NATIONAL ADVISORY COMMITTEE

ON MICROBIOLOGICAL CRITERIA FOR FOOD

(NACMCF)

PLENARY MEETING

Virtual Meeting

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P R O C E E D I N G S

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DR. KRISTAL SOUTHERN: Good afternoon, everyone, and welcome to the Plenary Meeting of the National Advisory Committee on Microbiological Criteria for Foods, commonly referred to as NACMCF.

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

So, I will now proceed to taking roll call. One moment. Sorry. I will now proceed to taking roll call of the NACMCF Executive Committee and the NACMCF Committee members. When your name is called, please unmute and announce yourself by stating here or present.

So, we'll start with the NACMCF Executive Committee. Our USDA Undersecretary for Food Safety and NACMCF Chair, Dr. Emilio Esteban.

DR. EMILIO ESTEBAN: Here.

DR. KRISTAL SOUTHERN: Thank you. And the Food and Drug Administration's Acting Director of the Centers for Food Safety and Applied Nutrition and the NACMCF Vice Chair, Dr. Donald Prater.

DR. DONALD PRATER: Present.

DR. KRISTAL SOUTHERN: Thank you.

So, then we'll move onto the NACMCF liaison from the Food Safety and Inspection Service, Dr. Denise Eblen.

DR. DENISE EBLEN: I'm here.

DR. KRISTAL SOUTHERN: Thank you.

And our liaison with the Food and Drug Administration, Dr. Eric Olson. And maybe he'll join us later.

And our liaison with the Centers for Disease Control and Prevention, Dr. Megin Nichols.

DR. MEGIN NICHOLS: Present.

DR. KRISTAL SOUTHERN: Thank

you, welcome.

And our liaison with the Department of Commerce, Dr. Jon Bell.

DR. JON BELL: Present.

DR. KRISTAL SOUTHERN: Welcome.

And last for our Executive Committee is the Department of Defense liaison, Colonel Alisa Wilma.

COLONEL ALISA WILMA: Present.

DR. KRISTAL SOUTHERN: Welcome.

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

So, that you all for your support and leadership.

We'll now move to roll call for the NACMCF Committee members. And again, when your name is called, please unmute and announce your presence by stating here or present.

In alphabetical order, we'll start with Dr. Bledar Bisha.

DR. BLEDAR BISHA: Here.

DR. KRISTAL SOUTHERN: Welcome.

Dr. Heather Carleton.

Dr. Anna Carlson

DR. ANNA CARLSON: Here.

DR. KRISTAL SOUTHERN: Thank you.

Dr. Hayriye Cetin-Karaca.

DR. HAYRIYE CETIN-KARACA: Here.

DR. KRISTAL SOUTHERN: Dr. Ben Chapman.

Dr. Vik Dutta.

DR. VIK DUTTA: Present.

DR. KRISTAL SOUTHERN: Dr. Betty Feng.

DR. BETTY FENG: Here.

DR. KRISTAL SOUTHERN: Dr. Larry Figgs.

DR. LARRY FIGGS: Here.

DR. KRISTAL SOUTHERN:

Dr. David Goldman.

Dr. Michael Hansen.

DR. MICHAEL HANSEN: Here.

DR. KRISTAL SOUTHERN: Hello.

And Dr. Aris Havelaar.

DR. ARIS HAVELAAR: Present.

DR. KRISTAL SOUTHERN: Ms.

Janelle Kause.

Dr. Ramin Khaksar.

DR. RAMIN KHAKSAR: Here.

DR. KRISTAL SOUTHERN:

Lieutenant Colonel Noel Kubat.

Dr. Elisabetta Lambertini.

DR. ELISABETTA LAMBERTINI:

Present.

DR. KRISTAL SOUTHERN: Ms.

Shannara Lynn.

MS. SHANNARA LYNN: Present.

DR. KRISTAL SOUTHERN: Thank

you.

Dr. KatieRose McCullough.

DR. KATIEROSE McCULLOUGH: Here.

DR. KRISTAL SOUTHERN: Dr. Indaue Mello.

DR. INDAUE MELLO: Present.

DR. KRISTAL SOUTHERN: Dr. Eric Moorman.

DR. ERIC MOORMAN: Here.

DR. KRISTAL SOUTHERN: Dr. Abani Pradhan.

DR. ABANI PRADHAN: Present.

DR. KRISTAL SOUTHERN: Welcome. And Mr. Shiv Rana.

MR. SHIV RANA: Present.

DR. KRISTAL SOUTHERN: Thank you.

Dr. Marcos Sanchez Plata.

Dr. Kristin Schill.

DR. KRISTIN SCHILL: Present.

DR. KRISTAL SOUTHERN: Okay.

Dr. Nikki Shariat.

DR. NIKKI SHARIAT: Here.

DR. KRISTAL SOUTHERN: Dr. Abigail Snyder.

DR. ABIGAIL SNYDER: Here.

DR. KRISTAL SOUTHERN: Welcome.

Dr. Max Teplitski.

Dr. Bing Weng.

DR. BING WENG: Here.

DR. KRISTAL SOUTHERN: Dr. Ben Warren.

DR. BEN WARREN: Here.

DR. KRISTAL SOUTHERN: Welcome.

Dr. Randy Worobo.

And Dr. Rishome Yeloweshea.

DR. RISHOME YELOWESHEA: Present.

DR. KRISTAL SOUTHERN: And is there any committee member who did not have an opportunity to announce themselves or joined after we did the roll call?

Okay, hearing none, I recognize that we have twenty-three committee members present, which meets quorum, and I now call this

meeting to order.

So, now I'll go back a slide. NACMCF is a Federal Advisory Committee that provides impartial scientific advise 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.

The Food Safety Programs of the USDA Food Safety and Inspection Service and the Food and Drug Administration are strengthened through 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 benefits from NACMCF work.

NACMCF members are appointed by the Secretary of Agriculture through a rigorous process that helps 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 points of view of all stakeholders.

It is an honor to be appointed to the NACMCF and we are incredibly thankful to the members that provide the scientific advise to our federal agencies involved in food safety.

At today's meeting, the committee will provide progress updates for their work on the FDA Cronobacter species in Powdered Infant Formula Charge and the USDA FSIS Genomics Charge.

So, before we dive in, I wanted to provide a few housekeeping items to keep in mind as we continue through the agenda. If you've joined our previous NACMCF Plenary Meetings, you should be familiar with these. So,

it might just be a little reminder.

But first, I want to please note that this morning Plenary Meeting is being recorded. FSIS will post the recording and transcripts when they become available on the FSIS website.

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

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

If, during registration, you indicated that you wish to provide oral comments and confirmed your intent to do so via a follow-up E-mail from the NACMCF Secretariat, I will call on you during the respective comment

period.

The event producer will provide additional instructions when we reach that point in the agenda.

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

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

Welcome, Dr. Esteban.

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INTRODUCTORY REMARKS

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DR. EMILIO ESTEBAN: Thank you, Kristal, and good afternoon to all of you or good morning, or good evening, depending on where you're joining us from.

I want to welcome the Executive Committee members, the committee members themselves, and the public. The work that you do for us is essential in us having a consistent and positive food safety system.

We have a full agenda today, and I look forward to hearing the updates from the two work groups that are working on genomics and food, and the work that is happening on Cronobacter species in Powered Infant Formula. Those are the two charges that we have active today.

As I said, I look forward to hearing all the progress you've made and to see what the next steps are. Your contributions are

essential to NACMCF, to public health, and, of course, to food safety. So, I very much look forward to hearing where you are with those charges.

I'd like to turn it over to Dr. Prater, please, from the FDA, my colleague.

DR. DONALD PRATER: Greetings. Thanks, Dr. Esteban, I really appreciate that warm welcome, and let me add my welcome to all the committee members of NACMCF with its diverse committee membership including academia, industry, federal, state, and consumer representation, as well as gender, racial, ethnic, and broader diversity is ideally suited to advise us on these subjects, and we look forward to the information that NACMCF will provide on these charges.

Before I talk about the charges, I also wanted to share some information here about the Human Foods Program Reorganization at FDA. As many of you know, the reorganization of the FDA's work on foods has been approved by

Congress, and we plan to fully implement it in October. We anticipate a smooth transition, which will lead us to a strong Human Foods Program. The proposed reorganization is really the largest in recent history and a major undertaking for the agency.

Jim Jones is our first Deputy Commissioner for the Human Foods Program, and we are already benefitting from having all of our work under a unified single leader.

Now that we're working through the plans to merge all the Human Foods functions, resources, and personnel, from the Center for Food Safety and Applied Nutrition, the Office of Food Policy and Response as well as certain Office of Regulatory Affairs Functions and Personnel into the Human Foods Program. This shift will streamline our work, allowing for faster decision making and breaking down the siloed functions related to human foods.

Besides offices dedicated to specific areas of our foods work, we've designed

one new one that will focus on data signals and risk prioritization. This office is called the Office of Surveillance Strategy and Risk Prioritization, and it has a mission to detecting risks related to human foods.

To be honest, in the past, we've really been awash in data and not had the capacity or technology sometimes to analyze them. But now with technological advances like whole genome sequencing and artificial intelligence, we'll be able to more efficiently and effectively find out what those data can really tell us about risk.

For example, FDA has been doing some cutting-edge research using genomics to detect sources of risk to produce and other foods. Because of advances in technology, we can do this work now, even in a time of limited resources. We can use whole genome sequencing to look for food-borne microbial pathogens that pose a risk and better focus our resources to address those risks.

The committee's work on the Cronobacter Species in Genomics charges that has taken place will provide great signals and information that we use as part of our risk prioritization, and I'm really looking forward to hearing the updates about the work on these two charges later this afternoon.

I'm also excited to discuss an upcoming call for new charges, charges that could provide us with information and data that will really help us to better assess food safety risks.

So, I wanted to thank you all -- all of the committee for all the hard work you've done. I know it takes a lot of your valuable time, and we really recognize and appreciate that.

I also want to thank the Executive Secretariat staff who are so critical in making everything work smoothly including today's meeting.

So, with that, let me turn it

back over to Dr. Kristal Southern.

DR. KRISTAL SOUTHERN: Thank you. Thank you, Dr. Esteban. I know how -- how diligent and hard the committee has been working on the charges, so I know that they've got some really good presentations for you both.

And then also thank you, Dr. Prater, for the update on the changes that will be coming soon with FDA. We look forward to continuing that relationship with NACMCF and FDA as you all go through these new changes.

So, with that, we'll now proceed with the presentation from Dr. Elisabetta Lambertini and Abby Snyder, who are the co-leads for the Cronobacter Subcommittee. Welcome, Doctors Lambertini and Snyder.

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UPDATE ON FDA CHARGE

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DR. ELISABETTA LAMBERTINI: Good afternoon, everyone. In the next half hour, myself and my co-chair, Abby Snyder, will provide

updates on three charge questions. And before that, I want to do a quick recap of all the four charge questions.

Question 1, which is substantially completed, so we won't talk about it today, asks what is the current prevalence and level of Cronobacter species contamination in powdered infant formula and their association with human infections.

Question 2 asks what factors, for example, virulence factors, host factors, dose of exposure, place an infant at greater risk for Cronobacter species infection and serious adverse health consequences or death.

Question 3 asks what food safety management practices, for example facility and equipment design, hygienic zoning and packaging, preventative controls, verification activities, should manufacturers of powdered infant formula employ to further reduce the risk of Cronobacter species contamination of formula and/or the production environment.

Question 4 asks, given that powdered infant formula is not sterile, how could food safety messaging be improved for infant care providers with emphasis on use of sterile, ready-to-use formulas for infants at greatest risk and safe infant formula preparation and storage for infant formula in general.

So, progress so far on all these questions, now we are seven months in from November to now. We had two subcommittees working meetings in November and April. We had to find the scope and outlines for all the questions, and we have consulted several subject matter experts, SMEs. We have two systematic reviews in progress, and one being prepared. We are moving along with drafting the charge with the goal of having the first full draft this fall.

This is just a quick reminder of the composition of our working group, which we are using to address different questions.

So, for question 2, which asks

which factors in the organisms and in the host are associated with serious adverse consequences.

So far, the working group has defined which main topics should be included in the answer, which you can see in the box on the left. The green dots simply signal the order in which these topics are being addressed.

The work so far is focused on virulence factors for Cronobacter species including survivability, stress adaptation, pathogenicity traits, and others such as antimicrobial resistance and others that may arise from the literature.

Other topics that we will be included includes host factors such as age-specific vulnerability and impact of comorbidities and the impact of microbiome factors.

And the dose of exposure, although we have seen there is very little information on this topic.

In terms of approaches used so

far, which you can see on the right, we have a comprehensive literature review in progress, and we have received excellent input from Professor Steve Forsythe, who has devoted much of his career to Cronobacter. So, we are very grateful for this information.

For the literature review, you can see here some parameters. The literature review is reaching its end. We had two databases consulted. Search criteria included terms for the organism and terms for virulence, pathogenicity factors, and host factors. There was no restriction on age, as we want to also look at adult infections potentially, and no restriction on time.

After the screening, we found 417 articles that were considered relevant and are not being synthesized in the draft.

A couple of slides on preliminary findings for question 2 based on both input from subject matter experts and the literature.

Now, we can confirm that Cronobacter Sakazakii is the species primarily associated with infections in newborns and babies, followed by Cronobacter Malonaticus with a lower number of cases.

There are other species that have been found in infant food or ingredients or relevant environments, but their pathogenicity is still in question.

Using multilocus sequence typing, primary pathovars that have been identified include Sakazakii ST4 associated with infant meningitis, Sakazakii ST12 associated with necrotizing enterocolitis, and Malonaticus ST7 associated with adult infections.

Now, in terms of the genetic factors, there are putative virulence factors that have been identified, but their role in pathogenicity remains inclusive so far. So, we expect to have a lot of caveats here.

For example, there are limitations in the study models with tissue

culture and animal studies not fully representing the condition in the neonatal GI tract, which impacts our understanding of the rule of this factor in pathogenicity.

There are classification challenges with the assays currently available leading to potential misclassification of Cronobacter isolates and the association between genetic elements and isolates. So, there can be misunderstanding on the pathogenicity of individual isolates.

And other overlooked factors such as the potential effects of residual like polysaccharides or endotoxin from dead bacterial content in infant formula that may lead to an increased permeability of the GI walls and has increased susceptibility. This is something that is still being researched, but interesting to point out.

So, this is all we have for now for question 2. The work continues and I'm passing the microphone to Abby for the next two

questions. Thank you.

DR. ABBY SNYDER: Thanks, Elisabetta. Thank you, okay.

So, I'll be describing the progress for work group 3, who is addressing this question related to manufacturing practices. So, note here in the charge question, it specifically mentions these topics; facility and equipment design, hygienic zoning and packing, preventative controls, and verification activities. And the charge question goes on further to ask what practices within those topics should be employed to further reduce the risk of Cronobacter.

So, some of this work group's discussion so far is focused on whittling down to specific activities that further reduce Cronobacter risks rather than attempting to simply summarize all the foundational programs that are commonly used to ensure food safety and manufacturing. Thank you.

So, the work group has taken -- each work group has taken a slightly different

approach to managing their workflow.

Work group 3 has been meeting monthly to outline and initiate drafting responses to the charge.

So, here you can see the outline that the group has developed and the sections where writing has started.

The great points here outline an introductory or summative material, and the black text are topics where the main responses will be housed.

So, the first major point in the response will concern strategies to reduce the risk coming from incoming dry ingredients that will not receive a subsequent kill step before product release.

The second major point concerns facility and equipment engineering such as zoning and hygienic design to reduce cross contamination during manufacture.

The third is process preventive controls designed to inactivate Cronobacter. And

so, this includes review of potential novel processes.

And the fourth is sanitation preventive controls, which includes a review of common and novel methods, their benefits and weaknesses, as well as discussion on environmental monitoring.

And the final section, which is not in the drafting stage yet, concerns root cause investigations and corrective and preventive actions. Next slide.

Working group 3 has heard from two subject matter experts early in their process, and they plan to engage with additional subject matter experts in the coming months. The two experts who have already spoken to this group include Jeff Kornacki and John Alvey, and this is in addition to the subject matter experts that presented at our initial Plenary meetings. So, this is simply an update on subject matter experts that they've heard from since then.

So, this single slide provides

some summary of the points collected from those presentations as well as initial discussion within the working group.

So, taking a look at points 1 and 3 here, stating the PIF is produced using either a straight-through process or through dry blending, and then also acknowledging the important role then of suppliers in ensuring the microbial safety of those ingredients. So, you can see how this point resulted in that standalone discussion topic and the outline regarding suppliers.

Additionally, the work group heard about maintaining hygiene in the environment through sanitation and the application of different microbial targets within environmental monitoring programs.

So, this included some evidence on the benefits and limitations of indicators such as the group Enterobacteriaceae or Eb. Eb are commonly used indicators that are useful in sanitation verification programs, but these

indicators do not replace the need for environmental monitoring that specifically targets Cronobacter.

And then finally, the importance of excluding water from the manufacturing environment was discussed and the committee is considering future additional subject matter experts on this topic related to identifying sources and methods of elimination for moisture ingress. Next slide.

So, those findings and the initial work on the outline are based on noncomprehensive assessments of the literature as well as discussion with experts. And work group 3 has also initiated a comprehensive literature search by working with the National Ag Library to define search times and a search protocol for systematic review. And in particular, this search is targeting research on existing control measures for Cronobacter species in the production of PIF. And so generally speaking, the body of literature available on this topic is

relatively small. Next slide.

Okay. Transitioning now into the final charge question addressed by work group 4, this is the communications question. It asks how food safety messaging to infant care providers can be improved. And the messaging topics emphasized within the charge question really get at two points. The first is the use of ready-to-feed infant formulas and the second is the preparation and storage of PIF. Next slide.

So, in terms of workflow, work group 4 has prioritized hearing from subject matter experts and is still in the process of developing their systematic search.

And so, to date, they have heard from a number of risk communication experts at USDA, FDA, and CDC, and they've also reached out to schedule future presentations from the American Academy of Pediatrics as well as INCA, the Infant Nutrition Council of America, which represents infant formula producers.

Work group 4 has adopted the following structure for outlining their response. They are generally responding to the charge question through the following structure by answering questions related to what should be communicated, that is what is the content of the message that should be delivered to improve food safety messaging to caregivers.

They're also answering to whom that messaging should be delivered and by whom, which implies that it should consider important risk communicators outside of the traditional caregivers in this effort.

Finally, the question of how is also being addressed, meaning what practices in risk messaging should be employed to deliver food safety messaging to infant care providers.

Group 4 has also started preparing and discussing some of their draft text based on this noncomprehensive review of the literature in discussion with experts, and they have again future plans for the scoping review.

Next slide.

So, under the topic of what to communicate, the work group has identified the following topics of discussion.

And so, the first is prioritizing messages towards caregivers of high-risk infants defined by age and other risk factors. So, review on messaging, supporting the use of ready-to-feet formula for the high-risk groups. This would also include messaging on PIF prep and storage.

A notable area of importance for risk communication is messaging around the use of hot water to prepare formula, and it's been a major topic of discussion in the group. The work group's initial assessment of the literature also indicates there's a lack of research on caregiver practices.

So, for example, given this messaging, how do caregivers actually behave in practice? What is caregiver awareness about the risks of Cronobacter, and so on. Next slide.

The next topic concerns identifying the groups who are important targets of this messaging. So, this of course includes primary caregivers like parents, but also caregivers who may have infant feeding responsibilities such as grandparents or daycare staff, and therefore, communication messaging should acknowledge generational and cultural differences addressed more under the how to communicate section.

Additionally, the work group identified groups who themselves serve as sources of information for infant caregivers, which is various healthcare professionals who then are therefore important recipients of risk communication messaging as well because of that role. Next slide.

So, healthcare providers are both important groups who receive messages on risk and then communicate it to the caregivers.

So, for example, a high-risk infant in the NICU, that neonatologist and

nursing staff are essential risk communicators engaging with caregivers on infant feeding practices during this critical period in the infant's life.

Other important risk communicators include, of course, public health organizations and also depict manufacturers themselves, considering the potential role for product packaging labels or inserts in communicating preparation and storage information.

Other settings outside of traditional guidance materials or even social media include birth classes and healthcare appointments early in the infant's life during the period of greatest risk from Cronobacter. Next slide.

Finally, the work group considered how and when to communicate and so currently, that includes noting the types of communication or communication frameworks in use.

So, for example, situational messaging like that used for ongoing regular use of PIF versus messaging that's used in crisis settings like that during an outbreak or recall.

And so, the importance of visuals, language, and literacy to promote access and understanding is being considered by the work group, and as a note on the additional findings, the work group has identified gaps in research on ways to measure success on accessibility and understanding.

The work group has heard subject matter experts discuss different theoretical frameworks that distinguish between hazard and risk, so increasing caregiver awareness about Cronobacter and potential mitigation strategies as opposed to explicit do this and not that type of instruction. Next slide.

And so, with that, we'll go ahead and wrap up our discussion on this charge question. I will just add that in terms of next

steps, we are planning for our Plenary meeting in September, and the further development of a first draft of the subcommittee's response later in the fall. Thanks.

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PUBLIC COMMENT ON FDA CHARGE

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DR. KRISTAL SOUTHERN: And thank you. Thank you Dr. Lambertini and Dr. Snyder for your leadership of the Cronobacter subcommittee and the updates you provided today.

So, we're going to start moving into questions and comments on the Cronobacter charge progress updates. We'll start with the Executive Committee members. Are there any questions or comments from our Executive Committee members on the updates that were just presented?

I see you popped up onscreen, Dr. Prater. Go ahead, feel free to go ahead and speak.

DR. DONALD PRATER: Thank you

very much, and sincere thanks for all the work. I can tell a lot of progress has been made on the whole number of questions. So, I don't -- I don't have any reflections or comments to offer right now other than just I really appreciate all the good work, particularly on the communications, and that's really a multifaceted area in terms of what to communicate, where, and by whom. So, I appreciate all the good thinking on that. So, thank you so much for that great readout. No specific questions at this point, but I'll look forward to hearing more. Thank you.

DR. KRISTAL SOUTHERN: Thank you. And also, if you think of anything, certainly let us know and we'll make sure that the committee receives those questions or any additional comments.

Okay. So, I'm going to now move to the committee members. Oh, I see a hand up. Please, go ahead.

DR. EMILIO ESTEBAN: So, again,

much like Don, this is a lot of work to get us to this point. So, I agree that one of the main outcomes of this is going to be messaging.

So, I was wondering, have you had any thoughts about how you're going to target that? I know you mentioned some specific avenues, but how are we going to be able to measure the effectiveness of that communication message? Have you -- has the committee discussed that, effectiveness measures?

DR. KRISTAL SOUTHERN: And Elisabetta and Abby, if you want to pop on, thank you.

DR. ABBY SNYDER: Sure, I will take a stab at it unless Elisabetta wants to chime in, that's great too.

I think the committee has targeted or identified a gap in research on the top, and so would like to see research on that in the future.

For example, surveys of caregivers and focus groups, which I think some

of the regulatory research teams are currently doing, to assess people's perceptions about the relative risk of Cronobacter. Do they know what it is? Do they know which groups of infants are at risk for it? Do they know what practices are used to mitigate it? So, that would be one measure of success.

There's also a need, I think, for observational studies. So, the committees discussed if we develop a message of this kind and then you give it to a consumer and have them follow the instructions, for example, for PIF preparation, what do they actually do?

I think the committee has identified a big gap. You give them instructions with time, temperatures, or some combination of those, and it still could be quite variable in terms of what activities are actually done. So, those would be two examples of the type of research that would help us get success of risk messaging.

DR. EMILIO ESTEBAN: Thank you.

DR. KRISTAL SOUTHERN: Thank you. Thank you for the question and also thank you for chiming in.

Do we have any other questions from our Executive Committee members or comments? All right. Okay.

We'll move on to questions or comments from the NACMCF Committee members on the Cronobacter charge progress updates. If you have -- if you're a committee member and you have a question or comment, please raise your hand and you may unmute yourself when your name is called.

Okay. I am not seeing any hands. So, we're going to go ahead and move on to see if there's any members of the public that wish to provide an oral comment on the FDA Cronobacter charge and the progress updates.

We did not receive any request for oral comments on this topic during registration. So, we'll open it up to members. If you do have -- if you do -- if you would like to provide an oral comment on this topic, excuse

me, we request that all commenters please introduce yourself by providing your name and affiliation before providing comment. Each person will be provided three minutes to make their comments, and then the event producer will move onto the next person in the queue. So, I'll now turn it over to the event producer to provide any additional instruction and let us know if there are any hands raised and persons in the queue.

EVENT PRODUCER: If you would like to make a public comment on this subject, please press the raise hand icon at the bottom of your Webex screen to enter the oral queue.

If you are dialed in through the phone only line, you can please press *2 on your telephone keypad to enter the queue.

And finally, if you would like to submit a written comment, you can please send your written comments through the Webex chat panel on the right side of your screen.

DR. KRISTAL SOUTHERN: Thank

you. And do we have any?

EVENT PRODUCER: I am not seeing any comments in the queue at this time.

DR. KRISTAL SOUTHERN: Awesome sauce. Well, we'll keep it moving.

So, there will be another public comment period if you do think of something, and if we have time, we can go back to this topic.

So, we'll now proceed with the presentation from Drs. Vik Dutta and KatieRose McCullough, who are the co-leads for the Genomics Subcommittee. Welcome Drs. Dutta and McCullough.

DR. VIK DUTTA: Thank you, Dr. Southern. Can you hear me okay and see me?

DR. KRISTAL SOUTHERN: Yes.

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UPDATE ON FSIS CHARGE

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DR. VIK DUTTA: Good afternoon and good morning, everyone, and thank you for the opportunity to share the update from the Genomics

Subcommittee on behalf of all the members.

We have been working hard. Although our time scale has been not as long as the Cronobacter team, but nonetheless we're hoping to share the update with you and look forward to answering your questions.

Just real quickly, the charge question is for the agency FSIS, how can the genomics be used to rank pathogens subtypes -- rank pathogens by subtypes, and so that is a wide question that has been subsequently broken down into four subparts, the first one being how can genomics be used to differentiate microbial pathogens, i.e. Salmonella, STEC, LM, and Campylobacter subtypes by risk to public health in the food products that are regulated by the FSIS.

The second piece of that question is what type of genomic-based methods or approaches are currently being used in the US and by similar public health entities internationally.

The third being what are the research and knowledge gaps that should be addressed to fully operationalize a genomics-based approach.

And lastly, around the strategic vision on how might genomics inform FSIS and other agency actions along the farm-to-fork continuum.

So, as you can see, it is a wide charge with a diverse set of knowledge and expertise that was needed, and the subcommittee decided to focus on question 1 and question 2 first to really prepare ourselves before we dive into more of the planning and analysis of the research and the knowledge gaps and before we really started jumping into the strategic vision.

So, with that, we have organized ourselves into two work groups, one for question 1, and the other one for question 2. The question 1 also has subsequent subgroups that Dr. McCullough will speak to.

The question 2 workgroup

started off with multiple subgroups, but then we came back to address question 2 as one work group.

At this point, the ongoing meetings are happening with a goal to meet in person on September 23rd and our hope is to have at least first draft if not a context to our response created with these questions and then when we meet in September, our hope is to really start asking question 3 and question 4, at least the basis structure of how we would like to respond to them.

So, in order to do that, thus far we have relied heavily on our resources, i.e. the subject matter expert presentations. We have had twelve of those and four are pending, and this is likely going to grow as the subcommittee leads itself through this process.

And in terms of the resources, we have just started engaging with the National Ag Library, although the work has been going on for a while. We are finally seeing some outputs

that the subcommittee can use. Obviously peer-reviewed literature and the expertise of the members themselves.

For the methods, we are relying heavily on the validation databases, and I'll speak to that in a minute.

And, of course, the NACMCF Secretariat's help and guidance is very much needed as we continue our work.

So, here's a list of subject matter experts. Instead of trying to sort of break them into question 1 and question 2 and the subsequent subgroups, we have kind of provided you a list to give you an idea that we are seeking feedback from a diverse source of expertise from very different backgrounds. Just to hone into, you know, how we responded to this question, and this is more critical for the methods piece of our response because a lot of these methods are not mentioned in any literature out there. So, we are relying heavily on our subject matter experts to guide us, to show us a

path forward, because we may not be able to cite any references.

At the same time, we want to also keep our eye on the horizon as it relates to emerging technologies. And so, the goal is to utilize not just the literature itself in terms of what's available but also to rely on the expertise of a lot of our subject matter experts.

So, the other leg to stand on is the literature source itself. Like I said, we have been going back and forth with the National Ag Library for a few months now, and what we are showing you here is a criteria that we have come up with together as a committee where we're using search terms from the pathogen's name, the subtype terms, but also to define the public health risk. We have decided to use the human health outcomes as one of the criteria to limit how we search.

At this point, we are beginning to get our early literature results back and the subcommittee plans to go forward and start diving

into it and start sorting through the literature.

We have also decided not to split between questions 1 and 2 because the methods tend to get cited within these sort of larger epidemiological and risk-based papers. So, the goal is to have one search done at the National Ag Library, and then all of us can then dive in and take our respective pieces and start pulling out the literature that are relevant to our response.

With that, I will pass the microphone to Dr. McCullough to see if she has anything else to add.

DR. KATIEROSE McCULLOUGH: Thank you, Dr. Dutta, and excellent, excellent job outline our progress to this point.

You know, the NAL update that I'll give is that we're still in the process of finalizing all of our search terms as indicated, and so, we are really looking forward to leaning on this heavily. We already have a lot of gold standard literature that the committee is pulling

as needed as they're continuing their writing for question 1 and 2 right now, and we're hoping that as the literature search is finalized and we continue it, it will help us bolster the literature we've already pulled and really help us identify those question 3 gaps of what we're seeing after the search. So, thank you so much.

The next slide will cover what we've done so far on question 1.

So, question 1, as Dr. Dutta indicated, we've separated into three subgroups, and that is 1A, 1B, and 1C.

And so, 1A, we've classified to be appropriate genomic and pathogen attributes, and so our leaders for that are Heather Carleton and Aris Havelaar, and they have done a fantastic job pulling some of the foundation of what we really need for that question section, which we break it down a little bit on the next slide later. But so far, those sections have been assigned, and writing has started.

Like I've indicated, we've

pulled some gold standard papers that are really important for this section that need to be included to make sure our literature search criteria is appropriate.

We've also started listing different datasets and what those contain and what they've pulled. So, what are the datasets out there that are available that look at different genomic or pathogen attributes that we can lean on and point to, and where would they be helpful. Where would we think modifying those or adding to or supplementing that information.

For 1B, that genomic data and risk assessment. Abani has done a fantastic job leading that with the support of Aris again. We're making him pull double duty. And those sections have been assigned and writing has started. I think this 1B, as far as question 1 goes, has made the most progress up to date. They've pulled a tremendous amount of papers already, and they have also started listing out those papers that use different genomic data for

hazard identification, characterization, exposure assessment, or risk characterization. So, essentially pulling those different important things and what they have from each of those papers that were really helpful. So, the writing of those sections has already commenced.

And then 1C, which will really be supported by the group efforts in 1A and 1B has started. Those sections have been assigned, and we've already started a table of health outcomes that really was drafted to help us with our NAL search but lists the different health outcomes for each pathogen that hopefully we can tie to different genomic attributes or genes to those that would be important to, you now, assign risk and say, you know, in a perfect world, are we able to select for those things that are identified and classified pathogens based on if they're associated with these different health outcomes. So, we've started that work of brainstorming and look to further build that out as the efforts continue.

On the next slide, we have it broken down into sections for 1A, 1B, and 1C. We are calling this our questions map. So, you can see the contributing authors to each of those sections and their draft dates to present at this point.

So, for question 1A, which is appropriate genomic and pathogen attributes, we have available datasets and the associated metadata to, again, include all of the information that's already out there and available, and making sure we're aware that even though it might be in different places and then outline different attribution approaches.

That's going to be something that's important to understand as we're leaning on any sort of data that is indicating or a health outcome, you know, how we attribute to certain species, I think is going to be important, especially as we build out our strategic vision in question 4 as well as those epidemiological risk factors of concern.

We started a list as well, listing out different risk factors that may be important in leading to more severe illnesses by pathogen.

In 1B, again, this one is the risk assessment one that has done the most work for question 1 thus far, the hazard analysis and hazard identification. Janelle and Eric have done a tremendous job building out our outline and will be starting to write that section very shortly. That's really building out how we use the literature behind hazard analysis and identification when incorporating genomic data, part of risk assessments.

Abani and Max are leading the exposure assessment portion, and they have done good work on outlining again a lot of the literature and pulling the important things from those gold standard papers for exposure assessment.

And then Aris and Hayriye are leading the hazard characterization and dose

response section, and then once all that work is done, the group in total will put that all into context with risk characterization.

And then on genomic attributes, product risk factors and identified genes, like I said, a lot of the work in 1C will be bolstered off of what's done in 1A and 1B. And so, both from the human health and product characteristic perspective, we want to identify different genes and risk factors associated with those genes that may really be able to help us build out what we want done in question 4. And, like I said, that table of health outcomes, we've already built that out as a draft 1, and we'll continue to build that out as we dig through literature and get some results back from NAL.

With that, I'll pass it back to you, Dr. Dutta, to talk about our progress in question 2.

DR. VIK DUTTA: Thank you, Dr. McCullough. So, in terms of question 2, if you just read the test of the question, it became

clear to us over time that we just need to make sure that we do a good job and as comprehensive as possible, and that in itself, we're realizing, is a multi-layered approach. So, we spent quite a bit of time in talking about the structure of our response and that includes the criteria for what is genomics-based method that should be included.

As you can imagine, certain methods like PCRs are widely cited everywhere, but on the other hand, things like shot-gun genomics don't have enough literature. So, we are trying to balance that out and making sure that we are as comprehensive as we can be as we respond to the question.

And then also the categorization of the methods and technologies. Not all methods are reporting results that are pertinent to food safety decision-making. Some of them are actually building blocks towards that final tool that has been utilized for reporting the results. And so, there was an important work

done to make sure that the different tools and methods and technology, the CIDT databases, they're all getting categorized appropriately, and I'll share an example with you about how we are going about that.

And, of course, the validation sources are wide and diverse, and they go beyond our borders into international arenas, and even there they have, you know, most of the countries have their own -- all developed have their own validation systems and databases. So, we are looking to those as well to make sure that we are as comprehensive as we can be.

And that work is, I would say, is on the tail end of it. Of course, it's going to be a virtual cycle, and we will continue to look for any new methods as they emerge. But the collection of the data in itself was happening simultaneously, so we have built a large database where we are not only capturing the methods for the categorization but also all the different pertinent information that are, you know,

required -- would be required for the agency to consider, for example, the computation of resources and reliance on sequencing and so on and so forth.

So, there's a big database that is being built despite what will be actually captured in the text itself. So, at the end of it, we expect to have a very large and comprehensive methods database available to the agency.

And with that said, we have started drafting our response. This was our way of kind of forcing ourselves to start putting pen to paper and start documenting what we have been doing so far.

And so, that work is continuing, and we hope to have -- I'll show you in a minute -- we hope to have that completed within the next couple of months.

So, here's an example of how we are categorizing different methods. If you're a bioinformatician, you're probably familiar with

most of these, if not all of them, and Dr. Shariat did a wonderful job leading this work for the subcommittee. But the idea was to categorize all these different tools that are available in the public realm for easy sort of tracking of how do they help with the larger data analysis and ultimately decision-making.

And so this kind of allows us to know all the pertinent information as it relates to categorization versus annotation and so on and so forth.

This is done for the whole genome sequencing tools, and there's another one coming up with CIDT/genomics, and again, Dr. Shariat is doing good work for us along with other committee members.

So, as Dr. McCullough said, we have a roadmap -- a question map that we have both built to track the progress and Dr. Shannara Lynn has led the work in terms of drafting our response from all the sort of materials that have been -- that have been created so far like the

database I shared with you for question 2 and question 2A with help from myself and Dr. Shariat. And this response, I would say the first draft has already been presented and we are beginning to sort of start going back to the -- and fine tune the response that I mentioned and then also this, like I said, it's a virtual cycle as it relates to the database. You know, we're kind of working back and forth to make sure we are as comprehensive as we can.

With that said, the question 2B, Dr. Khaksar is leading that work. We are looking forward to taking a stab at it tomorrow and this is again worked on in partnership with Dr. Kristin Schill and Dr. Shariat and then after that, we plan to attack the whole question 2C with Dr. Sanchez leading that part. And, like I said, we hope to have this completed within a month or so. Again, this is an idea to kind of put a deadline in place so we can start drafting, even if it's an early draft, that's, you know, that's a good place to start.

So, with that, I will share the microphone back with Dr. McCullough.

DR. KATIEROSE McCULLOUGH:

Thank you, Dr. Dutta, and we -- we discussed a little bit this outlining our plan for how we're tackling the question. But here's the sort of next steps that we have. We have another -- tomorrow we have one more SME presentation, likely more to come, especially as we continue to write into the work and identify additional SMEs that we may need to bring in for a gap we've identified or to answer a question more specifically. But we really want to start reviewing draft sections of question 1 and 2.

As Dr. Dutta said earlier, we really envision a lot, and the bulk of the technical work is in question 1 and 2.

In question 3, the gaps that need to be filled will be based off of the work done in question 1 and 2. And so, we want a very strong draft of question 1 and 2 prior to really commencing our work on question 3. And then

question 4, we need to understand the gaps and what's possible and what's not possible based off of the work in 1, 2, and 3 before we can really build out a strategic vision.

And so, the goal is for our in-person meeting in September to have a very, very strong close to final draft of questions 1 and 2 that we will be able to review again in close to final format by that point, and then really spend a lot of time in person brainstorming on questions 3 and 4 and building out our plan for this.

And so, here's our roadmap for our next meetings coming up when we will be able to review those things. We certainly have a high likelihood of adding additional meetings, whether those are for SMEs or just additional meetings where we have to review drafts as we build that forward. But here's sort of our agenda from here until September at a minimum of what we are expecting to continue to make so we're on track to meet the overall goals and objectives in the

timeline given from USDA.

And so with that, Dr. Dutta and I are happy to take any questions. Dr. Southern, back to you.

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PUBLIC COMMENTS ON FSIS CHARGE

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DR. KRISTAL SOUTHERN: Thank you. Thank you both and so, we will now -- thank you Dutta and Dr. McCullough for your leadership of the Genomics Subcommittee and the updates you provided today.

In the standard format, we're going to start with the Executive Committee to see if any of you all have any questions or comments for the committee on the genomics charge.

Dr. Esteban, go ahead. I see you.

DR. EMILIO ESTEBAN: Not surprisingly, I have questions for you. Vik and KatieRose, thank you very much for this work.

You know how important this is and on a personal level, I love this work. I really look forward to the output.

Just a quick question. I looked at all the presentations that you just provided. It seemed to me that there was nothing dedicated to one pathogen or another. It seemed to be generic. And so, my question is clearly there's different levels of knowledge of the genomes or different types of pathogens. So, are you planning on at some point splitting pathogens or are you going to keep it all on a generic framework, if you will?

DR. KATIEROSE McCULLOUGH: I'm happy to take a first stab at that and then Dr. Dutta, please.

Absolutely we'll be breaking it down by pathogen and our discussions have it broken down by pathogen.

I can answer for question 1 as it relates to different human health outcomes and different epidemiological factors that we're

evaluating, those can be very pathogen specific. Some of them are generic, but there's a lot of very pathogen-specific health outcomes that we would like to ideally be able to select for, right?

If there's a certain type of E. Coli, which we know there's a lot of research that shows certain genetic components of E. Coli lead to higher HUS. And so, we are breaking it down by pathogens. We have no pathogen-specific conclusions at this time, but we envision to be able to have those by our September in-person meeting.

So, yes, our brains are aligned, and I don't know if that's a good thing for you or a scary thing to say that our brains are aligned. I guess we could hopefully rediscuss that at our September meeting.

Vik, what did I miss?

DR. EMILIO ESTEBAN: Thank you, KatieRose. If all scientists agreed, we would have a very boring life. So, yes, I'm glad we

disagree.

A second question, if I may, unless somebody else has another question.

DR. KRISTAL SOUTHERN: Vik, did you want to add to anything that KatieRose was saying? Yeah, we'll do that and then move on to your next question.

DR. VIK DUTTA: Perfect. So, Dr. Esteban, to answer your question, the first component is absolutely right. We have to look at the pathogens because that is how we have collected data so far. But that is the lens of GGS, right, or genomics as we know it.

What we are also realizing as we do our work is that there's a range of emerging technologies such as amplicon-based sequencing or the shotgun metagenomics. All these tools are less dependent on the pathogen itself and they are more sort of matrix dependent and/or technology dependent. And so, are there any answers that -- and we are kind of clumping them into CIDTs, which may not be a perfect way

of doing it, which kind of tells you the challenges we are facing every day. But nonetheless, I feel that there is a pathogen component and then there's going to be a generic component such as deploying sequencing technology on the enrichment itself that may give us even more insight that we are not thinking about today.

Now, the implications of that, the practicality of it, you know, all of that will have to be considered. But it may be one and two as we continue our work.

DR. EMILIO ESTEBAN: Okay, thank you. Thank you very much. I think Dr. Goldman had put something in the chat, but I'll let your moderate manage that.

DR. KRISTAL SOUTHERN: Dr. Esteban, did you have another question and then we'll --

DR. EMILIO ESTEBAN: Let -- let's answer the one from David and then if I may come back, I will come back.

DR. KRISTAL SOUTHERN: Okay. So, we'll come back to you then.

So, David, are you able to unmute yourself? I don't think so. I think Dr. Goldman may be having some issues with unmuting himself. So, there is a --

DR. DAVID GOLDMAN: I'm -- I'm here.

DR. KRISTAL SOUTHERN: Oh, great. Did you want to --

DR. DAVID GOLDMAN: But I'm in an airport, so that's why I put my comment and question in the chat, if you don't mind.

DR. KRISTAL SOUTHERN: Not a problem. I'll go ahead and read it.

So, Dr. Goldman said for risk management purposes, the ecological context from which the isolates arose are critically important. So, I would ask the committee to emphasize the importance of metadata to our understanding of the pathogens of concern.

So, thank you, David, for that

comment. I don't know, Vik and KatieRose if you -- if you wanted to -- I saw that you also wrote back. Thank you. I didn't know if you wanted to add anything to that before we move on.

DR. VIK DUTTA: I would say, Dr. Southern, that I agree with Dr. Goldman. I think that is an important -- the metadata adds more to, you know, the ecological context of the metadata has to be kept in mind as we continue our work. So, I agree with that.

DR. KATIEROSE McCULLOUGH: Yeah, and some of the work we've done where we've pulled, you know, this is what current databases have. It's specifically related to what metadata they have that's available and what they -- what they don't have.

So, we're totally aligned with you, and we'll hopefully have a better build out with more specifics at our next meeting, and I think potentially too, without getting too ahead of ourselves, I think some of that question 3, the gaps in metadata, we're going to have some

good work or, you know, good discussion with what's really important and where we can't come to conclusions because we're missing or lacking metadata.

And then on question 4, the strategic vision moving forward, we're talking about what metadata is really going to be critical to make further advances in this area.

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

We also have -- before I move to the chat, Dr. Esteban, did you have additional questions or comments?

DR. EMILIO ESTEBAN: I really look forward to the first draft of this report. I'm curious about the CIDT because obviously lab companies, CIDT developers, are way ahead of where we are with a lot of detection of which targets they pick. And so, a lot of the outcomes that we're finding based on CIDT results sort of filters the information that we have, right?

So, I'm very curious to see how

this works if we're going to integrate developments in human detection of a syndrome, a pathogen, a biofile, whatever -- how we pick our targets. How we pick our targets for the bug itself, you know?

So, I'm just curious. It's more of a comment than, I guess, a question.

DR. VIK DUTTA: Yeah, I fully agree with you, Dr. Esteban. That's one of the concerns -- work that we need to do to make sure that we are addressing the food safety decision-making. I fully agree.

DR. EMILIO ESTEBAN: Now, I'm done.

DR. KRISTAL SOUTHERN: We also have -- are you sure? I don't know about that. No, I'm just -- certainly, if you think of anything else, obviously let us know, put your hand up.

Before I move on to -- and I see a comment in the chat from one of our committee members -- are there any other

Executive Committee members that have any questions or comments before we move to more discussion amongst the committee? I'm not seeing any hands. Okay.

So, there is -- so, as well, I'll open it up to our committee members. If you all have any questions or comments for -- from these -- the updates that were just provided.

While some of you all think about any comments or questions, I will read from Aris Havelaar, who is one of our committee members. He put in the chat, "We also aim to discuss access to such metadata, which may limit their use."

And Aris, if you want, you know, feel free to come off mute and expand upon that if you'd like, or if that's the sole comment, that's fine too.

DR. ARIS HAVELAAR: Thank you, Kristal. Yeah, I just wanted to make the point that obviously the metadata is really important, but there's a lot of privacy regulations and

other ethical constraints that may limit the sharing of metadata, the access of different groups. So, that's something that we also plan to map out and maybe give recommendations on how to move forward with that.

DR. KRISTAL SOUTHERN: Great, thank you. Thank you for sharing that.

Do we have any other comments or questions from our committee members before we move to public comment? And I'm not seeing any hands or chat messages. All right.

So, we're going to go ahead and move on to public comment. I did not -- I do not have anyone registered to provide oral comment, but if you would like to, just a reminder, we request that you introduce yourself by providing your name and affiliation before providing your comment, and you will be provided three minutes to make your comment and then the event producer will move on to the next person in the queue.

I'll now turn it over to the event producer to provide any additional

instruction and let us know if anyone is waiting to provide comment.

EVENT PRODUCER: If you would like to make a public comment, please press the raise hand icon at the bottom of your Webex screen. If you are dialed into the phone only line, you can press *2 on your telephone keypad to enter the queue. Or finally, if you would like to enter the written comment, you can paste it in the chat panel on the right side of your Webex screen.

DR. KRISTAL SOUTHERN: I am not seeing any chat messages. Are there any hands raised?

EVENT PRODUCER: There are no hands raised in the queue at this time.

DR. KRISTAL SOUTHERN: Okay. I'll just pause for a moment just in case someone is just looking for the raise hand function. If you are, it's at the bottom of the screen next to the little happy face with a plus, there's a hand. All right. I'm not seeing any

hands raised. The one -- one -- we do -- we are a little bit ahead of schedule, which is absolutely fine by me, but I do want to just circle back that if there was anyone who has now since thought of some comments they would like to provide either on the genomics charge or the Cronobacter charge and the updates that have been provided, I'll just pause for a moment to see if there's anyone who would now like to provide those comments or yeah. And then again, if you don't want to provide an oral comment here, again, you can put it in the chat, and we'll make sure that the committee members have record of that.

Do we have any hands up?

EVENT PRODUCER: No, there are no hands in the queue at this time.

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CLOSING REMARKS

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DR. KRISTAL SOUTHERN: Awesome. Well, before we wrap up, I want to share a couple

of updates.

In January of this year, just a reminder that the most recently completed NACMCF report on Enhancing Salmonella Control in Poultry Products was finalized and published in the Journal of Food Protection. The QR code on the screen will take you directly to the report if you have not already read it.

Also, at the top of the meeting, I spoke briefly on NACMCF's purpose and membership selection, and we'll say to you all, are you interested in learning more about the committee's work and how to submit nominations? Well, we'll be hosting a virtual fair. It's still in the planning phases, but we're going to be doing that so you can learn more about these topics and other aspects of the committee. More information is to come on that. We'll have more information on the date and how to register for that virtual fair, and that will be announced in the coming months. So, please be on the lookout for that.

And then lastly, you heard a couple of -- during the presentations, you heard our co-chair speak about our next Plenary meeting, and you may have even heard the keyword that there will be an in-person portion of it. So, our next NACMCF Plenary meeting will be Tuesday, September 24th at 10 a.m. Eastern Time, and this meeting will be in a hybrid format with the option to attend in-person in Washington, DC or virtually. As always, a meeting announcement and registration will be announced in the Federal Register closer to that meeting date. So, that's another thing to be on the lookout for.

So, those are all of the general updates that we have today. I want to thank our committee members, subject matter experts, and members of the audience for participating in today's meeting. I also want to thank the NACMCF Executive Committee and the NACMCF Secretariat for your support and leadership.

And again, if you do suddenly

think of some public comments after you've had an opportunity to digest the information received today, feel free to -- even if you want to now, you can put it in the chat -- but there are always ways if you look on the FRN on how you can also submit a -- the Federal Register Notice on how you can also submit written comments to NACMCF.

So, I will now turn it over to Dr. Esteban for closing remarks.

DR. EMILIO ESTEBAN: Well, as always, I'm impressed with the advice that we get from these committees and it's not cheap to manage those committee meetings, but it's money well spent. I always follow those meetings with the impression of how much incredible knowledge is out there that we should always consider in our deliberations. So, thank you very much for all you do.

I look forward to our upcoming meetings, and I really, really look forward to seeing you in person later this year. So, thank

you very much for everything.

Translators and captioners, you're awesome. I don't know how you say awesome in sign language, but you're really good. Thank you very much.

Event moderator, thank you very much, and Kristal, I will turn it back to you.

DR. KRISTAL SOUTHERN: Thank you very much, Dr. Esteban. And we've completed the purpose of today's NACMCF Plenary meeting. We now stand adjourned. Everyone have a good rest of the day. Thank you so much.

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(WHEREUPON, AT 2:19 P.M. THE MEETING WAS ADJOURNED.)

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C E R T I F I C A T E O F R E P O R T E R

I, Jemima Brennan, Notary Public, before whom the foregoing testimony was taken, do hereby certify that the meeting transcript is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of the action; and that the testimony was reduced to typewriting by me or under my direction.

This certification is expressly withdrawn upon the disassembly or photocopying of the foregoing transcript, including exhibits, unless disassembly or photocopying is done under the auspices of Hunt Reporting Company, and the signature and original seal is attached thereto.

Jemima Brennan

Jemima Brennan, Court Reporter