UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOODS

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September 30, 2011
9:00 a.m.

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

MODERATOR: GERRI RANSOM, M.S.
Executive Secretary

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MICHAEL LANDA, J.D., Vice-Chair
ARTHUR P. LIANG, M.D., M.P.H., CDC Liaison
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MAJ ROBERT DOLE, DoD/SADVC
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MS. ANGELA RUPLE, U.S. Department of Commerce
DR. ROBERT TAUXE, CDC
DR. ROBERT WHITAKER, Produce Marketing Association

ALSO PRESENT:

MR. ROBERTO CARPINTEYRO, FSIS, Office of Policy
SANDRA SHARP
JUDE SMEDRA, FSIS, OPHS

I-N-D-E-X

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

(9:00 a.m.)

MS. RANSOM: Good morning and welcome to the National Advisory Committee on Microbiological Criteria for Foods, first Plenary Session for this year.

Before we get started, I just want to mention to members of the audience, could you please make sure that you sign in with the front desk. Thank you.

And let me also mention, if anyone does want to make public comment, please also sign up with our folks out at the front desk. Thank you very much.

And we're going to get started, and I'm going to turn the floor over to our Chair, Dr. Hagen.

DR. HAGEN: Good morning, everybody.

So thanks for being here. Chuck tells me to remind you all that you do not need to press any buttons to speak into the microphones. So anybody who is used to testifying and going back and forth,

you don't need to do that.

So thanks for coming. I am Elisabeth Hagen, and I am the Under Secretary for Food Safety here at USDA, and I also have the honor of being the Chair of this National Advisory Committee.

This is the first full meeting of the 2010-2012 Committee, and it's also my first time joining a Plenary Session as the Chair. So thank you for being here with us, thank you for allowing Mike and I to join you and hear about all the good work that you've been doing this week, and thank you for doing the work that you've been doing this week.

As some of you may know, before I became the Under Secretary here, I was with the USDA's Food Safety and Inspection Service for four years, and most of that time was spent in the Office of Public Health Science. So I actually have a long-held appreciation and deep respect for what this Committee does. As a matter of fact, I was thinking about this this morning. Gerri Ransom was on the panel that interviewed me for my very first job here. Do you remember that?

MS. RANSOM: Yes, I do.

DR. HAGEN: Yeah. And I was brand new to Government, hoping to, you know, hoping to get this job, and she introduced herself, and she told me that she was the Executive Secretary of the National Advisory Committee on Microbiological Criteria for Foods, and I have been sort of a student of microbiology my entire life, since I was in high school, and I'm an infectious disease doctor by training, and I thought, oh, my God. There's an advisory committee just about microbiological criteria in food, and you get to be in charge of it. Wow. I thought that was so cool. Anyway, Gerri did, she made a good choice and she apparently scored me fairly well on the first thing, and here we sit.

But, anyway, I've been a colleague of Uday's since 2006. So I've known about the work of this Committee for a long time, and I was pretty excited when I realized that in the Under Secretary role I was going to get to be involved with this Committee.

So you all know that NACMCF is really among the most respected advisory committees in the entire Federal Government. I think that's for a few reasons. I mean we get some of the top experts in the nation. We get some of the best expertise compiled here together, and we produce tangible results. We actually produce real recommendations that really impact every agency that is involved in the regulation of safe food, really the industry that produces food. The work of this Committee is really very, very important, and you all work very, very hard. I mean the commitment and the work ethic on this Committee is really very impressive.

So as I said, we have these tangible results, and we share them with and we give them to every agency that's involved in the regulation of the of safety foods. That includes obviously USDA's Food Safety and Inspection Service, FDA's Center for -- I always mess this up.

MR. LANDA: Food Safety and Applied Nutrition.

DR. HAGEN: Yeah, I always mess that up,

the Applied part. We have the National Marine and Fisheries and the U.S. Department of Commerce and the Veterinary Service Activity at the U.S. Department of Defense who all benefit from the work of this Committee. And not only do those agencies benefit, but obviously every single person who puts food on the table in this country benefits from the work of this Committee.

So this is a really big deal, and we really appreciate your service, and we take your commitment very seriously.

So food safety microbiology is obviously a very complex challenge, but it's so very worthwhile to take a crack at and to figure out because the numbers that we are facing are really astounding. You all know those numbers. You know that one in six Americans get sick from the food that they eat every year. So the work that you're doing on this Committee is really so very worthwhile.

We talk a lot about prevention around here all the time. In fact, everybody's probably sick of hearing me talk about prevention, but it takes this

real commitment to prevention. It takes this real commitment to the improvement of public health, to get this kind of work done, and it means it takes different perspectives as well. So it takes the perspective of consumer advocates. It takes the perspective of food safety regulators, of industry, of academia.

And so to better meet this goal, one of the things that we've done this year is we have had Secretary Vilsack appoint a consumer representative to this Committee. So Ms. Susan Grooters has been appointed to the Committee this year, and we thank you so much for sticking it out and waiting. We know it took longer than we all would have liked it to have taken, but thank you for joining us, and we have a letter and a certificate for Susan, yeah.

MS. RANSOM: It's in front of her.

DR. HAGEN: Very good.

MS. RANSOM: She was not to open it until now.

DR. HAGEN: She's not allowed to open it yet? That's what it is.

MS. RANSOM: Until now.

DR. HAGEN: Okay. So you can take a look at it if you want to.

MS. GROOTERS: Thank you.

DR. HAGEN: So, Susan's joining us for a two-year term as our consumer representative, and currently, Susan, I want to make sure I've got the title right, is the Director of Research and Education with STOP Foodborne Illness, and we all know that she's going to add a very important voice to this Committee and to the Subcommittee that she's working on, and we're really excited about this perspective on the Committee.

So as I said, it really takes these diverse perspectives. It takes this diversity of expertise to really make this whole thing work, and we thank you for bringing that to us.

So now on to what you all have been up to. I know Mike is going to say a bit more about this, but let's talk about the charges that you've been working on this week.

The first is the control strategies for

reducing foodborne Norovirus infections, and the second is the microbiological criteria evaluating them as indicators of process control.

As I said, Mike is, I think, going to speak a little bit more specifically to the charges, but these are two very important, very practical questions that we have put before you, and we're really looking forward to hearing about the work that you've done not only this week. I mean I know that you've been working on these charges for quite some time.

Just on the Norovirus, you know, for those of you who are not on the Committee, who are joining us in the audience today, human noroviruses are really now the most commonly reported causes of foodborne illness in this country. They make up the majority of the burden of foodborne illness, and we still don't know enough about them. We still don't know enough about how they contaminate food, how we can prevent foodborne illness from this particular group of viruses. So we think that there's the right expertise in this room and some of the

additional experts that the Subcommittee has pulled in to help us answer some of those questions.

And then on the other charge, the microbiological criteria as indicators of process control, you know, the Department of Defense purchases food for our men and women in uniform all over the world, and it's imperative that they are able to evaluate by using the right criteria whether that food was produced in a way that is safe and wholesome and is acceptable to the customers.

So if there's one thing that's been happening across the food safety landscape, it's this. I think that we're asking really tough questions. I think most of you in this room are scientists. So you understand and appreciate and love the importance of questions, and really tough questions and sometimes asking questions that are not easy to answer or sometimes are not comfortable to answer, and those are the kinds of questions we've been asking ourselves here at USDA over the last year certainly, really since this Administration came in.

For us, you know, we're asking all the time, are we reacting to food safety problems or are we getting in front of them? And that sounds like an obvious question. It perhaps has an obvious answer, but sometimes when we look at the policies that we have in place or the direction that we're attempting to go, it's really important to keep asking that question. Are we preventing illness in the first place? Are we reducing and working to eliminate the risk of pathogens before they ever reach consumers in the first place?

And then as I said, some questions can be difficult to answer or challenging or uncomfortable. Are we really effective? Are we efficient? Are we doing this in the best way possible with the resources that we have? Are we coordinated? This is one that we get questions about all the time, and I think we have a lot of room for improvement.

Are we making the best uses of our resources? And are we using the best available science? And that's where you all really come in.

So we need your perspective. We need your

insight. We need your ideas. We need your expertise to help us move this whole thing forward.

So that's really what I wanted to say this morning. I think in conclusion, I'd just like to leave you with the fact that your work really matters, and we don't take it for granted. We know how busy you all are. We know that you lead entire professional lives outside of this Committee, and we know how much we're asking of you, but your work really matters. I know that it matters to my Secretary, Tom Vilsack. I know that it matters to Secretary Sebelius, and as I know as I said before, that it matters to everybody who puts food on their table in this country. So thank you, and I'll turn it over to Mike.

MR. LANDA: Thanks, Elisabeth. Good morning. I, too, would like to welcome you, members and guests, to this Plenary Session. Like Dr. Hagen, I joined the NACMCF Executive Committee in 2010, becoming the Vice-Chair when I became Acting Director of the Center for Food Safety and Applied Nutrition at FDA.

I come at the work of this Committee from a slightly different perspective. I'm a lawyer, not a scientist, and at FDA we think of sort of the three components, basic components to our work.

The statute, of course, guides us. The other components are policy making and the science, and although I am a lawyer, and some lawyers will tell you that law is the most important of the three as policy makers may tell you that policy is the most important of the three, I actually think science is the most important of the three, getting the science right.

It is conceivable I think that you can make sort of bad or less than good policy and still muddle through, and I think you can read the law in ways that are perhaps ungenerous and still muddle through, but I think if you don't get the science right, you can't muddle through. If you don't get the science right, you fail, and so I think that makes the work of this Committee, as an example, vital to the success of every agency in this country that deals with food safety.

We have, as Dr. Hagen mentioned, two Subcommittees with work underway. I'll just mention them briefly because you're going to hear reports about both of them.

The first is the Subcommittee on Control Strategies for Reducing Foodborne Norovirus Infections. The group is jointly chaired by Dr. Kelly Bunning from FDA -- Kelly's at the end of the table -- and Uday Dessai, who is next to Kelly. The topic is of concern to all of us, of course, because of the proportion of foodborne illness attributable to Norovirus. It's strikingly high even if it tends not to get as much play in the news as, for example, *Listeria* and *Salmonella* and some of our other bad bugs.

The second group we'll be hearing from this morning is the Subcommittee on the Study of Microbiological Criteria as Indicators of Process Control or Insanitary Conditions. That always struck me as an odd phrase. I suppose it should be indicators of lack of process control or insanitary conditions. Spencer Garrett, at the other end of

the table, from National Marine Fisheries Service, chairs that Subcommittee.

As Dr. Hagen mentioned, that work is critical to DOD, but it's also vitally important to I think others of us, not so much in the business of purchasing food, but in the business of regulating it in a direct way.

We'll be hearing reports from both of these Subcommittees this morning. We know how hard this work is, how much of it there is, and as Dr. Hagen said, this is sort of another duty as assigned for virtually every member of the Committee, Chairs and Co-Chairs and other members alike.

I would just like to close by again thanking you all for the work you do. It is foundational work in my judgment, and because it comes from an advisory committee, it's I think in many cases more widely and readily accepted than work any individual agency can do. That varies, of course, but I think as a general statement, that's true. And so the work becomes all the more important given the sort of neutrality of the

source, if you will.

With that, why don't we go around the table and have Committee members and staff introduce themselves and state their affiliations. Elisa.

DR. ELLIOTT: Hi, I'm Elisa Elliott. I work for Center for Food Safety and Applied Nutrition at FDA.

DR. LIANG: Art Liang, CDC, Food Safety Office, and I'm on the Executive Committee.

LTC BOHANNON: Lieutenant Colonel Mark Bohannon. I'm with the United States Army Veterinary Corps currently assigned to the Defense Logistics Agency.

MAJ DOLE: I'm Major Bob Dole. I'm assigned to the U.S. Army Public Health Command.

MR. CARPINTEYRO: Robert Carpinteyro, FSIS, Office of Policy.

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

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

MR. GARRETT: I'm Spencer Garrett with the

National Marine Fisheries Service and the National Oceanic and Atmospheric Administration.

MR. SMEDRA: Jude Smedra, FSIS, OPHS.

MS. RUPLE: Angela Ruple, NOAA Fisheries.

DR. BIRBARI: Wafa Birbari, Sara Lee Foods.

DR. WHITAKER: Bob Whitaker, the Produce Marketing Association.

MS. GROOTERS: Susan Vaughn Grooters, Director of Research and Education, STOP Foodborne Illness, formerly Safe Tables Our Priority.

DR. TAUXE: Rob Tauxe, Centers for Disease Control and Prevention, Deputy Director of the Division of Foodborne, Waterborne and Environmental Diseases.

DR. HOOVER: Dallas Hoover, Professor, University of Delaware.

DR. HARDIN: Margaret Hardin, IEH, Institute for Environmental Health, Seattle.

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

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

MS. RANSOM: Gerri Ransom, NACMCF Executive Secretary, FSIS, and we're back around again.

MR. GARRETT: Madam Chairperson --

DR. HAGEN: Yes.

MR. GARRETT: -- I committed my first faux pas of the day, and I'm sure it won't be the last, but I'm joined here by Sandra Sharp, a microbiologist in our laboratory that assisted me from not making a faux pas. So thank you very much.

DR. HAGEN: Good morning, Sandra. Thank you. We can hand-make you a name tag, too.

MS. RANSOM: I'm going to go ahead and welcome everyone again, the members as well as our audience. It is great that we are here at our first Plenary Session.

At this point, both of our Subcommittees have two meetings under their belts. They each met this spring, and they've met again this week. So we are at the point where we have some progress to report.

NACMCF is moving forward, and as I said, we've made great progress especially this week, and

I can attest to the fact that the Subcommittee members worked late hours this week.

The NACMCF Executive Committee has also been working to develop topics for the next work charges for NACMCF. New charges are under development, and we anticipate that these will become assignments for the 2012 Subcommittees.

At this point, we have draft topics, and we're working on developing the new charges. I just want to briefly mention those topics to let the Committee know what there is to look forward to.

We do have a *Salmonella* project to look at. This one is going to cover evaluation of *Salmonella* virulence and related molecular information to inform an assessment of public health risk. FSIS has suggested this topic. This project is to consider such items as molecular assessments of virulence, serotype data, and antimicrobial resistance. We will ask for NACMCF's input on which *Salmonellae* might cause a more severe disease so that improved mitigation and responses can be developed.

Now a second project is on the review and improvement of the Agricultural Marketing Service or AMS Federal Purchase Ground Beef Program. AMS in accordance with a recent National Research Council report would like to ask NACMCF to evaluate their purchase program for ground beef. A review of program micro sampling, testing and other requirements will be requested. NACMCF will be asked to provide recommendations for program improvements based on an appropriate risk-based strategy. This project will assist in improving the safety of the U.S. School Lunch Program. This charge is a good example of work that can be directly applied to agency food safety programs. Now, we are looking at this project as an extension to the DoD micro criteria charge, and discussions did take place this week regarding this work.

A third charge is on new technologies for genotyping and subtyping foodborne pathogens that rapidly link clinical outbreak data to the food source. This charge was recommended by the NACMCF New Technologies Report. This is to be a joint

FDA/CDC/FSIS charge. This charge will ask for advice on alternatives for molecular subtyping which may perform better than PFGE. We see this as an important charge, and it is always helpful when a Subcommittee reports direction for future work.

A fourth topic is on virulence factors and attributes that define foodborne Shiga toxin producing *E. coli* as severe human pathogens. FDA suggested this topic, and we are planning for this as a joint FDA/CDC/FSIS charge. This project will be designed to glean information that will assist new FSIS policies and plans for testing relating to the control of non-O157 STECs, and this charge will dovetail with other current work on STECs.

A last project I wanted to mention is the post-harvest treatment of molluscan shellfish and validation. This will be a National Marine Fisheries Service charge, and this work is being planned a little bit further out.

It is possible that new work of higher priority could be added, but for now, this is the work that we're looking at for the next Committee.

Now I mentioned the New Technology Subcommittee had recommended a charge as a further example of how NACMCF work is being applied. I want to mention their report. This report is the Response to Questions Posed by the FSIS Regarding Determination of the Most Appropriate Technologies for FSIS to Adopt in Performing Routine and Baseline Microbiological Analyses. This report was published in the June 2010 issue of the *Journal of Food Protection*. It includes a comprehensive review of new technologies to assist in evaluating those with the most potential for adaptation to FSIS pathogen testing. There are copies of this report outside on the table.

In addition to new technologies, this report provided many other recommendations. FSIS offices have been using this NACMCF guidance, and we have begun to prepare a FSIS response to the report to highlight how this report has assisted us related to new methods and programs. This report is in its final stages of preparation, and I anticipate it will be posted on the FSIS website within the coming

weeks.

Moving on, I want to make mention of some activities and important dates that will occur for NACMCF in 2012. Your NACMCF membership runs through May 10, 2012, and as we know, members may serve up to two consecutive two-year terms.

Now, we had originally planned to bring additional NACMCF members in to join this Committee before next May, but instead, we have decided to reconstitute the membership all at once in 2012. So early next year, we will initiate the process to establish the membership for the next term in a *Federal Register* notice soliciting nominations that will publish in early 2012. Current eligible NACMCF members will have the opportunity to reapply, and we are targeting having a new Committee in place with little lag time after the current time expires in May.

Okay. I want to mention that the current NACMCF Charter runs through November 1, 2012. In mid-2012, we will begin the Charter renewal process, again targeting that we get little lag time with the

new charter and the expiration.

Moving to a few items of protocol for today's meeting, if members would like to participate in discussions, please take your name card and set it vertically so our Chair knows to call on you, and also please remember to state your name and affiliation for the record because this session is being recorded.

For any guests wishing to make public comment, and I had mentioned this earlier, we do ask that you register, and we encourage that, and each registrant will have up to 10 minutes for their remarks.

I also want to point out to our guests, and I'm sure you've seen it already, but there's a table out front with various documents related to NACMCF including some of our recently published reports.

One final item I need to mention today, and this is a little administrative issue, but please members, fill out your travel expense sheets for your reimbursement, and provide this to Karen Thomas-Sharp along with your receipts. We are at

the end of our fiscal year. So we do need to process the travel.

And with that, I wish you a good meeting, and I'm going to turn the floor back over to our Chair, Dr. Hagen.

DR. HAGEN: Thank you, Gerri. So I think it's time to move to the next part of the agenda, and we're going to have Drs. Kelly Bunning and Uday Dessai tell us about the work on the Norovirus Subcommittee.

DR. BUNNING: Good morning. Am I loud enough? Can everybody hear?

My name is Kelly Bunning. I'm with the FDA Center for Food Safety and Applied Nutrition, and I'll be presenting the progress report for the Noro Subcommittee on behalf of my Co-Chair, Uday Dessai, and our Subcommittee members.

So the title of our charge is Control Strategies for Reducing Foodborne Norovirus Infections. I guess I'm in control of everything here.

One of the things as Chair and working with

Uday and Gerri when we put this Subcommittee together, the first thing we noticed was that everybody had a strong background in food safety and food microbiology and we had good representation from industry and academia and the Federal Government and some state people, but what we didn't have was a virologist or any real technical experts on Norovirus.

So our first Subcommittee meeting that we had in June 7th through 9th was totally geared towards orienting our Subcommittee to the charge itself as well as trying to educate them the best way we could on Norovirus, and we did that by bringing in a series of technical experts, and I'll tell you who they are with the next slide, and in the end, I think we probably achieved our goal, at least based on my gauging of the enthusiasm and the level of discussion that occurred during those presentations.

So here's the subject matter experts who not only came on board to help educate us and orient us towards NACMCF and the charge, but also have

stayed on and are serving as technical advisors. We began with Aron Hall and Jan Vinje from the Centers for Disease Control and Prevention, and as most of you know, they are involved with foodborne disease burden and attribution. There was a Morbidity and Mortality Weekly Report that issued in March 2011. That's a pretty good source. If you really want to see what the state of Norovirus play is at CDC and where their programs are, I would refer you to that.

We also note that around the world and in the United States, there's a lot of active reports or groups that have either looked at or are presently looking at Norovirus in foods as well as other foodborne viruses. We are acutely aware of all those activities and, of course, we don't want to duplicate, but we have some of those people or some of those activities summarized by Sherri Dennis and Wendy Fanaselle from FDA's Center for Food Safety and Applied Nutrition, who came and principally talked about their risk profile for foods and also some initial risk assessments that are going on either at FDA with shellfish or the WHO

Codex risk assessment activities that are presently going on right now.

If you notice in the charge questions and actually the full charge is under Tab 6, we had some issues where the rubber really meets the road. We had two essentially program managers come in and ask to have some questions put into the charge, and they were from FDA's Retail Foods Program, Kevin Smith who is in charge of the Food Code, and from USDA's Food and Nutrition Service, Brenda Halbrook, who came in and informed us about some issues they have with the School Lunch Program in regards to Norovirus, and relative to the questions they asked, you can consider them essentially risk management questions because they are the program leads. They came in and informed our Committee of exactly how those programs work, how the Food Code works, how things get adopted, what their needs are, and how they work for the Conference for Food Protection, and in turn similar programmatic function of the School Lunch Program.

And then last but not least, we're

certainly concerned about science, and so in terms of a review of the state of science and what ongoing research activity is going on at the national level or international level, LeeAnn Jaykus came in and spoke to us for about two hours and gave an excellent summary. Many of you know that she's leading a consortium of people and just received a 5-year, $5 million a year, $25 million grant to take an integrated approach to try and solve some of the issues related to Norovirus. So she was clearly a key person to have come and speak to us.

The next series of slides are going to take care of several issues that I've been asked to talk about today. First, to try and get through and explain to you as briefly as I can what's in the charge, and we're going to do that by talking about the charge questions, how after we met and were educated, how we decided to move forward and address the charge, and then you'll learn a little bit about our membership and how we've integrated to work together and also work separately in work groups to begin to address the charge. So you'll learn a

little bit about our approach that we've started.

So what we decided after being educated so well by our technical experts was that we were going to break into work groups and begin to address different questions in the charge.

The first work group decided to take on questions 1 and 2, and it's pretty clear from looking at those that we're starting to get at burden and attribution of disease, both in this country and internationally, and I asked Bob Tauxe from CDC as a federal representative to our Subcommittee to lead that work group, and the other members are Susan Grooters and Dallas Hoover, and technical experts that volunteered to help and participate are Aron Hall from CDC and LeeAnn Jaykus(NC State U).

The second work group will appear over the next two slides. They involve questions 3, 4, 6 and 7. This work group really when you segregate those questions out of the flow of the charge, they really are dealing with mitigation and control in one form or another, and so that group has named

themselves that. The federal representative on our Subcommittee is Daniel Engeljohn, and he agreed to chair this work group, and they are working to answer questions 3 and 4 with members Nandini Natrajan, Margaret Hardin, and Wafa Birbari, and as you can see, these are where the questions about how we can possibly either what likelihood is there that there are any data or what data do we need, at least in the short term, to try and effect any changes in the Food Code, or are the present recommendations in the Food Code accurate or well enough to help protect from Norovirus?

To continue, question 2, because they have the most questions, but I think they're going to condense it down as best they can, but they also have the most technical experts. So Kevin Smith, I've mentioned is the Director of FDA's Retail Food Protection Division, and that group has the leadership of that group for the Food Code. Laurie Williams is on his staff. Brenda Halbrook is, of course, from the School Lunch Program, and I see back in the audience is Stephanie Mickelson, one of

our guests today. She works with Brenda.

I did want to mention that when we started meeting this week, we've beefed up this work group, and another person who really came forward and did excellent work this week and was introduced to that work group was Girvin Liggans on Kevin Smith's staff. I didn't have time to put his name into the slide, but I think all the work group members were very happy with his contributions this week, and I'm happy to at least give him a verbal shout out now. In future reports, you'll see his name appearing there.

We also had from Dan Engeljohn's staff, Roberto Carpinteyro who came on board to help that work group. He's doing technical support as well as he does have a foods background. So he's a young person who's helping to contribute to NACMCF efforts.

The next work group is Work group 3, and this deals with question 5, which really gets at the state of play of where the methods are for detecting Norovirus, and in that context, how surrogates are

detected, and because of the way that question was formed, it also gets into how surrogates are used in place of Norovirus to study the effects of inactivation studies through various means. I was the federal representative who chaired that work group to the Subcommittee, and our members who are helping to address that are David Golden and Lee Johnson, and our technical experts that are advising us are LeeAnn Jaykus and Jan Vinje from CDC.

Our fourth work group is Work group 4. This is the risk assessment question number 8. This question asks about what data are available to possibly go forward with a formal quantitative microbial risk assessment or whether ever one can be done at this stage, and if not, what other risk-based approaches can we at least start to implement. The federal chair who's leading this Committee is Uday Dessai, my Co-Chair for the Subcommittee. We have Dallas Hoover and Wafa Birbari as Subcommittee members who are serving on this work group. I have Elisa Elliott in green because technically she's not on this Subcommittee or the Committee, but she's a

member of the Executive Committee, and she's also a great help. And our technical experts are Wendy Fanaselle and Sherri Dennis from FDA who are, according to their own language, they eat and breathe and live risk assessment. So --

Work group 5 actually consists of everybody. They actually aren't debating this question yet. We're going to work within our Work groups 1 through 4 and knit those documents together at a certain stage, not yet, but we're getting pretty close. They've made significant progress this week, and once we come together as a full Subcommittee and look at where the work group products have come together, and we're satisfied with that, we'll sit down and try to tackle question 5 together, and this question really deals with how NACMCF can recommend some type of generic facility control plan, not a complete plan, but something that various institutions, whether they be restaurants or cruise ships or as it says there, can have a place to start and begin to develop their own plans to help control Norovirus in their particular

situation.

So after our first meeting in June, that's how we became more educated about Norovirus, how we decided to tackle the charge relative to the various charge questions and what at least our initial approach is. Before we came together this week, each of the work groups has had numerous teleconferences to try and draft some material, get their key references and some of their draft data gaps and recommendations together, so that when they came together this week, they could have a more functional working session and make good use of their time.

So that brings us up to the progress report for this week. In the course of, of course, I've mentioned that the work group breakout sessions did occur for the majority of the meeting this week, but we also had some more subject matter experts come in and present to us.

Most notably our Co-Chair, Mike Landa, who came for an hour to meet with the Subcommittee, of course, thanked them for their service, but I think

we had a chance to let him spend some time with the members, and they could really ask, not only about Norovirus, but other things that they wanted to discuss with the CFSAN Center Director. So I can tell you, Mike, that after that session, everyone was very appreciative of you, first of all taking the time, a full hour, coming down and that on behalf of the members who expressed that appreciation, I wanted to let you know about it.

We also had a very unique discussion with some of the members of FDA's Center for Drugs and Evaluative Research, and this was brought on from something we discovered in our first meeting about hand antiseptics and the fact that when they make claim to use new ingredients, that they are essentially, since the change from safe to safe and effective that occurred in the early '70s and '80s in the FDA Act, that those products now have to be approved drugs. I can tell you that we had a great discussion and great stimulation around this. It's a very convoluted regulatory paradigm. So I don't think any of us feel like great experts about it,

but there is some summary information on the web that I can certainly direct you to.

For us as food scientists and food microbiologists, I think what we took away from that discussion that is important to mention today is that when we think about what studies have been done, what that data may be telling us relative to all the shortcomings that we know about with methodology and surrogates, how can we at least make some recommendations or move forward with some science in the near term to effect at least a degree of protection or controls in any particular area that we start to deliberate, and relative to that, what science needs to be doing in the future, and once it becomes identified, that maybe a change or a control can be affected to some degree, how would that information be used by our chairs up through the chain to either look at the high bar that's been set by these, and whether that bar can be lowered to allow some of these things on the market or not. Again, this is policy stuff. We're focusing on the science, but at least that gave us some focus as to

what the regulatory bar is now, how science and any improvement may affect those changes and, of course, what's the best way to move forward at least in science. That's what we're going to try and deal with and focus on, but we'll leave the regulatory high bar or the lowering of that bar or any policy changes to somebody else.

So progress reports over the course of the week, I mentioned earlier that the first group chaired by Rob Tauxe from CDC is the burden and attribution work group. They were able to summarize the published estimates or are in the process of summarizing the published estimates of the burden of illness, hospitalizations, and deaths due to human Norovirus, the fraction of illnesses transmitted through foods and foods most frequently implicated. They're also identifying gaps in our epidemiological knowledge and defining key areas that will advance science.

For the mitigation and control group chaired by Dan Engeljohn, that group is assessing the relevant references and available research and

identifying their information gaps. They have key areas that will help answer the charge questions such as route of transmission, hand sanitizers and hand surface sanitizers, and inactivation technologies. They're beginning to see where the research has been and also what current research is going on now, and they're also determining the available tools and challenges to barriers to bringing those forward.

For detection and surrogates, Work group 3, we kind of started off, and I was chairing that work group, relative to the detection, of course, we're going to summarize the literature and where the best detection methods are or at least what the current state of play is, but I kind of encouraged them to, there's a recommendation in the research gap from the New Technologies Report, and I encourage you to pick it up, but it talks about at least when you're dealing with a tough issue, it talks about what an ideal method would look like, and it's a device you can use to focus what the state of play is for a certain issue relative to where do you want to go.

So I'm just going to read this real quick. It says the ideal method, and here we're talking or seemingly talking about bacteria, but it says, "An ideal method might include the following characteristics: rapid or real time detection at a higher degree of sensitivity and specificity, low limit of detection, simplicity and ease of use, cost efficacy, high throughput and reliability, the ability for multianalyte detection, adaptability to a wide variety of sample matrices, discrimination between viable and inactivated cells and production of a enumerative data, portability and simultaneous isolate characterization and subtyping."

I mean that is the ideal method, right? When you try to take the ideal method for what you would have for Norovirus, of course, it's not viability. You just have to introduce this notion of whether it's infectious or not because viruses aren't alive in food. They persist in food.

So what's the state of play right now with methods development versus trying to get to this ideal? And, of course, we know that there are some

typing mechanisms. There actually is a method to detect and subtype Norovirus at the same time that the Danes have just published. We're in the process of analyzing that right now, but that's how I kind of have that group focused, and I think it's a good way.

What's the state of play versus how can we get towards the ideal? We may never get to the ideal, but if you're going to advance the science, what would you do? What would your general recommendations be? Or, this is one of the good things about NACMCF, we can make general recommendations, but a lot of these ongoing activities kind of make general recommendations and stop there. NACMCF can choose to get into the weeds here and say these are the best approaches, and we have that flexibility under this type of committee.

And then the last work group is risk assessment, and they have been drafting a general framework to answer the charge question. They're reviewing all ongoing risk assessment efforts and they're really drafting -- this was a request that I

made, that Sherri Dennis picked up on immediately and helped really focus this group. They're going to sit down and try and draft a risk management questions that would help jumpstart a risk assessment from the point of view of our industry representatives, from the point of view of our federal regulators, from the point of view of our consumer representatives, and that tends to drive what type of risk assessment you would do or how you would conduct a particular risk assessment, and that's how they're going to kind of start.

So after we've done all of this, some of the common themes, just to kind of summarize where we're at right now that we've identified, just very quickly, we know that the issue of Norovirus and foods is very complex. There are multiple sources of contamination, both direct and indirect. The data are conflicting, and that this has to do with study design issues and what we know about surrogates now relative to Norovirus being more characterized both at the genetic level as well as behavior. The surrogate studies in many ways are

not really accurate relative to what we know about Norovirus.

The science is continually evolving. There's papers publishing every day, and we're getting those. We are down to actually, as things are moving forward, we're actually making direct phone calls to the investigators and seeing how we need to proceed, and again the principal example of the evolving science is, as I mentioned, the adequacy of the analytical methods.

And, of course, because of all of this, there are numerous data gaps, and then it really kind of tells you that solving the problem of trying to reduce or prevent Norovirus infections will require a multipronged approach, and we need to intervene at multiple points in the food supply and at various transmission cycles.

So we have a timeline to try and get done. The graph is pretty self-explanatory. It shows where we've met and what I've just reiterated about our two Subcommittee meetings to date. We're planning on having at least two more face-to-face

meetings, maybe three, depending on funding. We know that LeeAnn has asked to make herself available, if we can meet in the winter sometime, and we'll try to work that out relative to her schedule, but we do actually want to try and complete the document by the time we have our plenary session next September, and so this illustrates our plan to complete our work.

Of course, part of that process involves getting a draft into the hands of our other members who are serving on the other Subcommittee, getting their feedback, leading to a meeting where we can eventually hopefully adopt the document.

And then I had mentioned that many of us are not Norovirus experts, but we did have a member on our Committee who was Norovirus expert, and the week before we met in June, Dr. Dean Cliver, who I think is a great friend of many people in this room, passed away. So I can tell you that we miss him greatly. Of course, he was a great contributor to food microbiology and food science in general, but some of the sentinel early papers in Norovirus were

done by Dean, and if we are fortunate enough to get our paper through the Committee and published in the *Journal of Food Protection*, we'd like to dedicate our NACMCF white paper to his memory, and I'd like to acknowledge Margaret Hardin who has helped at least facilitate that with the *Journal of Food Protection* to make sure that that will happen very smoothly. Dean was a great friend.

So thank you. I'm happy to take any questions, and either I or a member of the Subcommittee will be happy to try and answer them.

DR. HAGEN: Does anybody have any questions for Kelly or Uday at this point? I mean we'll have time later in this morning's program, but are there any questions about what Dr. Bunning presented?

DR. BUNNING: Thank you.

DR. HAGEN: So, Spencer, you're up next I think. Spencer Garrett is going to present on the other charge that we've been working on for some time and certainly a lot this week.

MR. GARRETT: Thank you, Madam Chair. Before I begin, I've been in these different types

or kinds of meetings. I'm known for having a fairly thick skin, but that thick skin is getting kind of chilly, and I don't know if (laughter) I see people putting coats on and sweaters. I should have worn my winter jacket instead of my summer jacket, but anyway, if we could do something about that, it would be greatly appreciated, I'm sure.

What I would like to do, and I don't really have a PowerPoint presentation, but what I would like to do then is to remind our Committee members what the actual DoD charge was, and then perhaps for the people in our audience as well, and then we'll go to our report.

But in your little books here, it's under Tab 7, and the charge questions to the Subcommittee were as follows:

Because of the many questions regarding microbiological criteria, that might indicate poor process control or insanitary conditions, the National Advisory Committee on Microbiological Criteria for Foods, NACMCF, has been asked for its guidance to clarify the following issues:

One, describe processes and important considerations that could be used to develop microbiological criteria for a particular product, e.g., raw ground beef, ready-to-eat something or other, sliced luncheon meat, at various points in the process that might indicate poor process control or insanitary conditions. Describe how the processes and considerations could differ in other regions of the world where processing conditions may make certain indicators or levels of indicators more or less appropriate.

Secondly, at the point of production, how many *Staphylococcus aureus*, *Bacillus cereus*, generic *E. coli*, coliforms, *Enterobacteriaceae*, *Enterococci*, and/or gas forming anaerobes in ready-to-eat finished products might indicate (a) a possible process control problem of insanitary conditions or (b) potentially hazardous product unfit for distribution. How might the levels and the applicability of these criteria vary between ready-to-eat products, e.g., processed meat, poultry, egg products, refrigerated meat salads, and bagged leafy

green salads?

Thirdly, at the point of production, what level of mesophilic aerobic plate count in ready-to-eat finished products and in non-intact raw meat and poultry products might indicate a possible process control problem or insanitary conditions? How might these criteria vary between different ready-to-eat products, again, e.g. processed meat, poultry and egg products, and refrigerated meat and poultry salads? How might these criteria vary between different non-intact raw products such as beef trimmings versus ground product? How might these levels be expected to change during the expected shelf life of the product?

Fourthly, are there other potential indicators, e.g., microbiological, biochemical, or molecular parameters, of process control that should be considered? If so, how might these apply at various points in the processes of major product categories, e.g., meat, poultry, and egg products, bagged leafy green salads and refrigerated meat and poultry salads?

And then lastly, describe various sampling plans, such as the International Commission on Microbiological Specification for Foods, two or three class plans that may be applicable for the various analytes and products identified in the questions, and the table provide the appropriate values, e.g. ranges, log, colony forming units per grams, categories, acceptable, marginal, unacceptable, and if applicable, the recommended sampling plan in Table 1.

As you can see, it's a snap. (Laughter.) Come on. You can't be all serious now.

So what I would like to do then is give a progress report on how we're addressing these issues.

Our approach in addressing the five questions was to divide the charges into the following components.

Describe processes and considerations to be used to develop a microbiological criteria for foods purchased for the military.

Two, identify which indicator organisms,

sampling plans, and microbial population limits are appropriate for each food category, and how they could be used to identify adequate processes and process control.

Three, identify other indicators, whether they be microbiological, biochemical, or molecular, that process controls should consider.

The food categories considered, we broke them down to be these.

One, ready-to-eat foods processed for lethality, including the aforementioned, as I indicated in the charge, meat, poultry, eggs, seafood, and molluscan shellfish.

Secondly, ready-to-eat foods which included combinations of cooked and uncooked ingredients such as deli meats, salads, and prepared sandwiches and so forth.

Three, ready-to-eat raw foods including bagged salads, raw molluscan shellfish, overall fruits and vegetables, sprouts, cold smoked seafood, and frozen fruits and vegetables.

And, four, non-ready-to-eat raw foods

including intact and non-intact meat, pork, poultry, and seafood.

Now, since the Committee charge is to identify which indicator organisms, sampling plans, and microbial population limits are appropriate for each food category, and how they could be used to identify adequate process control, we believe that the aforementioned categories will facilitate and frankly focus and are focused on how we address this entire, rather broad charge.

General tables were generally adapted from the International Commission for Microbiological Specifications, Book 7, for suggested sampling plans based on combinations of health concerns, conditions of use, and the performance characteristics were two class and three class sampling plans which when known then would identify the probability of accepting contaminated lots.

The seven indicator organisms from the original charge were retained, and other analysis such as pathogen or toxin testing were included as appropriate.

In addition, the group developed flowcharts for each food category to identify process control points appropriate either to testing or indicator organisms, which could be used to determine if the process, in fact, is being controlled.

Also, we've developed a data collection table to collect data for a metaanalysis to identify the appropriate indicator organisms from the aforementioned food categories, along with sampling plans and limits.

The current sources of information include the Department of Defense Appendix O that we received from the charge, different publications from the National Academy of Sciences, also the different publications again from the International Commission for the Microbiological Specifications from Foods, actually our own publications that we've done in times past because various aspects of this, different other committees have looked at various aspects of these charges. New Zealand which has a rather robust, if you would, sampling program and they've looked at this entire issue, we're examining

that for our metaanalysis. The Institute of Food Technology, and also we've looked at, and we will be looking at some more data from the DoD microbiological testing data for other commodities.

We, in fact, did look at the data from bagged salads from DoD from 2001 and 2011, to see if we could determine any trends on the various counts between the indicator organisms. Criteria from additional information sources for our metaanalysis will include trade associations, retailers, food service, performance standards from FSIS, and also we do intend to look in this context, the purchasing specifications for the School Lunch Program and also the data that AMS has, as well as the FSIS performance standards reductions.

All of those will be seen and analyzed for inclusion in our metadata analysis.

Now, the next steps that this Subcommittee will do will be to continue to collate microbiological criteria and populate our data collection, and we did do some population of that while we were here. What we want to do is try to

get all this data together, do the metaanalysis, and try to develop some sort of understanding of the contemporary use of all these criteria that are being used both domestically and foreign, as well as sampling plans and the action levels for each food category.

The other indicators, whether they be microbiological, chemical, biochemical, or molecular, will also be included in that analysis.

On a final note, our working group agreed that with other agencies and organizations, both nationally such as CDC, FDA, USDA, and the International World Health Organization, the regulatory agencies, and other scientific advisory committees such as Codex, the National Academy of Sciences, NACMCF ourselves, have all recognized that the hazard analysis critical control point theory, HACCP, along with the prerequisite programs, whether they be good agricultural practices, good manufacturing practices, and sanitary standard operating procedures, really, in fact, are the best strategies for preventing foodborne illnesses.

These food safety systems were developed when it was realized that food safety, in fact, and in my personal judgment and many others, food safety cannot be inspected nor tested in the food products.

However, while microbiological testing alone cannot ensure food safety, it does have important roles to play within the HACCP and in conjunction with the aforementioned prerequisite programs, to help determine whether or not a given critical control point or even a control point is under control. If it is determined that a critical control point is not under control, then corrective actions can be taken to get it back under control.

In terms of end product testing, microbiological tests can be used along with other various activities such as statistical process control and others to verify that a HACCP system is working properly. Given that HACCP is a proactive system to prevent foodborne illness, if microbiological testing is used, more emphasis should be placed on using it to verify process control to ensure that the critical control points

are under control and relatively less emphasis should be placed on end product testing to verify that the HACCP system, in fact, is working properly.

Madam Chair, to paraphrase Winston Churchill on all this, Winston S. Churchill, I might remind the Committee members, the S does stand for Spencer. A lot of people don't know that. I didn't know it until I was 21. Thank you.

But anyway, to paraphrase Winnie, we're not at the end, we're not close to the beginning of the end, but we're very close to the end of the beginning. Okay. And that's my report, Madam.

DR. HAGEN: Thank you, Mr. Garrett, and thank you to Drs. Bunning and Dessai as well for a readout from their Subcommittees.

This is the point in the program I think, Gerri, right, where we move onto questions and comments. We didn't have anybody register, any of our guests register to make public comments. So we can just open up for questions at this point. If you have a question or a comment, please come to the microphone and identify yourself. Thank you.

MS. RANSOM: Okay. It looks like we have no questions from the audience, and do any Committee members have questions or comments for the Subcommittee Chairs?

Okay. All right. I think we got some very -- Spencer, go ahead.

MR. GARRETT: I would just like to make a concluding remark before the end of the meeting.

MS. RANSOM: Okay. All right. I think we got some very comprehensive reports from our Subcommittee Chairs and we got an idea of the in-depth scientific work that NACMCF puts in, and again I want to mirror what Dr. Hagen has said, and that we do value this work very much, and you assist federal agencies and stakeholders as well, and NACMCF work is highly respected.

So I guess at this point, we can turn it back to Spencer.

MR. GARRETT: Thank you, ma'am. About three different things. Uday, thanks for the coffee to warm me up. I really appreciate that.

Secondly, I'm not certain if I mentioned

that we will be having working groups for our Subcommittee because we all understand what next year's budget is going to be or likely to be.

And then finally I want to make a note that this in all likelihood will be my last attendance as a federal member of this Committee. I plan to retire in 2012, hope to come back perhaps as a member, but I want everyone to know that along with this Committee, along with my activities and expert consultations and things, both with the World Health Organization and FAO, I consider to be the epitome of my scientific career, and it's certainly been intellectually stimulating, and it's really a wonderful thing that this Committee truly does. Thank you very kindly.

MS. RANSOM: Okay. And again our sincere thanks to Committee members for the work that you do perform for us, and thank you to our audience for attending today, and with that, I'm going to turn it over to our Chair to close our meeting and make the final statements.

DR. HAGEN: We give you the gift of time

this morning. You all get 50 more minutes that you didn't think you were going to have. Thanks for a great week. Thanks for the commitment to this Committee, and we're really looking forward to the continued work on both the Subcommittees.

MS. RANSOM: Thank you, and we declare this meeting adjourned.

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

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

Washington, D.C.

September 30, 2011

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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TIMOTHY J. ATKINSON, JR., Reporter

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