UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOODS

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PLENARY SESSION

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September 9, 2015
10:00 a.m.

Residence Inn by Marriott
333 E Street, S.W.
Washington, D.C.

CHAIR: MR. BRIAN RONHOLM
Deputy Under Secretary for Food Safety, FSIS

VICE-CHAIR: DR. SUSAN T. MAYNE
Director, Center for Food Safety and Applied Nutrition
Food and Drug Administration

MODERATOR: DR. JAMES E. ROGERS
Executive Secretariat
National Advisory Committee on Microbiological Criteria for Foods
FSIS

COMMITTEE MEMBERS:

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DR. ARUN BHUNIA
MS. VANESSA COFFMAN
MAJ BARBARA CLOUTIER
DR. PETER FENG
DR. STEVEN INGHAM
DR. MOHAMMAD KOOHMARAIE

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

COMMITTEE MEMBERS (Continued):

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DR. ROBERT LaBUDDE
DR. RICHARD LINTON
DR. GUY LONERAGAN
DR. EVELYN MBANDI
DR. PETER MURIANA
DR. ALISON O'BRIEN
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DR. ARTHUR P. LIANG
DR. MARIANNA NAUM

FSIS STAFF MEMBERS:

DR. UDAY DESSAI, Senior Public Health Advisor
MS. KAREN THOMAS, Advisory Committee Specialist

I-N-D-E-X

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

(10:00 a.m.)

DR. ROGERS: Good morning. Welcome to today's Plenary Session of the National Advisory Committee on Microbiological Criteria for Foods or NACMCF.

My name is James Rogers. I am the Executive Secretariat for NACMCF and I work for Food Safety Inspection Service of the USDA.

To start off, a little bit of technical, for the microphones, you have to push the button to speak. When you do speak, please introduce yourself and your affiliation, and then because only two microphones can be open at once, please turn the microphone off.

Okay. We're going to start today's meeting with a presentation from our Chair, Mr. Brian Ronholm. Brian, you may speak from there.

MR. RONHOLM: All right. I think this is working. It's less a presentation, then more kind of opening remarks. So good morning, everyone, and thank you very much for being here for today's plenary session.

As Jim mentioned, I'm Brian Ronholm. I'm the Deputy Under Secretary for Food Safety, and I'm the Chair of NACMCF as we affectionately call it, and this is our first full meeting of the 2015 - 2017 Committee, and I'm very pleased to be welcoming aboard 11 new members and 19 returning members and I want to thank each and every one of you for your commitment in lending your expertise to this committee.

Since becoming Chair of NACMCF, I've gained an understanding and a real appreciation --

(Microphone feedback)

MR. RONHOLM: Sorry, I want to make sure that, you know --

-- of the work this committee performs. We have an especially strong membership for this term that includes valuable and diverse expertise. This is a great fit for USDA as we work toward advancing a science-based, public health agenda.

There are no easy answers to complex problems and that is why you are all here, and that is why this committee exists. NACMCF is among the most respected scientific advisory committees because of

its extremely hard working and dedicated group of scientists and professionals.

And, it's also because the work performed in this committee goes beyond these walls. It gets directly applied and put to use across the federal government and the agencies with jurisdiction over food safety issues.

Whether it's FSIS, FDA, CDC, the National Marine Fishery Service, and the Veterinary Service Activity at DoD, we all benefit from your work.

Food safety microbiology is a complex challenge, and it's a challenge that is always evolving. As a result, there will always be work to do. So it takes a real commitment to illness prevention and to public health to address these issues. And it will take the kind of diversity of expertise and experience represented on this committee to meet such a complex challenge.

The committee was established to help build and maintain an integrated national approach to food safety, one that goes from farm to fork and one that best protects consumers.

Over the next two and a half days, you will begin working on two issues. First, effective *Salmonella* control strategies for poultry and second, virulence factors and attributes that define food borne Shiga toxin-producing *E. coli* as severe human pathogens.

Since we are restarting these subcommittees with newly assigned Chairs and a number of new members, we recognize that you will have the added challenge of reviewing past work and assessing the approach of previous subcommittees.

Both of these issues you will be undertaking can improve the way we combat food borne pathogens and prevent illness. Both can help our agencies address some very real challenges of today's food safety system. And ultimately, and most importantly, both of these studies can be used at the federal level to make decisions that protect Americans from food borne illness.

Salmonella continues to be one of the major food safety challenges in the U.S. FSIS has instituted a number of new measures and policies such

as the *Salmonella* Action Plan to address the national concern of this pathogen in our food. To better protect public health, we need more information on what makes a particular *Salmonella* strain more or less virulent to humans.

Additionally, we want to know where on the poultry carcass does the pathogen reside and what additional control steps should the Agency consider in controlling the presence and levels of the bacteria in our food. We believe there's enough expertise in this room to help.

The FDA is very interested in what makes Shiga toxin-producing *E. coli,* or STECs, virulent to humans and how it can isolate and identify virulent strains in the products they regulate. We also believe that the expertise on this committee can greatly assist with this issue.

If there's one thing that's happening across the food safety regulatory landscape and should be happening is that we are asking the tough questions. Most of you are scientists. So I'm sure you can appreciate just how important it is to seek answers to

tough questions in order to advance our knowledge and improve food safety.

In the food safety world, these tough questions include, are we reacting to food safety problems or preventing them in the first place? Are we reducing and working to eliminate the risk of pathogens before reaching consumers? Are we effective, efficient, coordinated, making the best use of our resources and using the best available science? Are we ready and equipped for the 21st century food system?

USDA and FDA and other food safety stakeholders are asking if we are doing all that we can to protect public health through food safety, and we are searching for solutions. That's why you're here this week, to help us answer those questions. We need your perspective, your insight, your ideas to make our food safety system the strongest available.

I can't emphasize enough the message I present to you today, and that is your work is critically important. It matters a great deal. It matters to the Secretary of Agriculture. It matters

to the Secretary of HHS. It matters to our food safety agencies as we work to make our food safety program stronger, and most of all, it matters to the American people who count on us to make decisions that prevent food borne illness.

The committee is a forum for sharing ideas, for getting input from everyone with a stake in food safety, and for thinking about ways to tackle challenges that we encounter along the entire farm to fork spectrum.

So thank you again for serving as a member of NACMCF. This is an important advisory role, and you have a key part to play as we build a stronger food safety system. We take your work seriously and together we have a lot to accomplish. Thanks so much for your time and for your commitment to food safety and public health, and I look forward to your work.

And now it's my pleasure to turn the floor over to our NACMCF Vice Chair, Dr. Susan Mayne. She's Director of FDA Center for Food Safety and Applied Nutrition or as we all call it, CFSAN. Dr. Mayne was appointed in her current position in January of this

year, and in her role, she leads CFSAN's development and implementation of programs and policies related to the composition, quality, safety, and labeling of foods, additives, and cosmetics.

Dr. Mayne came to FDA from Yale where she was the CEA Winslow Professor of Epidemiology and her distinguished career at Yale included two leadership positions, Chair of the Department of Chronic Disease Epidemiology and Associate Director of the Yale Cancer Center.

Now, in addition to her work at Yale, if that wasn't enough, Dr. Mayne received a BA in chemistry from the University of Colorado and earned a Ph.D. in nutritional sciences with minors in biochemistry and toxicology from Cornell, such an underachiever.

She also was -- if that wasn't enough, she is author or coauthor of more than 200 scientific publications.

So in other words, Dr. Mayne has probably forgotten more about science than I'll ever know. And if you could all do me a favor and never do a side-by-

side comparison of our resumes.

So, thank you. Dr. Mayne.

DR. MAYNE: Thank you. Okay, -- turned yours on. Okay, all right. Can you hear me? Sounds like it's working. All right. Well, thank you so much for the warm welcome. It is my distinct pleasure to be here today, representing FDA, an opportunity to partner with Brian and all our colleagues from USDA on this very important initiative. It's my first formal NACMCF meeting. So it's my real pleasure to be here.

As a new member and on behalf of FDA, I really want to begin by acknowledging all the different agencies that have participated in this really important issue, FDA, CDC, the Defense Veterinary Service of DoD, NMF, all the strong support that you've given to NACMCF, and with FSIS as the lead, helping to move things along under very difficult fiscal operating constraints, unknown budgetary cycles, as well as government closures and weather problems for travel. I experienced one of those myself trying to get to CDC for a meeting that was snowed out.

So I've learned in the last seven months that I've been at FDA, I've been learning about NACMCF. I've sat on a few of the phone calls and seen some of the preparatory work for the committee, and so today I get to really see it in action with the two subcommittees today that are going to be working on some really important issues as you heard from Brian, really important issues.

So NACMCF continues to be a very strong vehicle for external advice, by limiting the federal partner members to one per agency and having the subcommittees chaired by the external members, Alison O'Brien, Carolyn Hovde for STEC, Gary Acuff and Guy Loneragan for *Salmonella* in poultry. We can only give you our most sincere thanks for the work that you've done with regard to your leadership and stepping up to public service.

And public service is so important and, in fact, that's what brought me to the FDA. I was an academic for 27 years. I had an opportunity to participate in some of these really important policy initiatives. I was on the U.S. Food and Nutrition

Board. I loved the application of science for policy, and that's what you're doing here today, is using your knowledge, using your expertise to help make a difference, and I really applaud each and every one of you for that work.

The diversity is what's so key I think to the mission of NACMCF in terms of making it work. We've got representation from academics. We've got industry partners, federal, state. We've got consumer groups represented, and we have a wonderful diversity of backgrounds and expertise and ethnicity and gender on this committee, and that is so important in terms of achieving the mission that we want to achieve.

I want to, in addition, recognize our consumer rep, Ms. Vanessa Coffman, and the Keep Antibiotics Working coalition that's also working on behalf of NACMCF.

It is about the science. I am a scientist by training, I always rely on the science. I've seen how the science informs the policy, the work that we're doing and in this setting, that's how this group will move forward. It's not just the experts in a

given field reviewing and recommending needs for the field, but a broad perspective, a broad community of science experts working in consultation with technical experts of a given field, applicable to the charge to help us, the federal partners, the stakeholders, and the nation to assess the current state and then to plan to move forward to obtain the best, most impactful science.

And so I really want to thank all the incoming committee members for their service. I know that this is time away from your day jobs. This is busy, busy time for all of us, but we thank you for the time and for the dedication that you're giving to this work. As I said, that's how I really got interested in public policy, a service like this, that I think is so, so important and I recognize and applaud you for that.

I also want to thank the work, the hard work of the committee for some of the past efforts including the response to the questions posed by the Food and Drug Administration, the Food Safety and Inspection Service, the Centers for Disease Control

and Prevention, and the National Marine Fishery Service, and the Department of Defense Veterinary Service Activity regarding control strategies for reducing food borne norovirus infections that was chaired by Margaret Hardin and Dave Gombas, and we thank you for that very hard work.

And also, response to questions posed by the Department of Defense regarding the microbiological criteria as indicators of process control for -- or insanitary conditions. That was chaired by Skip Seward and Jeff Kornacki, and we thank you again for the hard work that goes into these various activities.

So in conclusion, I just want to say that this -- the work of this committee is incredibly important to CFSAN. It's incredibly important to the FDA. It's incredibly important to the American people. I want to thank everyone who's here today for your efforts on behalf of food safety. We are very, very grateful for all you do in your role as public servants. Thank you very much.

DR. ROGERS: Thank you, Mr. Ronholm and Dr. Mayne.

I'm very excited about opening this plenary meeting for the introduction of the two new charges. I'm also very happy to welcome the new members of NACMCF. As our returning members know, and you will learn, there's a lot of process in an advisory committee, but I beg your patience as we work our way through because your work will pay off as we receive your scientific advice and as your reports are used to apply to food safety programs around the federal government.

We will now go to introductions, and so again, please introduce yourself and your affiliations. We'll start at this end of the table, please.

DR. KOOHMARAIE: Good morning. My name is Mohammad Koohmaraie. I'm a new member. I was with USDA ARS for over 20 years and left and joined a private firm, IEH Laboratories Consulting Group in 2008. So --

DR. TAUXE: Good morning. Rob Tauxe at the Centers for Disease Control and Prevention in Atlanta. I'm Deputy Director of the Division of Foodborne,

Waterborne, and Environmental Diseases there, a medical epidemiologist.

DR. ONIFADE: Hello. I'm Tiffiani Onifade, and I come to this Board from previously serving as the over -- Foodborne Illness Investigations for the State of Florida, and now I am the Director of Food Safety for the Florida Department of Agriculture and Consumer Services, and I am new to the Board.

DR. FENG: Good morning. Peter Feng, I'm a research microbiologist with Center for Food Safety Applied Nutrition, FDA, been to FDA 27 years. I'm the subject matter expert for *E. coli* and pathogenic *E. coli.*

DR. PETRAN: Good morning. I'm Ruth Petran with Eco Lab. My role there is to lead food safety and public health efforts for our company globally and I'm a returning member of the committee.

MS. COFFMAN: Hello. I am Vanessa Coffman and I am a new member. I am also your consumer rep this year. I come from Johns Hopkins where I am a Ph.D. student. I also work for the Center for a Livable Future which is a part of the Keep Antibiotics

Working coalition and formerly I was at STOP Foodborne Illness doing policy coordination for them.

DR. LINTON: Good morning. Rich Linton from North Carolina State University. I'm a professor of food microbiology and Dean of the College of Agriculture and Life Sciences and this is my second term on the committee.

DR. INGHAM: Good morning. I'm Steve Ingham, Administrator of the Division of Food Safety, Wisconsin Department of Agriculture, Trade, and Consumer Protection, and this is my second term on the committee.

DR. LONERAGAN: I'm Guy Loneragan. I am a veterinary epidemiologist and professor of food safety and public health in the Department of Animal and Food Sciences at Texas Tech University, and I'm a returning member.

DR. RUBY: Morning. My name is John Ruby, a microbiologist by training, work for a company called JBS where I oversee food safety, and I've been there for 15 years. This is my first time on the committee.

DR. KOTTAPALLI: Hello, everyone. My name

is Bala Kottapalli. I am a senior principal microbiologist at ConAgra Foods. I'm responsible for food safety and micro programs for ConAgra products. I've been there at the company for 3 years and before that I worked for Kraft, now called Mondelez. I'm a new member for NACMCF.

MS. RUPLE: Good morning. My name is Angela Ruple. I'm with the Department of Commerce, National Marine Fishery Service, where I'm the lead microbiologist for the National Seafood Inspection Laboratory, and I am a returning member.

DR. LIANG: Art Liang with CDC. I'm a member of the Executive Committee for NACMCF.

DR. NAUM: Good morning. I am Marianna Naum. I'm the FDA liaison to NACMCF, and I am a member of the Strategic Communications and Public Engagement Group and the Deputy Commissioners for Food and Veterinary Medicine.

COLONEL HANFELT: Good morning. Colonel Margery Hanfelt. I'm a veterinarian with the Defense Health Agency Veterinary Services on my first time on the Executive Committee.

MAJOR CLOUTIER: My name is Major Barbara Cloutier. I'm a veterinarian, currently assigned with the Armed Forces Health Surveillance Center here in Silver Spring, Maryland. This is my first time on the committee.

DR. BHUNIA: My name is Arun Bhunia. I'm Professor of Food Microbiology. I'm a microbiologist in the Department of Food Science at Purdue University, and I'm a returning member.

DR. MBANDI: Good morning. I'm Evelyn Mbandi with FSIS, Office of Policy. I'm the Deputy Director of Risk Innovations and Management Staff. I'm a returning member.

DR. O'BRIEN: My name is Alison O'Brien. I am professor and chair at Uniform Services University in Bethesda, Maryland. My group has worked on STEC for a while, and I believe this is my fourth term on this committee, not consecutive, second consecutive.

DR. MURIANA: Hi, I'm Peter Muriana. I'm a food microbiologist at Oklahoma State University in the Department of Animal Science, and I'm a returning member.

DR. POST: Hi, I'm Laurie Post. I'm new to the committee. I am the Director for Food Safety and Regulatory Affairs at Deibel Laboratories. I came to Deibel after a 27 year career at Mars Global Chocolate where I was lead for microbiology and food safety.

DR. SCHULTZ-CHERRY: Good morning. I'm Stacey Schultz-Cherry. I'm a Professor in Infectious Diseases at St. Jude Children's Research Hospital where my lab specializes in influenza and enteric viruses, and I am a returning member.

DR. LaBUDDE: Hi, I'm Robert LaBudde. I'm a consulting statistician with a company called Least Cost Formulations, Limited, and I'm also a Professor of Statistics at Old Dominion University, and I'm a returning member.

DR. PARVEEN: Good morning. I am Salina Parveen, a professor in food science and technology program at the University of Maryland Eastern Shore. I teach graduate level courses in food toxicology and food microbiology and conduct research in food safety and water quality. I am a returning member.

DR. OCASIO: Good morning. I'm Wilfredo

Ocasio, and I'm Chief Science Officer for the National Food Laboratory, a testing and consulting firm based in the San Francisco Bay area, and I'm a returning member.

DR. ROGERS: Okay. Thank you for the introductions. I want to remind everyone that we will have a public comment period later on in the program. For anyone in the audience that wishes to make a public comment, please register with us at the table outside where we have a signup sheet. Each registrant will have up to 10 minutes for their remarks.

Although we're introducing two new charges today for NACMCF, we also have another list of upcoming charges. I just wanted to note for the executive committee that we will be circulating that list and bringing the list up for discussion as to what should be the next two NACMCF charges or should we add two new charges to the list.

Okay. We will move to the presentations. Our first speaker today will be Dr. Uday Dessai, the Senior Public Health Advisor of the Office of Public Health Science, Food Safety Inspection Service, the

United States Department of Agriculture. He will present the new FSIS charge on *Salmonella*. Doctors Guy Loneragan and Gary Acuff will serve of Chairs of this subcommittee. So I now turn the floor over to Dr. Dessai.

DR. DESSAI: Thank you, Jim, and good morning, everybody. Can you hear me?

Again, morning, Chair and the Co-Chair, members, old and new, and the audience.

I've been over the NACMCF operations for about 8 years and have seen how challenging it gets to handle the charges once the charge is given to a committee or subcommittee handles the charge. There are a number of things that happen in terms of even understanding the charge, and once you understand the charge, then you need to go back and forth with the agency that gives you the charge so you are in line and the committee has really understood the charge and then you gather all the best science out there to make those recommendations to the agency.

Sometimes it happens that the questions in the charge can be quite confusing and the committee

can then decide to basically go one way or the other, but explicitly stating that given the charge question, this is what we understand and we choose to go this way.

Now, why am I talking about all this, even before talking about the charges? That's because as we go through the charges and the questions, you might see now and later on that some things may be clear, some things may not be clear and that's why. This is the background that I'm providing you so you know how to really approach those questions.

Now *Salmonella* is a problem. We've heard about it. We know *Salmonella* is a problem. We know *Salmonella* is unlike any other bug, and the challenge is humongous. And, unfortunately, some size of the attribution of *Salmonella* totally, unless it switches, a million annually, comes from the products that we regulate, we as FSIS, and we have major commodities and there are some numbers which are thrown around, poultry being one of the major contributors.

So when we -- we were talking about this charge. We've been talking about this *Salmonella*

charge for quite a while now, and the charge was developed with the initial idea to have a broad capture so the committee basically can think broad and then decide which way to go, to what you're going to see today. The charge has been finally fine tuned to a species which is poultry and eventually to a few questions which are of great importance to the Agency, and there are about six questions which we'll go through.

However, things have changed. This is a rapidly changing field and things keep changing. From the time we develop the charge to now, there may have been changes. For instance, whole genome sequencing has really picked up speed and it is at a entirely different level. So if you think there are opportunities within the charge to add additional components, you can feel free to do those, but connect with the Agency, agency leadership and see that you're going the right direction.

So for having said that, let's go over a few slides here. The estimates of *Salmonella* illnesses out of the 1 million annually, about 360,000 are

supposed to be associated with FSIS regulated foods and FSIS has done a number of things to take control of *Salmonella*.

Now every action, there is a lag and then the effect is seen. So we put in place one FSIS strategic plan which ends next year, and the next one will start in 2017, and the common theme in both these charges is great science, the best available science to make regulatory decisions, that's number one. Number two is innovation. So that is with the current plan and that is with the next plan as well. Modernization, innovation, best science. So that's the theme.

Given that theme, NACMCF fits the best here because that's the function NACMCF does, providing the agencies unbiased scientific advice.

So *Salmonella* action plan which many of you are familiar with, this was put in place for a while and then, of course, last year we had our one-year report and a lot was talked about it, but the bottom line is, as a result of this action plan, we were able to get all those different things which need to be

done to control *Salmonella* and reduce *Salmonella* in FSIS regulated products.

One of that was modernization of poultry slaughter, and there are a number of activities which are coming in. For example, we're getting new performance standards. They'll be announced very soon. We've also tightened some of the existing performance standards. We are trying to capture new commodities to have new performance standards. There's a lot of activity around *Salmonella* and *Salmonella* control. So our products get safer and the Salmonellosis attribution to FSIS gets reduced.

And, of course, we've been waiting for a long time. We had those two very demanding charges. One is norovirus. The other one was DoD charge which we finally finished and finished very well despite the challenges that we've had. Those were difficult topics.

And so here is *Salmonella* charge, another difficult topic. It's a demanding topic. It's a demanding field to basically understand what *Salmonella* is, how *Salmonella* gets into poultry, how

can we control *Salmonella* and how can we demonstrate that we have controlled *Salmonella* and then move forward. So basically a demanding charge, one more demanding charge.

Going to the questions, very specific questions. We have six questions and some of the questions have sub-bullets there, but those six questions in totality try to capture what we do not know about *Salmonella* or what we partly know about *Salmonella*. So when you answer those questions, with all the available science around, nationally and internationally, other people who have worked on *Salmonella* and other systems who have controlled *Salmonella* in effective manner, when you review all that, you will be answering all that knowledge, scientific knowledge in six questions that FSIS is asking you.

The first question is about virulence. What criteria define *Salmonella* that are highly virulent to humans? Are markers serotype specific? What tools are available for continuing to identify the most virulent food borne *Salmonella*? And this may have

been rather difficult, more difficult a few years ago, but today with whole genome sequencing technology and the work ongoing and by the time you guys conclude the charge, there will be much more information that will be available on this specific aspect.

Question number 2 has three sub-bullets there. Where does *Salmonella* reside inside and on the surface of poultry and how do those populations of bacteria contribute to food contamination? We've been in *Salmonella* business for a long time, and this is a learning experience.

Discuss the locations, persistence, and resistance to interventions. I'll come back to this point in a little bit.

Discuss the latest information on ecology of *Salmonella* within or on poultry regarding the gut, cloaca, bone marrow, the heart, skin follicles, skin surfaces, lymphatic systems, immune evasion, and others. These are all the things that we thought of. There might be others that you might be able to add.

And the last bullet there is, discuss strategic -- strategies to mitigate risk factors at

these locations. And that's the challenge, and this point is important one.

I'm going back to the first bullet there. The resistance part of it is interesting, and you can see from the most recent reports on NARMS that we presented where we sample *Salmonella* in the ceca, then on the carcass or the product, and then at the end in retail. Interestingly, the resistance seems to be increasing when low in ceca, higher on the surface and the highest at retail.

So there's a challenge here to understand what's going on and a opportunity for you to inform FSIS how do we deal with this situation?

Question number 3 has two bullets there. Would removing flocks of highly *Salmonella* contaminated birds entering the slaughter plant reduce food borne illness in humans? It seems like a simple answer there, but rather complicated.

What are the important considerations to arrive at a threshold level of *Salmonella* associated with incoming birds that would necessitate additional control steps in the food safety system or HACCP plan?

And those threshold levels could be expressed as prevalence levels, for example, CFUs per gram of the feces.

What are the key considerations, steps for an alternative processing scenario if the threshold level is exceeded? This would be a important point for us to be able to make determinations in reducing *Salmonella* at every stage.

Question number 4, what would establishments who slaughter and/or process poultry consider when determining appropriate level of *Salmonella* that would necessitate additional control steps in the food safety system or HACCP plan? What are the factors that affect the threshold level and at what point of processing should measurements be made? Measurement of *Salmonella* has been a demanding kind of a issue. We've been doing measurements in terms of sometimes percent positives, prevalences, and those MPNs. MPNs are very important because numbers are important, not just the prevalence, but getting those numbers in a consistent basis in a way that is feasible to every establishment is a challenging task.

Question number 5, this is based on question number 3 and 4, so as informed by question number 3 and 4, what methods are best suited to measure pathogen levels or raw poultry -- on raw poultry and in products more rapidly than current tests? What is a sampling scenario that would enable an establishment to test incoming birds for a threshold *Salmonella* level and have a result in a timely manner so that processing can proceed as appropriate? Threshold *Salmonella* level, the committee can decide what that is. Is it going to be percent positives? Is it going to be prevalence? Or, is it going to be MPNs, the numbers that you're talking about?

Question number 6, that's the last question, that the charge has. Considering the farm to table continuum for poultry, what are the top three focus points, control measures or best practices, that would be compatible with industry-wide practices, which could be addressed or implemented to achieve the highest rate of reduction of *Salmonella* with regard to both food borne illness and on product?

Now I think you'll be spending substantial

time on this particular point here because this is the one that the Agency might be able to translate into actions to reduce *Salmonella* further beyond what we've already done.

Now on the charge, I see, of course, you know, I applaud Guy and Gary for their willingness to chair this workgroup, demanding workgroup rather, and I'd like to really applaud all the members who are participating in this charge. Some of you have participated in other charges and others, the newer members, this is the first time, and for the newer members, I want to say this, these subcommittees work 24/7, just making you aware. It's a lot of hard work. People don't even take breaks. When I was running NACMCF, somebody said, you're running a sweat shop. It wasn't me. It was just the people who were so dedicated in moving the work forward. So again, congratulations for taking on this challenging work.

Another point I just want to make here for having been on NACMCF management for over 8 years is that because of the rotation, 2-year rotation, if you are able to do substantial work in those 2 years, that

is really helpful because if you haven't done that, when the committee rolls over, there are changes that happen. You're pretty much back to, it may not be square one, may be square two. So it is very important to get most of the work, the groundwork, and put it in the form of documents so even if there's a rollover in the committee, you can -- the next committee can pick where you actually left.

So in summary, what are you going to do? What NACMCF is? Your role here has been discussed before, but what you're going to do is very, very vital and very critical for FSIS for us to be able to reduce *Salmonella* in our products, those 360,000 illnesses we are talking about. We're talking about illness rate of 15, which is right now, to about 11.4, which is quite challenging. So we depend on you to provide us those recommendations so we can bring about that change and meet our Healthy People 2020 targets. Thank you.

DR. ROGERS: Thank you, Uday, for presenting the new NACMCF charge on *Salmonella*.

We are slated to have a 15 minute break. I

have about 10:20. So we'll resume promptly at 5 minutes to 11. Thank you.

(Off the record at 10:38 a.m.)

(On the record at 10:53 a.m.)

DR. ROGERS: Okay. We're about to prepare for the next presenter.

(Pause, background conversations)

DR. ROGERS: Okay. Next we'll hear from Dr. Peter Feng, a research microbiologist for the Food and Drug Administration. Dr. Feng will introduce the FDA charge for Shiga toxin-producing *E. coli*. Doctors Alison O'Brien and Carolyn Hovde are the incoming Chairs for this project. Dr. Feng.

DR. FENG: Good morning, Mr. Chair, Madam Vice Chair, and fellow committee members and visitors. It's a real pleasure for me to represent the FDA to present this charge on Shiga toxigenic *E. coli*.

You can read on the slide, this is the main charge, the language of the charge, the virulence factors and attributes that defined food borne Shiga toxigenic *E. coli* severe human pathogens.

I've summarized the five questions that are

outlined in the charge and these are shown here. Current knowledge on the virulence and pathogenicity of STECs, methods available for STEC and virulence testing, criteria for assessing severe health risks, and criteria for distinguishing STEC pathogens from non-pathogens, and finally, data gap for molecular risk assessment.

Instead of going through the charges in detail, what I've done is I've prepared a presentation kind of summarizing or kind of covering a lot of these questions that are outlined in the charges, and then to illustrate the complexity of this whole world of pathogenicity, risk assessment, and STEC, using a situation I go through almost every day, the presence of STEC in fresh produce, which is a area of primary concern for the FDA.

So this is a diagram showing the pathogenic *E. coli* groups that we know of. All these pathogens are classified or grouped based on virulence factors, but you're going to see very quickly that this is a very misleading diagram and that's because most of the virulence factors that are carried by pathogenic *E.*

coli are mobile genetic elements, so they can be transferred. A horizontal transfer will disseminate these virulence factors to other groups and so there's a lot of overlap in pathogenicity.

But there's one common theme that all these pathogenic *E. coli* have and the common theme is they have to be able to enter the body which is usually by ingestion. They have to be able to adhere to intestinal epithelial cells and then elaborate the virulence factors that they produce.

So let's focus on Shiga toxigenic *E. coli* which is a topic of the charge. Shiga toxin-producing *E. coli*, or also known as STEC, the only criteria to be classified as an STEC is the production of Shiga toxins. There's roughly somewhere around 300 serotypes of STEC that are known and if you, you know, read some other authors such as Mora from Spain, he said there's 472 serotypes of STEC that are known, that have been recorded.

Two main type of toxins, Shiga toxin 1 and Shiga toxin 2. Toxin 1 is also known as 1a, phage-encoded, identical to the Shiga toxin for use by

Shigella dysenteriae type 1. Two variants exist in *E. coli*, there's 1c and 1d. Toxin 2, also known as 2a is also phage-encoded, is more often implicated in severe disease such as HUS. Many variants in type 2, you have 2b through the 2g.

Okay. 2d is a very interesting toxin. 2d is used to be known as 2d activatable because this toxin can be activated by elastase in the human mucus and it becomes 10 to 1000 times more cytotoxic for Vero cells.

Not all these subtypes seems to affect humans. The ones that are implicated most often in severe diseases are 1a, 2a, 2c, and 2d.

Okay. Some like 1c is the most common serotype found in STEC isolator from sheep and the infections a lot of times, 1c, are asymptomatic from very mild diarrhea.

Also we know that Shiga toxin without an adherence factor seems to be insufficient to cause severe diseases, and many of the STEC of the 300 and some serotypes do not seem to carry known adherence factors and I put known in question mark because

there's so many other adherence factors that we're not aware of.

Okay. So in the end, not all STECs are -- seems to be pathogenic for humans, but some estimates around 50 to 100 serotypes are -- can be considered as pathogens.

Enterohemorrhagic E. coli on the other hand is -- represents a pathogenic group and this is a pathogenic subset of STEC and all these guys do have adherence factors, the primary adherence factor being intimin protein encoded by the *eae* gene that's located on the LEE pathogenicity island. Prototype O157:H7, but there are many, many EHEC serotypes.

Many definitions have been proposed for EHEC. The simplest one is simply an STEC with intimin, a STEC with adherence factors. There's around 30 *eae* alleles or generic variance of *eae* but *eae* is also a virulence factor in pathogenic *E. coli*. So it's a shared virulence factor.

But being Mother Nature, there's also always exceptions. Serotype such a O113:H21, O91:H21, the O104s, the O104:H4 that caused the big outbreak in

Germany 4 years ago, they do not produce *eae* or they do not produce intimin, but their EHECs have caused HUS. So it's postulated that these *eae (-)* strains have other means to be able to adhere to intestinal epithelial cells.

Another definition of EHEC is simply an STEC that has been implicated in severe diseases, namely hemorrhagic colitis or hemolytic uremic syndrome, and the third definition is an STEC with the same clinical, epidemiological, and pathogenic traits.

These are very complete definitions, but the problem when we work with foods is, when we isolate an organism from food, we know it's an STEC because you have Shiga toxin genes, but we have no benefit of symptoms or clinical data.

So the dilemma we have is we really don't know whether we have a STEC on our hands that may be non-pathogenic or we really have an EHEC that's going to cause severe disease in humans.

And because the virulence factor, Shiga toxin, is carried in the phages, and there's a lot of horizontal gene transfer going on, there are many,

many other organisms that have been found that had the capability to produce Shiga toxins. The *Dysenteriae* type 1 used to be the only *Shigella* that produced Shiga toxins and this is where the name Shiga toxin came from, but then there has been isolation of *sonnei* that caused diarrhea in Germany, a bloody diarrhea in Finland, *flexneri* carrying -- producing Shiga toxins have been isolated in Haiti and Dominican Republic.

E. coli, of course, we have over 300 serotypes of STECs, but there are many hybrid organisms. For instance, the strain that caused the HUS outbreak in Germany is a hybrid of enteroaggregative *E. coli* that had acquired the ability to produce Shiga toxins. So it's a hybrid of EAEC and STEC.

We have looked at several all nontypeable H52 strains that have been isolated from commodities like cilantro, cantaloupe, and also raw milk cheeses and these are hybrids of enterotoxigenic *E. coli* because they carry, you know, the stable toxin genes of ETEC and also Shiga toxin 1 from STECs. These are hybrids.

And recently I read of O26:H6 strains which are hybrid of STEC and extraintestinal pathogenic *E. coli* which is commonly associated with urinary tract infections. So it illustrates that the mobility of this virulence factor is non-pathogenic *E. coli*.

Other like enteric organisms, E*nterobacter cloacae* have been known to produce Shiga toxin and cause HUS in Germany, Australia. You have *Citrobacter freundii* that produce Shiga toxins, *Aeromonas veronii*, *Acinetobacter haemolyticus*, all these have been known, documented to produce Shiga toxins.

So one speculation is that people have found very high titers of Shiga toxin phages in sewage. So one speculation is that a lot of these other organisms are acquiring the ability to produce Shiga toxins by infection through phages as they transit through the human sewage.

So in essence, what we have, the real picture of Shiga toxin-producing *E. coli* is we have -- the large circle represents Shiga toxins, okay, the many types we have. We have *eae* gene which is the being adherence factor which is shared between EPEC

and EHEC. We have O157:H7 in the middle. We have *eae (-)* EHECs that are known to cause HUS, and we have a whole bunch of other organisms include ETEC, ExPEC, and EAEC that also have the ability to produce Shiga toxins. Okay.

Don't get the impression that these things are common. They are very, very rare, but they have been documented to exist.

Okay. The complexity of the non-O157 STECs, it is over 300 serotypes known. To make it very, very complex, the regional variation importance. In different regions of the world, don't seem to have problem with some serotypes, others do. For instance, Australia, O157:H7 doesn't seem to be a major problem, but in the U.S. and Europe, it is a major problem.

So over the years, you know, different regions have kind of elaborated their own serotypes of concern. In the European Food Safety Authority, they came up with what they call the Big 5, which comprise of these five serotypes. After the O104 outbreak with fenugreek seeds, they added O104 to their sprouts regulations. So it's a Big 5 plus the O104 strain.

I then heard of a Big 9 term used which comprised of these nine serotypes and this has also appeared in Europe.

In the U.S., FSIS, in 2001, designated the Big 6 as the -- and these are the six serotypes that have been designated. O157:H7 remains to be a top priority of concern, health concern.

The one thing about focusing on serotype is we're actually dealing with a situation of Big X because you really don't know what are the serotypes are going to pop tomorrow and cause problems and this is exactly what happened with O104:H4 because it was on nobody's radar and it just popped out and caused the largest HUS outbreak in the world.

Regardless of what serotypes people focus on, the testing strategy is essentially the same. Most people use sequential multiplex PCRs to test enrichments. Usually the first run enrichment they'll test for Shiga toxin and *eae* and if those are positive, they'll come around with a second round which tests for specific serotypes. All this is done by PCR.

The limitation of this strategy is you're using a multiplex assay. In other words, you're testing multiple targets in a sample that contains mixed flora, okay. So it's not uncommon that each of the positive signals that you get on your testing are actually coming from different cells. So you can have one cell that give you the Shiga toxin signal, another cell that give you *eae* signal, another one that gives you the O type signal. Okay.

And that basically forced us into the need to confirm where we have to go through very laborious procedure to isolate and verify that all the targets are within the same cell.

To give you an idea how complex this procedure is, in the O145 outbreak in romaine that -- romaine lettuce that happened a couple years ago, one of the labs that isolated the pathogen from the Romaine lettuce actually spent the whole weekend in the lab and screened through over 70 colonies before they actually found the organism. So it's a very labor intensive procedure.

Another problem about the limitation in this

testing strategy of focusing on Shiga toxin, *eae*, and O types, of course, is you're going to miss *eae (-)* EHECs like O113, O91, O104. Okay.

Each of the O types have many H types, okay, and not all these H type had the same health concern. To give you an example, O157:H7 obviously is a health concern, but the O group also -- the O157 O group also has H3, H12, H16, H38 and so forth and these, a lot of them are not regarded as a pathogens. Another example is the O91 group. O91:H21 is a health concern, but H10, H14 probably less of a health concern.

How about Shiga toxin positive *eae* (+) STEC, but not part of the Big 6 or Big 5. You know, some people advocated we're going to release these products. Personally I think if you have a strain that has Shiga toxin and adherence factor, that's probably a danger factor. It's probably playing Russian roulette if you're going to release that product. Okay.

We know that not all Shiga toxin subtypes affect humans. So are we going to start testing for Shiga toxin subtypes? And that's a very elaborate

process because there are three Shiga toxin 1 variants and seven toxin 2 variants.

We know there's 30 *eae* alleles. Are all these virulent for humans? We really don't know. So that's certainly a data gap, okay, and if we have to start subtyping for the *eae* alleles, that's going to be a humongous task for the analysts.

And lastly, when we focus on specific serotypes, we're going to miss others that are maybe found in foods. To give you an example, a couple years ago, there was a isolate of O113:H21 that was found in a cilantro sample from the supermarket, and we've decided to take regulatory action on that sample. So, but focusing on specific serotype, what are missed on that one?

So the premise that FDA really operates on is based on the law which is outlined in Section 402(a)(1), which states that food is considered adulterated if it contains substances that are injurious to health.

So to expand that, the position that we're kind of working on is that the presence of pathogenic

STEC in food is a health concern. The difficult part, of course, is how do you determine pathogenic, which brings me to the topic of health risk. This is what, you know, part of the charge of -- to the subcommittee, okay.

I firmly believe that nothing in this life is risk free. So in that sense, all STEC I think have some sort of risk. So instead of defining them as non-pathogenic STEC or pathogenic STEC, I tend to prefer to use the term low risk or high risk STEC because I think all STEC, you know, if -- even a strain that's non-pathogenic to one individual, if it's infected into a immunocompromised individual, then they get symptoms. So I tend to prefer low risk versus -- and high risk.

Now some of the strategy has been proposed years ago by Dr. Karmali when he came up with the seropathotype scheme of doing risk assessment, namely incidence of illness, severity of illness, and what serotype is involved. Okay. It's a pretty logical approach to determine risk, but there were a lot of holes and it didn't really fit in many situations.

So I think risk-free certainly is not attainable in our business, but I think the best we can do is to minimize the incidence of severe risk, in other words, hemorrhagic colitis and HUS. So that's the best we can do.

Some known risk factors we can say about STEC. First of all, Shiga toxin and *eae* is a very good predictor that the strain may cause severe disease such as hemorrhagic colitis and HUS. We also know that some -- only certain Shiga toxin subtypes causes illness, a severe illness: 1a, 2a, 2c, and 2d. We know that Shiga toxin without adherence factor is not enough to cause severe illness. This much we know.

The known factors, however, is the human factor because different people have different susceptibility to pathogens, okay. I've heard of -- or read about instances of identical twins getting infected with the same strain, one child came up with symptoms, one did not.

And then very recently I read this article about a O78:H- strain in Finland produced Shiga toxin

1c which is not one of the toxin subtypes that are usually associated with severe disease. The strain didn't have adherence factor. So normally you would not consider this to be a health risk strain. It was isolated from the feces of all five family members, okay, the parents and all the siblings, totally asymptomatic. The two-year-old came down bacteremia, bloody diarrhea, HUS. So the human factor is bigger known in our business in determining health risk.

So people have been -- people that work with Shiga toxigenic *E. coli* have always been trying to come up with some handles or to determine health risk. So there was a meeting held by the Canadian Food Inspection Agency in Ottawa about 5 years ago, and a couple of thoughts emerged from that meeting.

One of the proposal was based on virulence factors and serotype, okay. And the group, we basically decided the toxin 2, but not 2e, 2f, or 2g, adherence factor *eae* and certain O types, and because there was also a very large European contingency, we couldn't agree on the serotypes. So we decided to stick, in the U.S. we'll go with the Big 6, in Europe,

they're going to stick with the Big 5.

Another proposal was made by the Danes and this is based only on virulence factors. 2a and/or 2c plus adherence factors is considered a severe health risk. 2d by itself, and that's because 2d has been by itself has been known to cause instances of HUS. Toxin 1a and *eae* only some serotypes, not all the serotypes.

If you look at all these proposed criteria, some key risk factors emerge, risk adherence factors, Shiga toxin subtypes, and also serotype of the organism, and I will also borrow from Dr. Karmali seropathotype classification, I think the history of having caused severe diseases is also an important factor.

So how applicable are these proposed criteria to real life situations? And I'm going to show you that with produce, which is one of main concerns.

Now here's a real Hallmark card that was sent to me by a friend. Here's we have Mr. *E. coli* who sells vegetables. So his store is called *E. coli*

Vegetables and he can't understand why his business so lousy.

Now this card 20 years ago would not have been funny because if you tell people that eating fresh produce is dangerous, people will say you're crazy, okay. Unfortunately, it's a real problem we have today because one statistic I read said that the fresh produce market in the U.S. is somewhere around $3 billion a year, if you break that into cost, somewhere around 2.7 million bags of salad or fresh produce sold every day in the United States, and that's a huge, huge market.

We know produce is very complex microbiologically. These are just a list of some of the survey studies that have been done. Typically total bacteria count can be in the range of a million to 10 million per gram. That's very normal. Coliform count usually is around over 10,000. *E. coli*, however, doesn't seem to be a common organism in fresh produce. Here's a couple large surveys done in the UK and only .5 percent of the samples had over 100 *E. coli* per gram.

In the U.S., we have done a couple studies. We have 16 percent of the samples to have *E. coli*, but all of them were less than 10 organisms.

But there are some exceptions. You see the study from Brazil, that looked at 133 salad samples, 73 percent of the samples had fecal coliform over 100 organisms per gram. So if you're thinking about going to Rio for the Olympics next year, be careful with their salads.

Now UK does have a limit for indicator organisms in produce. Less than 20 is acceptable, 20 to 100 marginal, greater than 100, unsatisfactory. In the U.S., we have no indicator limits for fresh produce. So we only regulate based on presence of pathogens.

We know pathogens also exist in fresh produce, and the largest publicly available database on pathogen produce is probably that generated by USDA Microbiology Data Program. I was advisor to this program for about 6 years, and they -- this is the samples, the type of produce they looked at, okay, broken down per year. An average around 10 to 15,000

samples were tested for *Salmonella*, O157, ETEC, and STEC. Unfortunately, the program was succumbed to budget cuts in 2012.

So I started to keep tab on STEC isolation from produce working with this group, and you can see that in the first initial years, only a handful of STEC were isolated and mostly from this type of products. Okay. Nothing real significant.

2008, they added spinach and this is as a result of the 2006 spinach outbreak with O157:H7 and you can see the numbers started going up and often associated with spinach. 2009, 12 out of the 13 came from spinach, 14 out of 30 came from spinach, and so forth. So assuming that estimated around 2200 samples of spinach tested per year, you essentially come up with a prevalence rate between .5 to 1 percent in spinach.

If you tabulate all STEC isolations based on commodities, it's more obvious, 70 out of the 132 STEC isolated from produce came from spinach. So somehow there seems to be an STEC in spinach connection because we don't see this with incidence of *Salmonella*

or ETEC. So something about spinach and STEC that we haven't quite figured out.

When we're working with the -- doing sample analysis, this little leaf of baby spinach tumbled out of a bag that was labeled triple washed, and you can see all this brown stuff caked over it. So triple wash does not guarantee that it's clean.

So how well did this STEC fit the health risk criteria that was proposed? Well, if we go with the FSIS Shiga toxin, *eae,* Big 6 plus, because it includes O157:H7, 7 out of the 132 organisms fits the 4 - O157:H7, the O121 strain, and 2 - O26 strain that produced Shiga toxin 1.

The European Food Safety Authority criteria of toxins, *eae,* Big 5, only six of them fit.

From the Canadian study, Proposal A, toxin 2, *eae*, Big 6, only 5 of them fits because the 2 - O26 is only produce Shiga toxin 1. So they dropped out. Same thing with the EFSA Big 5, you -- only the 4 - O157:H7s fit.

Proposal B, which is based on virulence factors, toxin 2, *eae*, the 2 - O165:H25 strains fits

the criteria because they produce both toxins and they have *eae* adherence factor. 1a and *eae*, 4 isolates fit, O26 is certainly pathogenic but these two other guys is uncertain.

Then Shiga toxin 2d alone we had actually found 15 out of the 132 isolates to produce Shiga toxin 2d alone, but there are various serotypes and many of these are nontypeable.

So to pursue further about the virulence or the virulence potential of the 2ds, as I mentioned, 2d is mucus activated to become more cytotoxic and it has been implicated in HUS.

In collaboration with Angela from Alison O'Brien's lab, we studied 14 of these 2d alone strains from produce and found that 6 -- that these had 6 to 21 times activation on mucus. So these are activatable toxins. Six out of the nine strains that we examined by mouse had 20 to 60 percent lethality on streptomycin treated mice. So it certainly suggests pathogenic potential.

With the sequencing, however, 6 of the isolates had *Shigella* type antigens, B9. Only this

strain O181:H49 had a history of human isolation. Rest of them had no incidence of human isolation or causing outbreaks. So it's really difficult to determine whether these guys are really virulent or not or can cause severe disease or not.

EHECs that did not fit criteria, there were 5 - O113:H21s and 1 - O91:H21s, all isolated from spinach that were not describing any of the proposed criteria. Also 50 percent of the STEC strains only had partial serotype or untyped.

So the bottom line is we had over 100 out of the 132 STEC strains. They are STEC because they carry Shiga toxin genes, okay. They had other putative virulence factors like enterohemolysin, STEC agglutinating adhesin, Sub A/B and so forth, but it was really difficult to determine whether these are truly health risks to cause severe diseases.

So bottom line is that most of the STEC were isolated from produce. It was extremely difficult to make health risk decisions.

Now there are many, many putative virulence factors that, you know, people have been looking, you

know, for years trying to get a better handle on what are the critical virulence factors, and so there are many, many putative virulence factors that have been proposed.

Enterohemolysin is a very common one that's found in a lot of the strains that cause severe diseases. We know it's a mechanism for the bacteria to acquire -- but its role, precise role in pathogenesis is really uncertain because there are some very pathogenic strains that do not express enterohemolysin. It's also found in ETEC, atypical EPEC, and also generic *E. coli* has been found to produce enterohemolysin.

STEC agglutinating adhesin is a very common gene in strains that do not have -- do not produce *eae*, okay, but as time went on, it doesn't seem to show any close association with HUS. Others like subtilase cytotoxin, it's a very potent toxin, even more cytotoxic than your Shiga toxins. Okay. But it's not found in all *eae* (-) strains and so, you know, most people say we need some more EpiData to determine the health risk of illness.

Then others, you have sab, you have non-LEE effectors, espP, cytoskeletal [sic] distending toxin, and so forth. So there's a whole battery of these putative virulence factors that we're going to have to examine to see whether they're truly involved in pathogenesis.

So I'm going to skip through the next few slides which I'm going to present to the subcommittee and then jump to the last slide which is going back to the charges, okay.

Current knowledge on virulence and pathogenicity of STEC. Well, we do have some current knowledge. We know Shiga toxin adherence factors are important, okay, but we don't think that's the whole picture, especially for the *eae* (-) EHECs. You know, these guys had to have some sort of -- to be able to adhere and we don't know quite what that is.

Are methods available to test for STEC and virulence testing? Absolutely. But these are very tedious because we need to isolate and confirm. Okay.

Criteria for testing severe risk. Many have been proposed, but as shown by the example with

produce, they're not always very effective.

Distinguishing between STEC pathogen, non-pathogens, it certainly exists, but there is uncertainties, namely human factor.

And lastly, data gaps for doing risk assessment, many, many, many putative virulence factor has been proposed, okay, but we have to also make a distinction that *eae* (+) and *eae* (-) strains, you know, tend to have virulence factors that aren't -- that are not shared.

So this is essentially a very quick summary of the complexity of dealing with STEC, you know, in the commodities that are regulated by FDA. Thank you.

DR. ROGERS: Thank you, Dr. Feng, for your comments on the STEC charge.

Okay. We're in the section of our program where we can have public comments. I want to remind you that the comments will be limited to 10 minutes. If there is anyone in the audience that would like to make a public comment, you'll have to come to the front podium microphone and please remember to state your name and affiliation.

Okay. So it seems like we have no public comments for this meeting.

So we're at the close of this Plenary Session. I saw Mr. Ronholm has left. He usually closes the Plenary as the Chair. I will give him like 30 seconds, and then I will step in.

DR. MAYNE: We have 30 seconds?

DR. ROGERS: Thirty seconds.

DR. MAYNE: Okay.

(Pause/background conversations)

DR. ROGERS: Okay. Seeing that he has not reappeared, since I do have his comments, we would like to thank everyone who participated today, and we offer our deep appreciation to the members of the committee and the experts who will share their time and scientific expertise that will assist us in the work of NACMCF.

As Executive Secretariat, I now call this meeting adjourned. Thank you for your attendance.

(Whereupon, at 11:25 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.

September 9, 2015

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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