isn't even available and the uncertainty is extremely high. So getting those public health objectives, we need to

take into account how much uncertainty there is and how much can we achieve those goals in terms of numbers if you will.

DR. HURD: More questions? I have another one, and that's okay.

In relation to the public health goals and whatnot, have you had your Committee look at the FSIS strategic plan? And if you haven't, I encourage you to look at it and ask the question, does this plan give you enough information to do what you need to do? You know, is there enough specificity in that because I know a lot of people worked really hard, and it's a five-year plan, to see if, indeed, it will inform the process. Is that enough information to do that bullet, align it with the public health objectives? If it is, great. If it's not, then we'll have to rethink how to get that information to your process.

DR. DESSAI: Thank you.

DR. HURD: Okay. If there's no more questions for that subcommittee, do you want to continue on or take a break? All in favor of a

break? One. That's good enough. Fifteen-minute break. We have lots of time, lots of food. The food came late. So take a break. It's not a vote, I know. (Laughter.) But, you know, I have respect for those kind of things.

(Off the record.)

(On the record.)

DR. HURD: All right. Welcome back. I thought it would be worthwhile for us to have a break, and I was right, wasn't I? Everyone had a good time talking. It was hard to come back in here. So -- plus we had lots of good food that I didn't want to go to waste up there.

This is now the time for public comment, and I know there's a lot to be said. I see a lot of conversation going on out there. No one has signed up for public comment, but you are still welcome to do that, correct? But please do state your name and affiliation so our record keepers have that information down.

So I'll open the floor, and also these folks can say things, too, if they want. All right.

Please, somebody say something. I could pick on my former graduate student, Steven Larsen back there, but I won't.

Okay. This is also an opportunity because these two Committee reports are not done, the cement is still wet. So you can provide some input to them, that sort of thing, but if not, we will -- all right. You folks are all too nice.

(No response.)

DR. HURD: So we'll wrap it up then and particularly say thank you to those members of the subcommittees who stayed through this week, those who worked hard pushing a deadline, trying to get it done. We will have a very busy plenary next time. We're thinking tentatively in the March area, correct, Gerri?

MS. RANSOM: Yes.

DR. HURD: I think we'll have two new charges to look at and at least two reports to look at by then. So with that, I will thank you again and, Steve, do you have anything else to say?

DR. SUNDLOF: To just repeat what you said,

Scott, that we really again do appreciate all the hard work that's gone into these two subcommittees that will be reporting next spring, and again, also thanks for staying.

DR. HURD: All right. So I officially call the meeting adjourned. Thank you.

(Whereupon, at 11:00 a.m., the meeting was concluded.)