UNITED STATES DEPARTMENT OF AGRICULTURE

+ + + + +

NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOODS

+ + + + +

PLENARY SESSION

+ + + + +

June 4, 2013
10:17 a.m.

PPIII
355 3rd Street, S.W.
First Floor (Auditorium)
Washington, D.C.

EXECUTIVE COMMITTEE MEMBERS:

CHAIR:	ELISABETH HAGEN, M.D. Under Secretary for Food Safety U.S. Department of Agriculture
VICE-CHAIR:	MICHAEL LANDA, J.D. Director FDA, CFSAN
CDC LIAISON:	ARTHUR P. LIANG, M.D., M.P.H. Senior Advisor for Food Safety, CDC/DFWED

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

EXECUTIVE COMMITTEE MEMBERS: (Continued)

FDA LIAISON:	MARIANNA NAUM, Ph.D. Strategic Communications and Public Engagement, Office of the Deputy Commissioner for Foods and Veterinary Medicine, FDA
COMMERCE DEPT. LIAISON:	CALVIN C. WALKER, DVM, Ph.D. National Seafood Inspection Laboratory National Marine Fisheries Service
DEFENSE DEPT. LIAISON:	BRADFORD W. HILDABRAND COL, VC DVM, MPVM, DACVPM Veterinary Advisor, Defense Logistics Agency
EXECUTIVE SECRETARY:	GERRI RANSOM, M.S. Director, Executive Secretariat USDA, FSIS, OPHS KAREN THOMAS Advisory Committee Specialist USDA, FSIS, OPHS
MODERATOR:	GERRI RANSOM, M.S. Director, Executive Secretariat USDA, FSIS, OPHS

COMMITTEE MEMBERS:

DR. ARUN BHUNIA
DR. WAFA BIRBARI
LTC ROBERT DOLE
DR. DAVID GOMBAS
DR. LARRY GOODRIDGE
MS. SUSAN VAUGHN GROOTERS
DR. MARGARET HARDIN
DR. SCOTT HOOD
DR. DALLAS HOOVER
DR. STEVEN INGHAM
DR. JEFFERY KORNACKI

COMMITTEE MEMBERS: (Continued)

DR. ROBERT LABUDDE
DR. RICHARD LINTON
DR. GUY LONERAGAN
DR. EVELYNE MBANDI
DR. PETER MURIANA
DR. NANDINI NATRAJAN
DR. ALISON O'BRIEN
DR. WILFREDO OCASIO
DR. MICKEY PARISH
DR. SALINA PARVEEN
DR. RUTH PETRAN
DR. JENNIFER QUINLAN
MS. ANGELA RUPLE
DR. STACEY SCHULTZ-CHERRY
DR. ROBERT SEWARD
DR. ROBERT TAUXE

FSIS:

DR. UDAY DESSAI

ALSO PARTICIPATING:

DR. CARL SCHROEDER

I-N-D-E-X

I-N-D-E-X

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

(10:17 a.m.)

MS. RANSOM: Okay. I'll just make a quick announcement. We have some table mikes here. Not everyone has one. If you push the button in front, you'll mute it. So, let's see, go ahead everyone and mute while you're not speaking, and your green circle will turn red when you mute it. Okay. And we also have a number of handheld mikes around the room if you need to use those.

Okay. Good morning everybody. I'd like to welcome you to today's plenary meeting of the National Advisory Committee on Microbiological Criteria for Foods, or NACMCF. I'm Gerri Ransom, the NACMCF Executive Secretary with FSIS Science Staff. We're going to start off today by hearing from our Chair. I -- I'm going to turn the floor over to our Chair. And our Chair is Under Secretary -- USDA Under Secretary for Food Safety, Dr. Elisabeth Hagen.

DR. HAGEN: Good morning. Can everybody hear me? Hi, it's good to see everybody. Thank you for coming and welcome to today's plenary session.

This is the first full meeting of our 2013-15 Committee, and I am very pleased to be welcoming 22 of you who are new to the Committee and 8 returning members. I think we're going to have a chance to visit. I'm a little overscheduled this morning. I was hoping that I'd have a chance to really just chat and meet-and-greet with some of the new folks, but I think we're going to do that tomorrow. Gerri's got some time on the schedule to do that tomorrow. So, thank you every one of you. I know you all have very busy day jobs, some of you have multiple busy day jobs, and I really appreciate you coming and participating with us for this term and lending your expertise to this Committee.

So I've been sharing NACMCF now with Mike since 2011, and I've really come to have a real understanding, but also a deep appreciation for just how important the work of this Committee is and just how dedicated the people are who we get on this committee. This is one of the most respected scientific advisory committees out there. I feel very comfortable saying that. And it's because we have

this extremely hardworking and very dedicated group of scientists and professionals. And it's also because I think the work that you all do here goes well beyond the walls of these meeting rooms that we congregate in. It's directly applied and it's put to use across the Federal Government to make better foodborne illness prevention policy.

So, you all know food safety microbiology is quite a complex challenge. I'm not sure where to ideally situate this thing. As long as we have 1 in 6 Americans getting sick from the food they eat, we have a lot more work to do on this Committee and in the agencies that this Committee supports. It takes real -- a real commitment to be able to get somewhere with this challenge. It takes commitment to prevention, to public health, if we're really going to make any headway. So this kind of commitment, combined with effective federal agencies and cutting-edge science, are what we need to be able to build the strong programs that support that type of policy.

So we're all here, and this Committee was established so we could help build and maintain an

integrated national approach to food safety, one that goes from farm to table, and one that truly protects consumers. Over the next couple of days, you're going to begin working on two issues. The first is going to be control strategies for reducing foodborne norovirus infections and the study of microbiological criteria as indicators of process control and insanitary conditions. Both of these issues that you're going to be undertaking can improve the way that we target foodborne pathogens and prevent illness. And both can help our industries address very real challenges in today's food safety system. Ultimately, most importantly, both of these studies can be used at the federal level to make decisions that will better protect Americans from foodborne illness.

So on Norovirus first, human noroviruses, as you all well know, are now the most commonly identified cause of foodborne outbreaks in the United States, and yet we really don't know that much about how and why. We have a lot that we still need to understand to better protect public health, including simple things like what the overall burden is, how

they're transmitted and how they contaminate food, and what the best practices are to control them. And we definitely believe that there's enough expertise in this room, there's absolutely enough expertise in this room, that we can make some real headway on this issue.

And on microbiological criterion, the Department of Defense, when they're -- when buying food for our military personnel around the world, evaluates whether the food produced in establishments is safe and wholesome. Microbiological criteria can aid in these decisions, but there's no standardization or consensus on acceptable microbiological levels in different product classes in the United States. So we also believe here that you can greatly help in addressing this issue.

And if there's one tough thing that's been happening across -- if there's one thing that's been happening across the country when it comes to the food safety regulatory landscape, it's this: we're all asking tough questions. Mike's team is asking tough questions, we are, and certainly all of you who work

in academia and in the private sector, are also asking these kind of questions. In our world, the food safety world, we're asking things like, are we reacting to food safety problems or are we actually preventing them in the first place? Are we effective? Are we doing this as -- in the most efficient way possible? Are we as coordinated as we need to be in our approach? Are we using the best available science, and making the best use of our resources? Certainly all of us who work in federal agencies have had to ask that question over and over again, and particularly in light of the events of the last year. Are we making the best use of our resources? Can we be doing more with less? Are we doing the best that we can, given the technology that we have? Are we ready and equipped for the 21st century food system?

So USDA, FDA, and other food safety stakeholders are asking if we're doing all that we can to protect public health through food safety, and we're always searching for solutions. And that's where you all come in. That's why you're here, because you, on these issues, and on the others that

will come to you during your time on the Committee, are going to help us answer these questions. So some of you have heard me say this before, but I think it's important enough to repeat. The work that you're doing here on this advisory Committee, this matters. The work that we do in food safety every day in our agencies matters, and people need to hear that. As I said, you all have very busy professional lives. You're all very accomplished. It was competitive to get into this Committee. We know that you are able to contribute elsewhere, and that you are, and we just want you to know that it matters. It matters to me, it matters to Mike, it matters greatly to our Secretary, Secretary Vilsack and Secretary Sebelius, and obviously it matters to the American people that we're here and charged with protecting from foodborne illness.

So just, that bears repeating, and I don't want you to ever think that we take that for granted. We really appreciate the commitment that you're making. So I thank you again for serving as a member of NACMCF. And you've taken on this really important

advisory role. You've got a key part to play as we build this stronger food safety system. And thank you again for your time and your commitment to public health.

And I'd like to turn it over to my Co-Chair, Mike Landa, the Director for FDA's Center for Food Safety and Applied Nutrition. Oh. You have one. Okay. I'll turn mine off.

MR. LANDA: The question is, does it work?

UNIDENTIFIED SPEAKER: Yes.

MR. LANDA: I guess so. Thanks Elisabeth. Thank you very much. Good morning, and again I'd like to welcome our members and guests to the plenary session. NACMCF is an extremely dedicated group, and I want to express my appreciation and thanks for your time and your willingness to serve and to work hard, perhaps harder than you anticipated, and I guess you'll see soon enough, to share your food safety expertise, which is certainly more than adequate for the task before you.

I've participated in NACMCF since 2010. I come at the work of the Committee from a slightly

different perspective because I'm a lawyer by training, by practice most of my career, rather than a scientist. And so, naturally enough for me, the first thing I look at for a food safety regulatory agency, or any other regulatory agency, is the law, statute, followed by regulations. And also, of course, have to look at science and policy. And I'll borrow something you may have heard -- some of you may have heard me say before from a former colleague of mine, Anne Wion, who's a -- for many years a Deputy Chief Counsel for Regulations and Hearings at FDA's Office of Chief Counsel, and she was thinking of a agency like FDA, the USDA is resting on a three-legged stool: one leg is law, one is science, and one is policy. Of course, for the lawyers, the most important leg is the law; for the policymakers, the most important leg is the policy; and for the scientists, it's the science.

I'm a lawyer, and perhaps I'm not being true to my profession, but I actually think in this context the most important leg is the science, mostly because the cost of getting it wrong is so high. If there is an interpretation of the law that's either unduly

generous or unduly ungenerous, someone will sue. The court will correct the Agency's interpretation. Policy mistakes over a -- some period of time are almost inevitable, but if you get the science wrong, your credibility is undermined, your foundation is undermined. So I really do think it's the most important part of that three-legged stool. And that, of course, makes what you do all the more important for our -- for all the agencies concerned.

As Elisabeth mentioned earlier, we are restarting the two subcommittees with newly assigned Chairs and a number of new members, making your tasks perhaps unusually difficult. You have to review past work, assess the approach the past committees were taking, and of course, move forward and deliver recommendations in a fairly short period of time. But your recommendations, recommendations on both the control strategies for reducing foodborne Norovirus infections and the study of microbiological indicators and criteria as indicators of process control or insanitary conditions will help inform FDA and -- as well as USDA, on the best ways to address these

pathogens and ultimately help reduce the number of foodborne illnesses associated with them.

Control strategies for reducing foodborne Norovirus infections is a topic of concern to the first subcommittee as well as to all of us because of the great proportion of foodborne illness attributable to Noro. In fact, in the last couple of years, Noro outbreaks have been making the news almost as much as *Salmonella* and *E. coli*. Also, of course, in terms of the numbers over the years, it's Noro, Noro, Noro, and that hasn't changed for a long time.

Let's see if we can't make some progress in changing it. The second subcommittee in the study of microbiological criteria as indicators of process control or insanitary conditions is critical to DoD, but it's also important to others of us, not so much because we are in the business of purchasing food, some of us, at least, are not, but we are in the business of regulating food in a direct way. And the better the indicators we have for process control or insanitary conditions, the better the job we can do at regulating. So a number of agencies can benefit from

an interest to both charges.

Again, let me just say I know how hard the work is, the challenges before you, the amount of information that there is to sort through, and as Elisabeth indicated, that this is for all of you yet another duty as assigned. Although, I guess it's a duty you volunteered for, so perhaps our sympathy should be somewhat tempered by that.

Let me close by again thanking all of you for the work you do and will be doing, and the future contributions to the Committee. Your efforts will lead to foundational work in my view. And because your recommendations come from an advisory committee, they'll likely become more widely and readily accepted than work any single agency can do on its own. And it carries of course, but I think as a general statement it's true, making again the work all the more important given the neutrality of the source and the various perspectives that each of you bring to this effort.

I would just like to thank Gerri Ransom and her staff, before turning it over to Gerri, for

pulling all the meetings together. As I was coming down the subway, I was thinking that if it is true that the devil is in the details, for arranging all these meetings, Gerri and her staff know the devil all too well.

(Laughter.)

MR. LANDA: Over to you, Gerri.

MS. RANSOM: All right. One intermediate comment here.

DR. HAGEN: I just wanted to jump in too, because I don't know whether I'll be here at the end of this -- at the full meeting, so I wanted to also thank Gerri too. I -- it's hard to imagine how an advisory can be like this, even functioned before Gerri Ransom. Those of you who have been around for a long time know just how incredible she is and I know, in terms of keeping it together for me and for Mike, she's really indispensable, and Karen Thomas-Sharp on her staff as well. So I just wanted to make sure that I thank you before you start talking, and tell everybody how wonderful we think you are --

MS. RANSOM: Okay. Thank you for all of

the --

MS. HAGEN: -- and embarrass you.

MS. RANSOM: Thank you for embarrassing me and for all the praise.

(Laughter.)

MS. RANSOM: I want to reiterate that it's great that we are holding our first plenary meeting. It has taken a lot of work and effort on the part of everyone at this table to make this happen. Now our returning members know, and our new members are learning that there's a lot of process to advisory committees, but it's necessary for the balance, transparency, and success of the Committee. So your patience as we work our way through does pay off, and you will see as scientific advice from your reports is applied to food safety programs and as your work gets published.

Now, I'd like to start with us going through some introductions. We've done this already, but we now have our guests in the audience, so I'd like to go ahead. And let me start with Skip on that side and let's go around the table and let us know if you are a

NACMCF member or what your role is here with us. Thanks.

DR. SEWARD: Okay. Skip Seward, Seward Global Consulting. I'm a member of the Committee and I'll be Co-Chairing the subcommittee on -- to address the questions posed by the Department of Defense.

DR. MBANDI: Evelyne Mbandi, member of the Committee with FSIS, and I will be on the DOD subcommittee.

DR. SCHULTZ-CHERRY: Stacey Schultz-Cherry. New member, Department of Infectious Diseases, St. Jude Children's Hospital, and I am a virologist.

DR. HOOVER: Dallas Hoover, University of Delaware, Noro Committee member.

DR. GOMBAS: David Gombas, United Fresh Produce Association, member and Chair of the Norovirus subcommittee.

DR. MURIANA: Pete Muriana, microbiologist, Oklahoma State University, new member. I'll be --

DR. BHUNIA: Arun Bhunia, Purdue University, for microbiologist purposes. I am member.

DR. PARISH: Mickey Parish with FDA's Center

for Food Safety and Applied Nutrition, and I'm a new member of the Committee.

LTC DOLE: I'm Lieutenant Colonel Bob Dole. I'm with the Department of Defense. I'm a veterinarian and NACMCF member.

MS. VAUGHN GROOTERS: Susan Vaughn Grooters. I'm with the Center for Science in the Public Interest. I'm a NACMCF member. I'm a consumer representative.

MS. RUPLE: I'm Angela Ruple with NOAA Fisheries and I'm a returning member to the Committee.

DR. WALKER: Calvin Walker with NOAA Fisheries. I'm the Department of Commerce Liaison to the Committee.

DR. NAUM: Marianna Naum. I'm the FDA Liaison for the Committee with the Deputy Commissioners Office of Foods and Veterinary Medicine at FDA.

MR. LANDA: Mike Landa, Director, the Center for Food Safety and Applied Nutrition with Food and Drug Administration, the Vice-Chair of the Committee.

DR. HAGEN: I'm Elisabeth Hagen, I'm the

Under Secretary for Food Safety at USDA and the Chair of many.

MS. RANSOM: Gerri Ransom again, Executive Secretary of NACMCF and I'm with FSIS science staff.

DR. LIANG: Art Liang, I'm the CDC Liaison for the Committee.

COL HILDABRAND: Colonel Brad Hildabrand. I'm representing Department of Defense Veterinary Service Activity, on the Executive Committee, served previously from 2006, 2009 and I'm back for about the last 6 months.

DR. NATRAJAN: Nandini Natrajan, returning member of the Norovirus Committee, from Keystone Foods.

DR. PARVEEN: Salina Parveen, University of Maryland, Eastern Shore. I am a new member of the Committee.

DR. BIRBARI: Wafa Birbari with Hillshire Brands. I'm a NACMCF member with the Norovirus subcommittee.

DR. LONERAGAN: I'm Guy Loneragan, I'm a Professor of Food Safety and Public Health at Texas

Tech University, and I'm a new member of the Committee.

DR. INGHAM: I'm Steve Ingham, Administrator of the Division of Food Safety, Wisconsin Department of Ag, Trade and Consumer Protection, new member of the Committee.

DR. PETRAN: I'm Ruth Petran with Ecolab. I'm a member of NACMCF and on the Norovirus subcommittee.

DR. KORNACKI: I'm Jeff Kornacki, President of Kornacki Microbiology Solutions, Inc. I'm a new member to the NACMCF Committee and Co-Chairing with Skip, the study of microbiological criteria as indicators of process control or insanitary conditions.

DR. HOOD: I'm Scott Hood with General Mills, new member to the Committee.

DR. LINTON: Good morning. I'm Rich Linton with North Carolina State, Professor of Food Microbiology and Dean of the College of Ag and Life Sciences, and a new member of the Committee.

DR. OCASIO: I'm Wilfredo Ocasio with the

National Food Laboratory, and a new member to the Committee.

DR. GOODRIDGE: Larry Goodridge from the Department of Animal Science for the Colorado State University, and I am a new member.

DR. HARDIN: Margaret Hardin, IEH Laboratories & Consulting Group, returning member, Co-Chair of the Norovirus subcommittee with Dave Gombas.

DR. GLASS: Kathy Glass, University of Wisconsin, Madison, Food Research Institute, Subject Matter Expert for the DOD microbiological criteria subcommittee.

DR. O'BRIEN: Hi, I'm Alison O'Brien. I'm Professor and Chair of the Department of Microbiology and Immunology at Uniformed Services University. I'm a returning member. It's been over a decade, and I'm on the Norovirus subcommittee.

DR. TAUXE: Rob Tauxe, Centers for Disease Control and Prevention in Atlanta, returning member to the Norovirus Committee.

DR. LABUDDE: Robert LaBudde, Least Cost Formulations, a consulting company, a member -- new

member of the Committee, member of the -- organisms subcommittee.

DR. QUINLAN: Jennifer Quinlan, I'm a food microbiologist at Drexel University in Philadelphia. I'm a new member to the Committee on the micro criteria subcommittee.

MS. RANSOM: Okay. Thank you. I think we got everyone at the table. Did --

Okay. I wanted to make mention that we will have a public comment period later on in the program. So for anyone wishing to make public comment, please register outside with Karen. We'll go ahead and take the comments at the end of the program.

Before we get to the science part of the program, I want to mention a few items. This Committee membership is at the front end of a 2-year term and your term runs through January 15, 2015, too many 15s. Our one consumer affiliate on the Committee, Susan Grooters, her second 2-year term is about to begin. She's on a slightly different schedule than the rest of the Committee, so she will be with us through June 2015. Now, the current

Committee charter runs through February 2015, and this charter is available on the FSIS website. An item of mention that I want to highlight is that we had a retirement take place at NACMCF this year. Spencer Garrett of the National Marine Fisheries Service, Department of Commerce, retired on April Fool's Day this year. Spencer --

UNIDENTIFIED SPEAKER: So you're still waiting for him to come back?

MS. RANSOM: We're still waiting for him to come back, yes. Spencer was a longtime member of the NACMCF Executive Committee, and also a NACMCF member. Spencer provided much leadership and expertise to NACMCF and he will be greatly missed. Most recently, Spencer chaired the micro criteria subcommittee that completed the School Lunch Project for the Agricultural Marketing Service and we're going to hear more about that a little later on. And Spencer also has initiated the work for the DOD micro criteria subcommittee, which is going to be continued with this Committee. Spencer was famous for running a tight ship, and of course being from the National Marine

Fishery Service we would expect this, but he always kept us on track. We wish Spencer well on his retirement.

And he's already introduced himself, but Dr. Calvin Walker is joining us from the Department of Commerce, National Marine Fishery Service, and he follows Spencer as the liaison role there for the National Marine Fisheries Service in Department of Commerce.

Okay. It was mentioned that for NACMCF work for -- term, we heard about the Norovirus and the micro criteria work for DOD. The Executive Committee felt it best not to start new work projects at this juncture until the Norovirus and the DOD micro criteria projects were completed. We do have a number of projects in waiting for NACMCF that are in various stages of development.

I want to make mention of one charge, and this is in line to be up next, but we have -- because we have a lot of support and interest in this project from members as well as others. This project is on STECs. This is the project, virulence factors and

attributes that define foodborne Shiga toxin-producing *E. coli* as severe human pathogens. FDA developed the concept for this charge and we are planning this as a joint FDA, CDC, FSIS charge. This charge will dovetail with current work on -- other current work on STECs. And the charge is currently being updated.

To give you an idea of some of the questions being considered for this charge, I'll just give you a few of them that we're thinking about. What defines or differentiates an STEC as a human pathogen from other STECs that have not caused disease? What methods are available to detect STECs and specific known virulence factors? I know many of our new members are looking forward to this charge, and this Committee has some strong expertise in this area to be applied to this work, so we're looking forward to when we do get to this work.

Okay. Now today, we're going to hear three updates on subcommittee work. We have a colleague here from the Agricultural Marketing Service who will talk about the application of some recent NACMCF work. And we also have representatives of the past Norovirus

and a continuing member from the micro criteria subcommittee who will talk about these charges and where these groups last left off. Okay. Our first speaker is going to be Dr. Carl Schroeder and let's see, he's around the other side, but he's got a --

Our entryway is a little bit narrow, but our first speaker, Dr. Carl Schroeder, is from the AMS Livestock, Poultry, and Seed Program. And Carl is the Director of the Food Safety and Commodity Specification Division. And I'll turn the floor over to you, Carl. Thank you.

DR. SCHROEDER: Thank you. On behalf of AMS, thank you for the opportunity to be here. It's a real honor to speak in front of this distinguished group. We received the invite from Gerri a couple of months ago to come here today and speak with you and she had indicated that she believed this was a really good example of how the work done by this Committee is translated into policies to make our food safer, and we agree wholeheartedly. The recommendations that the Committee made were adopted on the 28th of March 2012, and within 2 months, we began implementing those

recommendations for our upcoming purchase season. And we're quite convinced that the recommendations from the Committee have only strengthened the food safety of the products we purchase for the School Lunch Program.

By way of background, the Agricultural Marketing Service recently underwent a significant change in two of the larger offices, the Livestock and Seed Office and the Poultry Office combined. And as part of doing that, AMS believed that they needed to create a standalone Food Safety and Commodity Specification Division. And they did that and kindly invited me over from FSIS to lead that. And so that's been a real pleasure. I've been there for about 6 months and I look forward to working with you all in that capacity. My boss, Craig Morris, who is the Assistant Administrator for AMS, was supposed to be here today. We have a new administrator and Dr. Morris is with her as she visits many of our stakeholders in Iowa. So both Craig and Ms. Alonzo, our new administrator, send their very best.

Kerry Smith, who I believe many of you that

were on the Committee worked with as you were developing your work on this issue, Kerry received a promotion in AMS and she is now one of the managers in our Office of Science and Technology. And Kerry also sends her very best.

In the Federal Ground Beef Purchase Program, AMS, in fiscal year 12, purchased approximately 145 million pounds of beef that goes to various nutrition assistance programs, most notably the School Lunch Program. And as part of that, we conducted 75,000 microbiological tests. We test every lot of beef, approximately every 1,500 to 2,000 pounds, and so we generate an enormous amount of data. We're very proud of our food safety record. We believe it's especially important given the population that we serve, the schoolchildren, that we do it right and that we constantly look for ways to improve what we do. And it was with that in mind that we came before the Committee a couple years ago to ask the Committee to do a review of our work.

There's a paper outside that was recently published in the *Journal of Food Protection* that talks

about the Committee's work on this issue, and we're very happy to see that paper published. It's important that we be transparent and let the larger scientific and food safety community see the work that you do. But I'd like to very briefly step you through the three points that are in the Executive Summary, which are basically the three issues that we asked NACMCF to look at. Number one was, we had long tested for *Staphylococcus aureus* and we wanted to discontinue that testing. We didn't think those resources were well spent. We went before NACMCF, NACMCF was able to do a review, come back as detailed in the paper in the report, really provide, I think, overwhelming scientific evidence as to why it made sense to discontinue testing for *Staph aureus*. And we took up that recommendation, again, within a matter of months, and made it -- and that saved us considerable resources.

Another question that was before the Committee was, should AMS consider the use of alternative screening procedures beyond just those listed in the FSIS microbiological, excuse me,

Microbiology Laboratory Guidebook. And the Committee came back and said, yes, with the very important caveat that all of those methods be tested and benchmarked against the FSIS *Microbiology Laboratory Guidebook* standards. And so we worked with our contract labs to do that.

As one example, we now allow from IEH, some alternative screening methods that were vetted and appear to be every bit as robust as what's described in the FSIS guidebook. They -- we believe can be done quicker and at less cost, which is advantageous. And so we are now, based on the NACMCF recommendations, allowing our laboratories to use alternative screening methods, which is going to result in lower cost and quicker turnaround time for our vendors.

The third and final issue that I'll make mention of is NACMCF looked at our overall plan, and one of the recommendations it made was that we discontinue testing for pathogens in product that we know is destined for cooking at an FSIS-inspected establishment. And on its face, we agree. We think that makes a lot of sense. In practice, we want to

make sure we get it right. There are some issues. We need to make sure that we can adequately trace what product is going to cook versus what is served raw, and we want to take our time and make sure that when we do that, we get it right. So this year, we still have -- for this purchase season, we have not changed that policy. However, I believe that we're moving towards doing that for our upcoming purchase season.

But that then leads me into the final bulleted item under the Executive Summary. And I happen to think in reading NACMCF's work that this is one of the very best recommendations. It says that AMS should continue ongoing program reviews in consultation with FSIS and ARS to determine if any requirements need to be strengthened for supplier eligibility, processing, et cetera. And that rings true with us over at AMS. Again, we talked about the importance of getting it right for the schoolchildren that consume the product we give to them, but also, based on the fact that we gather 75,000 test records per year; as far as I know, that's the largest microbiological testing program in the U.S. Federal

Government, if not the world. And I think because we gather so much data, it's very important that we be good stewards of those data.

And I'll close by saying, in the weeks ahead, in fact tomorrow; we're beginning meetings with all of our stakeholders. We're going to work with FSIS, with ARS, with CDC, with all of our federal partners. We're going to work with our industry and our vendors. We're going to work with consumer advocacy group stakeholders to really have a discussion about our sampling program, look at the NACMCF recommendations and make sure that as we move forward, we continually strive to strengthen our microbiological testing program. And so I look forward to working with all of our stakeholders to do that. And I'm hopeful that we'll have an opportunity to be back here next year to give you an update on our progress. So with that, again thank you very much for the invitation, and we look forward to working with the Committee. And thank you for all the work you've done. It's been a great help to us. Thanks.

MS. RANSOM: Okay. Thank you, Carl, for

giving us a comprehensive view of how that project worked out. And yes, this is a great example of showing application of the Committee work.

At this time, we're going to move on to hear from an additional subcommittee. I'm going to ask that Dr. Uday Dessai come up. Uday is from -- he is the Director of the FSIS science staff in the Office of Public Health Science, and he had rotated off NACMCF. He was on the past Committee, and he was a Chair of the subcommittee of control strategies for reducing foodborne Norovirus infections and Dr. Kelly Bunning of FDA served as a Co-Chair with Uday. So with that, over to you.

DR. DESSAI: Good morning, guys. It's important to mention about the AMS charge that the Committee was a phenomenal force on putting the existing work away and then accomplishing the AMS charge in less than 6 months. So I think those of the members who actually worked on the charge, worked a week at a time in different locations to get this charge done. And that's how we were able to finish the charge well ahead of time. Now, I think we might

have a little technology issue here.

UNIDENTIFIED SPEAKER: I'm just going to see if she can get it unlocked.

DR. DESSAI: Gerri, can you get this working?

MS. RANSOM: Let me see if we can find someone to fix that --

DR. DESSAI: Okay. In the meanwhile --

(Off the record for background discussion on technical issues.)

(On the record.)

DR. DESSAI: Okay. All right, the Norovirus subcommittee had been working for a while now, and this is a daunting task. I've been on this Committee as a Co-Chair, like Gerri said, with Kelly. Kelly, of course, took the major share of the responsibility here. I was just supporting him. But the most important thing about this charge is, while most of the charges would have, you know, need for data, there will be data gaps, information not available, but this charge especially has a lot of areas which are grey, which are evolving. And over the time that we've been

dealing with this charge, we had a whole lot of learning happening for the Committee.

Now, incidentally, the subcommittee that actually learned a whole lot has moved on, in part. We have new members coming in. We have a wealth of information that we have gathered that's available for us, as well as, we have the expert advisors who will be advising this Committee as we move forward.

So what I'll do is I'll just take you through very briefly on what we did over these -- over a year and a half pretty much. The charge questions are with you. All of the handouts are outside, so we'll not go over the charge questions, but the goal of all the work we did until now and as it is today, is to orient you guys to generally what has been attempted and what will we do.

We have -- you can look at the listing -- list here. We had lots of partners. We had the FDA partners asking questions about Norovirus. We had CDC. We have FSIS. We have the School Lunch Program. So we had a lot of partners which put a list of questions together. And we assembled a range of

specialists, whether from CDC or NC State University (Lee-Ann Jaykus). So we learned most of what is happening with Norovirus. We also had the School Lunch Program people to come and tell us their needs, as well as, FDA told us what their issues are through Kevin Smith.

And the subcommittee, rather a small subcommittee at that time, we had only 19 members, so we got a smaller portion of that, was divided into five groups. The fifth group was -- we'll talk about that later, but the four groups, the work was divided, questions were grouped into common themes, and the work was divided so we could accomplish this work. The first work group talked about the burden of illness and attribution, those kinds of issues from CDC's angle.

Then we have the second work group, mitigation and control and intervention, actually. This work group has the most work, this was a large work group, and with the most challenges. Because for many of these questions we do not have data that is reliable. If it's available, can we translate the

data? Those questions still remain. So this work group did a phenomenal amount of work, which is going to be available to the new Committee.

And the work group number three was on detection and surrogates. The main problem here is, why does this just get carried in the food systems? And then they get carried further as the distribution happens. How it gets introduced at different points, but they don't multiply and we don't culture them, especially Norovirus. So this is a major area where you need surrogates, surrogates which are true, as close to Norovirus as possible. And that's been a challenge over the years. A lot of work has been done. So we learned a whole lot. The Committee learned a whole lot about the limitations of using surrogates and we have that information for the new Committee.

Detection, there is a slew of work that is happening in detection, including right from cell cultures to molecular methods. So there's a whole lot of work that was discussed, which is available for the new subcommittee.

Risk assessments, now this is again a complex question. And what we did was we kind of assembled generic information on how risk assessments can be done and, with respect to Norovirus, what is that we need to conduct risk assessment? What are the risk management questions? And in that context, of course, we'll be collecting a whole lot of questions from other subgroups as well as data leads and questions from the other partners in terms of what type of risk management issues do you have? We've done part of that; we'll continue doing more of it as we go along.

Group number five and this is the group I was talking about. This is a specific question where the NACMCF subcommittee will actually develop very generic type of plans for certain systems, such as restaurants and then long-term care facilities, schools, airplanes, and of course, cruise ships. We had a presentation by the cruise ship people, which was very interesting. A lot of progress has been made there, so we'll be able to learn something from there. So these are -- after the four subcommittees meet and

then once we have kind of developed the document or the concept, then we can go ahead and then develop these plans as the whole group.

We had a lot of activity in terms of learning. We invited a number of experts listed here, and learned from them. In their circumstances, how do they deal with Norovirus and what are their challenges? We had subject matter experts that we've invited, and we'll keep subject matter experts engaged in this process from CDC as well as from USDA, ARS, and other sources.

Now, the next few slides will give you a quick summary of what I was talking about, summarizing published estimates for burden of illness and attribution. You can see that, you know, CDC is working on this and we have made some progress, quite some progress at this point. A lot of data gaps have been identified and areas to advance science have been identified as well.

The work group two, mitigation and control interventions, this group did a ton of work and I think there is a whole lot of work still to be done

with this group. The major areas were route of transmission, hand sanitizers, then hard surface sanitizers, inactivation technologies. And we don't -- quite some interesting things about the sanitizers, the claims the sanitizers make, effectiveness issues, and the regulatory challenges that FDA faces with this area.

Work group three, detection and surrogates, like I talked about, current methods of choice and detection and characterization. We learned quite a bit, probably will learn more because we have the NoroCORE grant, which is a NIFA grant, which is ongoing. That's a $25 million grant. And I think it's already 1 year in progress now, so we'll learn more about methods, et cetera. We'll learn about surrogate issues. Also, what's been done in the past, and pros and cons have been documented.

The work group four, risk assessment, like I said, we have put a framework how risk assessments are to be done. There are various sources all over, right from WHO to FSIS' own sources, EPA, on how risk assessments are done. And this charge basically will

give a snippet, just a summary, of how risk assessments should be considered, considering Norovirus issues. Also, this component will be developed more as other groups make progress.

Now, this timeline for this charge provides this with -- to be decided, TBD, because earlier than we had timeline, we had fixed time for us to finish this project. And by this September, we should have actually finished the project if we had the Committee functional for all the time. But now that the Committee is not -- has not been functional for a long time, as well as, Committee will not be meeting in person -- earlier we had the freedom to meet in person. Travel was easy. Travel is different now. So the fact that the Committee, new Committee, brave new Committee, will have to really do a whole lot of work online with pieces, 2 hours, 3 hours, get together -- that is -- that -- we haven't seen how that goes because we've done this kind of work earlier when you finish up a charge, but now the charge is not even halfway through and we need to follow this process.

So we have really kind of learned as we go, so we have not put any timeline on this. Of course, the aspirational goal is getting this done by September. I'm not declaring it, but just putting it out there. So I think today, tomorrow, and the day after, you will, as a team, meet and make decisions about where we are and where do we go from here, and just a rough idea about when can we get this completed? So I think that was my last slide, if you have any questions?

MS. RANSOM: Okay. No questions for Uday? Thank you, Uday, for giving us a comprehensive picture of where the group was and where they're going to continue on. Okay. And I want to thank Doctors Margaret Hardin and Dave Gombas for agreeing to chair this subcommittee. They are the brave new Chairs, and Mike Landa thinks you should stand, Margaret and Dave.

(Laughter.)

MS. RANSOM: Go ahead and stand. They won't stand.

(Laughter.)

MS. RANSOM: I'm not sure if that's a good

sign or not.

(Laughter.)

DR. GOMBAS: -- we're good.

MS. RANSOM: Okay. Now at this time, we're going to hear from a continuing member of the DOD subcommittee, and this is Ms. Angela Ruple. She's from the National Marine Fisheries Service, Department of Commerce, and she's the one -- one of the few surviving members of this subcommittee.

MS. RUPLE: Thank you, Gerri, and thank you, Uday, for getting my slides set up.

DR. DESSAI: I think it's ready. Okay.

MS. RUPLE: As Gerri indicated previously, Spencer Garrett was the former Chair of this subcommittee. I won't pretend to have the years of knowledge and experience that Spencer has, but as a previous member of this subcommittee, and one of the few remaining members, I was asked to give a brief overview of what the subcommittee has accomplished thus far and where we might be going within the next few days. It's not working.

UNIDENTIFIED SPEAKER: What's going on?

DR. DESSAI: It's not doing it.

MS. RUPLE: It's not doing page up.

UNIDENTIFIED SPEAKER: Just use this one.

MS. RUPLE: Okay.

UNIDENTIFIED SPEAKER: Yeah.

MS. RUPLE: Thank you.

UNIDENTIFIED SPEAKER: No problem.

MS. RUPLE: As a brief background, this charge has been around for quite some time. It was initially introduced to the full Committee at the plenary session in March of 2009. Due to several difficulties in getting the charter renewed and actually establishing a committee, there wasn't a whole lot of work done between that introduction and the time that we actually got started doing the real work in 2011.

So in April of 2011, the subcommittee met in Washington, D.C., and during that meeting, we reviewed a lot of background information. We had presentations from experts and just sort of tried to get a feel for what the charge was. Then we met again in September of 2011, and at that meeting, we were able to

establish a little more of a framework of how we wanted to approach the charge. Then, as we heard earlier today, this subcommittee was asked to put work on this charge on hold and to focus our efforts on the charge that we heard about this morning from AMS.

And it's very rewarding to hear that the recommendations that came from the subcommittee, we did do a lot of work in a short amount of time, and it's very rewarding to hear that that -- those recommendations are being applied. So it just shows us that the work of this Committee is very important and we look forward to continuing that work.

By way of background, the DOD purchases food globally for our military personnel, and they have established their own standards for pathogens, such as *Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7, *Clostridium perfringens*, and various microbial toxins. But along the way, they've encountered numerous circumstances where the numbers of potential pathogens or indicator bacteria have generated some concerns about the safety and/or the wholesomeness of the products that they're responsible for. So over the

years, they -- they've established their own standards. They have people, their own auditors and processing establishments. They also rely on the processing establishments, themselves, to set specific criteria.

But the DOD felt that these standards needed to be evaluated for their applicability to the current processing. We all know that technology changes frequently, and so they would like to see the NACMCF Committee look at these standards that they've already established and make some recommendations on how to proceed with that in the future. Specifically, they determined that these standards need to address all stages of the process, from the production to the distribution. And some of the standards that have been established by other agencies and also by the processing establishments themselves, focus on one small aspect of that, where DOD would like to take a look at the entire process.

And they've asked NACMCF to give some guidance on the role of microbiological or other indicators to evaluate raw materials or product

components in food service establishments, and they felt like that would greatly enhance their role in providing food safety for our military. So the specific charge that was given to NACMCF came in the form of several questions.

The first, which was to describe the processes and important considerations that could be used to develop a microbiological criteria for particular food commodities and to look at various points in the process where these criteria might be applied, and also to determine how these different criteria and considerations would differ in other regions of the world. It was important for them to point out to the Committee that some of the purchases that they do are not just commodities purchased in the United States, but they're doing purchasing globally.

The second question posed to the subcommittee was to determine at what point in the production and how many various microorganisms in ready-to-eat products might indicate a possible process control problem or, perhaps, a hazardous product, and how might these levels and criteria

differ between different types of ready-to-eat products?

The third question dealt with levels of mesophilic aerobic plate counts in ready-to-eat finished products and how might the criteria be developed for specific ready-to-eat products, and how this -- how they would differ between non-intact raw products, and how would they be expected to change during this -- the shelf life of the commodity.

The fourth question was to look at other potential indicators. Are there other indicators that might better indicate process concerns and possibly potential hazards?

And then the fifth question, we can't talk about setting criteria without discussing sampling plans. So the fifth question to the Committee as part of the charge was to look at various sampling plans that are available and determine how these sampling plans might be utilized by the Department of Defense.

So they also recommended a -- an approach to us. This was a very broad charge and we're actually very hopeful that we'll be able to narrow the focus of

this charge during this meeting so that we can better address their needs. But they (the DOD) have suggested that we review a number of criteria that have already been set by other national and international organizations. So we spent a good deal of time in our first meeting reviewing some of this information.

And so as we reviewed -- again, we did a review of the recommended criteria, as well as some others that some of the subcommittee members brought to the table, and then we did -- decided as a group to establish some specific food group categories that we could use to kind of wrap the criteria around. We then, once the subcommittee was in agreement on the food categories we would use, we divided into working groups to address the specific questions that had been posed.

Just a quick overview of the basic food categories that we identified were ready-to-eat products that were processed for lethality, for example, processed meats, poultry, eggs, hot smoked seafood products, and cooked frozen fruits and

vegetables. The second category was ready-to-eat combination products that may have had some raw ingredients and some processed ingredients, and then raw ready-to-eat products, such as bagged salads, raw molluscan shellfish, whole raw fruits and vegetables, sprouts, cold smoked seafoods, and raw fruits and vegetables. And then the last category was non-ready-to-eat products, such as beef, pork, poultry, and seafood.

The first work group that was established was to look at the processing considerations. And basically, that group designed flow diagrams for processing of each of the food commodities in the categories that had been developed. That group established a flow diagram that identified the steps within each of the processes where controls might be put into place and where criteria might be developed.

Now, the second work group was to address Questions 2, 3, and 4, that basically talked about indicators, both those that are currently used by DOD, as well as those that may be new, that could potentially be used. That group did quite a bit of

work, and I was not a member of that work group, so I can't get into detail, but they've established a -- well, let's see -- they reviewed a lot of the literature that was available and they've established a table looking at applying the criteria developed by these different groups to the commodities that had been identified.

And the third work group was to look at sampling plans. We had -- that was a very small work group, but they did a great deal of work and they've established a table that looks at different sampling plans and how they could be used within the food commodities identified.

We're very happy to have Dr. Jeffery Kornacki and Dr. Skip Seward as our new subcommittee leaders, and we look forward to working with them. Those of us who were on the previous subcommittee will be here to provide whatever assistance, but we look forward to looking at some new possible direction, and narrowing the scope of the charge. In talking with these two gentlemen, it looks like one of the things that they would like to accomplish this week is to go

back and review some of the food categories that were identified and look at the processing flowcharts to see where we need to go from here, as well as to review some of the historical data that has been provided to us by the Department of Defense, and to identify and review updated literature. They've pointed out that some -- obviously, this charge has been around for a long time and maybe some of the data that we have is outdated. So we want to spend some time this week trying to update our resources.

And I'll close with a slide I borrowed from the Department of Defense when they initially gave us this charge. And I -- for those of you who can see the slide, might be able to see that there is an indicator of a lack of process control present in this slide. And if you can't see it, there seems to be a frog in this bag of lettuce.

(Laughter.)

MS. RUPLE: And with that, I'll entertain any questions.

MS. RANSOM: Okay. No questions for Angela. Thank you very much, Angela, for a comprehensive

report on your charge, and we look forward to the restart of this work. And thank you, Drs. Skip Seward and Jeff Kornacki for agreeing to chair this subcommittee. Are you guys willing to stand up? Skip is standing up.

(Laughter.)

MS. RANSOM: All right.

(Applause.)

MS. RANSOM: Okay. At this point, I want to ask, are there any questions at the table or any from Committee members or experts for any of the speakers today? Okay.

DR. LABUDDE: For Mr. Schroeder --

MS. RANSOM: Robert, Robert you have a question for?

DR. LABUDDE: Mr. Schroeder.

MS. RANSOM: Okay. Carl.

DR. LABUDDE: You mentioned that you have a vast quantity of testing data, which includes indicator organisms and pathogens, for meat products at least, that go back several years. Is any of that data available for review?

DR. SCHROEDER: That's a very good question. The short answer is, not publicly as of this minute. However, we're working on hopefully posting those data to our website very soon. That's a decision we hope is made shortly. I don't know if they will be or not. There are some legitimate concerns from our vendors about -- for some of our programs, we only have two vendors, and so it's not that difficult to piece together who Vendor A and Vendor B is. But with all that said, I think its -- or we at AMS think it's in the public interest to make those data available so that we shed light on it and everybody can use them for risk assessment or policy creation, or whatever. And I also think they tell a very good story. When we look at those data, the number of pathogens we see and the process control indicator organisms all indicate that the vendors that produce for AMS are producing a very microbiologically safe product.

DR. LABUDDE: As a follow-up, has AMS published any summary reports of this data that would indicate, for example, the connection between indicator organisms and pathogens on --

DR. SCHROEDER: Not that I'm aware of, however, again I go back to -- I'm very hopeful that in a matter of days, if not weeks, those data will be available. And I'm comfortable in saying that even if we do not post them to our website; we would be very pleased to make them available to the NACMCF Committee to assist with your deliberations. Thank you.

DR. KORNACKI: Just a follow-up question, you mentioned, you know, the data were applicable to, I think, U.S. suppliers. Any thoughts as to how it might be applied more globally?

DR. SCHROEDER: I'm not sure. One of the requirements for the AMS purchase programs is that the product must be produced domestically. And so we have, as I mentioned, with all of our testing that we do, we have a very intense snapshot of what's going on in the industry, but all those data are limited to U.S. And I'm not sure what conclusions, if any, we could use to draw globally. But I do think it underscores though, the point of hopefully, if we get those data out and make them available to everybody, then you can look at them and start trying to form

hypotheses and draw questions about what other use they might have.

You're welcome.

MS. RANSOM: Okay. Thank you, Carl.

Okay, now, at this time, we are at the public comment period of our meeting. As I understand, no one signed up out front, but I want to open questions to members of the audience for any of the speakers today. Going once, going twice, okay, three times you're out. All right, that's the end of our public comment period. Anything else before we move on? Okay.

Now I wanted to make an announcement. Today we have heard that the *Listeria monocytogenes* telebriefing is going to be happening at noon. I know CDC is involved and the telebriefing is starring Dr. Tom Frieden, Director of CDC, Elisabeth Hagen, our Chair, and Mike Taylor, FDA, will be participating. This is going to take place at noon. We are going to get a room set up with a phone if anyone would like to listen in. So it may be possible for you to grab lunch and come back. We will keep you posted. Our

folks out front will know where this is going to take place. I don't have a location yet. Okay. All right, at this point we are now at the close of this plenary meeting. And before I close the meeting, I'd like to turn the floor over to our Vice-Chair, Mr. Mike Landa, from FDA.

MR. LANDA: Genuine thanks today to everyone who participated and my appreciation and Elisabeth's as well to all the members of the Committee and the experts who will be sharing some of their time as well as all of their expertise to assist the -- not the -- the work -- this important work and we should perhaps be more linear in sharing it.

MS. RANSOM: Okay. All right, I thank everyone today for participating and I now call this meeting adjourned at about 11:23 a.m. Thank you.

(Applause.)

(Whereupon, at 11:23 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

PLENARY SESSION

Washington, D.C.

June 4, 2013

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.

_____

MICHAEL GILMAN, Reporter

FREE STATE REPORTING, INC.