UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)
FOOD SAFETY AND INSPECTION SERVICE

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NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS (NACMCF)

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TUESDAY,
SEPTEMBER 24, 2024

The meeting was convened at 10:00 a.m., at the U.S. Department of Agriculture, James E. Whitten Building, 1400 Independence Avenue, SW, Washington, D.C., Emilio Esteban, Chair, presiding.

MEMBERS PRESENT:

BLEDAR BISHA, University of Wyoming
HEATHER CARLETON, Centers for Disease Control and Prevention
ANNA CARLSON, Cargill Protein
HIRIYE CETIN-KARACA, Smithfield Foods
BEN CHAPMAN, North Carolina State University
VIK DUTTA, bioMerieux
BETTY FENG, Purdue University
LARRY FIGGS, Douglas County Health Department (Retired)
DAVID GOLDMAN, Groundswell
MICHAEL HANSEN, Consumer Reports
ARIE HENDRIK HAVELAAR, University of Florida
JANELL KAUSE, Food Safety and Inspection Service, U.S. Department of Agriculture
RAMIN KHAKSAR, Clear Labs
ELISABETTA LAMBERTINI, Global Alliance for Improved Nutrition
SHANNARA LYNN, National Oceanic and Atmospheric Administration
KATHRYN ROSE MCCULLOUGH, North American Meat Institute
INDAUE MELLO, Newman's Own
MARCOS SANCHEZ-PLATA, Texas Tech University

ABANI PRADHAN, University of Maryland
SHIVRAJSINH RANA, Reckitt
KRISTIN SCHILL, University of Wisconsin-Madison
NIKKI SHARIAT, University of Georgia
ABIGAIL SNYDER, Cornell University
MAX TEPLITSKI, Produce Marketing Association
BING WANG, University of Nebraska-Lincoln
TESHOME YEHUALAESHET, Tuskegee University

EXECUTIVE COMMITTEE MEMBERS PRESENT:

EMILIO ESTEBAN, Chair, Under Secretary for Food Safety, USDA
DONALD PRATER, Vice Chair, Acting Director, Under Secretary For Food Safety and Applied Nutrition, U.S. Food and Drug Administration (FDA)
KIS ROBERTSON-HALE, Deputy Assistant Administrator, OPHS, FSIS
MEGIN NICHOLS, Deputy Director, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention
ERIC OLSON, NACMCF FDA Center for Food Safety and Applied Nutrition (CFSAN) Liaison
JON BELL, Director, National Seafood Inspection Lab, National Oceanic & Atmospheric Administration, Department of Commerce

USDA STAFF PRESENT:

KRISTAL SOUTHERN, Designated Federal Officer, Food Safety and Inspection Service (FSIS)
JOHN JAROSH, Deputy Director, Microbiological and Chemical Hazards Staff, Office of Public Health Science, Food Safety and Inspection Service
EVELYNE MBANDI, Director, Microbiological and Chemical Hazards Staff, Office of Public Health Science, Food Safety and Inspection Service
BRYCE MERRILL, OPHS, FSIS
GLENN TILLMAN, Biological Information Specialist, OPHS, FSIS

SHANTEL WILLIAMS, Administrative Officer,
Resource and Program Management Staff,
Office of Public Health Science,
Food Safety and Inspection Service

ALSO PRESENT:

MARCUS CRUZ, ASL Interpreter
STEVE FOLEY, FDA
WENDY MCMAHON, FDA
BETHANY PEACOCK, ASL Interpreter
ALISON RILEY, FDA
BEN WARREN, FDA CFSAN

A-G-E-N-D-A

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

10:05 a.m.

DR. SOUTHERN: All right, good morning, everyone, and welcome to the Plenary Meeting of the National Advisory Committee on Microbiological Criteria for Foods, commonly referred to as NACMCF.

We have the great pleasure to have this meeting in a hybrid format with our members, Executive Committee and members of the public attending here in person at the USDA Headquarters in Washington, D.C., and then we also have the pleasure of having folks join us online as well.

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

At today's meeting, the committee will provide progress updates on their work for the FDA or Food and Drug Administration Cronobacter species in powered infant formula charge and the USDA FSIS Genomics charge.

So NACMCF is a federal advisory committee that provides impartial scientific

advice and recommendations to the US Department of Agriculture and other government agencies on public health issues relative to the safety and wholesomeness of the US food supply. Food safety programs of the USDA and USDA Food Safety Inspection Service and the Food and Drug Administration are strengthened by NACMCF recommendations.

The programs of other federal agencies concerned with food safety including the Centers for Disease Control and Prevention, the Department of Commerce National Marine Fishery Service and the Department of Defense Veterinary Services also benefit from NACMCF work. NACMCF members are appointed by the Secretary of Agriculture through a rigorous process that helps us to ensure that membership is fairly balanced and can support the functions to be performed. 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

NACMCF and we are incredibly thankful to our members that provide the scientific advice to our federal agencies involved in food safety. So Before we dive in, I want to provide a few housekeeping items that we can keep in mind as we proceed through the agenda. If you have attended a NACMCF meeting before, you've probably heard these a dozen times, but we'll go ahead and go through these, but first, I want to note that this morning's plenary meeting is being recorded and FSIS will post the recording and transcripts when they become available on the FSIS website.

This is a hybrid meeting and with the exception of our committee members and designated speakers, our online attendees' 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 and, 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 email with the

NACMCF Secretariat, I will call on you during the respective public comment period and the event producer will provide additional instructions when we reach that point in the agenda.

Lastly, the chat feature is available for all attendees. Any comments made in the chat will be shared with the committee after today's meeting and 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.

All right, so we're going to now proceed with roll call. We'll start with taking roll of the NACMCF Executive Committee and the NACMCF Committee Members. When I announce your name, please announce yourself by stating here or present; and I'll just note for our online attendees, due to the mic placement in the room, you may not be able to hear the members announce themselves, but we will make sure to capture that attendance.

We will start with the NACMCF Executive Committee members that are present in

person. We welcome the US Department of Agriculture's Undersecretary for Food Safety and our NACMCF Chair, Dr. Emilio Esteban.

DR. ESTEBAN: Present.

DR. SOUTHERN: Present. The Food and Drug Administration -- excuse me, well, Dr. Prater is online, but we'll go ahead and our FDA Acting Director for the Centers for Food Safety and Applied Nutrition and NACMCF Vice Chair, Dr. Donald Prater.

DR. PRATER: Present.

DR. SOUTHERN: Thank you, welcome. Then we welcome our liaisons. From the Food Safety and Inspection Service, Dr. Denise Eblen, is the liaison. I think we have in her place here joining us Dr. Kis Robertson-Hale.

DR. ROBERTSON-HALE: Present.

DR. SOUTHERN: Rear Admiral, excuse me, Kis Robertson-Hale present, thank you. For the Food and Drug Administration liaison, Dr. Eric Olson, I think is online.

DR. OLSON: Present.

DR. SOUTHERN: Welcome and we also have in person our liaison for the Centers for Disease Control and Prevention, Dr. Megin

Nichols.

DR. NICHOLS: Present.

DR. SOUTHERN: Present, thank you. We should also have a couple of other Executive Committee members joining online. From the Department of Commerce, Dr. Jon Bell.

DR. BELL: Present.

DR. SOUTHERN: Welcome and lastly, I didn't see Colonel Wilma, but from the Department of Defense we have Colonel Wilma is our liaison. Colonel Wilma, are you present online?

(No audible response.)

DR. SOUTHERN: All right, so hearing that, we have our attendance from our Executive Committee members. Our Executive Committee helps to ensure that NACMCF is in compliance with the Federal Advisory Committee Act and it's regulations and they provide guidance, support and assistance on processes required by USDA and FSIS, so thank you all for your support and leadership.

We'll now move to the roll call for our NACMCF Committee Members with our in person folks, and just a reminder, when you hear your name, please announce that you're present by

stating here or present and, again, to our online attendees, you may not hear them because they don't have mics as they're speaking.

We'll start with Dr. Bisha.

DR. BISHA: Here.

DR. SOUTHERN: Dr. Carleton from the CDC.

DR. CARLETON: Present.

DR. SOUTHERN: Dr. Carlson.

DR. CARLSON: Here.

DR. SOUTHERN: Dr. Cetin-Karaca.

DR. CETIN-KARACA: Here.

DR. SOUTHERN: Dr. Chapman.

DR. CHAPMAN: Here.

DR. SOUTHERN: Dr. Dutta.

DR. DUTTA: Here.

DR. SOUTHERN: Dr. Feng.

DR. FENG: Here.

DR. SOUTHERN: Dr. Figgs.

DR. FIGGS: Here.

DR. SOUTHERN: Dr. Goldman.

DR. GOLDMAN: Here.

DR. SOUTHERN: Dr. Hansen.

DR. HANSEN: Here.

DR. SOUTHERN: Dr. Havelaar.

DR. HAVELAAR: Here.
DR. SOUTHERN: Ms. Kause from FSIS.
MS. KAUSE: Here.
DR. SOUTHERN: Dr. Khaksar.
DR. KHAKSAR: Here.
DR. SOUTHERN: Dr. Lambertini. Dr. Lambertini is on her way. And Ms. Lynn.
MS. LYNN: Here.
DR. SOUTHERN: Dr. McCullough.
DR. MCCULLOUGH: Present.
DR. SOUTHERN: Dr. Mello.
DR. MELLO: Here.
DR. SOUTHERN: Dr. Pradhan.
DR. PRADHAN: Here.
DR. SOUTHERN: Mr. Rana.
MR. RANA: Yes, here.
DR. SOUTHERN: Dr. Sanchez-Plata.
DR. SANCHEZ-PLATA: Here.
DR. SOUTHERN: Dr. Schill.
DR. SCHILL: Present.
DR. SOUTHERN: Dr. Shariat.
DR. SHARIAT: Present.
DR. SOUTHERN: Dr. Snyder.
DR. SNYDER: Here.
DR. SOUTHERN: Dr. Teplitski.

DR. TEPLITSKI: Here.
DR. SOUTHERN: Dr. Wang.
DR. WANG: Here.
DR. SOUTHERN: Dr. Warren.
DR. WARREN: Present.
DR. SOUTHERN: And Dr. Yehualaeshet.
DR. YEHUALAESHET: Present.
DR. SOUTHERN: So those are our members who are present here in the room and for online attendees that may not have heard, we have everyone present, except Dr. Lambertini, who we have awareness is on her way.
Now, to our committee members joining online. When your name is called, please unmute and announce yourself by stating here or present. Lieutenant Colonel Kubat.
(No audible response.)
DR. SOUTHERN: Okay. Dr. Moorman.
(No audible response.)
DR. SOUTHERN: And Dr. Warobo.
(No audible response.)
DR. SOUTHERN: Thank you. So, hearing none, I recognize that we have 26 committee members present at this time, which meets quorum and I now call this meeting to order.

With that, I'll now turn it over to our Undersecretary for the USDA, Undersecretary for Food Safety and NACMCF Chair, Dr. Emilio Esteban for opening remarks. Welcome, Dr. Esteban.

DR. ESTEBAN: Good morning.

(Chorus of good morning.)

DR. ESTEBAN: Wow, you guys are asleep, more coffee, please.

You know this is very special. I mean, we haven't had a meeting like this in person in a long, long time. And as I'm hearing the names and seeing all of you, I've had a chance to work with most of you at some point in my career, which is sad for me, I guess I've been here too long, but I respect the amount of brain power that's in this room. It's really remarkable and it's very important because they activities that this committee does for USDA and for food safety, in general, is impressive. So we really lean on you for this type of advice.

Before I get into my official remarks, for the sign language interpreters I will try to slow down. I usually speak fast. What you guys do is remarkable. I don't know you do it. I

speak with my hands a lot and I really don't mean what I say.

Kristal, putting this together, you and your team, it's work of giants, really putting together -- I put meetings together with three people and it takes forever and you have here, you know, several dozen people and got it done so thank you for what you do.

Now, to the committee members, we really, really, really appreciate the work that you do. As a matter of fact, the 2022 recommendations that you gave us were the core or the basis of what we actually ended up proposing for the Salmonella proposal that we just published. You recommended we take several steps. We enhanced our exploratory sampling work. We conducted a very detailed risk profile looking to the quantitative risk assessments that included genomic work into its' structure. We do take into account all of your advice.

We have two charges that we're going to get reports on today. One is the genomics charge and the other charge is Cronobacter in infant formula. Both of them are very, very important for us. As you know, one of the things

that I've been trying to do as the Undersecretary is get FSIS, get the agency, to move forward in adopting genomics into our experience, our Cronobacter experience.

This is an example of that. This risk assessment including that. I think the future that we can see for the agency includes a lot more of that genome stuff. I mean with 2,500 serotypes of Salmonella, over 200 serogroups of listeria toxin-producing E. coli, different species of listeria, different species of Campylobacter, I think we just have to focus on the things that matter and for genomics, we can probably reduce all that confusion into some actionable items.

So I really look forward and I'm going to blame you if it doesn't work.

(Laughter.)

DR. ESTEBAN: So for those of you in the Genomics Committee, if it doesn't work, I'm going to blame you, but if it works, you get the honor of being the success story, right?

We really take your advice. Please keep giving it to us. As you know, we publish the Salmonella Rule in August. We're taking

comments until November 7. We've received a plethora of requests for extension, apparently the work you do is too complicated. People need more than 90 days to understand it, so we're going to have to continue that discussion, but it's foundational. The changes we are doing with your input are foundational in the future of where we're going to go in this agency. So I really, really expect your brains to be on to provide us with good advice and, as history shows, we will take your advice. So thank you very much. Is Don going to have opening remarks?

DR. SOUTHERN: Yes.

DR. ESTEBAN: Thank you. I'll stick around as long as I can to criticize your work -- sorry, to give you input on your work.

(Laughter.)

DR. ESTEBAN: And we'll give it back to you. Thank you.

DR. SOUTHERN: Thank you.

(Applause.)

DR. ESTEBAN: Thank you, Dr. Esteban. We will now hear from, well, I'll just say if anyone hasn't heard Emilio give opening remarks before then he can be quite the comedian at

times. But we really do appreciate the work you guys do and we do take it very seriously.

So, with that, I will say we'll now hear from the Food and Drug Administration's Acting Director for the Center for Food Safety and Applied Nutrition, CFSAN, and our NACMCF Vice Chair, Dr. Donald Prater, who is joining us online. Welcome, Dr. Prater.

DR. PRATER: Thank you, Dr. Southern, and greetings everyone. It's really a pleasure to be here with you, albeit virtually. I'm really sorry that I'm not able to join there in person because I see so many friends and colleagues in the room there, but unfortunately, I was not able to join today in person. But be assured, I'll be here participating virtually with the committee today and I'm anxious to hear the public comments.

I want to join Dr. Esteban in welcoming everyone here today. It's a terrific opportunity to come together and discuss some of these charges. As we always mention, but it's worth re-mentioning time and again, NACMCF with its' diverse committee membership including academia, industry, federal, state and consumer

representation, ideally suited to advise us on these subjects and we look forward to the information that NACMCF will provide on these charges.

Before I recognize the charges, I do want to share some information here about FDA's Human Foods Program reorganization. We are on the cusp of this reorganization which will occur on October 1st, so now we're less than a week away. For the last 15 months, it's been my great honor to lead FDA's Center for Food Safety and Applied Nutrition. It's been a very professionally gratifying experience to have a front row seat to the breadth and depth of our work, the incredibly talented and dedicated staff that we have and the strong scientific basis on which we advance our public health mission.

We've been preparing for this reorganization for over a year now and we anticipate a very smooth transition that will lead us to a strong Human Foods Program in FDA. I've mentioned this before, but in case some of you all haven't heard, this reorganization is probably the largest in recent history and is really a major undertaking, not only for the

Foods Program but for our agency in general.

We have Mr. Jim Jones, who is our first Deputy Commissioner for the Human Foods Program and we're already benefitting quite a lot from his leadership and working underneath him. And in the new organization, I will serve as the Principal Associate Commissioner to Deputy Commissioner Jones and I'm very much looking forward to that role.

So, as I have described, we will consolidate a number of the activities related to Human Foods, such as laboratories compliance activities and policies into a single organization and that will really streamline a lot of our work and a lot of the enhancements that we envision with respect to surveillance and risk-based decision making.

Another key change in our new program is the creation of three risk management offices that will lead the strategic and scientific coordination and advance our top priorities of preventing food borne illness, enhancing food chemical safety and reducing diet-related chronic disease and death. One of our major risk pillars, one of our major offices, of course,

will be the Office of Microbiological Food Safety, and this office will coordinate the research, education and regulations that support industry in identifying and implementing practices that prevent bacteria, fungi and other microbes from contaminating foods.

We'll also have a new Office of Food Chemical Safety, Dietary Supplements and Innovation, and a third office, a Center for Nutrition Excellence. I really want to underscore the fact that the scientific advice and the work that the subcommittees are doing, particularly on the Cronobacter charge, but also the genomic charge, this is really critical to how we will be doing food safety in the 21st century. So, very grateful for the work that you all continue to do and the recommendations that you all provide to us. It really does underpin our work.

With that, let me go ahead and express my thanks also the Executive Secretariat staff who are so critical in making everything work smoothly for today's meeting. Thank you all very much and looking forward to the discussions to come.

DR. SOUTHERN: Thank you, thank you, Dr. Prater and speaking of FDA, the Cronobacter species in powdered infant formula charge is a charge from FDA that seeks a better understanding of the factors that contribute to Cronobacter species contamination of powdered infant formula and on the production environment needed to increase the effectiveness of prevention and management strategies.

The NACMCF Cronobacter Subcommittee is co-lead by Drs. Elisabeta Lambertini and Abigail Snyder. They will provide the progress updates on the committee's work to address the charge. Before I welcome them, I do want to just say one thing, we throw a lot of titles around and different names for people and you all are all familiar with the NACMCF members.

When we break out into these different charges, they are subcommittees and their co-chaired by two folks that are chosen to essentially lead that subcommittee and assist me, as the Designated Federal Officer, assist the NACMCF Secretariat and also to just help spearhead the work getting done. They organize all the drafts. They help to sit in on the

meetings. They do a lot of work to just help the committee to continue the work and meet all their deadlines and ensure that they're meeting their requests and the questions that are presented to them through the charge from the various agencies.

I don't think we've ever acknowledged the work that the co-chairs do. We always acknowledge the work of the committee which is amazing, but there are these few other folks that do a little additional to help ensure that the committee works well and so, I do want to, before you guys give your presentations, extend my awesome thanks to you all. You have been wonderful to work with; and with that, I do want to welcome, we'll first have our updates from the Cronobacter subcommittee charge and I welcome Drs. Lambertini and Snyder to give that presentation, so thank you.

DR. LAMBERTINI: Good morning. It's wonderful to see you all. We'll give about 10 minutes of report out, mostly focused on process report at the beginning and then on the last day, we'll give more of a content and draft recommendation report out.

As a recap, we have four questions to our charge. The first one was almost entirely completed in the last phase last year and the scope was to review data on occurrence and levels of Cronobacter in PIF ingredients. PIF, powdered infant formula. In this space, we are reviewing the evidence again. We do not see much need for additions at this point, but before we close the charge, we will do another pass and update any newer information.

I could say the draft recommendation that is forming here is very simple. We need more data, especially for the US, we don't have much to work with. So overall, we are making good progress. We had two full meetings, this is the third one. We have a good outline and starting grounds for all the three remaining questions. We have consulted several SMEs and you will hear a little more about that information that we are including, and we have two systematic reviews in progress; one on question 2 and one on question 3.

Just to recap, that we organized in primarily three working groups with the first being the review of question number one and we

have had very good attendance with biweekly meetings for all the working groups and a very high level of participation. Also, kudos to everyone for showing up and being so well organized.

In terms of progress on question 2, question 2 aims to understand the host-pathogen interactions, both from the genotype and phenotype of the pathogen or the hazard and what characteristics of infants may put them at higher risk.

For question 2, we are almost done with a systematic literature review on virulence factors and host factors. So, we have prioritized the pathogen characteristics, keeping in mind the core of the question being host-pathogen interaction. In terms of virulence, we are considering survivability, pathogenic strength and others, such as antimicrobial resistance. For host factors, we are looking at age as a factor, comorbidities and microbiome profiling.

We have primarily consulted one subject matter expert, Professor Stephen Forsythe, who has really pointed us in the right

direction and provide useful synthesis of the evidence on this matter. We are going to say a little more about this in the report out.

As an update on the literature search, this is just a bit of the methods. There was a large number of articles retrieved and screened, so we have some good material to work with here. The focus, virulence, pathogenicity factor and host. I'm not going to go in details on here, just showing you the materials we are working with. It's been quite a big lift to screen and review this body of evidence.

The plan for the next three days is to continue this work and wrap up the work on data extraction from the literature review and advance the draft. So, these three days are really for adjusting and drafting and writing and the guiding questions that we want to focus on in these couple of days, are what factors play a role in distinguishing Cronobacter species or subtypes that may be more clinically relevant, focusing both on Cronobacter genomes and sakazakii specifically.

In the second guiding question is what factors contribute to the heightened risk posed

by Cronobacter as an opportunistic food borne pathogen to certain subpopulations, so zooming in on the host subpopulation. I think that is all for question 2 and I will pass on the report to Abby, thank you.

DR. SNYDER: Thanks, Elisabeta. Hello, everyone. I'm going to be giving the updates for work groups three and four. I'm going to start with three. Question 3 concerns food safety management practices that can be used by PIF manufacturers to further reduce the risk of Cronobacter.

Just a bit of an administrative update on this one, so this work group is collaborating with the National Act Library to conduct a systematic literature review. When last we updated you, they developed the search protocol. As of today, they've run the search, there were about 1,800 results. The work group has done title and abstract screening. Fewer than 400 results now meet those inclusion criteria, so that work group will use this body of literature to evaluate and substantiate their recommendations going forward.

As you may recall, the work group is

organizing their response in kind of five categories or themes. They are ingredients and suppliers, facility and equipment design, process controls, sanitation controls and then root cause investigations/corrective and preventive actions. I'm going to touch a little bit on each of these. While recommendations are still incipient, you can get a sense of the sort of themes of the discussions within those work groups.

Within the first, that is ingredients and suppliers. The work group has been discussing the different types of ingredients that are used in PIF production, particularly those that may be added after a kill step. So, in dry blend operations that could include vitamins and minerals, carbohydrates, milk powders, fats and oils and other proteins.

The work group has been discussing surveys of Cronobacter prevalence related to Q1 that are kind of unevenly distributed among those different types of ingredients. So, while that may pose a barrier to PIF manufacturers assessing risks from different ingredients, other information that PIF manufacturers may evaluate could include the volume that that supplier

produces for PIF versus the volume that that supplier produces for other foods or potentially non-ready-to-eat foods as part of assessing those suppliers.

There is discussion about evaluating suppliers to see if those suppliers are producing an ingredient added after a kill step, do they include controls for Cronobacter, are they operating under more conventional Salmonella control strategies.

The second subheading here is facility and equipment controls, one of the topics in still some of the earlier phases of development, I think, for the work group. This has generally kind of landed on engineering controls for hygienic air handling, those to reduce moisture within production facilities, verification activities to identify problematic locations or those for a potentially poor hygiene design and strategies to improve hygienic zoning.

The third example is process preventive controls. This is probably the subheading most supported by the systematic literature review that I referenced at the start. The work group did discuss whether or not to

include sterile shelf stable liquid infant formulas, as those process controls would certainly address Cronobacter, but decided that, except for perhaps a brief mention, that fell outside the scope for this work group, which is really charged with PIF processing controls, so work group four will touch briefly on the recommendations for the use of those products. This work group will focus on controls for powdered infant formula manufacturing.

Topic four is sanitation and associated verification activities, namely environmental monitoring. So, the work group is evaluating dry sanitation strategies, such as flushing as well as wet sanitation strategies, like the use of chlorine dioxide. They're gathering evidence about the efficacy of these different strategies, the quality of evidence to support validation of these different sanitation strategies, and circumstances that might limit the efficacy of these methods as well.

This section also addresses the need to dry the facility and the equipment after a wet sanitation before resuming production. So, things like blowing hot air through the system or

equipment, that is moot for COP, moved out of the production area using a hot room or ensuring otherwise that it's air dry before moving it back into production.

Thirdly, this section includes, as I mentioned, environmental monitoring, so recommendations to include Cronobacter specific testing with an environmental monitoring program for PIF manufacturing as well as suppliers of ingredients that are added after the kill step and then the complementary role of indicators, such as EB, or Enterobacteriaceae, quantification and detection of Salmonella.

And then the fifth and final one in this charge question is root cause analysis and corrective and preventive actions. Generally, this is focusing on mitigation of product risk and investigative strategies in the event of a Cronobacter positive in product or environmental monitoring program. For example, recommendation to collect investigative samples before implementing mitigation strategies, like collecting environmental samples before sanitation in the event of a positive.

To sort of wrap up the updates from

work group three, this group had a couple subject matter experts present at the start of their effort and I think they intend to have a few more in the next few months as they further refine their recommendations.

Transitioning now to question 4, this is the question that concerns risk communication to caregivers of high risk infants. That would be infants two months of age or younger or otherwise immune compromised and the risk communication is really kind of in two buckets, one is the use of that sterile ready-to-feed liquid formula I mentioned, and the other is preparation and storage instructions for reconstituted powdered infant formula.

Groups have taken different approaches to addressing the charge question and this work group has front loaded subject matter expert presentation. So they have heard from USDA, CDC, FDA and then since last we updated you, the American Academy of Pediatrics, the AAP. Mostly what I'm going to be sharing now are some of the takeaways from the more recent subject matter expert presentations.

This group is not conducting a

systematic literature review. There's a relatively small body of literature on this topic which they will gather, but we're not collaborating with the National Act Library to conduct that systematic search here. You may recall this group is structuring their response in kind of this form of the outline. They're thinking about what to communicate, meaning content, to whom and by whom, so who are the key groups to target with this communication and who are the key groups who do the risk communication and then finally, strategies for more effective risk communication, the how and the when.

So, as I mentioned, one of the topics that this group is addressing is recommendations about the use of the sterile ready-to-feed infant formula, which is definitely safer, right, there are definitely controls for Cronobacter as well as other microbial hazards and it doesn't require dilution so it avoids mixing errors. The downside of this is that it's more expensive and it's not universally covered by WIC. From the food technologists' perspective, it's got a great control but there are real implications to recommending this kind of across the board for

the burden that it places on consumers for the additional cost.

This was a topic we raised with the AAP SMEs, those subject matter experts. The takeaway from that presentation was their sense that NICU patients discharged and within the first six weeks of life represented a high risk group where recommendations for the use of sterile ready-to-feed infant formula would be most valuable. They expressed concern about universal recommendations for other infants in the first two months of life because of the burden of cost.

We also talked with AAP about the recommendations for hot water preparation of infant formula. Generally, public health guidance is something like bring water to a boil, wait five minutes, use that to prepare infant formula and the hot water would inactivate Cronobacter that may be present as opposed to end point temperature monitoring. The work group is evaluating -- and there are reasons for that approach, but the work group is evaluating the pros and cons of the content of the messaging, but was also interested in the role of

pediatricians and neonatologists as crucial stakeholders to communicate to parents that messaging regardless of what the specifics were.

Those SMEs indicated that this was not something that is typically on the list of pediatricians' talking points during those newborn appointments. They have a lot of other stuff they are trying to address and they also want to emphasize breastfeeding. They did indicate that nurses, for example, on postpartum units and those that direct the lactation or the infant dietetics programs may be the folks most likely to be sharing that information with new parents. So, that might be a primary stakeholder group to address.

That gets into the next component of this, which is to whom should this message be really targeted. The work group is considering not just who, kind of a broadening of the scope of who the target is, parents, grandparents, daycare providers, but also thinking about the people who are those important risk communicators, like nurses, like people who teach birth classes or provide lactation or postpartum support. Part of this, I think, response

recommendation will include the difficulty of reaching those groups, like there's not a listserv for those people and so how do you target messaging is an important critical aspect of this.

And then finally, the third component here is about optimizing risk messaging, so how and when, and so that includes some feedback we've gotten from USDA subject matter experts related to increasing hazard awareness as opposed to specifically or exclusively sort of didactic instructions. It also includes consideration of labels, product preparation instructions on packaging as key venues for risk communication as well.

So, that is the update from the Cronobacter group and I think I'm happy to turn it over for public comment.

(Applause.)

DR. SOUTHERN: Awesome, wow, thank you. What a great update. Thank you so much. Again, those are our co-chairs for the Cronobacter subcommittee and we have a number of members here who are also contributing to that work. We always start our comment and discussion

period with addressing our Executive Committee members. I see, Dr. Prater, you're online. You do have the opportunity to unmute yourself if you have any questions, but we will first turn it over and see if there are any questions in the room from our Executive Committee members.

For the Executive Committee, just one second, Dr. Hansen. I just want to check in with Dr. Prater. Dr. Prater, did you have any questions or comments for the Cronobacter group?

DR. PRATER: Thanks very much. I really appreciate the good and wholesome update, it's amazing how much work is being done in all the different subcommittees, but a sincere thanks to Dr. Lambertini and Dr. Snyder for all their work leading this. It seems like it's very well organized.

I don't have any particular questions at this moment, but just my sincere appreciation for some of those recommendations, observations that were shared during the report and we look forward to see more of that, so thank you very much.

DR. SOUTHERN: Thank you, thank you, Dr. Prater for your comments and kudos. We do

have a question here with Dr. Esteban. We've got to make sure that our speakers in the room get the mic, so there may be a slight delay between comments.

DR. ESTEBAN: Great, so question, when you were looking at the literature and looking at the consequences of your recommendations, were there any considerations given to international impacts of importing or exporting of commodities? When I attend meetings at the international level, the situation of the United States is very specific; there is a dire need for this type of products in other parts of the world. Are there any discussions of how these recommendations would maybe be picked up by some other country or impact the international availability of this commodity?

DR. SNYDER: Yeah, that's a great point.

DR. SOUTHERN: One moment. I want to make sure we get the mic.

DR. SNYDER: Of course. That's a great point and we'll make a note. I think it has come up in the first part of Q3's charge related to supplier considerations for

ingredients, but I think your additional comment about availability is another consideration that will add to that as well.

DR. SOUTHERN: Thank you. Do we have other questions or comments from the Executive Committee?

DR. NICHOLS: In reviewing the literature, did you find anything that would recommend a change in the packaging in which the powdered infant formula was provided to parents, such that they would not be able to reach their hand in, such as a pour spout or something else to avoid cross contamination?

DR. SOUTHERN: And for those listening, that was Dr. Megin Nichols of the CDC.

DR. SNYDER: I should say I'm also happy to hand this over to others within the work group if anyone wants to chime in.

DR. SOUTHERN: Absolutely.

DR. SNYDER: It has not been one of the topics of primary discussion with some of our subject matter experts. There is definitely literature on infant feeding that hand hygiene is critically important which could be extrapolated to methods to prevent cross contamination with

how the packaging is constructed, but I'm not currently aware of any literature right now on changing it, for example, to single serving or something along those lines. I will see if any other members want to add.

DR. LAMBERTINI: Yes, on question 1 on occurrence, we did look for that and we did not find much literature, but we will make a note to keep that in mind.

DR. SOUTHERN: Are there others from the committee that want to address Abby's point in the response to Dr. Nichols? No? All right, before we move on to discussion and questions with the committee members, are there any other Executive Committee members that have any questions or comments? No? All right, so we'll now move on to questions and comments from our committee members and we'll start with Dr. Hansen from Consumer Reports.

DR. HANSEN: Hi, this might sound a little bit like the skunk at the party, but I'm particularly concerned because it seems like all of these questions are assuming that the risk is primarily coming from the production environment with powdered infant formula and I think it

should be remembered that originally this was considered one species which was Enterobacter sakazakii, but then when they looked more carefully, it's actually a different genus Cronobacter, with at least seven different species.

All of them appear to have pathogen qualities and, furthermore, if you look at it from an evolutionary perspective, it looked the niche in which these things evolved was plant roots. So, actually there was a study published just this past July that looked at over 4,000 retail foods and 263 homes. It turns out both Cronobacter species, a number of them, and Cronobacter sakazakii, were found in 25 percent of the homes tested. The highest levels were actually found in the entry way and then also in the kitchen and other areas. Of 4,009 foods that were tested, five percent of them were positive, but certain subcategories such as --

DR. SOUTHERN: Dr. Hansen, one moment. They're having issues with that mic, so let's try switching to this one.

DR. HANSEN: Okay, of the 4,009 retails foods that were sampled, five percent

were positive for Cronobacter sakazakii, but certain categories were much higher. For example, grains, baked goods and flours, almost 26 percent were positive, nuts and nut butters 10 percent were positive, and also 10 percent of seeds, sprouts and beans were tested.

They did complete genomic sequencing on all the samples and this was not a case of contamination because every different house that they tested, they were completely different. The only similarities were within a given house and so it seems that it's widespread in the environment and actually, a couple of years ago, FDA themselves tested a bunch of flour powders and they also found Cronobacter sakazakii.

I would also point out that when they did the strain typing, the most common strain found was SQ4, which is linked with neonatal meningitis, and it was, in fact, the most common sakazakii found on kitchen surfaces and floors and also some food items, including pet foods, trees and peanuts and the genes associated with resistance in multiple classes of antibiotics were found in most or all of the genomes. The genes associated with infectivity and host

resistance, e.g., virulence genes, were also found in the majority of the genomes.

Most importantly, most of these genes were found on mobile genetic elements which means they could be transferred much more easily between Cronobacter species. In fact, I should just point out this summer on July 20, the Canadian Food Inspection Agency had to actually issue a recall of a Baby Gourmet Organic brand banana raisin cereal due to the presence of Cronobacter. That means, at least Canada considers that an adulterant in foods beyond powdered infant formulas.

We at Consumer Reports have talked to FDA, we actually think that it should be declared an adulterant for some of these foods and, in fact, also if you're going to educate the public, besides talking about how they deal with the packaged infant formula, they need to be concerned about the home environment, et. al. For example, if the toddlers are walking around on the floors, are they picking anything up there? This is all new, so I understand why the questions aren't there, but I think when new science becomes available, it should be

considered. Thank you.

DR. SOUTHERN: Thank you, Dr. Hansen. Before we address the comment, I do want to do a mic check. We're getting some feedback.

All right, so we've lost a mic in the room so there may be a slightly longer delay between responses. We want to make sure that the mics get to people, so not a problem. We'll work through that. So, thank you, Dr. Hansen, again for your comments. Did anyone from the committee want to respond to that or any additional questions from the comment that was received? I'll go ahead and help out with mic duty.

DR. SNYDER: Just briefly, you're not the skunk in the party and some of your points about cross contamination in the household are some things that are on the radar for this committee. We're aware of the study that you referenced.

Things like the hot water preparation instructions would work as an intervention, whether or not the Cronobacter was introduced in the home or in the production environment. Dr. Nichols pointed out the single serving packaging that also kind of gets at household cross

contamination, so that's definitely on the committee's radar within that Q4 charge.

For the complementary foods, I think we'll have a discussion in charge question 2 about host factors which will look at some of the epidemiological information on the ages of the vast majority of Cronobacter patients, who are so young that they would not be eating complementary foods, so that probably informed some of the committee's thinking on what foods are at risk.

DR. SOUTHERN: Thank you and so that was, for our online attendees, that was Dr. Snyder. Are there any other questions or comments on the Cronobacter charge in the room? How about online? We'll check in online with our Executive Committee members online as well as if there are any committee members online that wish to ask a question or make comment on the Cronobacter charge.

Okay, I am hearing and seeing nothing in the chat, nothing online. All right, so great. Thank you all. In the plenary meeting, we always have an opportunity for the public to comment. We had one person to register to comment online. I received a notification that

that person has not joined, so we do have a little bit of time if there are any other members of the public who wish to provide a comment during our public comment time. We request that all commenters please introduce yourself by providing your name and your affiliation before providing comment and you will be allowed three minutes to make your comments and then the event producer will move on to the next person in the queue. So, in order to do that, I'll turn it over to the event producer to give instructions to our online public attendees on how they can raise their hand and unmute their mics.

INTELLOR HOST: Okay, if you wish to make a comment, please go ahead and click your raise hand icon at the bottom center of your Webex screen. You will hear a notification when your line is unmuted, at that point then you'll state your name, affiliation and make your comment.

All right, I do not see anyone in the queue at this time.

DR. SOUTHERN: Okay, thank you. Before we move on, one last check, going once, going twice on the opportunity to comment or for

members, additional questions on the Cronobacter charge. Okay, awesome sauce. Oh, we've got one, Teshome. So, we have a question or a comment from our NACMCF member, Dr. Yehualaeshet.

DR. YEHUALAESHET: Thank you very much. Something stuck with me, when Dr. Megin was talking about the MAM. We had two big topics already on Salmonella, and now we're working on Cronobacter. We always input every important item. Is it really important as final edit to put something on education.

DR. SOUTHERN: What was the --

DR. YEHUALAESHET: Education to the users. It might now be important, but to me, can you boil down those things a little bit? Just that report says on our final documents, because we need to put the users, we have to tell the users what they are supposed to do to prevent or control the prevalence of this particular disease.

DR. SOUTHERN: Right, I think, and so Dr. Yehualaeshet was asking about, with the final report, how important -- and correct me if I get this wrong -- how important it is to provide that education open pointed in the report for the

users and consumers. And I think that really boils down to the charge questions themselves and that's the scope of the work for the committee and this particular charge does have a single question, if you go online to the NACMCF page for our online attendees, you can see all of the charge questions in one place. And there is one charge question for this particular charge that is very specific about the communication to consumers.

I can't speak to the past charge questions and how specific it got to that, but I do know that this one very specifically does ask for that information. So, thank you for the question. If anyone was asking if the goal is to provide advice to the agency, where is the consumer side of it, and that was because, this particular charge, FDA does request advice on how they should be communicating with consumers on this issue. Thank you.

All right, so, I'm now going to move on to our next presentation. Thank you, everyone, this was a great discussion. This is exactly why we're here. And we're going to now have the Genomics charge presentation.

The genomics charge is a charge from FSIS that seeks advice from NACMCF on the considerations, advantages, and disadvantages of using genomic analyses. FSIS also seeks to obtain information on current or emerging technologies and recommendations on strategies that could help rank and focus resources on food borne pathogen subtypes based on risk to public health.

The NACMCF Genomics Subcommittee is co-led by Drs. Vik Dutta and KatieRose McCullough. They are here today to provide progress updates on the committee's work to address this charge and I now welcome, Dr. McCullough and Dr. Dutta.

DR. MCCULLOUGH: Thank you, Kristal. I just want to start off by saying on behalf to the entire Genomics Committee, thank you to you, Dr. Southern, and the entire USDA team. This is a huge effort to put all of this together. And there's so many brilliant scientists at USDA that you guys have really served as great advisors for us and keeping us on the straightened arrow. So special shout out to you, Dr. Southern, and you, Dr. Tillman, who's our main genomics handler and

helps us sometimes remember our main focus, but we're very, very thrilled and really excited to be here.

We're excited to tell you about the tremendous amount of work that we have been doing on the genomics charge. To start off, I wanted to remind everybody or Vik and I wanted to remind everybody of the charge questions that we have. I think this charge was written as extraordinarily broad and oftentimes we'd have to -- we got to go back to our main questions and say, okay, what's the question? It's easy to get off in multiple different rabbit trails, but it is also what makes it so fun.

So, we've really been focusing all of our time up to this point on questions one and two. So looking at appropriate genomic and pathogen attributes, different product characteristics as well as different epidemiological factors that can relate to severity of illness, that characterization that a pathogen may have as well as the different available and applicable tools that are available and there's positives and negatives of those and how they all merge together. We kind of refer to

that as an alphabet soup in that question 2, which Dr. Dutta will give us an update. We'll talk about three and four later when we talk about our plans for the future.

So, so far, up to this point, we have had over 15 different SME presentations and we've had a number of different subcommittee meetings on genomics. We're, so far, have been organized with question 1 and question 2 and we're having obviously our first in person meeting here. Both question 1 and 2, meet approximately those question groups meet about every two weeks as well as our entire genomics subcommittee meets regularly as well, and then those who have been working on different sub parts of each of those questions, have been meeting periodically as needed amongst either the pair, the two or three people working on different components.

We also are working on a number of different resources including with the NAL team, the different validation databases and using the NACMCF Secretariat as a number of different resources to pull from.

Up here on the screen, is the list of subject matter experts that we have had either

come present or are planning on presenting. One of the ways that we want to make sure we're utilizing this tremendous amount of information from subject matter experts in the report is we have brought up at one of the last meetings, is we need to make sure we're capturing this information appropriately. We've had a tremendous amount of subject matter experts come in and may have more, even beyond the ones in green there at the bottom, present.

How are we making sure we're putting this in the report as appropriate? So moving forward, we are going to be summarizing each of those subject matter expert presentations on how the information they provide is related to the charge to make sure it is incorporated appropriately into the report once it is due to USDA. So luckily, we'll have those recorded and we'll make sure as a committee that we've gone through and incorporated and plug that information in as needed. But, like I said, we've had a robust amount of subject matter experts present to the committee and have more to come in the future.

We're also working with the National

Act Libraries to do a literature search. You can see the terms here on the screen which has been a labor of love with as broad of a charge as it has been. We've done a number of different options for search criteria and have come back with tens of thousands of papers depending on how we do the search, so we have since finalized search criteria and will be moving forward with them, but we're really, really thankful for the National Act Library team and look forward to talking to you about our next steps there with Dr. Dutta later.

All right, jumping into what we've done, progress so far on Q1. We both have two completed first drafts of question 1 and 2. So question 1(a), which is the epidemiologic and pathogen attributes section, the epidemiologic criteria that should be used to rank different subtypes, so far we've started with the introduction about genomics can play a role for pathogen identification and the role that genetics play overall. We've collated and collected the different available data sets that are out there and what metadata each of those data sets have, not just within the U.S., but

globally.

We've had a big passion of making sure that we're taking a global perspective here when we're talking about what important things have been collected out there, what resources are out there that we can really pull from to take this larger view from multiple different pathogens.

We've also discussed the different attribution approaches out there to understand how we can use genomics a little bit better and what's making people sick. I think attribution is super important, and there are a number of different ways that we look at attribution, both here within the U.S. and globally and the role the genomics can and cannot play in that needs to be included in there. So we've done a bit of a review of the different attribution approaches as well.

Then, we've looked at different epidemiological criteria and what role and how it intersects with genomics. So, we've discussed the importance of outbreak size and scope, so an outbreak that is maybe -- you know, not all outbreaks are considered equal is what I have on this slide. So outbreaks that are, you know,

from a potluck associated with somebody's backyard are very, very different than something you're seeing across the country, found in products in some sort of item that we're seeing coast to coast. So, how we take that information and how we communicate that from a risk perspective is going to be a little bit different and what role can genomics play in hopefully helping with that.

The link to sporadic illnesses as we know, only -- what, I think, it's about four percent of illnesses are associated with outbreaks and quite a bit of illnesses are linked to sporadic illnesses. So how do we appropriately link sporadic illnesses versus outbreaks to each other and those different pathways that are making people ill is covered.

And then, the frequency and severity of illness and the patient outcomes. So, not only how many people are getting sick, but how sick are those people getting with what and for what further complications or health outcomes is something that is both important in component 1(a) and 1(c) that we'll talk about a little bit later. Those different epidemiologic criteria,

if we can tie different genomic attributes to those, maybe we're able to take a more risk-based approach and so to, again, identify and figure out what role can genomics play, we need to sort of level set and talk about the important epidemiological and product characteristics that are out there that we can maybe tie genomics to.

Then, we're talking about again the different epidemiological risk factors of concern that relate to severity of illness that we talked about. We broke that down a little bit, looking at age and then immunity, so a lot of these things are not new, but also different culture and dietary behaviors. But all of these things can relate to those things that we talked about earlier, which is that severity of illness or what other long-term health complications could happen for somebody.

And so, sort of again, level setting the genomics, we're not looking for genomics to play a role in age-related epidemiological factors, but it is still an important consideration when you're talking about severity of illness. And so we felt providing a little bit of background and level setting on there was

something that the group thought was important.

Moving onto 1(b), which I have to give a shout out to Abani, he's been our fearless leader on group 1(b) and they have done a tremendous amount of work on the risk assessment portion, which is what's been done here. And so this is how pathogenomic criteria can be used to incorporate different things into microbial risk assessments, so there's been -- the report starts off by talking about the different approaches to risk assessment, then the use of genomic data in quantitative microbial risk assessments using the hazard identification and how that epidemiologic criteria fits in there.

Advances in hazard identification, so different genomic characterizations of different food borne pathogens, what already has been done, what hasn't been done, the limitations of current and conventional classifications, you know, and methods that are out there, like stereotyping. What are we missing in those approaches? What do we need more of? The impact on public health, the potential trade and industry implications of that as well.

And then the identification of the

highest pathogen subtypes and gene targets, so again, there have been some that have been done in this area as Dr. Esteban talked a little bit about earlier with the work they've done at FSIS on Salmonella. And so, how do we expand that to all pathogens and what has been done, where are the gaps in those and how do we continue to march forward.

Genomic applications and exposure assessments have also been covered. The use of genomic and hazard characterization in talking about dose response modeling and how dose response models for these target pathogens can account for variations that we see, as well as how that interacts with the host pathogen. The use of genomic information in those dose response models and that sort of mechanistic path forward is where we would like to be and then again, not only how do we take that sort of hazard characterization, but how do we then apply that risk characterization to that portion.

Then, finally, rounding up in question 1, which is the portion C, which is where we've talked about the genes for each of those pathogens that are already known. So we've

created a -- Dr. Carlson created a massive table with the help of other people that says, okay, here's the different genes that have been identified for each of these pathogens of concern and what are they associated with. What health outcome or what pathogen characteristic are they associated with and then how do we tie that to some long-term adverse health outcomes?

So, you can see here on the screen a little bit on the element Salmonella side that we've said, okay, here are some genes that have ties towards people having significant health outcomes long-term and so how can we maybe identify those or use a lot of this information as our foundation for question 3 and 4 moving forward when we're talking about research gaps and recommendations. So that sort of database that we're building of those different known genes under each pathogen to say, okay, now that we've collected all the information, we're really excited to spend the next couple of days to say, and then what?

I'll pass it over to Dr. Dutta.

DR. DUTTA: Thank you, Dr. McCullough. Good morning, all, if I haven't said it to you

already. So before I jump into the progress we have made with question 2, I would like to step back a little bit and share, first of all, my gratitude for NACMCF Secretariat for all of their help and the opportunity to allow us to work on this. And then, also thank our subcommittee members because they've been hard at work, I hate to tell you this is going to get more intense as it goes forward, but it's been fun so far and, you know, I think this is coming out really good.

One more thing I want to say before I jump in, two cornerstones are guiding the progress of this committee. Number one is more foundational, I would like to steal your words, Dr. Esteban, this is foundational work, and we recognize that. We recognize the responsibility that comes with it, and therefore we're taking our time to make sure that whatever we are coming up with is comprehensive and it makes sense.

So going back to the makes sense part, and that's more aspirational, and this is where Dr. Tillman and others have been really helpful in guiding us to not just give pie-in-the-sky recommendations, but be more realistic and be more practical and pragmatic in what we are going

to come up with as recommendations.

So with those two cornerstones guiding our work, diving into question 2, as Dr. McCullough said, it is a very broad charge. We needed to drill it down to something more manageable and we kind of bounced around for a while before we started providing this structure to our response, and what guided that structure is criteria for genomic methods that are to be included in our discussion.

So we're not talking about simplistic single gene PCRs, for example. And then categorizing methods because it was becoming clear to us that a lot of this alphabet soup is not realistic for all of us. And I've worked in this field for a long time and I, myself, am just catching up to some of these odd sounding names. We needed to really categorize that into something that whoever reads the report ultimately can work with it.

And then also, looking outwards into the validation sources, like AOAC, CLIA, AFNOR and so and so forth to see if there are methods that are already validated or accredited so that, you know, agency can pick up with them and start

working with them.

The second piece was collation of the methods data. We needed to just be comprehensive and come up with some idea and criteria to make sure that whatever we are sharing in the committee and it's sort of including most of it that it makes sense and it is as comprehensive as it can be, I'll get to that in a second, why it can be comprehensive and then, of course, drafting a response.

So, as far as the categorization of the methods, we came up with -- you don't have to read through this, this is just a representation of it. We basically split the methods into three different categories. One being culture-dependent diagnostic testing. We're talking about isolates here. The second being culture-independent diagnostic testing as it relates to PCR and amplicon sequencing and the third is metagenomics.

Behind these two categories, there is a very large table that the subcommittee has put together that is describing all the methods that are available to date, with important characteristics that we think would be useful in

our ultimate recommendations. It became clear to us, not that we didn't know already, but it was very clear that the landscape of methods and technologies is evolving faster than ever and so, you know, it needs a constant reconnaissance, no matter who's doing this and how you are utilizing that constant look has to be kept up.

But few early conclusions, we did not see any analytical methods, and that's a key point, that have been -- that can integrate the genomic data and the metadata for distinguishing strains based on likelihood of causing illness give exposure. And also, there are no methods that are validated and accredited at the AOAC given the charge questions and as they relate.

Now having said that, there are efforts at the AOAC, I'm giving you an example here, where there have been certain criteria that have been put together by the accreditation bodies to home in on what these methods, the genomics-based methods, should look like, what are the criteria for that. So there is that level of guidance that is out there, but as far

as methods are concerned, we did not see any one

method or one specific analytical method that could be -- that is accredited.

We have also -- because of that, we have come up with -- we are recommending housekeeping criteria for including currently used genomic-based approaches to food safety decisions in the U.S. and internationally. The idea being there is certain criteria that is made available to -- for downstream reference, which, no matter what technology comes up 10 years from now, it should follow that and then the committee nonetheless recommends a multifaceted approach that combines traditional competitive methods with the AIML approaches.

And this is a bit of jargon right now, but we hope to home in today and in the next three days as we go into questions 3 and 4 into what specifically that means so we can start getting some specific recommendations. So for the next three days or two and a half days, the hope is to complete the Q1 and Q2 response drafts. The National Act Library has provided some early inputs to the subcommittee. It took us a while to get there, so everything you have seen so far from the recommendations is the SMEs

pulling in the references, but going forward we do have the National Act Library outputs that we look forward to taking a deeper dive in, both including the protocol review and then also splitting the articles among ourselves so we can do a deeper review of whatever we have recommended so far, is that still relevant and if we need to add to that we can do that.

And then, focusing on creating a structure for Q3 and Q4, I just wanted to give you quick ideas on what are we thinking about in terms of what could turn in the recommendations. For example, performing a retrospective analysis of the existing data, so using the AIML tools with a specific objective to identify risk factors, such as emerging strains, virulence and adaptive genes. Basically, can we go back to all the data that we've been collecting for 10 plus years as a public health community, is there something else we can learn from that. Improving the quality of the genomes and the databases and the data itself.

We think there's room for improvement there and the efficient use of collection analysis, the genomic data is one of the areas we

would like to pursue. The idea being WGS 10 years ago on everything made total sense, because what we knew as a public health community was very little. Going forward, we have 10 years of data that can be maximized with what we're already doing to something more meaningful going forward. So we're not -- we don't have a need, for example, to do WGS in everything that's one of the ideas we're exploring.

And then, of course, pathogen-specific research gaps, thanks to Dr. Esteban and others, who made a comment during our previous plenary committee to look a little bit deeper into pathogen-specific gaps and we intend to explore that as well. And ultimately, we would love to recommend the creation of a real-time dashboard for public health purposes that provides statistical overview off the public health surveillance system with a clear delineation of the risk based factors on the known and evolving ones.

So with that, I will pause and happy to take any questions.

(Applause.)

DR. SOUTHERN: And, again, another

wonderful presentation from our subcommittee and the subcommittee co-chairs. So, with that, we will, as we always do, turn it over to our Executive Committee to see if there are any questions or comments and I know, Dr. Prater, you're online so feel free to hop on video and unmute yourself if you also want to ask any questions.

But before we do that, let me just mic check, are we good, event producer, on the sound? Okay. I think we have retired the one mic so we will continue working with two mics, so there may be, again, a slight delay in some of the responses and we will try to work around the room.

With that, Executive Committee members, do you have any questions or comments for the committee. For those online, you can't see Dr. Esteban's face, but he's smiling so either he has something or he's thinking.

DR. ESTEBAN: I am always thinking.

DR. SOUTHERN: Okay, because I was saying we're going to come back to you because I'm pretty sure you're not going to leave this meeting without a comment.

DR. ESTEBAN: Yes, clearly, I'm very interested in this whole genomics approach. I think this is great for the future. When I'm gone, you guys will still be working on this and by the sounds of the report, when I'm gone, you will still be working on this because you are opening more questions than the ones that we actually posed.

But one thing that I would like to make sure that have at least acknowledged or considered or something, we've been working on genome sequencing for 10 years, and like you said, we have very, very large databases, yet we've excluded the main source of genome sequences, which is all of the industry data. And so, is there a way that we can actually get that type of analytical data into this thought process?

Normally, industry doesn't like to do a lot of genome sequencing because a) their attorneys think that they are liable, which is a thought, attorneys. But, can we achieve some level of information without getting that much definition of the genome that they could still contribute to the database without being blamed

for an outbreak. There must be a different level of definition. Right now, I think we're trying to catch every single little gene thing in that ultimate description, but we have to give a little up that it doesn't reach that gradually -- that data, from industry. It would help us with public health. Have you been able to at least put that into your thought processes for the recommendations?

DR. DUTTA: This is Vik Dutta. Dr. Esteban, it's a very good question and my hope is that once we are done with it, with the committee's work, we do hope to recommend something in relation to that. More specifically, this was already -- and, again, I invite anybody else on the committee to add their thoughts as well. There are technologies that are emerging that do not go to the sort of detail of WGS, but still be able to provide enough dissemination to make decisions on, you know, whether you have the similar isolate or not. And then, also there are technologies that are emerging that can provide phenotypic characteristics like the -- antibiotic resistance or biocide resistance that can be helpful to the

industry as they're making their decisions about, you know, sanitation and processes and so forth.

Having said that, so the technologies are emerging and it's going to be a reality in the next four to five years. This committee's -- subcommittee's work is already informing us on that. The bigger question as we foresee, and again this is very early thoughts, we would gather everybody's feedback here, is that the industry would likely need some guidance from the public health agencies to say this level of information is useful for us to collaborate on, so that we can together as one public health community, make wiser decisions. And that guidance has to come from you because you know, of your role in the public health sector, but also you have access to WGS which informs -- there's no two ways about it, WGS is going to be the ultimate standard as far as method and dissemination is concerned.

So we hope to recommend, you know, at some point that the agency will have to provide some level of guidance to the industry to say these are other methods you could use and these are the kinds of information that we are looking

for from you, so that we can all make better decisions.

DR. MCCULLOUGH: Yeah, totally agree and I think one of the gaps that we're going to have to address is a lot of what you're talking about. And I think one of the things we're interested in is the communication gap because genomics isn't necessarily just for what industry has on their mind, but tying you potentially to an outbreak. Because it's a lot more than just relatedness, right, and so if there's a way where we can put together a framework that says, okay, we can identify a lot of these different other epidemiologic product characteristics that we've talked about in question 1 and can help you make a risk-based public health decision without tying it to relatedness.

I think that could be something we really talk a lot about in question 3 and 4 over the next couple of days to say this is how we can, so tell your lawyers to calm down, a necessary evil of the industry, right? One of mine signs my paycheck so I've got to be careful in case he's listening somewhere in the ether.

But I do think that there's going to

be a gap here in essentially that sort of communication of what it can do, what it can't do and how do we talk about this sort of gap of, okay, I'm giving you my isolate, I'm giving you this and what are you going to use it for, or what are you not going to use it for? And what is it going to come back me in this sort of data ownership data blinding. I think it's going to have thing that we chew on as a group and I'm seeing a number of committee people and seeing them nod their heads here.

Again, it's not just about relatedness. These tools can do so much more than that even though that's the biggest fear the industry has. But we are going to have to talk about that.

DR. CARLETON: I think one nuance there that you mentioned to bag the interest and learning more is how much data do you want from the industry? Are we talking about blind data trust, where the industry has the opportunity to share data and see if theirs manages without informing public health and then they take their own action? Or is this we know who is sharing the data with us? That's something we could

probably think about too, because that metadata is -- although it's more expensive to generate the sequence data, I think metadata is more expensive to share sometimes, so I think that will be an interesting one so if we could get the feedback about that one, too.

DR. SOUTHERN: Thank you all for your comments and just a quick ask from the group, when you speak, just say your name for our court reporter as well as for our online attendees and for those that were listening, you heard three voices and that started with Dr. Dutta, then Dr. McCullough and then also Dr. Carleton, so just FYI. And we have some more -- a question from Dr. Nichols, please go ahead.

DR. NICHOLS: Good morning, this is Megin Nichols from CDC. I really appreciate what you said regarding there's no established analytic methods that integrate genomic data and metadata from distinguishing strains based on the likelihood of illness given exposure. I think that is basically the golden ticket because to Dr. McCullough's point, once you have the data the question next is going to be what are you going to do with it and I think if we have

established standards or recommended methods, I think that alleviates some of the anxiety.

I also have a question. You mentioned the dashboard there at the end regarding a real-time dashboard providing kind of a statistical overview. I wondered if you might elaborate a little bit more on visioning for this. I was curious and pleasantly surprised, but want to know what that would involve and the audience for that. Thank you.

DR. DUTTA: This is Vik Dutta again. Actually, the idea came out of NOAA's dashboard. We're thinking about that's a beginning, right, but the hope is that we can maybe add. So, with the agency's framework that is out there right now, that Dr. Esteban alluded to, there is a comment about SPC, the statistical process control, and then, of course, it's a Salmonella framework so we are ultimately looking to gather more insights on that. There is a body of work that is happening out there is combining these two and providing a risk profile to a facility, you know, let's call it a processing plant, that can combine these two outputs.

I will not go into mathematics right

now, but the idea is to be able to for the naked eye, you can just see how things are progressing in your facility and how much of a risk, and that's a loaded word because it depends on how much data you're collecting, what kind of mathematics you're doing, the algorithms that are in place. But there is a way to combine all these outputs into a very simple dashboard. This is the kind of body of work that is happening out there that can inform a food safety director or a vice president to say, oh, am I doing a good job today. And, that again, that's exactly the same comment that was made earlier that, you know, working with the agency can be critical and I'm not talking just about -- besides CDC to say -- or FDA to say how do we look at that data together and how do we say this is okay or no, this is a level of information that must be shared back with us. But, again, we're starting from a place of the databases exist, the data exists and mathematically it's possible to put two and two together and turn into a dashboard. I hope I answered your question.

DR. ROBERTSON-HALE: Kis Robertson-Hale, FSIS. So, I guess, you know, with our

experience with the Salmonella framework and looking at genomics and Salmonella virulence, one of the questions we've heard is about the quality of the science on these markers. You know, how confident are we that we have a handle on what the genetic markers of virulence and pathogenicity are? Is there reason to doubt that we've captured everything because this area of research is so young? So, I guess the question to the subcommittee would be are you planning on characterizing the quality of the literature or the science to date in your description of what is known on this?

DR. MCCULLOUGH: Yeah, I'm happy to talk about that. We haven't at this point, we have literally just pulled together that sort of a draft one of collecting that, so I think especially as we're talking about the gaps, that is a huge gap. How confident are you on that, like you said, we really just scratched the surface and so some of those things may be very well documented, especially as we continue to do our annual review and saying, oh yep, we can be very confident about these ones. These ones, we're not so sure. Sometimes they might, what

we've seen is some of those genetic components, maybe, are tied to a couple of different things. Well, which is it? Are they really food typing both or are we mixing some of those signals.

And so I think that's going to come through and really very much so as sort of class -- we haven't discussed specifically classifying the evidence, but as far as if we come with gaps in recommendations, one thing that we're pretty passionate on is if we're going to make a recommendation, we want to have a lot of confidence in that information, right? And if we don't have a lot of confidence in it, that's a gap that we need to get confidence before a recommendation can be made. And so, I think we take that -- I hear what you're saying that feedback of classifying it, I think that's something we'll talk about over the next few days, so thank you.

DR. ESTEBAN: Can I go at it again? May I?

DR. SOUTHERN: Yes. Before you go, Dr. Esteban, just real quick are there any other committee members that want to address some of the discussion that's already happening? All

right, go for it.

DR. ESTEBAN: As you know right now, we're dealing with a small outbreak in deli meats, so to speak. You know, it took us 30 years from the original framework for some of the intellectual work we're trying to propose the data, that's three decades before we changed anything. So, now that we're changing it, this one needs to survive another 30 years, right, but not, because you mentioned something that is quite interesting. Can we actually develop a risk index in real time for each plant that they can use without having to, like we did today, either count the, you know -- bacteria or give us some other isolates.

They are still hung up on getting it themselves and there has to be a better way we're going to build the testing for the next 10 years that doesn't depend on the bug itself. In a little colony, in a plate for you to do sequencing. As I look at these large operations today, some of them are already doing a lot of sequencing, they just don't share the data, right?

Back to my first question for this

point, if we can actually work on guidance for creating that risk index, that's a risk management tool that we can use to minimize risk and maximize public health without having to get bugs out of the system. We need to actually at least have the vision of how, as regulators, thanks for your advice, as regulators, we should actually prepare for that. So, I'm asking you to build something based on a target that doesn't exist, but the advice that we seek from you will take us two to four years to get finalized whatever it is. It needs to be something that's useful for the next few years beyond when you give us a report.

So I'm asking the committee to get maybe a little bit creative in what it should look like five years from now. Thank you.

DR. SOUTHERN: Thank you, thank you, Dr. Esteban. Are there any responses or additional comments or questions from the Executive Committee?

DR. DUTTA: I want to make one quick comment and I'm going to put Dr. Nikki Shariat on the spot if she's willing, she's willing. Going back to your comment about the quality and fully

reiterate what Dr. McCullough said, and by the way this is Vik Dutta, again, there is another obvious gap that we are finding here. Dr. Shariat's work has only illuminated that, and others, which is we have been doing whole genome sequencing off of a colony that came from a soup of all sorts of organisms and the entire public health system is based on that and, rightfully so, 10 years ago it made total sense to do it that way.

Fast forward, as the technologies are evolving, one of them being built at CDC and there are others that are being built, you know, in the private sector as well. There is a possibility to get a sneak peek at the enrichment stage and target specifically for these organisms that we are working on here without having to go to that colony, you know, or take two colonies.

And that early insight may be able to further reduce the gap, if there is anything to what is it that we are linking the organism to. Now, in some cases, it's obvious that the one is going on, right, it's clear, but in routine sporadic cases, you know, we don't know how good

of a job are we doing, and I say this as a public health community, you know, collaborator, that we don't know how good of a job. So, the enrichment stage needs to be probably harnessed a little bit more and the technology is beginning to get marginal already. So, whatever confidence gap there is, it should further narrow it down if we were to focus on that, but again, that's an ongoing work and we all need to kind of work at it together. Sorry, Nikki.

DR. SHARIAT: I'm not sure how you want me to respond to that.

(Laughter.)

DR. SHARIAT: I agree with that you say, I think there's lots of emerging technologies, right, that are looking at the enrichment stage. Folks that are here, folks that are not here. I think one of the key problems, right, is that what's in an animal and what's adapted to growing in an animal is not necessarily what causes human illness. What is adapted to growing in the environment is not what causes human illness all the time, right? And so, can we take a step in those culture stages so that we're not dependent on a single isolate on

a plate?

DR. HAVELAAR: This is Aries Havelaar. Picking up on the point that Dr. Dutta makes, I recently read a paper from the UK looking at the diversity of Campylobacter in poultry meats and their summary conclusion is that you would need to test up to 87 isolates per sample to detect 95 percent of the observed genotype sequence diversity, so I think the point that you made that we're based on one or two or three colonies and they are typically the most rapidly growing, the most easily culturable, not necessarily the most dangerous types, so we've always been looking through, like, a clouded set of mirrors to what's happening in any food sample. I think this is something that we really need to address in our discussion, which methods are most able to identify the full diversity. Culture methods are very limited by just the nature of the amount of work, maybe the novel genomic methods may harness further.

And also, I think that's a mindset as a risk assessor, I tend to think in probabilities. I often hear these discussions being held in terms of high and low risk types

and I think that's simplifying it.

In terms of photography, it used to run in the 50 shades of gray that we need to deal with, so we also need to develop a probabilistic mindset. We're talking about probabilities and, of course, that requires even more data than thinking about categorizations. So, it's going to be challenging but I think we need to sort of first develop a new mindset that will help us sort of think about the complexity and then think how we can manage that complexity.

DR. KHAKSAR: Ramin Khaksar. So back to Dr. Esteban's comment about industry and agency's relationship because the whole agency has lots of whole genome sequencing data, not necessarily willing to have that kind of -- or creating that kind of data or sharing that kind of data for obvious reasons that you mentioned about, like lawyers. So maybe we should add in our recommendation. We should think about how we can create the loop of information that the agency can generate but not necessarily generate in all genome sequencing data, but that data can help the agency to manage and control the outbreaks or kind of make decisions for the

future of food safety without industry being incriminated for all those concerns that you mentioned.

And in that loop, we learned a lot in COVID, for example, how we can manage data and kind of see the pattern of movement of the pathogen. So, but in the same time, I don't believe that concern from industry will be removed. Unless something happens to, in terms of that lawyers concern that you mentioned. So I think we should create some sort of information, that's not necessarily a concern for industry, but helps the agency to manage outbreaks and food safety. So that loop should, that move on, kind of direction of information should be one way not agency can go back to industry and just make then and questions them. So that's the creative work that probably in the next few years we will have that kind of industry I have to show you the type of works that we, in the private sector and in academia, that they create. So anyway, I feel that that's one of the being creative, how can we feed an agency without industry being concern about their issues.

DR. SOUTHERN: And we can, because I

don't have a mic on me, we can go ahead and look if the committee has additional questions and comments, you guys can go ahead.

DR. SHARIAT: This is Nikki Shariat again, just a quick comment about as we make steps back into looking at enrichments, maybe pre-enrichments, maybe metagenomics in the additional sample, I think we also need to be mindful about the challenge, that for the most part, interventions that industry are using are working and so we need to make sure that we're finding viable pathogens in that piece, too.

DR. CARLETON: Yeah, and this type of change doesn't just impact FSIS, but it impacts the entire surveillance system, so any change that goes to a culture independent approach for subtyping needs to be done in lag step with CDC and FDA because that screen level information is still required to be able to connect clinical cases to potential sources of contamination so there's a balance there.

If you do more of the gene-based detection systems, if you detect this gene of interest, having some type of process where then you go onto isolation because right now for

better or worse, isolate-based subtyping information is still the gold standard, so I think there's -- what you're talking about is possible, but it requires a change to our public health surveillance system overall.

And I didn't say my name at first, so, Heather Carleton, CDC.

DR. SANCHEZ-PLATA: This is -- hello? Marcos Sanchez from Texas Tech. I definitely agree with the bias on the culture methods. That's something we know for several decades that's an issue, but the way I see it is as surveillance system, as a genomics-based surveillance system where we do, kind of a like a National Contaminants Program, like an ARMS (phonetic) program, where we look a report and we look at the trending analysis.

That will keep the industry somehow involved in it, but without having that compromise with the legal components, so if we can have something like the National Contaminants Program, where you have a report of the annual trending on the Cincinnati -- the trains, the originality, the genes, the serotypes and so forth, I think that would be more of a public

demand we have right now. Right now, you have to dig in to emphasize data to get some information on it and it's not there, whereas if we can have that public private partnership where we have a surveillance system but with a technique that, of course, NACMCF recommends and that provides enough information for the trending, but not compromising the industry, I think you could reach an agreement in that area.

DR. WARREN: Hi, this is Ben Warren. It's on right? Okay, Ben Warren. I just wanted to add in a little bit of a different perspective on the conversation. As we look at methodology and we want to take the conversation towards looking at risk factors and providing that disconnection from what old genome sequencing allows, from traceability and trace back in connection from a public health standpoint to something that may be in industry, you know, at a facility, in a product, in the environment.

One of the things that we have been talking a lot with industry and we will continue, is the importance of using genetic techniques when you do find pathogens in the environment or in your product. Maintaining traceability,

maintaining the ability to track that isolate and try to figure out where did it come from, where is it going. You know, beyond just the risk factors and the genetic elements that might raise that organism up, and, you know, in terms that it is important from a public health standpoint. But also being able to provide information that can allow trace back and connecting the dots when talking about root cause investigation.

I think that's an important thing that hasn't been mentioned that I certainly hope the committee keeps in mind as we make recommendations about methodology that we don't lose that important element of trace back and being able to investigate deeply when you're finding pathogens in a product or in the environment to figure out where did it come from. Because that is oftentimes just as or more important than the ability to take proper corrective actions and prevent it than just simply knowing, you know, does this have that virulence factor or another one. Thank you.

DR. SOUTHERN: Thank you.

DR. MELLO: Is there a mic for me? Indaue Mello. Just one point that I would like

to bring up is the fact that we have a tendency to talk about industry as a homogeneous group and it's actually quite diverse in terms of the size of the company, the knowledge level and the resources that they have.

When we talk about doing full genome sequencing or extra, you know, testing or getting more granularity in terms of what are the strains they were finding in the product or in the environment, I just want to remind the committee that you to go companies just to do a basic APC or even ATP during pre-auth, it's already an extremely large cost to those companies.

The food products have a very, very low margin and it's a very tough business to be in where you are pretty much competing with different brands, you know, sometimes in nickel and pennies and every cent really counts. And it's easy to talk about let's do this test and have data to generate and log in, in a way that nobody knows where it's coming from. But a lot of the food manufacturers, especially the small and the medium size, are struggling to even be able to produce anything and, you know, have some profit. So, that's also something to remember as

we're looking into how we can have methods that are better and more sensitive is there is tremendous cost to it.

DR. SOUTHERN: We'll take one more comment from the room and then just check in online.

DR. TEPLITSKI: Thank you, Kristal. Max Teplitski from International Fresh Produce Association. And I want to punctuate what Dr. Mello said, is that our trade association represents over 3,000 member companies from mom and pop operations all the way to multinational mega companies, like your favorite retail chains. When you talk to every one of them, the commitment to food safety is unwavering and there are many reasons for it including the reason that nothing depresses sales like a food safety event and it impacts the entire category.

I still remember the consequences of the spinach outbreak and certainly the ongoing listeria issue has impacted the entire category. So, you have a partner in the industry. And I'm very excited about this work. As we are looking at using genetics as a way to mediate risks and structure a risk-based regulatory strategy, I

want to make sure that we don't sort of jump into a hazard-based management and enforcement. I don't want us to think that the presence of a certain genetics signature all of a sudden indicates hazard enforceable, actionable hazard.

So, I'm excited to continue this work and the path toward continued risk-based, and risk appropriate, science-based regulatory approach. Thank you.

DR. SOUTHERN: Thank you, Dr. Teplitski, and thank you everyone in the room for this robust discussion. In the interest of time, I do want to just check in with our committee members that are online and Executive Committee members to see if there are any comments or questions from our committee members that are online. Dr. Prater, please go ahead.

DR. PRATER: Yeah, thanks very much, Kristal. I'm enjoying this robust discussion as well. It really reminds me how powerful these tools are that are in our hands right now; genomics and genomic sequencing in particular and how these are really game changers, I think, in terms of how we will do our work in the future.

It wasn't that long ago that we were

touting the benefits of genomics or genomic sequencing as being something that was really significant and then we were talking about data and we were saying in the 21st century better food safety begins and ends with better data. What I've come to really appreciate, and what I think you've highlighted in this discussion, is that also it is important that we think about data governance structures and how we share those data and information not only between industry and regulators but just across the entire community, so.

One of the things that we have taken quite some effort to look at as we reorganize FDA's Human Foods Program is how we are going to be able to leverage data information in the future. We've got our three risk colors, but importantly, we also have an Office of Surveillance Strategy & Risk Prioritization. So, I heard it mentioned how much this information can help us, in particular sometimes the metadata associated with it, in looking at a more comprehensive surveillance strategy of the food system.

So, I appreciate all the work that the

committee has been doing on this. This is, you know, I think, not only for FSIS or USDA, but also for FDA and CDC, something very important and we really value the recommendations that will come out of this subcommittee, so. Sincere thanks to Dr. McCullough and Dr. Dutta for their leadership and being able to organize this great work. I know you're going to have some fantastic discussions over the next few days. Thank you.

DR. SOUTHERN: Thank you, Dr. Prater. So, in the interest of time, I do want to move forward. We did not have any pre-registered guests for public comment and we don't have time to extend that public comment to others who did not pre-register. So, I will -- I just have a few general updates before we move on.

And so, a place to continue some of this discussion, which I am enjoying myself and I hate to bring us to an end, but we do want to end on time because you guys have a pretty packed schedule. But we do have additional public meetings this week and that is our subcommittee meetings on Wednesday afternoon beginning at 1:00 p.m. The public may attend virtually. If you pre-registered to attend the Wednesday

subcommittee meetings, you should have already received the links to those meetings and that would have gone to the email address that you used to register. You may contact NACMCF at USDA.gov, that's NACMCF@USDA.GOV, if you pre-registered and have not yet received the meeting links for the Wednesday afternoon subcommittee meeting.

The third public meeting we have this week is the close out meeting on Thursday afternoon at 4:00 p.m. That will also be on this similar platform, Webex, and that will be an opportunity for the subcommittees to provide brief updates, not only on the progress that they've made this week, but also some additional next steps, maybe some next steps that come up in some of the discussions that we haven't already heard of.

And so, this will be a hybrid meeting and members of the public will be able to join virtually. I think most people choose to join virtually, but that is one and if you want to come and join us in person, you certainly can.

And lastly, I just want to mention that you've heard from the great committee

members here and we really have some of the best of the best in the scientific community and while it may seem like we had our nomination period just last year, which we did, it's now time for nominations to open up again. So, we don't yet have a date when the nomination period will open up, but please be on the lookout if you're interested in nominating yourself or someone else to become a member of NACMCF in the coming months, later in the next couple of months be on the lookout for the Federal Register notice and other constituent updates announcing that the nomination period is open.

You can find a list of our members online if there's anybody that you know, and you want to ask them what's it like being a member, you can certainly reach out to your colleagues that you're familiar with and they can give you the spiel. My judgment -- my answer will be a little biased, so you might want to check with me.

Lastly, I just want to thank our committee members, subject matter experts and members of the audience for participating in today's meeting. And of course, thank the NACMCF

Executive Committee and the Secretary for his supportive leadership. Dr. Esteban alluded to the Salmonella proposed rule framework that's out for public comment, just a reminder that you can find the information in the Federal Register as well as on the FSIS website on how to provide comment on that. And if you feel so inclined, feel free to read the 2023 Salmonella Report that the previous NACMCF Committee did that contributed to that framework.

So now, I'll turn it over to Dr. Esteban, come on back up, to close us out for this meeting.

DR. ESTEBAN: You've heard enough from me today. You represent a good portion of the top tier of brain power to provide us advice on this topic and I really, really look forward to how you're going to destroy my future, sorry, help me build the future.

I'm not going to, you know, belabor this too much. Thank you very much for what you do. Thank you in advance for the work you're going to be doing over the next three days. You represent really industry, academia, consumers, government, what we get from here is going to

really drive what we do in the future. Like I said before, we're really depending on you, so, no pressure, just give us good advice that we can actually implement.

We can't waste much more time, people out there, industry, animals, all of these things are combined, I do really believe they want health and what we're doing here may be one portion of that, but I think ultimately it affects everything. So, go forth, destroy, create.

Thank you very much for what you're doing. I'll try to keep tabs on you. Thank you.

(Applause.)

DR. SOUTHERN: All right. And thank you, Dr. Esteban. We've completed the purpose of today's NACMCF Plenary and we now stand adjourned. So, thank you, everyone online. Have a good rest of the day.

(Whereupon, the above-entitled matter went off the record at 11:59 a.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript In the matter of: National Advisory Committee on Microbiological Criteria for Foods
Before: USDA/FSIS
Date: 09-24-24
Place: Washington, DC
were duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings; and that I am neither counsel for, related to, nor employed by any of the parties to this action in which this deposition was taken; and further that I am not a relative nor an employee of any of the parties nor counsel employed by the parties, and I am not financially or otherwise interested in the outcome of the action.

Court Reporter

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