Speaker 1: Welcome and thank you for joining the National Advisory Committee of Microbiology criteria for foods and plenary session. Before we begin, please ensure you have opened the WebEx chat panel by using the associated icon located at the bottom of your screen. If you require technical assistance, please send a chat to the event producer. With that, I will turn the conference over to John Jarosh. Please go ahead.

John Jarosh: Thank you. Good morning. Welcome to the plenary meeting of the National Advisory Committee on Microbiologic Criteria for Foods or as we call it, NACMCF. My name is John Jarosh. I am the deputy director of the United States Department of Agriculture Food Safety Inspection Service, Office of Public Health science, micro biological, and chemical hazard staff. I serve as the director of the NACMCF secretariat and I am the designated federal official for NACMCF. This morning's plenary meeting is being recorded. When they become available, the recording and the transcripts will be posted on the FSIS website at www.fsis.usda.gov. We will begin today's meeting by recognizing the NACMCF chair, deputy undersecretary for food safety, Sandra Eskin. Deputy undersecretary.

Sandra Eskin: Thank you, John and good morning, everyone. Again, I am the deputy undersecretary for food safety at USDA and the NACMCF chair. I'm pleased to welcome the NACMCF committee and members of the public to our 2021 plenary meeting. I'd especially like to welcome our 13 new committee members who you will hear from shortly. Thank you all for your willingness to dedicate your time and town to these important food safety questions, and thank you as well to the 17 returning members for your continued service on this committee.

NACMCF's committee members are experts in their field, microbiology, risk assessment, epidemiology, public health, and food science, and you all bring unique perspectives to the questions at hand. The recommendations and scientific advice that this committee provides are essential to USDA's food safety and inspection service, and to our federal partners at the Food and Drug Administration, the Centers for Disease Control and Prevention, the National Marine Fishery service at the U.S. Department of Commerce and the Department of Defense's Veterinary Sciences. NACMCF reports help guide the federal regulations and programs that reduce foodborne illness and enhance public health. This is an exciting time to be part of NACMCF as today, FSIS and FDA will each be presenting a new charge for the committee. We'll be asking the committee to focus your efforts on two food safety priorities, one control of salmonella in poultry, and two, control of cycloceratitis in mostly, I think, produce, but other products as well. Both agencies have prepared a corresponding series of questions for investigation.

We will also have time to hear from the public and I encourage the committee to consider public comments, both questions and suggestions, as you work through the charge questions. Over the course of this afternoon, in the next few days, we will split up into two subcommittees to delve deeper into the new charges. We look forward to receiving your reports and recommendations as we

work to build a safer food safety system. I'll now turn it over to Dr. Steve Musser, who is the deputy center director for FDA's Center for Food Safety and Applied Nutrition, who will be speaking on behalf of Susan Mayne, our NACMCF's vice chair. Steve.

Steve Musser: Thank you, Sandra. I hope everyone can hear me. It's a pleasure to be here this morning. Again, I'd like to welcome our members and guests to our plenary session. NACMCF is a very dedicated group. Again, on behalf of the partner agencies, I express appreciation and thanks for your time and willingness to share your food safety expertise. I'd like to acknowledge not just FDA and FSIS, but also CDC, DOD, and NOAA for their strong support of NACMCF. It is also important to acknowledge the NACMCF executive secretariats Leslie Good, Susie Hammonds, Evelyn Embondi, John Jarosh, and others who have made this possible. They worked very hard and put in a lot of administrative effort for NACMCF, especially during the COVID-19 pandemic in order to make sure that we have this invaluable to opportunity to meet together.

We have two charges to initiate, both of them quite important. Obviously, the FSIS charge enhancing salmonella control in poultry products is a critical and timely concern we share with FSIS. For FDA, I also want to point out the importance of better understanding the factors that can contribute to Cyclospora [inaudible 00:05:24] contamination of domestically grown and imported produce and of having recommendations from this committee for developing an effective prevention and management strategy. NACMCF is ideally suited to advise us on this subject. FDA looks forward to reviewing the information you'll provide and considering how it may inform ongoing efforts to reduce the number of cases of Cyclosporiasis attributable to produce consumption.

This would represent a significant accomplishment for the FDA in the new era of smarter food safety. I would like to also recognize Doctors Kathleen Glass, Elisabetta Lambertini, Max Teplitski and Peggy Cook for agreeing to leave the subcommittees in addressing these charges and offer special thanks to our other committee members, as well as technical advisors and subject matter experts for joining this effort. It represents a very significant time commitment and you are to be commended for your public service. Further, the diversity of the committee membership, including academia, industry, Federal, State, and consumer representation as well [inaudible 00:06:33] raise ethnic and broader diversity is of tremendous value to the committee going forward, as it has been previously. This committee continues to be a source of science based advice that has been extremely useful to the sponsoring agencies for many years. Thank you very much again in advance for your efforts I know you're all committed to putting into these charges. We all look forward to your reports to these agencies. With that, I'd like to turn it over to Mr. John Jarosh to continue with the agenda. Mr. Jarosh.

John Jarosh: Thank you, Dr. Musser. Now, we're going to conduct a roll call beginning with the NACMCF executive committee and follow by the NACMCF committee

members. We're going to proceed by letting each of you introduce yourself. Please, state your name and affiliation. I will prompt you if I need to and for the NACMCF committee members, we also ask that you state if you're new or returning. Let's get started with the executive committee. We've heard from our chair, deputy undersecretary Eskin and the vice chair, Steve Musser, Dr. Musser, FDA. How about Denise Eblin from our FSIS liaison.

Denise Eblin: Morning everyone. This is Denise Eblin. I am the assistant administrator for the Office of Public Health Science, FSIS. Thank you.

John Jarosh: Our FDA liaison, Dr. Eric Olson.

Eric Olson: Morning. This is Eric Olson. I am [inaudible 00:08:05] senior science advisor staff. I'd like to welcome everyone to the meeting. Thank you.

John Jarosh: Our CDC liaison, Dr. Arthur Lang.

Arthur Lang: Good morning. Art Lee Lang, Centers for Disease Control in Atlanta, over.

John Jarosh: Our Commerce department liaison, Dr. Jon Bell. He may not be here. Our defense department liaison, Colonel Wilma.

Elisa Wilma: Good morning, everyone. Colonel Elisa Wilma, Department of Defense Veterinary Services, currently serving as the director of Army Public Health Center and Aberdeen Proving Ground in Maryland. I am new to the executive committee this year, but I served on main committee last session. Thank you and happy to be here. Let's have a great meeting.

John Jarosh: Thank you, Colonel Wilma. Now, we'll move on to the NACMCF committee members.

Jon Bell: Jon, I'm sorry. This is Jon Bell from NSIL. I had a little trouble with my computer there. I'm with a National Seafood Inspection Lab with National Marine Fisheries Service NOAA and Department of Commerce. Thank you.

John Jarosh: Thank you, Dr. Bell. Sorry about jumping the gun there and moving forward. We'll go on to the NACMCF committee members and we'll start with Dr. Stan Bailey.

Stan Bailey: Hi, Stan Bailey here. New to the committee, been around a long time and know what most of you does, so it's a pleasure to be here and look forward to working with everybody. I'm with bioMerieux.

John Jarosh: We'll go on to Dr. Peggy Cook.

Peggy Cook: Morning. I'm Peggy Cook I'm with Neogen Corporation and I'm a returning member.

John Jarosh: Next would be Dr. Deanne Davis.

Deanne Davis: Good morning. Deanne Davis. I'm with Western Growers. We support the growing communities in California, Arizona, Colorado, and New Mexico, and I'm a returning member.

John Jarosh: Next is Dr. Francisco Diaz Gonzalez.

Francisco Diaz: Yeah. Good morning, everyone. I'm Francisco Diaz. I'm from the University of Georgia Central Food Safety and I'm one of the returning members.

John Jarosh: Next is Dr. Joseph Eifert.

Joseph Eifert: Hello, this is Dr. Joe Eifert and I'm in the Virginia Tech Department of Food Science and Technology and I'm a returning member of NACMCF and I love all things food microbiology. That's all.

John Jarosh: Next is Dr. Phillip Elliot.

Phillip Elilott: Good morning. This is Phil Elliot. I am a recent retiree from the Kellogg Company and I'm a returning member of the committee.

John Jarosh: Thanks. Next is Dr. Kathy Glass.

Kathy Glass: Hi, my name is Kathy Glass. I'm a research scientist and associate director of the Food Research Institute at the University of Wisconsin, Madison and I am a returning member to the committee.

John Jarosh: Next is Ms. Janell Kause.

Janell Kause: Good morning. This is Janell Kause. I am the senior advisor for risk assessment at USDA's Food Safety and Inspection service. I am a new member.

John Jarosh: Dr. [inaudible 00:11:34] Okay, I'm going to move on to Dr. Elisabetta Lambertini.

Elisabetta Lamb...: Good morning, Elisabetta Lambertini here. I'm a senior research scientist with the Global Alliance for Improved Nutrition and I'm a new member, delighted to be here.

John Jarosh: Next is Ms. Patty Lewandowski.

Patty Lewandows...: Hi, I'm Patty Lewandowski and I'm with the Florida Department of Health. I serve as the bureau chief of the Public Health Laboratories and I am a returning member.

John Jarosh: Next is Ms. Shannara Lynn.

Shannara Lynn: Hello, this Shannara Lynn of the National Seafood Inspection Lab. I am the lead microbiologist and I am a returning member.

John Jarosh: Next is Dr. Wendy McMahon.

Wendy McMahon: Hi, this is Wendy McMahon from Merieux NutriSciences. I'm a returning member as well.

John Jarosh: Next is Lieutenant Colonel Audrey McMillan Cole.

Audrey Mcmillan...: Hello, I'm Lieutenant Colonel Audrey McMillan Cole. I am a preventative medicine veterinarian currently serving as chief of veterinary services for Public Health Command Europe in Germany. I am new to the committee. Thank you.

John Jarosh: Next is Dr. Angela Milton Sofa. Next on the list would be Ms. Joelle Mosso.

Joelle Mosso: Hello. I'm Joelle Mosso. I work for Eurofins Scientific in our food testing division and I'm a new member.

John Jarosh: Next is Dr. Haley Oliver. Next is Dr. Omar [crosstalk 00:13:58]

Haley Oliver: Haley Oliver. I've been changed. My status has been changed. Thanks, Haley Oliver. Purdue University, returning member.

John Jarosh: Thank you, Dr. Oliver. Next is Dr. Omar [inaudible 00:14:11] Sorry, Omar.

Omar: No. No problem, John. Thank you. Omar [inaudible 00:14:17] independent consultant, returning member. Thank you.

John Jarosh: Next is Dr. Tonya Roberts. I think I got a message that she might have audio problems right now, but she might come on in a second. I'm going to move on to Dr. Scott Stillwell.

Scott Stillwell: Good morning. Scott Stillwell, retired Tyson Foods, currently with Stillwell Consultative Services.

John Jarosh: Dr. Max Teplitski.

Max Teplitski: Good morning, everybody. I'm Max Teplitski. I'm the chief science officer at the PMA Produce Marketing Association, soon to be International Fresh Produce Association. The goal of the PMA is to grow a healthy world and we represent over 2600 member companies along with the entire fresh product supply chain, so issues of Cyclosporiasis and salmonella are critical to us.

John Jarosh: Thanks. To Dr. Valentina Trinetta.

Valentina Trine...: Valentina Trinetta. Good morning, everyone. Associate professor, Kansas State University, returning member. Thank you.

John Jarosh: Next is Dr. Bing Wayne.

Bing Wang: Good morning, everyone. Bing Wang here, associate professor in the Department of Science and Technology from the University of Nebraska Lincoln. I'm a new member and my research centers around quantitative microbial risk assessment. Glad to be here.

John Jarosh: Next is Dr. [inaudible 00:16:01]

Dr. Tishumi: Thank you very much. Good morning, everyone. My name is [inaudible 00:16:07]. I'm working at [inaudible 00:16:08] University in the College of Veterinary Medicine in the Department of Pathobiology. I'm a professor in microbiology and molecular biology with main work on research and teaching. I'm a new member and I'm glad to join the advisory committee. Thank you.

John Jarosh: Next is Dr. Francisco [Zagment. 00:16:33]

Francisco Zagme...: Good morning. I'm Francisco [Zagment 00:16:35], managing director at Epics Analytics, which is a company specialized in risk analysis. I'm a deputy epidemiologist and risk analyst and I'm a returning member.

John Jarosh: Dr. Betty Fang.

Betty Fang: Hello, this is Dr. Betty Fang from Purdue University and I conduct research on human factor in food safety. Thank you. I'm a new member.

John Jarosh: There were three other members who were unable to join us today due to other commitments, Dr. James Dixon, Dr. Rob Tokes and Dr. Randy Worobo.

Randy Worobo: I'm actually here, John.

John Jarosh: Oh.

Randy Worobo: This is Randy Worobo. I'm a professor of food microbiology in the Department of Food Science at Cornell University and I'm a new member.

John Jarosh: Thank you, Dr. Worobo. That completes the role of the executive committee and the members of the new NACMFC committee. We'll move on here. Before we get started, I have a few business announcements. Most importantly, I want alert everybody to the charges presented today are available on the FSIS website at www.fsis.usda.gov. They can be found under policy and then advisory committees. Then, there's the NACMCF's page there. You can also search the website for NACMCF.

John Jarosh: ... page there. You could also search the website for NACMCF and should take you to the page. There's also a link provided in the meeting announcement. So you should be able to follow that as well. If you have difficulty finding the charges, you can email the NACMCF secretary at NACMCF@usda.gov. So that's N-A-C-M-C-F @USDA.gov.

Next, our meeting today has a public comment period listed on the program. Please note that we are only soliciting comments only related to the salmonella and cyclospora charges. We are not asking for comments beyond the scope of the NACMCF charges being presented today.

The event producer will go over this as we move to those periods, but for guests wishing to make public comment, please press the star key on your phone and raise your hand and the event facilitator will unmute your line. Once your line is unmuted, please state your name and affiliation for the record before making your comment. Your comments will be limited to three minutes. We want to make the best use of our time, so as many people as possible are able to make a comment. We're going to try to stay on the posted schedule. However, we've been advised by both of our speakers, that they may not use their full allotted times. If that's the case, we'll move on to the public comment period to again, provide as much opportunity for the public comment that we can fit into our schedule. So we do have several-

Rob Tauxe: This is Rob Tauxe, sorry, a returning member. Sorry. I've been having a little audio challenge here, but I think you can hear me now.

John Jarosh: Yes, Rob, I can.

Rob Tauxe: I'm Director of the Division of Foodborne, Waterborne and Environmental Diseases at the Centers for Disease Control and Prevention, returning member, as I said, and delighted to be here. Thank you very much. I'm going to be in and out, because of competing priorities as part of the response to the COVID pandemic. Thank you.

John Jarosh: Thank you, Dr. Tauxe, glad you could make it. So at this point in time, we'll move on to our our first presenter, Dr. Isabel Walls, a Senior Public Health Advisor with the United States Department of Agriculture, Food Safety, and Inspection Service in the Office of Public Health Science. Dr. Walls will present the salmonella charge on behalf the Food Safety and Inspection Service. Dr. Walls?

Dr. Isabel Wall...: John, can you hear me?

John Jarosh: Yes, we can.

Dr. Isabel Wall...: Thank you, John. Glad you can hear me okay. Well, good morning everybody. Welcome to the meeting. Very glad to see everybody here. My name is Isabel Walls. I'm going to walk you through the salmonella charge this morning. As you

can see, the title of the charge is, Enhancing Salmonella Control in Poultry Products. Next slide, please.

So the National Advisory Committee on Micro Biological Criteria for Foods is an Advisory Committee that provides impartial scientific advice to federal agencies. Members serve two year terms and they are selected based on their expertise. On my slide, you can see the food safety partners who receive advice from this committee and I note that they all had representation introducing themselves here this morning. Next slide, please.

So our current performance standards were initially established as part of the pathogen reduction, hazard analysis and critical control point rule you may remember back in 1996. Our current performance standards are used to verify process control. Our current performance standards are qualitative. We look at presence absence, but they are based on quantitative microbial risk assessments, and they are designed to achieve the Healthy People National Food Safety Goals. Next slide, please.

What we want to do, the Office of Food Safety is proposing a new salmonella strategy and we're seeking advice from the Committee. We want to leverage advancements in science and technology to develop new micro biological criteria with performance standards, to reduce salmonella, salmonellosis associated with FSI's regulated products, in particular poultry. So we want to consider criteria to encourage control of the quantity of salmonella, not just presence absence, and we want to consider salmonella serotypes more frequently associated with human illness. We also want to look at criteria at various points in the system. We want to consider criteria that would promote pre-harvest control, as well as along all points in the chain. We want to consider the use of indicator organisms, where they're correlated to salmonella to measure pathogen control. Next slide, please.

So the proposed charge then enhanced salmonella control in poultry products, our overarching risk management question is, "What types of micro biological criteria might FSIS use to encourage reductions in salmonella in poultry products, so that they are more effective in preventing human salmonella infections associated with these products?" So that's the big picture question that we're asking. Next slide, please.

Now there are a number of questions, and I have been asked to read them, so that is what I'm going to do. Again, these are all available on the website, but I'm just going to walk you through these questions. So question one, is looking at the public health impact. "Can we assess the public health impact of controlling specific salmon serotypes and, or levels, the amount of salmonella in poultry products and what type of approaches could be used?" So that's the first question, focused on public health. Next question, please.

The next question then, "What types of micro biological criteria could be established to encourage control of salmonella at pre-harvest as in life birds on

the farm? Should FSIS consider qualitative micro biological criteria for control of salmonella in a flock? How could FSIS use these criteria to address salmonella serotypes most frequently associated with illness? What industry data would actually provide evidence of control?" So a number of things to think about in question two. Next slide, please.

In question three, we're asking, "What types of microbial criteria could be established for poultry carcasses, parts, and commutative products prior to applying interventions and after interventions, considering the current technology? Could the quantity of salmonella, or the quantity of a micro biological indicator be used?" What are the key parameters that need to be considered? What data analysis techniques could be used and how would these criteria be linked to human illness? Key question. The second part then is, "How could serotypes frequently associated with human illness be considered in the development of microbiological criteria?" Next slide please.

So in question four, we're asking, "How might foodborne illness surveillance data on human salmonella illnesses, data from foodborne outbreaks associated with salmonella in poultry, and data on salmonella serotypes in poultry products be used to identify the salmonella serotypes of greatest public health concern?" Of course, that's where we want to put our focus on those serotypes of greatest public health concern. So how do we identify those? Should we only look at the most current data, like the last five years of foodborne illness, surveillance, outbreak, and pathogen testing data? Going forward, what methodology and criteria would focus on those salmonella serotypes most frequently associated with human illness, attributed to poultry products? How frequently should the priority salmonella serotypes associated with poultry be revised, considering changes in their occurrence, while still ensuring continuity in industry and regulatory testing? Is it appropriate to change every year, or should we look every three years or should we take a more longer term approach. Next slide, please?

For question five, we're talking about correlation between a reduction in the quantity of aerobic plate counts as an indicator organism between carcasses and finished products and the occurrence of salmonella in finished products for beef, pork, and poultry. As you know, we find very, very low prevalence, [inaudible 00:28:17] positive salmonella in our products. So is there a role for looking at indicator organisms, such as aerobic plate counts and how might this information be used to set micro biological criteria to assess pathogen control in poultry? Next slide, please.

As I said, there's loads of questions. Question six, "What rapid methods and technologies are available for the quantification of salmonella and how should FSIS make best use of these methods?" It's going to be a very important issue if we're going to look for numbers of salmonella, as opposed to presence absence. Next question, please.

Question seven, "Are there particular approaches that would result in selective identification of the serotypes of public health concern?" This really speaks to the enrichment methods and methods we're using to isolate serotypes. Are there approaches to mitigate a potential strain selection bias introduced by the laboratory method? If needed, what type of research could be conducted to ensure performance characteristics of current laboratory methods, the enrichment method, incubation, prescreening, that they do not result in biased stereotype detection. We don't want the method we're using to be selecting for certain strains if we are trying to focus on other strains. So this is strain selection bias. Next slide, please.

Question eight, "How should pathogen characteristics drive from whole genome sequencing, such as stereotypes [inaudible 00:30:02] antimicrobial resistance, very important issue be considered in the development of micro biological criteria? The final question near and dear to my heart, "What research is needed to support FSIS' new salmonella strategy, in terms of setting micro biological criteria? You knew we were going to put that one in, right? Okay. Next slide, please.

Okay. So we are going to have a session this afternoon where we're going to have a series of speakers and they should be able to answer most of your questions, but I can take one or two now from the Committee.

John Jarosh: So I see a couple of people with hands up. [Gotstilwell 00:30:56] do you have a question? Okay. Maybe not. I don't see anybody else with their hand up or...

Dr. Isabel Wall...: Okay. Thank you all.

John Jarosh: All right. So thank you, Dr. Wells. The Committee's work on the charge is very important to FSIS, as it will contribute to the USDA's mobilization of a stronger and more comprehensive effort to reduce salmonella illnesses associated with poultry products. The Committee now... Since we're a little ahead of schedule, I believe, will go ahead, and start the public comment a little early. So I'll hand it over to the event producer to see if we have public comments at this time.

Producer: We will now be entering the public comment portion of today's call. You will have three minutes to ask a question. You will raise your hand by pressing pound two on the telephone keypad. If you're on the audio and on the computer, you can raise your hand using the feedback button. At this time, we will be taking comments. (silence)

The feedback button is located just above the chat, the microphone sign. We are in public comment. (silence).

We do have one hand raised. Caller, your line's unmuted. You will have three minutes to present.

Katie Rose McCu...: Good morning. This is Katie Rose McCullough with the North American Meat Institute. With a lack of public comments, I thought I would just take the time to thank you guys for this charge. I think it is a very timely, appropriate charge and appreciate FSIS making sure that it's above the Committee for review and recommendation. I certainly think they're a great group of people to tackle this. I think the only comment I would have is where we seem to struggle as an industry with some disconnect, and this I know won't be a stranger to anybody here on the call, but I think it's important to talk about as they go into their deliberations and discussions later this afternoon, and tomorrow, is the disconnect we often sometimes see in salmonella in product, and then what actually makes people sick.

So we've really been able to drive salmonella down in product, but aren't seeing that in human illnesses themselves. I think that speaks to a lot of different things, including good data on attribution. So I think talking about some of these challenges, like good data on attribution, I think there's some laboratory method stuff that we can talk about, can really help demystify. Because I know sometimes people in industry and a lot of our members will get frustrated, because they drive that salmonella down and product and we're unfortunately not seeing the public health benefit. So I look forward to the Committee's discussion and hopefully some comments on how we can improve some of those things to better translate into what we see into consumers. Thank you so much and good luck with the charge.

Dr. Isabel Wall...: Thank you. [inaudible 00:35:39].

Tanya Roberts: Hello. This is Tanya Roberts. I'm late in joining the meeting. I was having a little bit of a computer problem. So I would like to introduce myself. I used to be at Economic Research Service in USDA and pioneered the cost of foodborne illness estimates. I was also served on the Interagency Risk Assessment Consortium too. But after I retired in 2008-

Tanya: ... Consortium too. But after I retired in 2008 is when I joined CFI, and so I'm the consumer rep today, or a consumer rep. And also, one of the comments I wanted to mention is when we think about controlling salmonella, why don't we look in depth at what is happening in Sweden? Because they've been very successful with their on-farm control and all the way through to the slaughterhouse. So that's what I would suggest that we do today in our committee. So yes, so that's my comment. Thank you.

Producer: Angela, did you want to make a comment? Your line is unmuted.

Angela: No, I don't see any of the controls, so that's what I was asking about.

Producer: On the WebEx screen, right above the chat, on the right side, there's a microphone with a dropdown carrot. Do you see that?

Angela: Yes. I think. I see a flag.

Producer: Where it says feedback, and right next to it is a raise hand sign?

Angela: Okay. Yes. Well, no. Okay, I'll look and see what I can figure out.

Producer: We are in the public comment point of this conference. If you would like to make a comment at this time, please raise your hand. It is right above the chat to the right side.

John Jarosh: It looks like one of our committee members, Dr. [Ushulett 00:38:54], might have a question.

Dr. Ushulett: Yeah, I have one question on the presentation from Dr. [inaudible 00:39:03]. Is that possible? Can I just make that question, please?

John Jarosh: Sure.

Dr. Ushulett: I have a question for Dr. [inaudible 00:39:10] or is that only... Hello? Hello?

John Jarosh: Yeah [crosstalk 00:39:22].

Dr. Ushulett: Okay. Yeah. In one of your slides, Dr. [inaudible 00:39:25], sorry, you mentioned that this advisory committee will provide impartial scientist advice. What does impartial means? Could you explain that?

Speaker 2: Impartial means impartial. It means that the people on the committee were not selected because necessarily where they worked, but because of their scientific expertise. And we anticipate them providing scientific advice. Yeah, focus on science, impartial scientific advice. John, perhaps you can help with that?

John Jarosh: Certainly I can contribute to that answer. [crosstalk 00:40:23] So Dr. Ushulett, the idea is that we've pulled as diverse group a group of people that we can, so that we have all aspects in various areas represented. And by bringing that together and getting that consensus from the scientists, hope the end product should give us as impartial advice as possible.

So, the agencies here, FDA and FSIS, have put these questions together to give them to the group of members on the panel like yourself. And so, you'll go and answer these and with as little interference as possible from us. So just speaking for FSIS, we'll give you... You'll get our charges to go work on. And yes, we have some people, we have one person on the committee representing FSIS, but they're just another member of the committee. Because we also have other members from industry and from academia, and we have Tanya, our consumer rep that you heard from a little bit earlier. And hopefully together, you'll all come up with a work product that is the work of the committee, and you'll present that back to us as your impartial advice. Does that help explain things?

Dr. Ushulett: [crosstalk 00:41:52] Yeah. Thank you very much for both answer. Thank you. I really appreciate it.

John Jarosh: No problem. We are still looking for anyone who wants to make public comment or if anybody on the committee has a question, we still do have time for that.

So not having anyone making public comments, and I don't see any more questions on the committee, we could move on and advance into our next presentation. So the next item on the event agenda would be Dr. Ben Warren, senior science advisor for food safety from the Food and Drug Administration Center for Food Safety and Applied Nutrition. Dr. Warren will present the cyclospora charge on behalf of the Food and Drug Administration. So do we have Dr. Warren's audio line open?

Dr. Ben Warren: I believe it's open, John. Can you hear me?

John Jarosh: Yes, sir.

Dr. Ben Warren: All right. Thank you. Good morning. Everyone. This is Ben Warren, as John mentioned, I am with the FDA Center for Food Safety Applied Nutrition Office for Food Safety. And it's my privilege this morning to present FDA's charge to the committee. Our charge this year or the cycle is preventing cyclospora cayetanensis contamination in food. Next slide, please.

Cyclospora cayetanensis is a protozoan parasite that causes gastrointestinal illness in humans. Cyclosporiasis in the US has historically been associated with travel outside of the US or consumption of contaminated imported foods. Since the mid-1990s, there have been foodborne outbreaks linked to various types of imported produce. And these range a variety of produce, like raspberries, basil, snow peas, mesclun lettuce, and cilantro. More recently, however, the isolation of cyclospora cayetanensis, as well as cases of cyclosporiasis in the US, have been increasingly associated with domestically grown, raw agricultural commodities and fresh cut produce. Next question, or I'm sorry, next slide.

So from the year 2000 to 2017, there were a total of 1,730 reported cases of cyclosporiasis in the United States. Some years we had no illnesses. And the highest within that time for frame had 692 cases in one year. In 2018 alone, there were 2,408 cases of cyclosporiasis in the US. In 2018 was marked with several outbreaks. One of these outbreaks was traced to salad sold in a quick serve restaurant chain, and it sickened more than 500 people in 15 states. Another one of these outbreaks in 2018 was associated with prepackaged vegetable trays, and it made 250 people ill in four states. There were another 2,299 cases in 2019 and 1,241 cases in 2020. With data currently available for 2021, there are already more than 1000 reported cases for this year. Next slide, please.

So after the 2018, FDA created a cyclospora task force. This task force has focused on developing strategies to reduce the public health burden of foodborne illness caused by cyclospora. The cyclospora task force is a multidisciplinary group in which FDA and CDC representatives work together to improve trace back during outbreaks, to determine potential contributing factors associated with contamination, and to identify knowledge gaps and potential preventive controls to reduce the number of illnesses. Next slide.

The cyclospora task force has identified the expertise within [inaudible 00:47:24] as uniquely positioned to provide impartial scientific advice on further development of the cyclospora strategy. Therefore, FDA is seeking advice from [inaudible 00:47:35] on addressing knowledge gaps and key issues related to cyclospora, such as sources and routes of contamination, prevalence, and control measures. Therefore, this charge contains a lot of questions. We have 18 questions that will be presented in the following slides. And as with the FSIS charge, I've been asked to read through each one of those. Next slide, please.

So the first question, what is known about the prevalence incidents and burden of disease of cyclosporiasis in the US and internationally? Are there specific segments of the US population that might be at higher risk for infection? And what is the geographic distribution of cases within the US? What is the diversity of cyclospora cayetanensis genotypes in the US, as well as internationally? What factors, for example, food safety practices, locations of farms, and others may contribute to contamination with cyclospora cayetanensis? Are certain factors, for example, the type of food, the season, where food is produced and others, more are significant than others?

The second question, how does the seasonality incidents and prevalence of cyclosporiasis compare throughout the United States and internationally, and what factors may contribute? So more specifically, extrinsic factors that may influence spoliation and survival, environmental factors influencing movement, for example rainfall, or are there other factors that are involved? Next slide, please.

Question three, what sampling data exists for cyclospora cayetanensis and food products and environmental samples, both domestically and internationally? From this data, what trends have been observed and what methods of detections were used?

Question four, what types of foods have been attributed to outbreaks of cyclosporiasis domestically and internationally? And what, if any, contributing factors, sources, or routes of contamination that have been identified in these outbreaks?

Question five, is monitoring for cyclospora cayetanensis by testing food products, agricultural environment, and agricultural inputs, being applied as a management stress strategy currently by industry by government or others? Are there best practices for monitoring the presence of cyclospora cayetanensis in

agricultural production? Including matrices, frequency, timing of sample collection, and sample numbers. Has monitoring led to the development and implementation of effective preventive measures? And if so, how effective have they been? Next slide.

Question nine. What preventive measures exist for the control of cyclospora cayetanensis, for example, using filtration? How effective have they been? What are the impediments to development of effective preventive measures for cyclospora cayetanensis, and how can they be overcome?

Question 10, what is known about cyclospora cayetanensis persistence and survival in food such as produce and the environment, for example, soil, water, or food contact surfaces?

Question 11, what is known about transfer and attachment of cyclospora cayetanensis from environmental samples, like water and soil, to produce? What other coccidian parasites would serve as a surrogate research model for cyclospora cayetanensis behavior? For example, a surrogate that could be used to evaluate control measures. Next slide, please.

Question 13, are there indicator organisms that can be used to determine the likely presence or absence of cyclospora cayetanensis in various matrices?

Question 14, what is known about the role of vectors such as non-human organisms, if any, in the transmission of cyclospora cayetanensis?

Question 15, what role do farm workers play in the transfer of cyclospora cayetanensis contamination during pre-harvest, harvest, and post-harvest handling? How might farm workers serve as both sources and routes of contamination, such as through the contamination of water or transfer to contaminated soil, to food contact services or produce? What are strategies that have been utilized to mitigate the contamination from farm workers? And have efforts to mitigate contamination from farm workers been successful? Next slide.

Question 16, are there practices for the maintenance and conveyance of wastewater seepage or human waste that may increase the incidence of cyclospora cayetanensis contamination? Are there practices that may be useful in the management of waste to reduce the potential for contamination by cyclospora cayetanensis? For example, third party toilet service or municipal wastewater treatment. Which wastewater seepage [crosstalk 00:53:50].

Speaker 3: What about this one too? So good.

Dr. Ben Warren: We're getting a little background from the event, producer, there. So which wastewater seepage and human waste treatments in the US are-

Dr. Ben Warren: Wastewater, septage, and human waste treatments in the US are effective against Cyclospora cayetanensis. Which treatments may not be effective against Cyclospora cayetanensis? Does municipal water treatment adequately reduce, control, or eliminate Cyclospora cayetanensis? Can effective municipal water treatment systems be scaled to treat agricultural water used in produce production? And how do practices compare for domestic growers versus international growers who export to the US? Next slide, please.

Question 17. What elements or points in the parasite's life cycle are potential targets of strategies to disrupt its progression, eliminate, or destroy [inaudible 00:55:00], stop dissemination into the environment, and prevent food contamination. What are control measures that should be evaluated for effectiveness against Cyclospora cayetanensis? Including control measures that can be applied to the environment and/or foods that may be consumed in the raw form. What is a recommended protocol for evaluating the effectiveness of control measures against Cyclospora cayetanensis?

And lastly, question 18. What are the relevant factors, available data, and data gaps needed to develop an informative quantitative risk assessment model for Cyclospora cayetanensis contamination and risk of illness?

Next slide please. As with the FSIS charge this afternoon, the subcommittee that is taking this charge will hear from a host of speakers that are largely made up of members of the Cyclospora task force who will be sharing information on all of these questions. FDA would like to thank [inaudible 00:56:10] and the members of the subcommittee in advance for taking this charge and lending your expertise toward preventing Cyclospora cayetanensis contamination in food.

John, I'm going to hand it back over to you at this time.

John Jarosh: All right. Does anyone on the committee have any questions for Dr. Warren?

Max Teplitski: This is Max Kapusky. It's not a question, but I just want to recognize the FDA's effort to address the Cyclospora issue and clearly recognizing Cyclospora is a big unknown, a growing concern and I applaud FDA for making this charge and continuing to push for understanding of Cyclospora and how it gets into foods and persists in the environment and the rest of the 16 questions that we're looking forward to tackling.

Dr. Ben Warren: Thank you, Max.

John Jarosh: I know you're going to go into much more detail this afternoon, Dr. Warren. But if anybody has questions from the committee, feel free to ask right now.

Producer: As a reminder, if you wish to ask a question or make a statement, to the top right corner of the chat box there's a raise hand icon.

John Jarosh: So yeah, I don't see any more questions from the committee right now. So, I would say thank you, Dr. Warren. I know the work of the committee is very important to the Food and Drug Administration and will contribute to the FDA's Cyclospora action plan and be part of the new era of smarter food safety at FDA.

And we can go ahead and open it up for public comment now, and I can hand it over to you, to the event coordinator, to see if we have any public comment. And we're looking for comments on the Cyclospora charge.

Producer: As a reminder, just raise your hand in the WebEx to have your line unmuted. The top right corner of the chat box is a raise hand icon.

Angela, did you have a comment?

Angela, did you have a comment?

So if anybody has a public comment they want to make, please raise your hand and the event producer will recognize you.

John Jarosh: So, not hearing any additional public comments. I think we can go ahead and move on to closing out this morning's meeting.

And so I'll say a little bit about this afternoon and we'll have the subcommittee meetings to address each of these charges. And they're scheduled from 1:00 o'clock to 5:00 PM Eastern today. And tomorrow, November 18th, the NACMCF secretariat has worked with the sponsoring agencies to invite speakers to the subcommittee meetings to provide a lot of good background information on the charges.

Representatives from the sponsoring agencies will also be present at these subcommittee meetings to answer any further questions that the subcommittee members will have. And they should be able to provide some clarification into any of the questions as needed and as we work through the process of working on these charges over the next term of the committee, the secretary will be here and available if the committee needs resources, whether we need to find some papers or journal articles, or if we need to identify some other speakers for you and try to provide you the resources you need as you work on addressing both charges.

On Friday, November 19th, the two subcommittees will come together and meet from 10:00 AM to noon Eastern time. At this meeting, the subcommittee chairs will provide an update for all the committee members to hear on what was accomplished during our subcommittees this week and discuss what the next steps will be moving forward as far as when you want to meet next and how you want to divide up the work and that kind of thing.

These subcommittee meetings, as well as the meeting on Friday, will be virtual using Microsoft Teams. For those who registered to attend and who wish to attend these meetings, you should have received separate invitations for all of the subcommittee meetings. If you wish to attend these meetings and did not receive an invite, please send an email to NACMCF@USDA.gov, so N-A-C-M-C-F @usda.gov.

The NACMCF secretariat will receive this information and make sure that you get the invite. Just in your message, please indicate which invite you're missing, or which one you want to attend and put that in the subject line and the email should also make sure you have your full name and your email address and your affiliation so that they can make sure that it gets routed properly. This will really be a big help to the NACMCF secretariat as they get you these invites.

So, we're now at the close of the NACMCF plenary meeting. We look forward to the continued discussion this afternoon and over the next couple days, as well as throughout the term of the committee members. And I want to say thank you to the committee members, the subject matter experts, the executive committee, and especially the members of the public for contributing and supporting NACMCF.

I do want to say a special thanks to the NACMCF secretariat. I appreciate your efforts and energy invested into doing all the behind the scenes work to make meetings like this one happen.

So, we have completed the purpose of today's plenary meeting by presenting-

Martin Paul: Dr. [inaudible 01:06:08]? This is Martin Paul. There are a couple comments in the chat box, if you want to review them and share some insight, that'll be great.

John Jarosh: Okay.

Martin Paul: Thank you.

John Jarosh: I can do that. You caught me right before I was going to close the meeting.

Martin Paul: Thank you.

John Jarosh: So I see one here. "Just curious, how does NACMCF collaborate with industry to develop some of the tools and R and D necessary to address and identify risk?"

So NACMCF, the way it's set up is that the agencies develop these charge questions that we just went through today and present those to the committee and then the committee has industry representatives, as well as academia, as well as government officials, that work on that. And so it's not necessarily developing tools and the research development necessary, it's more going out

and identifying the possibilities or looking at what tools are available out in the literature or out in industry itself, or what's being developed in academia.

And if the committee identifies a technology or a method or a risk assessment model, it would be something that they would be able to shape into their answer to some of the questions that have been asked by the agencies and then once the report is made at the end of the end of the term, that goes back to the agencies and then the agencies can take that unbiased advice and decide how they want to act in response to seeing it, identifying a new technology or a new method or something along those lines. Hopefully that addressed to your question. And I think that was from Sarah Powell Price, if I'm reading the chat correctly.

I don't see any other questions for comments that address ... So, I don't see any additional comments that are in the chat to address. So, I was about to conclude the meeting and so I'll continue with that and state that the purpose of this morning's meeting was to deliver these charges to the new committee and to introduce to the new committee and we've completed that purpose of today's plenary meeting.

So, I now call the meeting, the NACMCF plenary meeting, adjourned and thank you and have a wonderful day and we look forward to seeing everyone this afternoon as we break into our subcommittees to begin work on these charges.

Producer: That concludes our conference. Thank you for using event services. You may now disconnect.