NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS (NACMCF)

Virtual Advisory Committee Meeting

held on

Tuesday, November 14th, 2023

via WebEx

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WHEREUPON: (10:03 A.M.)

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DR. KRISTAL SOUTHERN: Good morning, everyone. Welcome to the plenary meeting of the National Advisory Committee on Microbiological Criteria for Foods, commonly referred to as NACMCF.

My name is Dr. Kristal Southern. I work at the USDA Food Safety Inspection Service where I serve as the Designated Federal Officer for NACMCF and the Director of the National Secretariat.

I recognize that we have 24 committee members present which means quorum, and I now call this meeting to order.

NACMCF provides impartial scientific advice and recommendations to the Secretary of Agriculture through the Undersecretary for Food Safety and to the Secretary of Health and Human Services.

The committee covers public health issues relative to the safety and wholesomeness of

the US food supply.

The committee also provides scientific advice and recommendations to the Department of Commerce and Defense.

The NACMCF has made important contributions to a broad range of critical food safety issues. For example, the previous committee from the 2021 to 2023 term completed the response to the USDA FSIS charge on enhancing Salmonella control in poultry products.

The report responds to questions posed by the Food Safety and Inspection Service enhancing Salmonella control in poultry products and was adopted in November 2022. In this report, it included nine recommendations to USDA. It was recently published in the Journal of Food Protection, and it's also available online on the FSIS NACMCF webpage.

This report from NACMCF is one of the key activities to gather the data and information necessary to support future action and move closer to the national target of a 25 percent reduction

in foodborne Salmonella illnesses.

In addition, the 2021 to 2023 committee completed the response to the FDA charge on Cyclospora cayetanensis in produce. The report responds to questions posed by the Food and Drug Administration. Cyclospora cayetanensis was adopted on August 30, 2023. This report included four recommendations to FDA. You can also find this report on the FSIS NACMCF webpage.

At today's meeting, we will introduce the new NACMCF membership for the 2023 to 2025 term.

Additionally, FSIS will introduce a new charge to the committee on genomics and the Food and Drug Administration will reintroduce the Cronobacter species in powdered infant formula charge so that this committee can continue the work started by the previous committee.

Before we dive in, I wanted to provide a few housekeeping items to keep in mind as we move forward.

First, please note that this morning

plenary meeting is being recorded. FSIS will post the recording and transcripts when they become available on the FSIS website at www.fsis.usda.gov.

This is a virtual meeting and with the exception of our committee members and designated speakers, your microphones are automatically muted when you logged in, and you will not have the ability to use your camera during the meeting.

A sign language interpreter will be present for the duration of the meeting. In addition, closed captions can be enabled by clicking the closed caption or CC bubble in the bottom left of your screen.

If during registration, you indicated that you wish to provide oral comments and confirmed your intent to do so via a follow-up e-mail from the NACMCF secretary, I will call on you during the respective comment period. The event producer will provide additional instructions when we reach that point in the agenda.

And lastly, the chat feature is available for all attendees, and any comments made in the chat will be shared with the committee after today's meeting. Attendees may also submit written comments according to the options and directions outlined in the Federal Register Notice announcing this meeting. These comments will also be shared with the committee when they become available.

I will now turn it over to the USDA Undersecretary for Food Safety and NACMCF Chair, Dr. Emilio Esteban for opening remarks, followed by remarks from the Food and Drug Administration's Acting Director of the Center for Food Safety and Applied Nutrition and NACMCF Vice Chair, Dr. Donald Prater.

Welcome, Dr. Esteban.

DR. EMILIO ESTEBAN: Thank you, Kristal, and good morning to all of you. A special welcome to the standing committee members and, of course, all the new members of this committee. Welcome to this session of NACMCF.

I want to thank you for sharing your expertise to his -- with this body. We look forward to hearing your recommendations. I can tell you that the Secretary and myself value your input tremendously and so, we hope that you can help us advance food safety in the United States.

As you heard from Kristal, during this session, we're going to reengage on discussions with Cronobacter, which has been very important to the United States and for the world. And so, we're looking forward to the deliberations on Cronobacter.

The other charge is one that is being introduced and has to do with genomics, and I am particularly interested in that one because when I was in a previous role as chief scientist for the agency, we introduced this technology into the FSIS laboratory system, and we've been very successful in implementing it operationally and we are now asking you, our advisory committee, with some guidance and input as to how we can best use this new technology and information to control

microbiological challenges that we have in our food supply. We want to, of course, minimize any public health risk.

I really look forward to the discussion ahead and both the USDA and FDA rely on you to provide us with the evidence-based information to control our pathogens and prevent illnesses.

Thank you again for being here today and some of the members I've been working with for a long time and some of the new members, I'm glad to see you're here to provide input. Thank you very much.

And now, I guess I will pass it on to the co-chair, Don Prater. Don, the floor is yours.

DR. DONALD PRATER: Well, thank you very much, Emilio, and I just want to also add my welcome to everyone. So, sorry that I'm not able to use my video today, but certainly, it's great to hear you all and want to be sure to welcome everyone to the meeting.

As most of you know, this committee has provided us with science-based advice for decades, and this support has been invaluable in helping us to carry out our public health mission.

Some of you may also know that that we have just welcomed our new Deputy Commissioner for the Human Foods Program, Jim Jones, to FDA. So he's very interested as well in following the work of this committee.

So I want to thank you all, all the previous committee members for all the hard work that you've done, all the new committee members for the hard work that you will do. I recognize that it takes a lot of your valuable time. But we certainly appreciate it and it helps us greatly in our food safety mission.

In addition, welcoming the new members on the committee, I understand about half of the current members are new at this point and so I want to just recognize the fact that we have a wealth of experience and a diversity of perspectives, which will greatly help the

committee's work.

I also want to take time to thank the executive secretarial staff, who are so critical and making sure that everything works smoothly, including today's meeting.

As Emilio mentioned, we have two important topics to discuss. So today -- later today, we'll hear about the different charges, including the whole genome sequencing charge to rank foodborne microbial pathogens on risk and better focus our resources to address those risks.

We recognize that FSIS leads this charge, but this topic is very important to FDA as well.

Whole genome sequencing is one of the most groundbreaking technologies that we have to advance food safety. Not only are we using it during our investigations to more precisely identify the cause of an outbreak or contamination event, but we are increasingly using this technology to drive our prevention efforts.

We're also pleased to get an update

from the subcommittee that's been working on FDA's charge regarding the prevalence of Cronobacter in powdered infant formula, as well as other foods in the environment. As you know, we turned to NACMCF after a series of Cronobacter illnesses among infants in the US, and we are already using the information we received so far from the committee and look forward to receiving additional information on the questions that we posed. This is critical to our ability to prevent future illness.

So you'll hear more about these charges later. But again, I just want to add my welcome and thanks for your ongoing commitment and dedication to food safety.

So let me turn back to Dr. Kristal Southern.

DR. KRISTAL SOUTHERN: Thank you, Doctors Esteban and Prater.

The NACMCF Executive Committee consists of the Chairperson, Vice Chairperson, the NACMCF Secretary and representatives from agencies

with an interest in food safety, including USDA FSIS, Food and Drug Administration, Centers for Disease Control and Prevention, the Department of Commerce and the Department of Defense Veterinary Services.

The Executive Committee helps to ensure that NACMCF is in compliance with the Federal Advisory Committee Act regulations and provides guidance, support, and assistance on processes required by USDA and FSIS.

They also provide advice on membership appointment and approve the final charges of the committee.

You just heard from our Chair, Dr. Emilio Esteban, and Vice Chair Dr. Donald Prater.

I now want to recognize other members of the NACMCF Executive Committee.

From the Food Safety and Inspection Service, our liaison is Dr. Denise Eblen. Our liaison from the Food and Drug Administration is Dr. Eric Olson. Our liaison from the Department

of Commerce is Dr. Jon Bell. Our liaison from the Department of Defense is Colonel Alisa Wilma, and our newest committee member is our liaison for the Centers for Disease Control and Prevention, Dr. Megin Nichols.

I also want to recognize two members within the Secretariat from USDA FSIS, our Director within -- one of our directors and within the Office of Public Health Science, Dr. Evelyne Mbandi and Deputy Director also within the Office of Public Health Science at FSIS, Dr. John Jarosh.

So, thank you all for your support and leadership.

NACMCF members are appointed by the Secretary of Agriculture through a rigorous process that helps to ensure that membership is fairly balanced. Committee members are chosen based on their expertise in microbiology, risk assessment, public health, food science, and other relevant disciplines in order to obtain the scientific perspective, experience, and point of view of all stakeholders. It is an honor to be

appointed to the NACMCF.

The 2023 to 2025 NACMCF committee consists of thirty individuals. This includes twenty-four scientific experts representing academia, industry, and state or local health department, one individual affiliated with a consumer organization to serve in a representational capacity, and five federal employees representing the agencies on the executive committee.

We're incredibly thankful to the members that provide this scientific advice to our federal agencies involved in food safety, and we're now excited to introduce the members of our 2023 to 2025 committee.

I will now call on each member to introduce themselves by stating their name, job title, and affiliation. And we'll start with Dr. Bledar Bisha.

DR. BLEDAR BISHA: Hello, everyone. It's an honor to be here. My name is Bledar Bisha. I am a food safety microbiologist and I

serve as an associate professor and department head at the Department of Animal Science University of Wyoming, Laramie, Wyoming. I work on emerging pathogens, ecology, and microbial resistance and I also work on rapid microbial diagnostics. Thank you.

DR. KRISTAL SOUTHERN: Thank you, Dr. Bisha.

Dr. Heather Carleton. She works with the -- she's our representative from the Centers for Disease Control. She is not at the meeting today, but we want to recognize her.

We'll now move on to Dr. Anna Carlson.

DR. ANNA CARLSON: Hi. Good morning, everyone. I'm Anna Carlson. I am a food safety scientist with Cargill and prior to coming to Cargill, I was a state foodborne disease rep for the Nebraska State Health Department.

DR. KRISTAL SOUTHERN: Thank you, Dr. Carlson.

Dr. Hayriye Cetin-Karaca.

DR. HAYRIYE CETIN-KARACA: Hi. This

is Hayriye Cetin Karaca. I am the senior research scientist for Smithfield Foods, and I'm very happy to work with the committee. Thank you.

DR. KRISTAL SOUTHERN: Thank you, Dr. Cetin-Karaca.

Dr. Ben Chapman.

DR. BEN CHAPMAN: Thank you so much for the time to introduce myself and I'm really excited to be on this committee. I'm Ben Chapman. I'm a department head and food safety extension specialist in the Department of Agricultural and Human Sciences at North Carolina State University.

DR. KRISTAL SOUTHERN: Thank you, Dr. Chapman.

We'll go to Dr. Vik Dutta.

DR. VIK DUTTA: Good morning, everyone. I'm happy to be here. My name is Vik Dutta. I am heading our Scientific Affairs Department in bioMerieux, Inc. I've been with the company with seven years. I'm a trained molecular biologist. Anything related to microbiology diagnostics, I have worked with in my previous

life, and I've also trained as a veterinarian way back when again. Again, I look forward to working with you all and nice to meet you.

DR. KRISTAL SOUTHERN: Thank you, Dr. Dutta.

Dr. Betty FENG.

DR. BETTY FENG: Good morning. My name is Betty Feng. I'm an associate professor and an extension specialist in Purdue University. I'm a consumer safety scientist. Thank you.

DR. KRISTAL SOUTHERN: Thank you, Dr. Feng.

Dr. Larry Figgs. I don't think he is on. He comes to NACMCF from the Douglas County Health Department in Nebraska.

DR. LARRY FIGGS: Yeah, Larry Figgs.

DR. KRISTAL SOUTHERN: Oh, you're here. Okay.

DR. LARRY FIGGS: I'm from the Douglas County Health Department up until November of this year. I retired this past Friday. So, I'm no longer affiliated with the Douglas County Health

Department.

DR. KRISTAL SOUTHERN: Thank you, Dr. Figgs.

And we'll move on to Dr. David Goldman.

DR. DAVID GOLDMAN: Good morning, everyone. David Goldman here. I spent twenty years in the federal government in food safety and science and in FDA. I was involved in one way or another in outbreak investigations that entire time. I'm a medical epidemiologist, public health physician, and I'm glad to see some familiar names and faces and I look forward to our work here. Thanks.

DR. KRISTAL SOUTHERN: Thank you, Dr. Goldman.

Dr. Michael Hansen.

DR. MICHAEL HANSEN: Yes. Hello, everyone. My name is Michael Hansen. I'm a senior scientist at Consumer Reports, where I've worked for more than twenty-five years, and I work on a range of food safety issues. Thank you.

And I very much look forward to working with this committee.

DR. KRISTAL SOUTHERN: Thank you, Dr. Hansen.

And Dr. Arie Havelaar.

DR. ARIE HAVELAAR: Good morning, everyone. My name is Arie Havelaar. I'm a professional in food safety in the University of Florida. I'm interested in epidemiology and risk assessment of foodborne diseases and more generally, diseases transmitted between animals and humans.

For the large part of my career, I've been working as a science policy interface in the National Public Health Institute as a member of the -- (indiscernible) -- with the World Health Organization. So, I'm looking forward to an extended experience now in the US system. Thank you.

DR. KRISTAL SOUTHERN: Thank you.

Ms. Janell Kause.

MS. JANELL KAUSE: Good morning,

everybody. I'm Jannell Kause. I'm the senior advisor for Risk Assessment here at the Food Safety and Inspection Service. I've been with the agency for about twenty-five years working on areas of microbial risk assessment work as well as more recently incorporation of genomics into risk assessment.

DR. KRISTAL SOUTHERN: Thank you.

Dr. Ramin Khaksar.

DR. RAMIN KHAKSAR: Good morning. I'm Ramin Khaksar, Chief Scientific Officer at Clear Labs, a biotech genomics company that provides end-to-end solution from sample-to-data for microbial sequencing application. Thank you, everyone.

DR. KRISTAL SOUTHERN: Thank you.

Lieutenant Colonel Noel Kubat.

LIEUTENANT COLONEL NOEL KUBAT: Good morning, everyone. My name is Noel Kubat. I am a Lieutenant Colonel with the US Army Veterinary Services. I spent fifteen years of my professional career with the Army. I'm currently

serving in a command position in Kentucky. Pleasure to be here.

DR. KRISTAL SOUTHERN: Thank you.

And Dr. Elisabetta Lambertini.

DR. ELISABETTA LAMBERTINI: Good morning. I'm Elisabetta Lambertini. I'm a senior scientist in research in leading food safety with the Global Alliance for improved nutrition. I am an engineer by background and my work focuses on risk analysis and data analytics in support of risk management programs. Thank you.

DR. KRISTAL SOUTHERN: Thank you, Dr. Lambertini.

Ms. Shannara Lynn.

MS. SHANNARA LYNN: I'm Shannara Lynn. I'm the lead microbiologist for the National Seafood Inspection Lab. I have been working for ten years working with the microbiology group and our genetics analysis.

DR. KRISTAL SOUTHERN: Thank you.

Dr. KatieRose McCullough.

DR. KATIEROSE MCCULLOUGH: Good

morning, everyone. KatieRose McCullough. I serve as the Director of Science and Public Health for the North American Meat Institute. We represent packers and processors of beef, pork, lamb, poultry, and items across the US. And I also serve as the chief scientist for the Foundation for Meat and Poultry Research and Education. We fund a tremendous amount of food safety research, and we're really looking forward to our work together. Thanks.

DR. KRISTAL SOUTHERN: Thank you so much, Dr. McCullough.

Dr. Indaue Mello.

DR. INDAUE MELLO: Good morning. Indaue Mello, Director of Quality and Food Safety for Newman's Own. My expertise is in managing and mitigating microbial risks in manufacturing plants as well as designing challenge studies and evaluating formulas for safety and quality.

DR. KRISTAL SOUTHERN: Thank you, Dr. Mello.

Dr. Eric Moorman is not with us this

morning, but he works with Butterball.

So we'll move on to Dr. Abani Pradham.

DR. ABANI PRADHAM: Good morning, everyone. I'm Abani Pradham, a professor and director of graduate program in the Department of Nutrition and Food Science in the Center for Food Safety and Security Systems at the University of Maryland in College Park.

My research interests are in the area of risk assessment and applications of pathogens, genomics, and machine learning. Glad to be here. Thank you.

DR. KRISTAL SOUTHERN: Thank you, Doctor Pradhan.

Mr. Shivrajsinh Rana.

MR. SHIVRAJSINH RANA: Hello and good morning, everyone. I am Shivrajsinh Rana. I am senior food safety manager at Reckitt overseeing and leading food safety programs and initiatives covering the infant and childcare nutrition business in America. I'm an experienced quality and food safety professional, have supported

multisite operations and coach and engage teams to drive impactful business results.

I'm proud to be a member of this committee, and I look forward to work with all of you and support my work to the best of my ability. Thank you.

DR. KRISTAL SOUTHERN: Thank you.

Dr. Marco Sanchez-Plata.

DR. MARCO SANCHEZ-PLATA: Good morning, everyone and thank you for the consideration to be on this committee. Marco Sanchez-Plata, associate professor on global food security with the National Center for Industry Excellence at Texas Tech University.

My research focuses on measuring the levels of microbial indicators of pathogens and the dynamics of change throughout the value chain of different food commodities. I'm looking forward to the types of discussion that NACMCF conducts. Thanks.

DR. KRISTAL SOUTHERN: Thank you very much.

Dr. Kristin Schill.

DR. KRISTIN SCHILL: Good morning, everyone. I'm Kristin Schill. I'm at the University of Wisconsin Madison in the Food Research Institute and I'm a research assistant professor. Nice to be here.

DR. KRISTAL SOUTHERN: Thank you. Thank you, Dr. Schill.

And Dr. Nikki Shariat.

DR. NIKKI SHARIAT: Good morning, everyone. I'm honored to serve on NACMCF this year. I'm Nikki Shariat. I'm an associate professor in the Poultry Diagnostic and Research Center in the College of Veterinary Medicine at the University of Georgia, and my research expertise is in Salmonella dynamics in food animal production and the environment with a focus on poultry. I'm looking forward to working with the committee. Thank you.

DR. KRISTAL SOUTHERN: Thank you, Dr. Shariat.

Dr. Abigail Snyder.

DR. ABIGAIL SNYDER: Hi. I'm Abby Snyder. I'm associate professor of Microbial Food Safety at Cornell University, and I'm happy to be here.

DR. KRISTAL SOUTHERN: Thank you.

Dr. Max Teplitski.

DR. MAX TEPLITSKI: Good morning. Max Teplitski. I'm the Chief Science Officer at the International Fresh Produce Association, and before that, I was a professor at the University of Florida and I had a career in the federal government focusing on genetics and genomics on microorganisms, especially those involved in food safety. Thank you and I'm excited to serve.

DR. KRISTAL SOUTHERN: Thank you.

Dr. Bing Wang. Oh, my apologies. She's not -- she won't be joining us at this session today. But she comes to us from the University of Nebraska Lincoln.

And Dr. Benjamin Warren.

DR. BENJAMIN WARREN: Good morning, everyone. I am Ben Warren, Senior Science Advisor

for Food Safety and FDA FSAN Office of Food Safety. Thank you.

DR. KRISTAL SOUTHERN: Thank you, Dr. Warren.

And Dr. Randy Worobo is also not present this morning. He comes to us from the -- from Cornell University.

And our last but not least member, Dr. Teshome Yehualaeshet is also not present today, but he also -- he comes to us from Tuskegee University. So thank you.

Thank you, everyone for your willingness to serve on this this great committee. We look forward to working with you over this two-year term and supporting you as you complete the work of the committee.

We will now proceed with a presentation from Dr. Glenn Tillman, who will introduce the emphasized charge on genomics.

Dr. Glenn Tillman has been with the USDA Food Safety and Inspection Service for over twenty years. He previously served as a

microbiologist working on foodborne outbreak analyses and characterizing -- a characterization of bacterial pathogens. From 2016 until earlier this year, he served as the Chief of the Eastern Laboratory Microbiology Characterization Branch. There, he led a staff focused on whole genome sequencing and antimicrobial resistance.

In his current position as a biological science information specialist, he works to advance the use of genomics and other issues of interest to the agency.

Glenn received his master's degree in toxicology and PhD in infectious diseases from the University of Georgia.

Now welcome Dr. Glenn Tillman.

And Silas, if you can turn over presenting -- presenter rights to Glenn too, please. Thank you.

Dr. GLENN TILLMAN: Okay, thank you, Kristal, and now I have the presenter rights. So, thank you very much, Silas.

So, as Kristal mentioned, I'm

introducing the genomics charge to the NACMCF committee today, and we're really excited about this charge as we move forward. We think it will be a really big, large boon for us as a regulatory agency along with our partners within food safety regulatory science.

So just briefly, this committee is quite aware of what whole genome sequencing is. This process of determining the DNA sequence of a bacterial or an organism's genomes and includes both individual genes, plasmids, and any type of transmissible elements and there can be genetic variation within the same species.

Why did we start using whole genome sequencing in FSIS. So ourselves and FSIS along with all of our public health and regulatory agencies around the country to identify the whole genome sequencing would be the preferred method for characterizing foodborne pathogens. It was able to give us a much greater detail than we were able to see with previous technologies, including pulsed field gel electrophoresis.

In addition to looking at source attribution in finding the cause of foodborne outbreaks, we're able to learn more about the pathogens that were causing illness.

We often work with our public health and other regulatory agencies within us to promote food safety using whole genome sequencing and genomics.

We deployed whole genome sequencing across this large network of federal, state, and local public health laboratories starting in around 2013 in our hands. These include -- the collaborations within them include the Interagency Collaboration on Genomics for Food and Feed Safety, what we call Gen-FS. We have the National Antimicrobial Resistance Monitoring System called NARMS. We have the FDA Genome Tracker, and we have the Centers for Disease Control and Prevention, CDC PulseNet.

And as we speak about whole genome sequencing at FSIS, we'd like to include a timeline on how we came to it and what some of the

major milestones were.

As I mentioned, around 2013 is when we at FSIS first started getting engaged in whole genome sequencing, along with the FDA and the CDC. Our first actual sequences that we ran in our own laboratories across FSIS was in 2014. We ran sequencing for several outbreak investigations.

But by 2015, we began running WGS on Shiga toxin-producing E. coli and Listeria monocytogenes in real time analyses and we uploaded our first sequence to NCBI around 2015.

By 2016, we began running one hundred percent of our Salmonella and Campylobacter from our sampling programs and uploading those in NCBI. So you can see that our capacity and capability went up very largely in a short amount of time.

By 2020, January specifically, we were obtaining Salmonella serotypes directly from whole genome sequencing data, and no longer utilizing the phenotypic identification of Salmonella serotypes.

And in 2023, we partnered with industry to create what we call the Campylobacter

allele code schemes, which supplement the ones from the CDC PulseNet.

So as I mentioned, we continue to kind of move forward and look for new avenues and promoting whole genome sequencing for food safety.

So, across our work, and since FY14, we've spent three distinct strategic plans at FSIS.

Our first strategic plan got at how can we implement whole genome sequencing, which we were successful on.

Our second strategic plan looked at how can we upgrade our infrastructure and start to apply whole genome sequencing. During that timeframe, we got to a point where now have fourteen -- (indiscernible) -- across our three FSIS Field Service Laboratories, and we're sequencing around 15,000 bacterial isolates per year and uploading this into NCBI.

So with our current strategic plan, our goal is to look at how can we continue to use WGS data analyses and build foundations for

regulatory policies, which is what brings us here today.

So, Kristal already touched on what NACMCF is, and so it's a committee that we're going to rely upon to get expert impartial scientific advice.

The major entities, Kristal already mentioned, we're one of those partners at FSIS along with folks at the FDA, Centers for Disease Control, Departments of Commerce, National Marine Fisheries Service, and the Department of Defense Veterinary Service Activities.

So today, we want to be able to produce a charge for FSIS, and we centered around several themes -- a theme, how can we use genomics to rank pathogen subtypes by risk.

We acknowledge that not all foodborne microbial pathogen subtypes inherently have the same risk associated with illness and a patient outcome. We're seeking advice on how to strategically use genomic analyses, in addition to any other current emerging technologies to help us

identify and focus resources on more risky pathogen subtypes. And we think that the direction of the committee will help us in a decision-making moving forward that can reduce microbial pathogen subtypes of public health significance.

In FSIS, we do work that aligns with our strategic plan. So our strategic plan outcome 2.1 says improve food safety by incorporating analysis of pathogen genomics with objective 2.12, define and assess the risk of a pathogen based on its genetic attributes, which can include virulence factors.

So again, we want to be able to align any future work we do with our strategic plan, and we feel that this charge will help us do that.

So our charge to the NACMCF committee consists of four overarching questions with subparts within there.

So charge question one is getting at the appropriate genomic and pathogen attributes. So how can genomics be used to differentiate

microbial pathogen subtypes by risk to public health and food products regulated by FSIS?

So subpart one, what epidemiologic criteria should be used to rank subtypes by risk for each of the pathogens of concern to FSIS. That's Salmonella, STEC or Shiga toxin-producing E. coli, Listeria monocytogenes, and Campylobacter including but not limited to outbreak size and scope, link to sporadic illness, frequency of illness, severity of illness, and patient outcome.

Subpart B, how can pathogen genomic data be incorporated into microbial risk assessments, in other words, hazard analysis, hazard identification, exposure assessment, hazard characterization, and risk characterization.

Subpart C, in addition to putative or known virulence genes, what other genomic attributes of pathogens of concern are associated with a higher risk to public health that can include antimicrobial resistance genes, plasmids or genes leading to persistence such as heat resistance and/or other tolerance attributes such

as metals, for example.

Charge question two looks at some of the available and applicable tools and analyses that are out in the public now.

So what types of validated genomic-based approaches are currently used by both international -- US and international entities to support their food safety systems?

What tools and technologies are deployed and have they been validated through an accredited standard, including but not limited to association of official agriculture chemists, AOAC, or Clinical Laboratory Improvement amendments or CLIA?

What analytical methods -- subpart B, what analytical methods that integrate genomic data and metadata, including but not limited to, genomic-wide association, machine learning or random forest, and artificial intelligence are available for distinguishing strains based on likelihood of causing illnesses giving exposure, and does the committee recommend a particular

approach among these available methods?

Subpart c, what genomic databases, analytic criteria, and information-sharing mechanisms are harmonized, both domestically and internationally, and how can genomic data or metadata currently publicly available and existing databases be improved to be more informative and meaningful in developing risk ranking models, tools, or analyses?

Question three, and this gets it knowledge gaps and research gaps that may exist currently. So in other words, what research or knowledge gaps should be addressed to fully operationalize a genomic space approach? Do current technologies or emerging technologies rely on well-characterized genes to identify a riskier pathogen subtype? If we need further research to link genomic factors with virulence and/or severe patient outcome, how would the committee recommend focusing this research?

Subpart B, how can currently available genomic information be leveraged to reduce time to

subtype determination in a high throughput laboratory, and how can rapid diagnostic tools be improved using genomic-based targets to identify riskier pathogen subtypes?

Subpart C, can genomic-based models or technologies be adapted to include emerging pathogenic subtypes; reoccurring, emerging, or persisting strains and plasmids of genes of public health interest in regulated products?

For example, how could the approach address the following: non-monocytogenes Listeria species, Polyphyletic Salmonella serotypes including but not limited to the virulent clade of Salmonella Kentucky, Campylobacter species other than coli/jejuni/lari, Shiga toxin-producing E. coli, genes that are association with virulence or multi-drug resistance, such as the MDR plasmid in Salmonella Infantis, and in other emerging pathogenic subtypes of the foodborne pathogens of concern to FSIS.

And finally, Subpart d, how can genomics be used for to differentiate vaccine

strains used in food safety from wild-type pathogenic bacterial strains that are circulating?

And our final question is on the strategic vision of this approach. So, based on the risk management questions and tools being deployed, how might genomics inform FSIS and other regulatory agencies along the farm to fork continuum?

How might regulatory agencies adjust sampling plans both exploratory and routine to optimize the use of pathogen genomic data?

Subpart b, how might genomics be used to inform future risk management strategies?

Subpart c, when implementing a risk management strategy, what are the benefits and considerations in using a genomic-based approach to identify and rank pathogen subtypes by risk to public health?

And subpart d, how might us regulatory entities interpret pathogen genomic information to support their agency regulatory actions?

So, in summary, we are seeking advice

from NACMCF on how to identify and rank riskier microbial pathogen subtypes, and just kind of broadly speaking, the genomic storage is looking for input on criteria for differentiating pathogen subtypes by risk to public health.

The pros and cons of a genomic-based approach.

Identify and overcome research or knowledge gaps to operationalize the genomics-based approach.

And finally, a strategic vision for deploying the genomics-based approach to risk rating of food pathogen subtypes.

And that was my final slide, Kristal.

DR. KRISTAL SOUTHERN: Thank you, Dr. Tillman. So, thank you for presenting the FSIS Genomics Charge.

The subcommittee meetings this week will allow us the opportunity to hear from subject matter experts and to dive a little deeper into the charge questions.

So we're going to move forward to see

if there are any questions or comments first from executive committee members, excuse me, executive committee or members of the committee on the FSIS Genomics Charge that you would like to address at this meeting?

If so, please go ahead and raise your hand, and for committee members and executive members, you all can unmute yourself when your name is called.

So we'll now see if there are any questions or comments from members of the public. Silas, do we have any hands raised?

HOST: At this time, there are no hands raised. As a brief reminder for attendees, you can press the raise hand icon at the bottom of your WebEx screen or press #2 on our phone lines if you would like to make a comment.

DR. KRISTAL SOUTHERN: Okay. So, seeing no comments from the executive committee or the committee members, we will move to the public, and as Silas mentioned, that you can raise your hand if you'd like to provide a public comment.

We request all commenters to please introduce yourself, by providing your name and affiliation before providing your comment. Each person will be provided up to three minutes to make their comments and then the event producer will move on to the next person in the queue.

Before we move to any hands that might be raised, we do have one person that preregistered to provide comments and sent confirmation through a follow-up E-mail with the NACMCF Secretariat. We will now move to welcome Deborah McKenzie to provide comments.

HOST: Deborah, your line is unmuted. you may go ahead.

DEBORAH MCKENZIE: My name is Deborah McKenzie, and I am the Deputy Assistant Executive Director and Chief Standards Officer at AOAC International.

AOAC promotes methods development, validation, and quality measurement in the analytical sciences, and since 1884, AOAC is renowned for its compendium of methods, the

official methods of analysis of AOAC International.

AOAC reviews and approves methods that have undergone rigorous systematic scientific scrutiny to ensure that they are highly credible and defensible.

AOAC methods are referenced and used by industry research organizations, test laboratories, academic institutions, and certainly regulatory agencies including FSIS and FDA.

In addition to culture-based techniques, phenotypic, and genomic-based technologies are increasingly used for pathogen detection, identification, and characterization, amplicon and meta genomic next generation sequencing along with real-time PCR, qPCR, digital PCR, and -- (indiscernible) -- are few of these technologies, for which AOAC validates and approves for fit for purpose methods.

With current and emerging pathogens, there are needs for consensus standards, and internationally recognized validated methods

employing these technological advances.

AOAC develops standard method performance requirements and guidance documents in support of approved validation methods published in the Official Methods of Analysis.

AOAC also certifies performance of methods based on proprietary technologies, and its performance tested methods program.

AOAC works with experts representing academia, government, and industry sectors to develop standards and methods to characterize, identify, and detect foodborne pathogens such as Cyclospora cayetanensis as well as for E. coli, Listeria, Salmonella, STEC, Cronobacter, etcetera, and to this end, AOAC has a strong portfolio of standards and methods both compendial and certified for detection, identification, and characterization of these pathogens.

But furthermore, AOAC has since 2016, moved into developing standards guidance in statistical analysis, bacterial strain verification, and standards for NGS applications

that complement traditional and molecular biological pathogen detection methods.

And so, while we look forward to learning the new committee's charged on genomics, we are aware of the strategic plans for the Food Safety and Inspection Service to coordinate, strengthen, and lead whole genome sequencing efforts among federal and state partners.

It is here that we ask the advisory committee to recognize the important contributions of external partners in genomic and for food safety and encourage collaboration in furtherance of mutual goals.

Thank you very much again for your time and consideration of these remarks.

DR. KRISTAL SOUTHERN: And thank you, Deborah McKenzie. We also received your comments through the online commenting for the meeting. So those will be -- the written portion of your comments will also be shared with the committee members. Thank you.

Okay, and Silas, can you -- are there

other hands in the queue to provide comments -- public comment on the genomics surcharge?

HOST: We do currently have one hand up in the queue from Dr. Arie Havelaar.

DR. KRISTAL SOUTHERN: okay. that is one of our members. Go ahead, Dr. Havelaar.

DR. ARIE HAVELAAR: Thank you, Kristal. Sorry for missing the rhythm of the meeting.

I'd like to ask the question to Dr. Tillman about the scope of the charge. It's written to basically look at the virulence and the risk of an individual isolate. But when I think beyond that isolate, in say, applying that in food safety regulations, questions like how representative is a single isolates for say, the pathogen community and natural foods or taking that one step further. What does that tell us about the suitability of a particular niche, a particular production site, prediction of a particular production system for more or less risky isolates to colonize that particular niche?

Thinking about applying this in a regulatory setting, you'll also need to think about the broader ecology of the pathogens in the food system.

So my question is, is that included in the scope or do you want to limit our advice to looking at single isolates?

DR. GLENN TILLMAN: Thank you, Dr. Havelaar. That's a great question. The scope is right now centered around the four pathogens of concern to FSIS with Salmonella, Listeria, Campylobacter, and Shiga toxin-producing E. Coli. But we do have several aspects of the charge which get at metagenomics and deeper dives into the essential microbial community of a food product and looking at that.

So, as we talk within the -- look further into the sub -- into the subcommittee, look at this, I think that we can bring -- we can possibly go that direction, and look -- and you all can look in there and see if that needs to be part of the advice back from the committee.

DR. ARIE HAVELAAR: Yeah. It doesn't necessarily have to be other technologies, but also things like isolating more than one culture from one sample when time series from samples. So considering even only using WGS, there may be information that we can look at diversity within samples over time if that's available. Yes, it's good to know that is part of the charge. Thank you.

DR. GLENN TILLMAN: It is, and we have -- we have some -- during the subcommittee breakouts, we have some presentations based on what our current scope is, what our laboratory systems doing, what our agency looks at. So maybe that'll provide some more information about where we are and then within the questions, within the charge, maybe some of that will provide maybe a direction forward for you all to look at and consider. So, thank you again.

DR. KRISTAL SOUTHERN: Thank you.

And are there other questions, other hands in the queue? And if you're an executive

committee member or a committee member, you should have the ability to unmute yourself if you have any questions for Glenn at this time, and then also, as he stated in the subcommittee meetings, we'll be diving a lot deeper into the questions and the subparts of the questions as well as have some presentations from subject matter experts where we'll go into a lot more detail. But certainly, if there's a question that we can't answer now, we'll certainly allow some time to do so.

Okay, Silas is saying there are no more questions -- no more hands or questions in the queue.

HOST: We do have one more hand up from Dr. David Goldman.

DR. KRISTAL SOUTHERN: Okay, yes. And Dr. Goldman is a committee member. Please go ahead. You can unmute yourself, David. Thank you.

DR. DAVID GOLDMAN: Yeah, thank you.

This is a really complex charge and

it's very important, having served in two regulatory agencies, it's really important to have a regulatory regime that reflects current science. So I think it's a very timely charge to NACMCF and I'll look forward to the work of that subcommittee.

I think just one thing comes to mind as I'm thinking about this. I think we've become very good and skilled and Glenn has led this at FSIS in identifying the virulence attributes and other attributes which cause known pathogens to be pathogens.

I think the challenge from a regulatory point of view will be when we identify those same attributes in other bacteria that have not yet been known to cause illness. And so, then you're dealing with the potential to cause illness and how do you regulate that?

So, I think the more we know about the science behind the genomics of bacteria in general, pathogens versus nonpathogens, I think the better off we'll be in terms of developing a

regulatory structure that's meaningful. Thank you.

DR. KRISTAL SOUTHERN: Thank you. Thank you, Dr. Goldman.

Okay. Are there any more hands or questions or comments?

HOST: There are no more hands up at this time.

DR. KRISTAL SOUTHERN: Okay, awesome. Well, we're ahead of time, so if we have time at the end of the agenda items, we can maybe circle back and see if others have any questions or comments that may come to mind between now and the end of the meeting.

We'll go ahead and move on. Thank you very much, Dr. Tillman, and also others for your questions and comments.

We will now proceed with the presentation from Dr. Benjamin Warren, who will reintroduce the FDA charge on Cronobacter species in Powdered Infant Formula.

Dr. Benjamin Warren is a Senior

Science Advisor for food safety at the US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety. In this role, Dr. Warren supports implementation of the Preventive Controls for Human Foods Rule and supports FDA activities to investigate and prevent foodborne outbreaks.

Dr. Warren received his PhD in food science, master's in food science and bachelor's in food science, all from the University of Florida.

In addition to serving on NACMCF, Dr. Warren is the US delegate to the Codex Committee on Food Hygiene. Welcome, Dr. Warren.

DR. BENJAMIN WARREN: Thank you, Kristal.

DR. KRISTAL SOUTHERN: Yeah, you should have consent or rights or they're coming.

DR. BENJAMIN WARREN: I do, thank you.

Okay, thank you, Crystal and good morning, everybody. It is my pleasure to reintroduce FDA's charge to NACMCF on Cronobacter

in Powdered Infant Formula.

As Kristal mentioned, this charge was originally presented to NACMCF a year ago and last session, NACMCF committee did extensive work on question one, and provided some interim response to that question as well as some information that was found on some of the others.

We're very excited for this session of NACMCF to pick that work up and to carry this charge to completion. So with that, I will go through the charge.

Okay, briefly, Cronobacter species, which were previously classified as Enterobacter sakazakii, are motile, Gram-negative, rod-shaped opportunistic pathogens of the family Enterobacteriaceae, and these cause foodborne illness primarily among infants and primarily, those infants that are less than two months old, or those that are immunocompromised, including immunocompromised adults.

Cronobacter are considered widely distributed, and they have been previously

isolated from a variety of environments, both residential home environments, as well as the environments of food manufacturing plants, from variety of food, including cheese, meat, and vegetable products, from animals and insects, for example, rats and flies, as well as from a number of clinical sources.

Although several species of Cronobacter may be capable of causing disease in humans, Cronobacter sakazakii is the species most often associated with illness. Yet the lack of historical mandatory national disease reporting for Cronobacter has made this challenging to draw conclusions.

FDA is very excited about the -- about Cronobacter illnesses in infants becoming reportable in the United States effective January 1st of 2024. So we're looking forward to getting more information on this.

Cronobacter typically manifests in infants with other issues such as those born premature or with weakened immune systems,

although term infants without any underlying conditions have experienced invasive Cronobacter infections as well.

Infections in infants younger than twelve months can be very deadly, with case fatality rates reported from ten percent up to eighty percent.

Cronobacter has been reported to survive for as long as two years in low-moisture foods such as powdered infant formula, and contaminated powdered infant formula has been previously associated with Cronobacter infections among infants, with the organism being isolated from powdered infant formula, rehydrated infant formula, and utensils used to prepare and/or administer the infant formula.

In 2021 and early 2022, a series of Cronobacter illnesses among infants in the US was associated with feeding powdered infant formula that was produced by a certain manufacturer at a certain facility. FDA inspection of the suspected manufacturing facility revealed the presence of

Cronobacter in multiple locations within the production environment, as well as other conditions unsuitable for producing safe powdered infant formula.

This led to the manufacturer initiating a voluntary nationwide recall and the temporary shutdown of that plant, which was a major contributing factor to the infant formula shortage experienced across the US in 2022.

More recently, FDA has issued warning letters to three infant formula manufacturers as part of the agency's ongoing commitment to enhance regulatory oversight to help ensure that the industry is producing infant formula under the safest conditions possible.

During inspections of these firms, the FDA issued inspectional observations and exercised oversight of each firm as they initiated recalls to remove product potentially contaminated with Cronobacter from the marketplace.

These findings have raised questions about the current control measures for Cronobacter

in dry processing environments and the extent of corrective actions when Cronobacter are found in the processing environment and/or product samples.

FDA has developed a draft strategy to prevent Cronobacter illnesses associated with powdered infant formula and the most recent version of this draft strategy can be found on FDA's website.

The FDA recognizes the expertise within NACMCF as uniquely positioned to provide impartial scientific advice that may be used to inform the further development of the strategy.

Therefore, FDA is seeking advice from NACMCF on addressing knowledge gaps and key issues related to Cronobacter in four specific areas, and the following slides will present these four charge questions.

The first charge question, what is the current prevalence and level of Cronobacter contamination in powdered infant formula in the US market? What is known about Cronobacter in other foods and the home environment and the frequency

in which these foods and environmental sources contribute to human infection?

As I mentioned at the start of this presentation, the previous NACMCF committee provided an interim report that focused on charge question one, and we'll continue to update that report. We're looking for the committee to continue to update that report if new information becomes available during this session of NACMCF.

Charge question two, what factors for example, virulence factors, host factors, or dose of exposure, place an infant at greater risk for Cronobacter infection and serious adverse health consequences or death?

Charge question three, what food safety management practices, for example, facility and equipment design, hygienic zoning and packaging, preventive controls, or verification activities should manufacturers of powdered infant formula employ to further reduce the risk of Cronobacter contamination of formula and or the production environment?

Charge question four, given that powdered infant formula is not sterile, how could food safety messaging be improved for infant care providers with emphasis on use of sterile ready-to-use formulas for those infants at greatest risk and safe infant formula preparation and storage for infant formula in general?

In closing, FDA would like to thank NACMCF and the members of the subcommittee in advance for taking this charge and lending your expertise toward preventing Cronobacter illnesses associated with powdered infant formula. We look forward to your response.

Kristal, I'll turn it back to you.

DR. KRISTAL SOUTHERN: Thank you. Thank you, Dr. Warren for the presentation and to reintroduce the Cronobacter charge.

Again, similar to statement about the genomics charges is that we have the subcommittee meetings this week for Cronobacter charge, and that will also allow us an opportunity to hear from subject matter experts and to dive a little

deeper into these questions.

So we'll go ahead and start with if there are any questions or comments from the executive committee, or members of the NACMCF committee on the FDA Cronobacter species in Powdered Infant Formula Charge.

Again, if you are a committee member, you can raise your hand, but you will also have the opportunity to unmute yourself.

Silas, are there any hands raised?

HOST: It looks like there are no hands raised at this time.

DR. KRISTAL SOUTHERN: Okay. Maybe everybody is saving all of discussion for the afternoon meeting. That's okay, too.

So without further ado, we'll go ahead and move to public comment. As a reminder, we request all commenters to please introduce yourself by providing your name and affiliation before providing comment. Each person will be provided three minutes to make their comments and then the event producer will move on to the next

person in the queue.

We did not have any person preregistered to provide Cronobacter, excuse me, provide comments for the Cronobacter charge. So we'll just open it up. If you would like to provide a comment, please raise your hand, and make us aware and we will note you -- we will call on you to comment.

Okay, Silas, do we have any hands in the queue for commenting on the Cronobacter charge?

HOST: There are no hands in the queue at this time.

DR. KRISTAL SOUTHERN: Okay.

So I will -- as you can see, we're well ahead of schedule, which is a first, at least as I've been the Designated Federal Officer for NACMCF. I will open it up then for any public comment on either the Genomics charge or the Cronobacter charge. And then also, of course, if there's any executive committee members or committee members who wish to provide comment or

question at this time, you may do so as well. And we'll just give it a moment to see if anyone would like to do that.

Okay, Silas, are there any hands?

HOST: There are no hands up at this time.

DR. KRISTAL SOUTHERN: Okay. So certainly if you change your mind or over your lunch, you have some other ideas or questions you want us to -- or comments to consider, we have the subcommittee meetings this afternoon, and you can certainly use the chat to express different ideas as well and that information will be shared with the committee.

So we'll move on to closing remarks.

I want to thank our presenters, our committee members, commenters, and members of the audience for participating in today's meeting. I also want to thank the NACMCF Executive Committee and Secretariat for your support and leadership. And a special thank you to our Advisory Committee Specialist, Miss Chantel Williams, whose work

behind the scenes helps to support the day-to-day operations and help the committee member -- to meet the committee member's needs.

So starting today at 1:00 p.m., we will begin the subcommittee meetings to continue discussions on the charges presented at today's plenary.

You should have received in your confirmation E-mail, I think this morning, Silas, you can provide additional details on that, the link to join the subcommittee meetings.

So, of course, we have two different subcommittee meetings that will be running at the same time concurrently, and those have different links. So make sure that you're clicking on the right link to access that particular meeting.

Upon joining the meeting, we will start the meetings promptly at 1:00 and those meetings will also be recorded and any instructions or housekeeping -- housekeeping notes for those particular meetings will be given at time.

Silas, would you like to provide additional instruction on -- to our attendees on how to join the subcommittee meetings, and I think we're going to put the link to the catalog page in the chat.

HOST: Absolutely. As Kristal mentioned, there are two separate links for our Cronobacter and Genomics subcommittees this afternoon. If you have any issues joining, please go ahead and send a chat message to the event producer and I will be happy to help you get into those meetings. You will just have to click the catalog link and join the meetings from either of those links listed on the catalog.

DR. KRISTAL SOUTHERN: Thank you. And do we have the link to the catalogs put in the chat for our attendees?

HOST: Yes, absolutely. I'm just locating the catalog link now.

DR. KRISTAL SOUTHERN: Okay, perfect. Thank you.

By catalog, just so everyone knows,

it's just a one-pager that provides for you each of the links for each day, which are different, depending on the meeting, and it includes different links for the agenda for the remainder of the week.

So we'll get that in the chat, and while that happens, I'm going to turn it over -- turn it back over to Dr. Esteban for closing remarks.

DR. EMILIO ESTEBAN: Thank you, Kristal, and thank you for your efficiency this morning. I'm very impressed with the speed with which we moved.

I'm looking forward to getting input from these very knowledgeable people. Like I said before, both of these topics are critical for public health, and I look forward to getting some guidance from NACMCF as to how do we follow those two things.

So I'm not going to delay this any further. Thank you very much, and I hope to engage with you in the afternoon session as much

as I can. Thank you.

DR. KRISTAL SOUTHERN: Thank you, Dr. Esteban.

So, we have completed the purpose of today's NACMCF plenary meeting, and we will -- we look forward to seeing each of you online at the subcommittee meetings that will begin at 1 p.m. Eastern this afternoon.

And Silas, are we still waiting on the link for the catalog? I don't want to sign off.

HOST: It will stay open. I will post it in chat.

DR. KRISTAL SOUTHERN: Okay. Will that chat -- that chat won't be available once we close out the meeting, correct?

HOST: Yes. I'm just going to keep the meeting open after I find the link. Just give me one quick moment.

DR. KRISTAL SOUTHERN: Okay. So, for the purpose of at least at this meeting, we now stand adjourned. But if you do need the link to the catalog, just hang on, and that will show up

in the chat, and we'll keep the meeting open a little longer so that everyone can have that information for the afternoon links for the afternoon meetings.

Also you should have received it upon registering, a confirmation E-mail this morning that also includes those links. So, just be mindful of that.

So with that we now stand adjourned. And yeah, thank you so much, everyone, and I look forward to our continuing discussions. Thank you.

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(WHEREUPON, AT 11:09 A.M., THE NATIONAL ADVISORY COMMITTEE MEETING ON MICROBIOLOGICAL CRITERIA FOR FOODS WAS CONCLUDED.)

C E R T I F I C A T E

I, Gary Euell, Professional Reporter, certify that I was authorized to and did report the foregoing proceedings and that the transcript is a true record. I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

WITNESS my hand and official seal this 26th day of November 2023.

Gary Euell

GARY EUELL

Notary Public - District of Columbia

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