UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOODS

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PLENARY SESSION

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May 16, 2023
10:35 a.m.

FDA Wing 3 Cafeteria
1400 Independence Avenue, SW
Washington DC 20024

CHAIR: DR. J. EMILIO ESTEBAN
Under Secretary for Food Safety, USDA

FACILITATOR: DR. KRISTAL SOUTHERN
Designated Federal Officer, USDA FSIS

NACMCF EXECUTIVE COMMITTEE MEMBERS:

DR. ERIC OLSEN
DR. DENISE EBLEN
DR. ARTHUR LIANG
DR. JOHN BELL
COL ALISA WILMA

NACMCF COMMITTEE MEMBERS:

DR. STAN BAILEY
DR. PEGGY COOK
DR. FRANCISCO DIEZ-GONZALEZ
DR. KATHLEEN GLASS
MS. JANELL KAUSE

NACMCF COMMITTEE MEMBERS (Continued):

DR. ELIZABETTA LAMBERTINI
MS. SHANNARA LYNN
DR. WENDY MCMAHON
DR. ANGELA MELTON-CELSA
DR. OMAR OYARZABAL
DR. ROBERT TAUXE
DR. MAX TEPLITSKI
DR. WING WANG
DR. BENJAMIN WARREN
DR. TESHOME YEHUALAESHET
DR. FRANCISCO ZAGMUTT
DR. JOSEPH EIFERT
DR. PHIL ELLIOTT (Virtual)
MS. MILLIE COLE (Virtual)
DR. SAFF STILLWELL (Virtual)

ALSO PARTICIPATING:

MS. SANDRA ESKIN
MS. SUSAN HAMMONS
MR. JOHN JAROSH (Virtual)
DR. JAMES KINCHELOE
DR. SUSAN MAYNE
DR. EVELYNE MBANDI

I-N-D-E-X

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

(10:35 a.m.)

DR. SOUTHERN: Good morning, everyone. Welcome to the Plenary Meeting of the National Advisory Committee on Microbiological Criteria for Foods, commonly referred to as NACMCF. So we do apologize for the delay in getting started. We did have an emergency in the room, and of course, you know, we take care of our people first.

As important as this meeting is, the people that go into making this committee great is more important. So, we're just happy that everything is worked out and we're all set and ready to go.

Due to the time difference, we may have some abbreviated agenda items, but we will try to get through the entire agenda as is. With that said, we'll go ahead and get started.

Now, for NACMCF, the purpose of the committee is to provide impartial, scientific advice and/or peer reviews to federal food safety agencies, for use in the development of an integrated national food safety systems approach that ensures the safety of domestic, imported and exported foods.

My name is Dr. Kristal Southern. I'm with the USDA Food Safety and Inspection Service. I've

served as the Designated Federal Officer for NACMCF, and the Director of the NACMCF Secretariat.

Today the committee will provide updates on their work to address the Food and Drug Administration's charges on *Cyclospora cayetanensis* in produce and *Cronobacter* species in powdered infant formula. Now this meeting is a bit unique, in that it is the first hybrid NACMCF plenary, in which we will have in-person and virtual attendees.

Before we dive in, I want to provide a few housekeeping items to keep in mind as we move forward. First, please note that this morning's plenary is being recorded. FSIS will post the plenary and transcript when they become available on the FSIS website, at www.fsis.usda.gov.

And because this meeting is being recorded, we have a court reporter in the room, and we ask that all attendees, whenever you speak, even if you've spoken before, please announce your name.

For online attendees, with the exception of our committee members joining virtually and our designated subject matter experts, your microphones are automatically muted when you join the meeting, and you will not have the ability to use your camera during the meeting.

And again, for our in-person attendees, we request that you use one of the microphones provided, or to come to the podium when you are speaking. A sign language interpreter is present for the duration of the meeting. In addition, closed captions can be enabled by clicking the closed caption, or CC bubble at the bottom left of your screen.

There will be two comment periods, two public comment periods today for members of the public. The first public comment period will be to receive comments on the *Cyclospora cayetanensis* in produce charge, and the second comment period will be to receive comments on the *Cronobacter* species in powdered infant formula charge.

If you preregistered to speak, and are here in person, I will call on you during the respective comment period. And for those online, you can use your "raise hand" feature, and the event producer will unmute you when it is your turn to speak.

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

Lastly, for online feature -- excuse me, attendees, the chat feature is available to also insert comment and questions. Any comments or questions made in the chat will be shared with the committee after today's meeting.

And in addition, attendees may 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'll now move on to taking the role of our NACMCF Executive Committee and the members of the NACMCF Committee. When your name is called, please announce yourself by stating here, or present. Starting with the NACMCF Executive Committee, U.S. Department of Agriculture's Under Secretary for Food Safety and NACMCF Chair, Dr. Emilio Esteban. He's here.

And Food and Drug Administration's Director of the Standards for Food Safety and Applied Nutrition, and our NACMCF Vice Chair, Dr. Susan Mayne.

VICE CHAIR MAYNE: Here.

DR. SOUTHERN: Food Safety and Inspection Service Liaison, Dr. Denise Eblen.

DR. EBLEN: Here.

DR. SOUTHERN: Food and Drug Administration Liaison Dr. Eric Olsen.

DR. OLSEN: Here.

DR. SOUTHERN: And to our online executive committee members, Centers for Disease Control and Prevention Liaison, Dr. Arthur Liang. Silas (ph.), is Dr. Liang on the call?

EVENT PRODUCER: Dr. Liang was just --

DR. LIANG: Oh, thank you both. I was on mute and couldn't get off mute. Art Liang, CDC, present, over.

DR. SOUTHERN: Thank you. Department of Commerce Liaison, Dr. John Bell.

(No response.)

DR. SOUTHERN: Silas, is Dr. John Bell online?

EVENT PRODUCER: Dr. John Bell is on the call. He is able to unmute his phone.

DR. BELL: Great, thank you. I'm here, thank you.

DR. SOUTHERN: Thank you. And we have one other Executive Committee member from the Department of Defense, our Department of Defense Liaison, Colonel Alisa Wilma. Silas, I don't know that she'll be joining, but if she is here, can you please announce

her present?

EVENT PRODUCER: If you are here, can you press the "raise hand" button on your screen to announce your presence?

It does not look like she is present on the Webex.

DR. SOUTHERN: Okay. We weren't exactly expecting her, but maybe. All right, so I'll now move on to our NACMCF committee members. Again, when your name is called, please announce your presence by stating here or present. I will start with our in-person attendees and then move to our committee members attending virtually.

And this is in alphabetical order, Dr. Stan Bailey.

DR. BAILEY: Present.

DR. SOUTHERN: Dr. Peggy Cook.

DR. COOK: Present.

DR. SOUTHERN: Dr. Francisco Diez-Gonzalez.

DR. DIEZ-GONZALEZ: Present.

DR. SOUTHERN: Ms. Janell Kause.

MS. KAUSE: Present.

DR. SOUTHERN: Dr. Elizabetta Lambertini.

DR. LAMBERTINI: Present.

DR. SOUTHERN: Ms. Shannara Lynn.

MS. LYNN: Present.

DR. SOUTHERN: And Dr. Wendy McMahon.

DR. MCMAHON: Present.

DR. SOUTHERN: Dr. Angela Melton-Celsa.

DR. MELTON-CELSA: Present.

DR. SOUTHERN: Dr. Omar Oyarzabal.

DR. OYARZABAL: Here.

DR. SOUTHERN: Dr. Robert Tauxe.

DR. TAUXE: Present.

DR. SOUTHERN: Dr. Max Teplitski.

DR. TEPLITSKI: Here.

DR. SOUTHERN: Dr. Bing Wang.

DR. WANG: Present.

DR. SOUTHERN: Dr. Benjamin Warren.

DR. WARREN: Present.

DR. SOUTHERN: Dr. Teshome Yehualaeshet.

DR. YEHUALAESHET: Present.

DR. SOUTHERN: Dr. Francisco Zagmutt.

DR. ZAGMUTT: Here.

DR. SOUTHERN: Okay. And Silas, I'll now move on to our online committee members attending virtually. So after I call the name, if you could raise your hand, or she'll unmute you. Dr. James Dickson.

DR. EIFERT: I don't think he was going to

be able to attend.

DR. SOUTHERN: Okay. We don't think that he's in attendance, so we'll move on. Dr. Joseph Eifert.

DR. EIFERT: Here.

DR. SOUTHERN: Oh, in person. Sorry, my apologies.

Dr. Phil Elliott.

DR. ELLIOTT: Phil Elliott's here.

DR. SOUTHERN: Thank you. Dr. Mahipal Kunduru.

(No response.)

DR. SOUTHERN: Okay. Hearing none, we'll move on. Lt. Col. Audrey McMillan-Cole.

LTC COLE: I'm here, present.

DR. SOUTHERN: Thank you. And Dr. Scott Stillwell.

EVENT PRODUCER: Dr. Stillwell is here. He's able to unmute himself.

DR. STILLWELL: Dr. Stillwell is here.

DR. SOUTHERN: Thank you. We have 20 of 29 members present, which meets quorum for today's meeting.

Next we'll proceed with opening remarks by the Under Secretary for Food Safety and NACMCF Chair,

Dr. Emilio Esteban, followed by the Food and Drug Administration's Director of the Centers for Food Safety and Applied Nutrition, and our NACMCF Vice Chair, Dr. Susan Mayne. Welcome, Dr. Esteban.

(Applause.)

CHAIR ESTEBAN: Well, good morning and welcome to the first hybrid session of NACMCF. We always provide excitement, and so the excitement cost us 30 minutes of the meeting. But I think, I hear that Ethan (ph.) will be out, and I imagine he will join us in a few minutes. This is good news.

Well, as Under Secretary, it's my honor to chair this committee. As you know, both FDA and USDA, we need all the science we can get, all the perspective we can get, all the inputs we can get from the stakeholders, to make the best science and to best, to support the best -- efforts.

During this meeting, we'll gear up to -- of the charges. One has to do with *Cyclospora,* the other one is the *Cronobacter.* And I think that you, we're aware that -- within public health is extremely --. So, you are a group of experts that we look to for advice, and we revisit, in many ways, that we did for the last few years. So, we appreciate -- we thank you, and I appreciate your being here today to share

with us your knowledge, your time.

Hopefully, we get to a conclusion, and I look forward to a lot of great advice and great relations related to public health. So with that, I will just turn it over to Susan, and -- then we'll get going with the committee. Thank you very much.

(Applause.)

DR. MAYNE: So good morning. I'm Susan Mayne. I direct the Center for Food Safety and Applied Nutrition. And I just want to give a very warm welcome to Dr. Esteban, who's attending in his role, and thanks to Sandy Eskin, who has played the leadership role of this committee for some time, and who will be missed, but we you know you're still going to be involved.

I also want to thank everybody who's here, and all the time that you've all spent participating. The work that you do, and the advice that you give us as federal agencies is critically important.

A few comments from me, and I may spend a few extra moments because this is my last NACMCF meeting. I'm retiring at the end of this month, from the FDA. And I've been serving on this committee for the last eight years, so this is a moment for me to reflect on a few things.

So, first of all, the work that you do is incredibly important. Yeah, we know we have two charges here, *Cyclospora*, the *Cyclospora* and the *Cronobacter* charges. I've seen firsthand -- and I am a scientist by training. I've seen firsthand how important the science is that you all do to inform us on the next steps.

And these are pathogens where there are big data and scientific gaps, and we will critically benefit from the work that you are all putting in, to help advise us as federal agencies. I know it's a lot of work. Before I came to FDA, I was an academician, and I served on federal advisory committees, and so I know what work that you're doing, and I really am very grateful. And on behalf of FDA, I express my most sincere appreciation for all the work that you're doing.

I want to thank all the exec sec folks here at NACMCF, who have supported us. Kristal's stepping into this important role, and she's replacing John Jarosh, who I don't think is here, but has done an enormous amount of work on behalf of NACMCF. And we are very grateful for the hard work that goes on behind the scenes, for all the accomplishments that come up with NACMCF.

The public comment period, we're very much looking forward to. As a federal agency, we really benefit from all of your input, all the public comments, and the resulting reports that will come out, and give us the information that we need, moving forward.

Special thanks to the chairs, who have spent an extra amount on this, specifically Dr. Max Teplitski and Peggy Cook, for their continued work on the *Cyclospora cayetanensis* charge, and as well, the *Cronobacter* chairs, Dr. Kathleen Glass and Elizabetta Lambertini, and so transitioning away from the very important work they've been doing on salmonella in poultry.

So *Cronobacter*, I'll just comment on, this has been such a unique food safety experience that we have had, with a pathogen that we really don't know a whole lot about. It's common in the environment. There are enormous data gaps, and we're very much looking forward to learning from you. We are a science-based regulatory agency and we need that science in order to continue to do our work.

So it's very important for us, and as we work with our federal partners, including the CDC on issues involving *Cronobacter*, so thank you for all of

that work. It's critically important as we tackle that new area of work.

A few final comments. While I won't be with FDA much longer, I can tell you I'm going to be very much looking forward to the output of this committee, and I'll be looking for that. And so, all the work that you continue to do is incredibly, incredibly important to us.

So with that, I'm going to turn it back to Dr. Kristal Southern, who will continue with today's important agenda, and I thank the USDA for hosting us here today.

(Applause.)

DR. SOUTHERN: Thank you, Dr. Esteban and Dr. Mayne. Dr. Esteban, both of us have taken on new roles in new months, and having worked closely with you in my previous role, it is an honor to continue that partnership, and I look forward to working with you on the leadership of NACMCF.

Dr. Mayne, though our time together has been limited, I know you're leaving the committee in great hands, and I wish you the very best in your retirement.

So, I know that we have a little time crunch here, but we do have a special presentation. And so

we're going to divert briefly from the agenda, and I will bring Dr. Esteban to the podium to do that.

CHAIR ESTEBAN: Thank you. So, I know that we're running short on time so I want to keep it brief. But sometimes people skip over on things, you know, recognizing what -- coming in. And so Kristal said that she's been proud of working with me for a long time. Oh, poor thing.

(Laughter.)

She doesn't know what she's walking into. But anyway, I just want to -- I want to just recognize Susan Mayne. You --. I've known Susan for many years, and I've always admired her for her belief in science, her communications ability, and the work she does every single day.

And so, Susan, we're really going to miss you here, your leadership, your management. And we're going to give you a little recognition for your distinguished service.

(Applause.)

CHAIR ESTEBAN: She says it's beautiful.

DR. MAYNE: Sorry, it's wrapped, so I don't want unwrap it, but it's a placard. And I want to thank Emilio. Yes we have worked together for many years. I'm thinking back, of --. Back in 2015 is when

I first started working with Emilio. So, we've had many years together.

I'm very, very grateful for all of his leadership, and everybody here who's advancing food safety, the work you're planning on the committee, as well as your professional work, to advance food safety. So thank you all, and I'm very grateful for this. Thank you.

CHAIR ESTEBAN: And uno mas, one more, please. For the last many years, Sandra Eskin --, leading this committee, and she's done a fantastic job. As you know, we're passionate about salmonella at FSIS, and the big push behind that has been Sandra.

We're not there yet. And we are -- the first chapter of that, and continue to push it. And it is frankly because I think, a lot of it, you've been giving us and hopefully you'll continue to give us --. So Sandra, please.

(Applause.)

So Sandra, thank you very much for all you do. She got to put up with me for another couple of years at least, so --.

(Applause.)

MS. ESKIN: Thank you. I appreciate it. Thank you all. It's a pleasure working with you. --

so quick, because I can't bring it home to my family.

DR. SOUTHERN: And so we thank you, Dr. Payne and Ms. Eskin.

We have one more special presentation, so Dr. Emilio Esteban, come on back up. We have one more.

CHAIR ESTEBAN: This one actually is, it's also a very special family. The designated federal official for this committee, leaving, is John Jarosh. And I met John Jarosh when we were working at the Midwest Lab in St. Louis. Then I dragged him over to the West Coast, to California, to work at the Western Lab. Then I dragged him to D.C. to work here, at headquarters.

And I think John --, a bench microbiologist, to work, and he went to the agency. And so I'm very, very proud. He's not here today, but Evelyne is here, as --.

Would you mind receiving it for him?

DR. MBANDI: My pleasure.

CHAIR ESTEBAN: Come up and join us and --.

(Applause.)

CHAIR ESTEBAN: John, if your online, turn your camera on.

DR. MBANDI: So, we want to say thank you so

much, John. The last couple of years have been very challenging but, you know, you pulled us through. John had, I'd say, three jobs, you know.

DR. SOUTHERN: Yeah.

DR. MBANDI: Yeah. So, thank you so much, John. We sincerely appreciate you. And thank you all.

DR. SOUTHERN: Okay, thank you. Thank you, everyone. I echo the remarks provided and extend a special thank you to you John, online. I have greatly appreciated your guidance during this transition and this, my transition into this role, and I know I have big shoes to fill. So thank you all.

And so before we move to our subcommittee updates, I want to remind the audience that the NACMCF report, addressing the charge, "Enhancing Salmonella Control in Poultry Products," has been posted to the FSIS website.

This report was adopted by the committee on November 15, 2022, and finalized in response to public comment in May -- excuse me, March 2023. We are now in the process of preparing the report for publication in the *Journal of Food Protection* later this year.

I will now begin with the updates, starting with *Cyclospora cayetanensis* in Produce Subcommittee.

The subcommittee is led by our members, Dr. Max Teplitski and Dr. Peggy Cook. Dr. Teplitski will read in the updates for the subcommittee.

DR. TEPLITSKI: Well thank Kristal very much, and thank you for all NACMCF subcommittee members, and that's a tremendous day.

For the *Cyclospora*, I'm going to provide a quick overview, and just to clarify, we're going to use shorthand, *Cyclospora*, when we intend to mean *Cyclospora cayetanensis* --.

We received 18 questions from FDA. We formed three working groups that joint meetings. And we had quarterly meetings, as a subcommittee. In addition to the initial subject matter expert presentations, experts from academia, USDA, ARS, CDC and testing labs following the short -- work of the subcommittee.

We presented peer-reviewed publications. We went through all the reports in the cruise database. We went through media presentations, so we searched everything that there is to search.

A quick summary. What we've learned is that the data on and isolation from the environment, although *Cyclospora cayetanensis* has been -- with great caution, resulting in what someone said the,

with the --, some uncertainty with the products that we use for the detection of *Cyclospora cayetanensis* in the environmental samples.

-- rates will bend the assertion that *Cyclospora cayetanensis* is a reasonable and -- in domestic or production environment should be dealt with lots of caution.

We also note that *Cyclospora cayetanensis* is a parasite that's found in humans with a history of travel to regions where it is endemic. There is no robust data to support the conclusion that *Cyclospora cayetanensis* established itself as an endemic parasite in the domestic --.

So with that, we'll transition to the presentation by -- Southern. Thank you.

DR. SOUTHERN: And just a reminder for our our presenters, because we do have something to --, that yes, we want to speed up our presentations because we lost a little time, but we want to be mindful that there is a person trying to interpret our notes for our attendees. So, thank you.

DR. COOK: Hi. I will be reporting for Team 1, assigned to work with me.

DR. SOUTHERN: Can you eat the mic?

DR. COOK: Yes.

DR. SOUTHERN: The IT people told me the phrase.

DR. COOK: Okay.

DR. SOUTHERN: Eat the mic.

DR. COOK: Okay. So question 1, "What is known about the prevalence, incidence and burden of disease of *Cyclospora cayetanensis* in the U.S. and internationally?"

And quick question, Kristal, you put in the slides, correct?

(Off mic conversation.)

DR. COOK: Okay. Part A is, are there specific segments of the population that have a higher risk for infection? What is the geographic distribution in the cases in the U.S.? What factors, as an example of food safety practices, location of the farms, may contribute to the contamination of *Cyclospora cayetanensis*, and are certain factors, in other words, a type of food, the seasonality, where the food is produced, degree of hand contact during growing and harvesting, more significant than others?

Cyclosporiasis occurs in persons of all ages, in either immunocompetent or immunocompromised hosts. Children are most likely to show cyclosporiasis than adults, and people with

immunocompromised conditions have highly significant higher rate of an infection.

The prevalence of *Cyclospora* infections is highly variable. The reasons for the variability are poorly understood, but include such factors as the area of the world, sanitary conditions, season, and personal attributes, such as age, duration of stay in an area, the social economics, status, livelihood and prior *Cyclospora* infections, and immunocompetence.

In the U.S., several isolated cases of cyclosporiasis, possibly associated with the exposure to drinking or recreational water, or with sewage, and consumption of contaminated produce has been reported. Domestically-acquired cases were concentrated in time, primarily in the spring and summer, and in the Eastern and Southeastern states.

Transmission of oocysts by contamination in soil is not still well understood. Early studies indicate identifying risks, factors and specific modes of transmission are necessary to understand the risk of the infection due to soil.

Surface water contamination of oocysts have the potential to transport and disperse the oocysts over long distances, and reintroduce them into crops with the use of irrigation or other product content

applications.

Question 2, "How does the seasonality, the incidence and prevalence of cyclosporiasis compare throughout the U.S., internationally, and what factors may contribute to it? Extrinsic factors, as well as influencing sporulation and survival, as well as environmental factors, influencing movement, such as rainfall."

Seasonal increases in the reported cases during the rainy season, spring and summer months are reported. The reasons for the apparent absence of symptomatic human infections for prolonged periods, where the parasite is present in the environment, and which biological conditions are needed for the survival of the parasite during the prolonged periods is unknown.

Factors such as rainfall, temperature, humidity and perhaps photo period could affect the seasonality, which clearly cannot be related to rainfall alone, as there is a marked seasonal variation in very dry environments.

Second part of B, on extrinsic factors, is oocysts are excreted and unsporulated in the feces. Infectious dose does not occur in the host. It's the sporulation of the oocyst which is thought to take

about one week in the environment. Under laboratory conditions, at 22 and 30C, *Cyclospora* oocysts stored in deionized water or potassium bicarbonate can sporulate in 7 to 14 days.

Sporulation was observed when oocysts were exposed to 37 in four days and 50C at one hour. Storage at 4C and 37C for 14 days retarded sporulation. Using information from the transmission vehicles implicated in outbreaks, an ambient, moist environment is most likely to encourage survival in a dry land.

Question 10, "What is known about *Cyclospora cayetanensis* persistence, survival in food such as produce and the environment," and references soil, water and food contact surfaces.

Due to the lack of animal or in vitro infectivity models, oocyst sporulation is often used as an indicator of viability, or other surrogate organisms were used in experimental studies related to the control of *Cyclospora.*

Methods that rely on temperature and time of storage have been evaluated for inactivating the parasite. Chemicals have been tested for the ability to interfere with the sporulation of *Cyclospora*. Surrogate parasites, such as *Eimeria* and *Toxoplasma*

were used in an evaluation of treatments, such as gamma radiation, freezing, heating and high hydrostatic pressure.

Question 14, "What is known about the relevant vectors such as nonhuman organisms in the transmission of *Cyclospora*?"

Of the 22 currently identified species of *Cyclospora*, only *Cyclospora cayetanensis* is known to infect humans. Humans are the only known naturally-occurring host of *Cyclospora*. The oocysts have been found in the feces of various animals.

Passive transport and spreading of *Cyclospora* oocysts sheds in human feces may be possible during the coprophilic practices of certain animals. Note, animals have been implicated as a cause of cyclosporiasis outbreaks, and no natural animal reservoirs have been identified.

The second part of question 14, "What is known about the role of the vectors, such as nonhuman organisms, if any, in the transmission of *Cyclospora*?"

Attempts have been made to infect a variety of animals by experimentally exposing them to the sporulated *Cyclospora* oocysts. This exposed chickens, ducks, mice, rats, sand rats, gerbils, hamster, rabbits, ferrets, pigs, dogs, a variety of monkeys and

baboons. No evidence of *Cyclospora* infections was observed in any of the animals.

Later studies with Swiss albino mice were able to show infections in the intestines of the animal. Despite this, the involvement of animals should not be discounted for the epidemiology of cyclosporiasis associated with fresh produce.

Question 15, "What role do the farm workers play in the transfer of *Cyclospora* contamination during the pre-harvest, harvest and post-harvest handling? Are there particular approaches that result in the selective identification of serotypes of public health concerns? How might the farm workers serve as both sources and routes of contamination, such as through contamination of agricultural water, or transfer of contaminated soil to food surface contacts or produce?

"What strategies have been utilized to mitigate the cross-contamination of farm workers? Have efforts to mitigate contamination from farm workers been successful?"

Fresh produce growers, harvesters, processors and shippers need to be aware of the potential mechanism of fresh produce to be contaminated with *Cyclospora* en masse, but use best

practices to manage the potential risk.

Farm workers can be carriers of *Cyclospora*, and may or may not be symptomatic and aware of their illness. Food safety programs at growing operations should include training or general hygiene, sick worker policy, personal protective equipment, management of the sanitary facilities, assessment of agricultural water for the potential human waste contamination, and appropriate handling of tools and equipment.

The second part of the 15th question, "What strategies have been utilized to mitigate contamination from farm workers?" This primary strategy to mitigate contamination of fresh produce with *Cyclospora* has been to focus on the prevention via farm worker training, including the topics of personal hygiene, clean clothing and other protective gear, such as gloves and boots, equipment management and appropriate sanitary maintenance of toilet facilities.

Testing is rarely used for reviewing equipment, services or irrigation water due to the expected low levels. Some operations may also use routine health evaluations and clinical testing.

Question 16, "Are there practices for the

maintenance and conveyance of wastewater, septage or human waste that may increase the incidence of *Cyclospora* contamination? Are there practices that may be useful in the management of waste to reduce the potential for contamination of *Cyclospora,* third-party toilet service or municipal wastewater treatment.

"Which wastewater treatment and septage and human waste treatments in the U.S. are effective, and what treatments may not be effective against *Cyclospora*? Does municipal water treatment adequately reduce, control or eliminate *Cyclospora*? And can effective municipal water treatment systems be scaled to treat agricultural water used in a production area, or the produce production?

"How do the practices compare for domestic and international growers?"

Cyclospora is considered a wastewater-associated pathogen. There's minimum evidence that the current wastewater treatment practices are sufficiently effective to reverse the potential health risks. Factors affecting removal include the type and level of treatment, use of multiple stage with long retention times, and exposure to different environmental factors, such as pH or sunlight.

Further work is needed to understand

specific wastewater treatment practices that will demonstrate sufficient effectiveness to benefit public health in the context of contributing populations.

Does municipal water treatment adequately reduce, control or eliminate *Cyclospora*? Existing regulations for water treatment are insufficient to protect the public from *Cyclospora*, because there are no regulations or management in drinking water or wastewater.

Can the effective municipal water treatment system be scaled to treat agricultural water in produce production? Our understanding of the effectiveness of municipal water treatment systems and their applicability to treat agricultural water is limited by the methodology applied to gather data.

Note that this remains important considerations for the specificity and sensitivity of the detection methods applied to management -- measurements.

And next, we'll have Dr. Francisco Diez present for Team 2. Thank you.

DR. DIEZ-GONZALEZ: Thank you, Peggy.

Good morning, everyone. It's a pleasure to be here. So I'm going to be reporting to you the finding from Team 2. I had the pleasure of chairing

you. Many thanks, Audrey McMillan-Cole and Joelle Mosso.

So, the questions that we had, the six questions, question 3, asks, "What sampling data exists for *Cyclospora cayetanensis* in food products and environmental samples, domestically and internationally?"

The two parts of this question, to include what trends have been observed, what methods of detections were used? Yeah. The first answer was, that while we were able to find 18 fresh produce surveys in the nine endemic and three nonendemic countries, from 1997 to 2017, mostly on lettuce and leafy greens.

And the values were, ranged from 1.6 to 25.7 in the endemic, and the nonendemic were from 1.3 percent to 12.2 percent.

For the question, part A, the trends were, so far, we couldn't find any because those studies are very limited, so there was not sufficient data to indicate it was a trend. The methods that were in use were predominantly culture methods, and went from using microscopy, the earlier studies and more recently, PCR and also utilizing -- PCR and also --.

Question 4, this reads, "What types of foods

are being attributed to outbreaks of cyclosporiasis domestically and internationally, and what if any contributing factors, sources or routes of contamination that have been identified?"

This question, we were able to find a volume of evidence on the fact that in addition to water on the foods, it's predominantly fresh fruits and vegetables that cause the cyclosporiasis infection, the *Cyclospora* infections.

Many semi-outbreaks were being reported, 54 percent of it being through fresh produce, and the top commodities or products have been linked to raspberries, basil, cilantro and salad mixes, but there's various other products that also be --.

Regarding the factors, clearly seasonality has a big effect, and the fact that the many domestically grown products are coming, are causing international outbreaks, it is suspected mostly from human feces. But no other factors have been reported, so clearly, there is need for more research into this topic.

Question 5, "Is monitoring for *Cyclospora cayetanensis* by testing food products, agricultural environment and agricultural inputs being applied as a management strategy currently?"

So far, in all our conversations with different groups and stakeholders, it doesn't seem that there's a routine testing program going on, in the U.S., at least.

The other parts of this question is whether our best practice for monitoring for presence of *Cyclospora cayetanensis* in agricultural production, including timing, sample collection, there is relatively limited information available. The -- the *cayetanensis* is listed as a pathogen of concern, but there is no details about how we're going to be addressing this.

The second part of the question, has monitoring led to development and implementation of effective preventive measures? If so, how effective have they been? So far, I guess we are relatively in the early stages. The CDC and the FDA have formed a task force on *Cyclospora* management, response and research action --.

And they've been recommending working with industry, academia and -- to develop test kits in order to be able to implement monitoring programs. And the FDA completed a four-year microbiological surveillance of fresh herbs and results. And they are still getting the news.

Question 8, this is about the, how we can assess the viability of oocysts. And there are three methods that the viability can be assessed. One is by culturing, is basically identifying live oocysts. Oops. I am here.

Question 8, let's see. Okay, good. So the oocyst can be placed in a nutrient-rich medium and then what we are able to detect by microscopy are the formation of sporozoites. Those are the -- when we will be able to tell whether the oocysts are viable or not. The problem with culturing methods are labor intensive, and requires the expertise and specialized equipment.

So, that's -- and the second methodology to use for assessing viability, that has been proven to be very successful, is using PCR or qPCR, because with this approach, we're targeting genes that are only expressed in lipolysis, such as -- genes.

So we can, we're able to determine whether oocysts are present in a sample, that it could be viable. The only tradeoff with this approach is that it requires very specialized equipment and expertise.

The third approach is flow cytometry), which seems very promising because it could be conducted with, using fluorescent light, and it requires less, a

lot less expertise. So it relies on the fact that oocysts, or live oocysts will be showing higher fluorescence intensity compared to dead oocysts.

Question number 9, "What current measures exist for the control of *Cyclospora cayetanensis*, for example using filtration?" How effective -- let's start -- I'm concentrating on moving up my screen. That's a problem when you're looking at the -- sorry. Well, you're all going to have to download the slides. But anyway, thank you for correcting me.

So, how effective have they been? "What are the impediments to development of effective preventive measures for *Cyclospora cayetanensis*, and how can they be overcome?"

So the approaches on those preventive measures, you could divide it into physical removal, physical inactivation and chemical inactivation. The physical removal, there are different research that use filtration, one study using sand, another one with zero --.

Washing, there's one study of looking at the effectiveness of washing. It seems that *Cyclospora* was hard to remove. Physical inactivation, that's an approach that's been tested extensively, but then we, in the case of UV irradiation, an area has to be in

use.

Heating, it's being tried with effective inactivation of there, one hour at 60 degrees Celsius, or 70 degrees for 50 minutes.

Freezing, it's been tried, and the data indicates that the *Cyclospora* survival after 48 hours at minus 20 degrees Celsius. High-pressure processing has been tested in, and using Eimeria surrogate.

Chemical inactivation, for the most part, was studied, trying chlorine. It's -- for the most part, most of the concentration has not been effective to inactivate the *Cyclospora*, and chlorine without dioxide was not effective at 4.1 milligrams per liter. Ozone has yet to be tested on *Cyclospora*.

Now what are the impediments involved in effective preventive measures for *Cyclospora cayetanensis* and how can they be overcome? First, the lack of methods. That's the main problem with the *Cyclospora*. We don't have a source of available oocysts, consistently.

We have a minimal study with surrogates, and there is an inability to culture oocysts. So methodology has been a big issue. So how can this be overcome as long as the -- plenty of research needs to be conducted in this area.

So, question 12, "What other coccidian parasites could serve as surrogate research models for *Cyclospora cayetanensis* behavior, for example, for evaluation of control measures?"

So, the responses we have for this question is, first, *Eimeria* is a very closely related coccidia to *Cyclospora*. They share very similar life cycle and -- characteristics, but *Eimeria* has been in limited use on using as a surrogate for inactivation on foods.

It's probably considered the best surrogate because of its taxonomy, and the other main reason why, is the availability of -- animal model. And *Eimeria* has an extensive number of tools that have been available for study.

The other proposed surrogate in the literature is *Toxoplasma gondii*, which is also a coccidia, but is farther related to *Cyclospora*. *Toxoplasma gondii* presents a number of benefits, some of them that we know a lot about this parasite. There are plenty of animals models, well defined, and it has even the, both -- because it has greater oocyst survival, good for a good safety factor for *Cyclospora*.

However, there is a main concern about the safety for lab workers in the case of *Eimeria*. You

don't have that limitation because it's very specific for animal, other animals, like chickens, and also, the current public concern for the use of cats in research. And also, they are fairly far, in terms of their lifecycle and the taxonomy.

We don't have, unfortunately, validation of those proposed surrogates yet. So again, one of those areas that we -- there is great need for additional research. And with that, I conclude my remarks, and I'm very pleased to now introduce Angela Celsa.

DR. MELTON-CELSA: Good morning. I'm Angela Melton-Celsa. I'm going to report for Subgroup 3. The questions we address are listed there, and I had the pleasure of working with Joe Eifert and Shannara Lynn in running out these questions.

So the first question was what are the available approaches for characterizing relatedness of different strains of *Cyclospora*. So, the genotyping methods using the targeted -- sequencing seem to be useful for -- investigations, and this has been applied to more than 600 samples submitted to the CDC.

But some outbreak cluster analysis suggests that we do need additional markers. It's not -- spore, a single genotype -- analysis as well for genome sequencing. They both look at sequence typing.

So for the next question, 7, the question about the available test methods for detecting and isolating *Cyclospora* from different matrices, and validation, and the matrices that have been validated.

So of course, by classification you can use for clinical samples. For this you do need intact oocysts, and it is impractical for food. You also need special people that have special -- meaning they're very knowledgeable on that kind of thing.

So other methods have been published for the BAM -- and filter filtration from water has already been mentioned. There's also a Chapter 19b that uses real-time PCR on 18S rRNA. It's been validated in several labs, and that matrices listed here, berries, herbs, lettuce, lime, guacamole.

On PCR plus for the 18S rRNA plus an eternal transcribed spacer has also been suggested. And the -- he already mentioned, whether it be sequencing, it means having real-time samples from a NACMCF source.

So question 11 is, "What is known about the transfer and attachment of *Cyclospora* from environmental samples such as water and soil to produce?"

So we do know that *Cyclospora* is transmitted by the fecal-oral route. Environmental water is

likely contaminated with feces. This was so demonstrated from this -- outbreak. I already had mentioned that there's inadequate hygiene facilities for workers that may contribute, as well as unclean food contact surfaces.

One thing we need to know a little bit more about is berries. So, we attach an -- parasite to the berry surface, may be enhanced due to those uneven surfaces, and some additional knowledge about adhesions that *Cyclospora* use for that kind of attachment would be helpful.

So for question 13, "Are there indicator organisms that can be used to determine the presence or absence of *Cyclospora* in various matrices?"

So, sorry this slide is a little bit crowded, of course. The presence of *Cyclospora* suggests there's fecal contamination. So, we had -- that's in question, are there some bacteria that we could use? Because parasites are difficult to identify, that might be used as indicator organisms. Another gap that might be useful is to try to find chemical indicators for *Cyclospora* presence.

For question 17, it's a question about what points in the parasite's lifecycle are potential targets or strategies to disrupt and control the

organism, and which of those control measures should we evaluate. And finally, what is the recommended protocol for evaluating the effectiveness of those control measures?

So, for the first part of the question, we think we need to target both the sporulated and unsporulated forms. In terms of environmental controls, we've already mentioned proper facilities for field workers and clean water. Another one would be to promptly transport produce from the field.

Again, I already also mentioned, due to the overlap of some of these questions, that typical chemicals are ineffective, and temperature is unreliable. And again, the question that was -- water is still up in the air. However, Altinox (ph.) and acid pepcid do remove *Cyclospora* from produce and has been used to detect *Cyclospora*.

So the recommended protocol for evaluating this, obviously on that would be to do spiking studies and then apply the various methods for the *Cyclospora*.

So for question 18, this is about relevant factors, the data and data gaps. We need to develop an informative, quantitative risk assessment model for *Cyclospora* contamination and risk of illness. So, we came up with a number of categories that need to be

addressed, such as sources and routes of contamination, prevalence and persistence of *Cyclospora*, and methods to -- risk and control strategies.

And in the interest of time, there are quite a few slides on this, I'm going to jump forward since we've already talked about numbers 1, 2 and 3. So I'm going to jump to 4, about the public health risk. So, for this one, it would be helpful to have an estimation of the effective dose. And when you do detect doses, are they infective?

And in areas where *Cyclospora* is endemic, asymptomatic infections may be more frequent, and the susceptible population are typically the young and the old. Where they're not endemic, most people are probably susceptible. And the infections though, may be asymptomatic.

So finally, for our control strategies, we've talked about some things that may or may not work, such as washing and temperatures. It is found that antimicrobials are not effective, but we may need more research on this, and additional control measures to eliminate *Cyclospora* may be needed.

And finally, we want to encourage anti-*Cyclospora* environmental and/or product sample data to

identify trends associated with produce as well as just for our research. Thank you.

(Applause.)

DR. SOUTHERN: Thank you to the *Cyclospora* Subcommittee for those updates. As a note to everyone, the *Cyclospora* Subcommittee is on track to complete their work and hold a plenary meeting to discuss and vote to adopt the report in August of 2023.

As we move closer to August, we will begin the process of scheduling a date for the plenary meeting, and that will be announced in a *Federal Register* notice.

So, before we move to public comment, I want to address the Executive Committee, or members of the committee, if there are any questions on the *Cyclospora* charge.

So, can you use the mic, please?

DR. BAILEY: Is this one that --

DR. SOUTHERN: I'm not sure if that one works, so that's important.

DR. BAILEY: So, the question I have is, you talked a lot about washing off the oocysts from the product. Is there any research about how attachment factors, or attachment -- how promptly it's attached?

How do we deal with that --? I'm just curious.

DR. SOUTHERN: Susie will get you a mic.

MS. HAMMONS: Okay. I'll swap him.

DR. MELTON-CELSA: Angela Melton-Celsa. We did not find anything really in the literature about how they attach, so we believe there's a gap.

DR. SOUTHERN: Okay, thank you. Thank you, Dr. Bailey as well as Dr. Melton-Celsa.

Are there any other questions in the room for the *Cyclospora* Subcommittee?

(No response.)

DR. SOUTHERN: Okay, seeing none, Silas, we'll move to the Executive Committee or committee members, as well as subject matter experts that should have speaker links, to see if there are any questions before we move to public comment.

EVENT PRODUCER: Those on the speaker link should be able to unmute themselves, or you can raise your hand if -- for the Executive Committee, if you would like to make a comment.

DR. SOUTHERN: Okay. And Silas, do we have any hands?

EVENT PRODUCER: There are no hands up from the Executive Committee at this moment.

DR. SOUTHERN: All right, awesome. Well

thank you very much. So we'll now move to public comment. We did not receive any requests to comment on the *Cyclospora* charge during preregistration, but we will open it up to the room and our virtual attendees.

As a reminder, this person making public comments will be provided three minutes to make your comment, and then we'll move on to the next person in the queue. We will let you know when you have 30 seconds remaining, so that you can start wrapping up your comments.

And to our virtual attendees, another reminder that if you want to comment, please us the "raise hand" feature, and the event producer will acknowledge you. Please state your name and affiliation before commenting.

So, I'll move to the room. Are there any members of the public who wish to make comments or questions about the *Cyclospora* charge?

(No response.)

Okay. We have no comments in the -- there is no one requesting a comment in the room on this charge. I'll now hand things over to the event producer to receive public comments on the *Cyclospora* charge from our online audience.

EVENT PRODUCER: As we move to the virtual public comment, you can press the "raise hand" icon at the bottom of your screen to enter the queue. If you are called in to our phone-only line, you can press pound 2 to enter the comment queue.

As a reminder, each attendee has three minutes to make a comment. You will be given a 30-second warning, and a stop warning before your line is muted and we move to the next person in the queue. Once again, that's the "raise hand" icon for the Webex attendees, and pound 2 for our phone-only attendees.

We are not seeing any hands up in the queue at this time.

DR. SOUTHERN: Okay. We will -- thank you, everyone, for your presentations of the *Cyclospora* Subcommittee. We, in the interest of time, will go ahead and move forward with the updates for the *Cronobacter* Species in Powdered Infant Formula Subcommittee.

This subcommittee is led by our members, Dr. Kathleen Glass and Dr. Elizabetta Lambertini. Dr. Lambertini is here to provide the updates from the subcommittee. Please welcome Dr. Lambertini.

(Applause.)

DR. LAMBERTINI: Good morning, everyone.

It's a pleasure to be here in person finally, for this -- committee. So, I only have ten slides, so that I pick up date on where we are and the plans for the next steps. So, we should be able to end on time. I'm going to talk about a little background, and then our approach.

As a quick reminder of why we're here, *Cronobacter* contamination in powdered infant formula has been associated with infections in infants, in particular from *Enterobacter sakazakii,* has been mostly associated with illnesses.

And *Cronobacter* presents some specific challenges, being isolated from a variety of foods and environment, including powered formula, and baby formula, as well as in -- environments, and a dozen other foods, so complex etiology here.

Also, *Cronobacter* can survive in all kinds, in moist or humid environments. I know you're aware of the recent event with infant illnesses and recalls, including one happening as we speak, and resulting shortages in formula.

So this focused a variety of -- questions. Central here is, what control measures and type corrective actions are for -- environments.

So, the NACMCF committee has been tasked

with advising the FDA strategy on the development, and we know, yeah, they then said that we have the task, but can we inform the strategy. So I think -- advancing my slide, now just --

I will briefly go through the charges, charge questions. We know that for this phase of the work, for this group, we are tasked with question 1 of the 4. Question 1 looks like, "What is the current prevalence and levels of *Cronobacter* species contamination in powdered infant formula in the U.S. market? What is known about *Cronobacter* species in other foods and in the home environment and the frequency with which these foods and environmental sources contribute to human infections?"

So you see that there are many sub questions here that we are tapping. We have September 2023 -- for this question

For the other questions, this is Phase 2, that we will pass on to the next group, and we'll have a later model sometimes in 2024, okay.

Question 2 asks, "What factors, such as virulence factors, host factors, dose of exposure, place an infant at greater risk for infection and serious adverse health consequences?"

Question 3 looks like, "What food safety

management practices," so getting at control, "for example, facility and equipment design, hygienic zoning and packaging, preventive controls and verification activities should manufacturers of powdered infant formula employ to further reduce the risk of contamination of formula and/or the production environment?"

And lastly, question 4, "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, as we work on question 1, we are also keeping in mind what comes next, and how we can inform the next questions. So, I worked on our approach. We have already started --, so we are still at the beginning and not quite sure what our findings does get.

We had three working groups, and we had subject matter experts, a couple of which we asked to meet with us during these three days, and they already made presentations, and we'll add more.

Our approach on this, span molecular

synthesis as a focus, but no -- is not a literature review. And these steps will go to -- synthesis, including defining the scope of specific searches, and finding inclusion and exclusion criteria, all the evidence, documenting the searching and vetting process, and -- synthesis that consolidates the evidence available.

We are assigning different searches to different members, to keep things going. We only have about two months, so we have all our specific searches to give you an idea of the sections that we will include in the report, or in the paper report.

Just to give you an idea, although they may be stated differently in the final, but we're looking at *Cronobacter* in infant formula in the U.S. but also keeping an eye on the evidence that we see worldwide, *Cronobacter* ingredients indicators that can predict occurrence or levels of *Cronobacter* involved.

The product ingredients environments, and then it can point of the etiology, looking at the various burden associated with formula and with *Cronobacter*, high-risk categories, infectious dose, that may not be a risk assessment, and those infection equations that needs a risk assessment.

And moving to classification and attribution

with different foods or harvest. And last but not least, *Cronobacter* indicators in our food and in environment, so we are skipping ahead, like in production, other foods, environments, and then we tie it all together.

So, in terms of sections, you will see three working groups, one with introduction and etiology, one focused on -- and in production environments, and one with other foods and environments.

Now, just a word on our timeline, we are exceedingly, in this table, it looks like we're halfway. We're not quite halfway. But we have started work. We have met, divided in working groups. We have already collected several evidence, literature, and defined the scope of our searches. And we hope we can keep the scope focused and aligned.

Now, we have -- I'm old school, but I'm, in this three days, in particular, finalizing the references that we have, and doing the bulk of the abstraction and tabulation. So, after that, we will continue meeting regularly, about twice a week.

And the next steps will be towards the end of July, possibly with an in-person meeting, doing -- for some of us. And at the point we should have a fully fleshed out draft ready for committee review.

Now, about a month later, end of August, we are sending the final draft to the committee. So as you see, we have just a couple of months to really do the bulk of the work, and then about a month for polishing it. So that is all I have, and I welcome any questions from the committee. Thank you.

So, and I want to thank everyone else on behalf of Kathy, who is not here in person, but she will join us for part of this meeting, when she does.

DR. SOUTHERN: Thank you, Dr. Lambertini.

As Dr. Lambertini mentioned in her update, the *Cronobacter* Subcommittee is on track to complete the first question of the *Cronobacter* charge by September 2023, when the current committee term ends. So this committee will provide a progress update at the same plenary in August, where we will vote to adopt the *Cyclospora* report.

The 2023 to 2025 committee, for which we will appoint members later this year, will work to address the remaining *Cronobacter* charge questions. So before we move to public comment, I will ask if there are any questions from the Executive Committee or members of the committee on the *Cronobacter* charge for our in-person guests.

And I've received notice that, at our --

when we use these mics, they couldn't quite hear us online, so we'll use this mic to -- bring it to you, except when there is public comment, we'll request that the person come up to speak.

So, are there any questions from the Executive -- excuse me, comments or questions from the Executive Committee for the *Cronobacter* Subcommittee?

(No response.)

DR. SOUTHERN: All right. Are there any questions from the members of the committee for the *Cronobacter* Subcommittee?

(No response.)

DR. SOUTHERN: All right. And Silas, can we check with our executive committee members and committee members online to see if there are any questions or comments to the *Cronobacter* Subcommittee?

EVENT PRODUCER: As a reminder to the virtual Executive Committee, you should be able to unmute yourself if you would like to make a comment, or press the "raise hand" icon. All right, we're not seeing any hands up at this time.

DR. SOUTHERN: Okay, thank you very much. So let's move on to the public comment portion. So, we did receive one request for preregistered comments. We'll move quick, start with Dr. James Kincheloe,

who's present in the room.

Dr. Kincheloe, will you please come to the podium to make your comment?

DR. KINCHELOE: Thanks, you all, for having me speak today. As noted, I'm Dr. James Kincheloe with the Center for Science in the Public Interest. We're a consumer advocacy organization.

The 2022 Abbott's recall that prompted the infant formula shortage and more recent 2023 Reckitt recall were preceded by a history with food safety problems at the production plants. These problems included positive *Cronobacter* test results that were not required to be shared with FDA.

I have three recommendations for the committee, setting from these root situations. First, the committee should prioritize examining and recommending manufacturer practices that FDA can take action on.

FDA already sent a letter to infant formula manufacturers in March of this year that described the areas of concern of how infant formula manufacturing facilities are controlling water in dry production areas. The committee should determine if there are additional important areas and practices to emphasize for these manufacturers, so that inspection actions

and agency policy decisions can be better.

Second, the committee has an opportunity to confirm the need for Congress to grant FDA's *Cronobacter* legislative authority request. This year, FDA asked Congress for the authority to require the reporting of final product test results from manufacturers of infant food for relevant pathogens like *Cronobacter.*

The agency also asked to be able to require more frequent environmental monitoring in manufacturing facilities, and for these test results to be available for FDA. The committee should closely examine the relevance of these practices for protecting public health.

If found to be important, they should be highlighted in the committee's reports to draw attention to the issue in Congress.

Third, the committee should emphasize the importance of requiring reporting of *Cronobacter* cases. The committee is charged with determining how food and environmental sources contribute to human infections. This charge is complicated by the facts that cases may not come to the attention of public health authorities, as *Cronobacter* is not a notifiable disease, and generally not a reportable disease.

Again, thank you for taking these recommendations into consideration, and thank you for your services.

DR. SOUTHERN: Thank you, Dr. Kincheloe. So, before we move to our virtual attendees, I just want to ask the room again if there any public commenters that would like to comment on the *Cronobacter* charge.

(No response.)

DR. SOUTHERN: Okay, seeing none, okay so we'll move to our online audience. I'll now hand things over to the event producer to seek public comments from our online audience.

EVENT PRODUCER: As a reminder to attendees, if you would like to make a public comment, you can press the "raise hand" icon on Webex, or press pound 2 on our phone-only line. Once again, you will be given three minutes to make your comment, and please state your name and affiliation before you state your comment.

We do have one caller in the queue. Caller, your line is unmuted. Please go ahead.

MS. BAUM: My name Mitzi Baum. I'm the CEO of STOP Foodborne Illness, the voice for safe food. STOP works on behalf of everyone who eats, to ensure

that food products put into commerce are safe for your families.

I'd like to thank the subcommittee for the time on this issue. *Cronobacter sakazakii* has been a known pathogen in the U.S. for almost 50 years. It has been known equally as long to cause neonatal meningitis, and can be lethal to infants less than two months of age, and infants born prematurely.

Cronobacter is known to be present in powdered infant formula manufacturing facilities. It contaminates the product and then ultimately the product is put into commerce to be fed to the most vulnerable population, infants.

The first charge of the subcommittee, to identify the prevalence and level of *Cronobacter* contamination of powdered infant formula in the U.S. market, is important. And the second, to identify risk factors that place an infant at greater risk for infection, serious health consequences or death, these are critical.

The background of the subcommittee work states there's a high prevalence rate of up to 15 percent contamination, which is very alarming. It also states that from 21 C.F.R., FDA regulations specify that manufacturers of infant formula must

establish a system of production and in-process controls covering all stages of processing is designed to ensure that infant formula does not become adulterated due to the presence of *Cronobacter.*

The American consumer trusts manufacturers to produce safe products for their infants. And what was discovered in September of 2021 was truly deplorable, by any standard.

As for the third charge, it's focused on the manufacturer. STOP questions why the industry is unable to determine how to reduce the risk of contamination to their product, and the facilities today, and why they aren't being held accountable to solve the problems that occur in their plants every day.

As to the fourth charge, it is abundantly clear that consumers do not know the risks associated with these powdered infant formula. First and foremost, it's not widely understood that powdered infant formula is not sterile, and it can inversely impact a baby.

It's listed on the label, however it's so overwhelming that it takes a minimum of six pictures to provide all the information on an infant formula label online. It's also not well known by parents

that *Cronobacter* will grow exponentially at 95 degrees Fahrenheit.

STOP Foodborne Illness is focused on developing an education campaign to increase the awareness of *Cronobacter sakazakii* for consumers and medical practitioners on how to reduce risk. STOP Foodborne Illness urges the subcommittee to continue working with urgency to protect the most vulnerable population, our children. Thank you.

DR. SOUTHERN: Thank you. Do we have other commenters online in the queue?

EVENT PRODUCER: There are no further comments in the queue at this time.

DR. SOUTHERN: Okay. Surprisingly enough, we actually made up all of our time. I was prepared to say that we'll go until 12:30 and we'll -- instead of starting at 1, we'll start at 1:30. But I do appreciate everyone for being mindful of the time and still getting through the entire agenda without any shortcuts.

So, this -- we do have -- I'll just give one last opportunity to those in the room, as well as those online, if there are any other public comments.

(No response.)

DR. SOUTHERN: There are no comments in the

room. Do we have any last comments online?

EVENT PRODUCER: There are no comments online.

DR. SOUTHERN: Okay, thank you. Thank you very much. Thank you to all the commenters who are participating in today's meeting.

So, this brings us to the end of our agenda. But before we conclude, I'd like to make everyone aware that the subcommittee meetings will begin this afternoon at 1 p.m. Eastern. And at 4 p.m. Eastern on Thursday, May 18th, the full committee will reconvene for a brief public meeting, excuse me, to provide progress updates on their work from their meetings this week.

For everyone that preregistered, you should have received an email with an update on the public portions of the sessions this week. Notably, the *Cyclospora* Subcommittee meetings and the Thursday afternoon regular session will have a hybrid form that meeting, meaning in person and virtual and open to the public. The link you received when you registered will take you to these meetings.

Because the *Cronobacter* Subcommittee is completing preparatory work on how to address the charge, and will be separated into small work groups

throughout the week, public participation will be limited to in-person for these meetings. We invite you to learn more about the *Cronobacter* charge in further subcommittee updates during the Thursday wrap-up session at 4 p.m. to 5 p.m. Eastern. Again, the link you received when you preregistered will take you to those meetings.

With that, I want to say thank you to the Executive Committee for supporting NACMCF, and I want to thank all of our NACMCF members for your updates and your commitment, excuse me, to the work of the committee. And thank you to our subject matter experts for consulting with the committee, and helping them to get the information they need when they need to answer charge questions.

I also want to thank the members of the public for contributing to and supporting NACMCF, and a special thanks to the NACMCF Secretary, Dr. Evelyne Mbandi, Mr. John Jarosh, Mr. Bryce Merrill (ph.), Dr. Susie Hammons, and our new advisory committee specialist, Ms. Chantel Williams (ph.). I greatly appreciate all of your efforts invested in supporting NACMCF.

So we have completed the first of today's NACMCF Plenary Meeting. We now stand adjourned.

Thank you. I will see you back at 1 p.m.

(Whereupon, at 11:56 a.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOODS

PLENARY SESSION

Washington, D.C.

May 16, 2023

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

_____

TOM BOWMAN, Reporter

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