

John Jarosh:

Good morning, everyone. Welcome to the plenary meeting of the National Advisory Committee on Microbiological Criteria for Foods, commonly referred to as 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 assures the safety of domestic, imported and exported foods. My name is John Jarosh, I'm the Deputy Director of the United States Department of Agriculture Food Safety and Inspection Service, Office of Public Health Science, Microbiological and Chemical Hazard Staff. I serve as the Director of the NACMCF Secretariat, and as the designated federal officer for NACMCF. This morning's plenary meeting is being recorded. FSIS will post the recording and transcripts when they become available on the FSIS website at www.fsis.usda.gov.

A couple of housekeeping items as we move forward. For Zoom attendees, your microphones will be automatically muted when you log in. Attendees will not have the ability to use their camera during the meeting. If you have been assigned a time to speak during a public comment period, when it is your turn, click raise hand, located on the bottom of your screen. You may need to move your cursor to make the toolbar appear if needed. If you're on a mobile device, tap your screen to display the toolbar, then raise your hand. The event producer will unmute you when it is your turn to speak, a popup message will appear and you'll need to accept the unmute message. During the open comment period, feel free to place yourself in the question queue ahead of time, by utilizing the raise hand feature. This will help the event producer locate you. Phone line attendees, if you're dialed in on the phone line only, you'll need to press #2 to enter the question queue during the open comment period. All attendees, please introduce yourself before providing comment.

Today the committee will discuss and vote on adopting a report they prepared over the past year in response to questions posed to the committee by the Food Safety and Inspection Service, on enhancing salmonella control in poultry products. Then the Food and Drug Administration will issue a new work charge to the committee on cronobacter species in powdered infant formula. Then I will provide a brief update on the committee work addressing questions posed by the Food and Drug Administration on cyclospora cayetanensis. There will be two public comment periods today for members of the public who indicated they wanted to make public comment when registering for today's meeting. Each person making public comment will be provided three minutes to make their comments and then the event producer will move on to the next in the queue.

We're going to try to stay on schedule, however, we have allotted a little more time to the public comment period, in order to provide everyone who indicated they wanted to make a public comment, the opportunity to speak. The first public comment period will be for receiving comments on the report, enhancing salmonella control in poultry products. The second public comment period will be for receiving comments on the new work charge, cronobacter species in powdered infant formula. The chat feature is available for attendees. Any comments made in the chat will be shared with the committee after today's meeting. The written comment, outlined in the Federal Register Notice announcing this meeting, was extended to December 30th, 2022. These comments will be shared with the committee when they become available. I'll now proceed to taking role of the NACMCF executive committee and the members of the NACMCF committee, when your name is called, please announce yourself. So I'll start with the executive committee, the Chair, Deputy Under Secretary, Sandra Eskin.

Sandra Eskin:

Here.

John Jarosh:

Vice Chair, Susan Mayne.

Susan Mayne:

I'm here.

John Jarosh:

FSIS Liaison, Dr. Denise Eblen. FDA Liaison, Dr. Eric Olson.

Eric Olson:

Here.

John Jarosh:

CDC Liaison, Dr. Arthur Liang. Commerce Department Liaison, Dr. Jon Bell.

Jon Bell:

Here.

John Jarosh:

Defense Department Liaison, Colonel Alisa Wilma.

Alisa Wilma:

Present.

John Jarosh:

And now I'll move onto the committee members of NACMCF. Just say that you're here when I call your name. Dr. Stan Bailey. Dr. Peggy Cook.

Peggy Cook:

Here.

John Jarosh:

Dr. De Ann Davis.

De Ann Davis:

Here.

John Jarosh:

Dr. Jim Dixon. I know he was going to be joining us late today, so we'll get him when he calls in. Dr. Francisco Diez-Gonzalez.

Francisco Diez-Gonzalez:

I'm here.

John Jarosh:

Dr. Joseph Eifert. Dr. Philip Elliott. Dr. Betty Feng.

Betty Feng:

Here.

John Jarosh:

Dr. Kathy Glass.

Kathy Glass:

Here.

John Jarosh:

Ms. Janell Kause.

Janell Kause:

Here.

John Jarosh:

Dr. Mahipal Kunduru.

Mahipal Kunduru:

Here.

John Jarosh:

Dr. Elisabetta Lambertini.

Elisabetta Lambertini:

Here.

John Jarosh:

Ms. Shannara Lynn. Dr. Wendy McMahon.

Wendy McMahon:

Here.

John Jarosh:

Colonel Audrey McMillan-Cole. Dr. Angela Melton-Celsa.

Angela Melton-Celsa:

I'm here.

John Jarosh:

Dr. Joelle Mosso.

Joelle Mosso:

Yes, I'm here.

John Jarosh:

Dr. Haley Oliver.

Haley Oliver:

Here.

John Jarosh:

Dr. Omar Oyarzabal.

Omar Oyarzabal:

Here.

John Jarosh:

Dr. Tanya Roberts.

Tanya Roberts:

Here. Here.

John Jarosh:

Dr. Scott Stillwell. Dr. Rob Tauxe.

Rob Tauxe:

Here.

John Jarosh:

Dr. Max Teplitski. Dr. Valentina Trinetta.

Valentina Trinetta:

Here.

John Jarosh:

Dr. Bing Wang.

Bing Wang:

I'm here.

John Jarosh:

Dr. Benjamin Warren.

Benjamin Warren:

I'm here.

John Jarosh:

Dr. Randy Worobo. Dr. Teshome Yehualaeshet.

Teshome Yehualaeshet:

Yes, I'm here.

John Jarosh:

Dr. Francisco Zagmutt.

Francisco Zagmutt:

Here.

John Jarosh:

So I have 19 out of 29, so we have a quorum for today's meeting. Next, we'll proceed with open remarks by the NACMCF Chair Deputy Under Secretary, Sandra Eskin, and the Vice Chair, Dr. Susan Mayne. Deputy Under Secretary.

Sandra Eskin:

Good morning. Can you hear me, John?

John Jarosh:

Yes, we can.

Sandra Eskin:

Oh dear.

John Jarosh:

Oh, there's a little feedback though.

Sandra Eskin:

Can you hear me now?

John Jarosh:

Yep. Now she's muted again.

Sandra Eskin:

How about now?

John Jarosh:

Yes, we can hear you. Can you send her a message to let her know that we can hear her?

Sandra Eskin:

Let's try now.

John Jarosh:

We can hear you.

Sandra Eskin:

Yay. Sorry. Good morning everyone, and hopefully you're not having as challenging a time connecting to the meeting as apparently I've had, but anyway. Again, I'm Sandra Eskin, the USDA Deputy Under Secretary for Food Safety and the chair of this advisory committee. I'm very pleased to be here this morning and to open the meeting. We have a lot on our agenda, not only the FSIS charge, but multiple FDA charges. Obviously since I'm at FSIS, I'm particularly interested in hearing about the report that the subcommittee has done, addressing many of the questions that we've asked about how to better ensure that the poultry products that make people sick aren't sold to consumers.

As you may know, on November 3rd, we held a public meeting to solicit comments on our proposed framework on this subject. This framework document laid out our thinking on a proposed approach that we believe could be more effective. We identified three components for discussion. One is requiring incoming flocks to be tested for salmonella before entering an establishment. Number two, enhancing the establishment process control monitoring and FSIS verification. And three, implementing an enforceable final product standard. As part of this framework, we want to make sure we are incorporating the latest science, data and laboratory technology into our approach, and that is why we reached out to NACMCF for your input.

The Office of Food Safety, along with FSIS, we want to thank the subcommittee that has been working on this charge, for your quick work in turning around the report. We requested that you provide our report within a year, half the time you are usually given for such a project. Again, not only are you addressing this important issue, but will be discussing two others related to FDA's work, one related to the cyclospora and there was a new charge on cronobacter in baby formula. Obviously there's a lot of work to be done in the coming months and we'll be meeting in person next in the spring to hear your updates. Thank you again for your commitment to public health, and I'll hand the mic over to Dr. Susan Mayne, the Vice Chair of NACMCF, for her opening report remarks. Susan.

Susan Mayne:

Good morning everybody. I'm Susan Mayne, I direct the Center for Food Safety and Applied Nutrition or CFSAN at FDA, and I'm joined by several of my FDA colleagues as well. And I just want to reiterate the welcome to our members and our guests to this NACMCF session. NACMCF is a very dedicated group of scientific experts and on behalf of FDA and partner agencies, I want to express our sincere appreciation and thanks for your time and willingness to share your food safety expertise. Prior to my joining the FDA, I served on various advisory committees for FDA and NIH and [inaudible 00:12:52], so I do have a personal understanding of the time commitments you have all been taking on on top of your other commitments and the importance of advisory committees to inform agencies work. In addition to my colleagues at FDA and FSIS, I'd also like to thank the CDC, DOD and NOAA for their continued unwavering support of NACMCF.

It's also important to acknowledge the NACMCF Executive Secretariats, Leslie Good, Susie Hammonds, Bryce Merrill, Evelyn Mbandi, John Jarosh and others who have made today's meeting and all the work underway possible. NACMCF currently has three charges in different stages of the process, all of them

quite important. The first being the FSIS charge for enhancing salmonella control in poultry products. I'd really like to thank the leadership of Dr. Kathleen Glass and Elisabetta Lambertini, for their work on the subcommittee to advance this charge, and to all the subcommittee members who dedicated time to work on this critical and timely concern that we share with FSIS. For the FDA charge on cyclospora cayetanensis, I'd like to thank the NACMCF subcommittee under the leadership of Dr. Max Teplitski and Peggy Cook, for their continued work to better understand the factors that can contribute to cyclospora cayetanensis contamination of domestically grown and imported produce, and developing recommendations for an effective prevention and management strategy.

FDA really looks forward to the information you will provide and in considering how it may inform ongoing efforts to reduce the number of cases of cyclosporiasis attributable to produce consumption as part of FDA's cyclospora prevention response and research action plan. One item on today's agenda is the adoption of the FDA charge to gain scientific insight into cronobacter in powdered infant formula. As you all know, a series of cronobacter illnesses among infants in the US has highlighted many scientific issues and challenges regarding cronobacter contamination and infection, that would benefit from scientific input and focus. A better understanding of the factors that contribute to cronobacter contamination of powdered infant formula in the production environment, is needed to increase the effectiveness of prevention and management strategies. We are asking NACMCF to investigate the prevalence and level of cronobacter contamination in powdered infant formula and in other foods, factors that place an infant at greater risk for cronobacter infection, manufacturing practices that could further reduce the risk of cronobacter contamination and food safety messaging for infant care providers.

This charge is part of a larger, more comprehensive plan to enhance the safety of powdered infant formula through the development implementation of a prevention strategy. We released an outline of the strategy this morning on FDA's website. The outline is intended to guide discussions with stakeholders in the coming weeks to further develop and refine our path forward. Following these engagements, we intend to publish an updated summary of our strategy on [fda.gov](https://www.fda.gov). NACMCF, with its diverse committee membership, which includes academia, industry, federal, state, and consumer representation, as well as gender, racial, ethnic and broader diversity, is ideally suited to advise us on these subjects and we look forward to the information NACMCF will provide on these charges.

The committee continues to be a source of science based advice that has been extremely useful to the sponsoring agencies for many years. We recognize the significant time commitment that all committee members and staff contribute to addressing these charges, and you are all to be commended for your public service. We look forward to continuing to work with you all and to your forthcoming reports on these issues. With that, I'll turn it back over to Mr. John Jarosh, to continue with today's agenda.

John Jarosh:

Thank you, Dr. Mayne and Deputy Under Secretary Eskin. The committee will now proceed to a discussion of the report on enhancing salmonella control in poultry products, followed by a public comment period, and then a vote on adoption of the report. Committee members, to participate in the discussion, please raise your hand to be recognized or just jump in as you see fit. I'll let Dr. Glass and Dr. Lambertini decide how they want to recognize you. You should have complete control of your mute button and may want to mute yourself when you're not speaking, to assist the discussion. You can also turn on your cameras if you desire, but Kathy will be sharing her screen too so everybody can see the report and see what we're talking about. Some of the subject matter experts that consulted with the subcommittee may be available on the speaker line for discussion if you need them.

When speaking, please identify yourself to help with the meeting transcript. We've allotted 50 minutes for discussion. However, if you need a little additional time, we do have some flexibility to go over our scheduled meeting time, but just a little time, so be judicious with your time. I'll be standing by if you need me. I'll now turn things over to the co-chairs of the salmonella subcommittee, Dr. Kathy Glass and Dr. Elisabetta Lambertini, it's all yours.

Kathy Glass:

All right, thank you very much. So I want to also thank, right off the bat, the subcommittee members that have worked so tirelessly on this expedited charge. So the Food Safety and Inspection Service has asked NACMCF to address a charge on enhancing salmonella control in poultry products. In today's plenary session, we will first provide an overview of the charge questions as presented by FSIS, my co-chair, Dr. Elisabetta Lambertini and I, will give a summary of the subcommittee's responses to each individual question and then we will open the mic to take comments from committee members and subject matter experts after each presentation. Due to the time limits of this meeting, we aim to cover each question in about five to seven minutes. After the committee has completed the review of the full document, Mr Jarosh will then oversee the public comments from registered speakers.

You can follow along on the document online and also a copy was sent to the committee members. We have already received written comments from the agency subject matter experts and committee members to add further details and references. These comments will be addressed by the subcommittee, along with any other comments received today and during the public comment period. The document we adopt today that will include necessary revisions, will then be posted on the NACMCF website and then formatted and submitted for publication in the Journal of Food Protection. As an introduction to this charge, chicken and turkey are major sources of animal protein in the United States. Of the estimated over one million cases of foodborne salmonellosis acquired annually in the United States, approximately one quarter are attributed to the consumption of chicken and turkey products. Although salmonella's killed during cooking, under cooking, such as in raw, breaded and stuffed chicken products and cross-contamination with other ready to eat foods in the refrigerator and during preparation, are contributing factors to the transmission of this pathogen. FSIS instituted salmonella performance standards for raw poultry carcasses, chicken parts, and raw comminuted poultry products.

Although there has been a steady decline in prevalence of salmonella on these parts, the number of illnesses have not decreased. In an attempt to resolve this discrepancy, NACMCF reviewed the scientific evidence on salmonella control in the United States and abroad, foodborne illness surveillance data, quantitative microbial risk assessments, and microbial testing of indicator organisms versus salmonella on poultry throughout the farm to fork continuum. Based on this information, this document seeks to provide guidance to FSIS and the poultry industry on what types of microbiological criteria might be used to identify effective intervention strategies, pre-harvest and post-harvest, to reduce salmonella in poultry products and thereby prevent human salmonella infections associated with these products. The specific risks management questions posed to NACMCF are, can we assess the public health risks impact of controlling specific salmonella serotypes or levels of salmonella in poultry products?

What types of microbiological criteria could be established to encourage control of salmonella at pre-harvest? What types of microbiological criteria could be established for poultry carcasses, parts and comminuted products prior to applying interventions and after interventions? How might foodborne illness surveillance data on human salmonella illnesses and data on salmonella serotypes in poultry products, be used to identify the salmonella serotypes of greatest public health concern associated with specific poultry products? How might indicator organisms, such as aerobic plate count, be used to set microbiological criteria to assess, process or pathogen control in poultry? What rapid methods and

technologies are available for the quantification of salmonella? What methods result in selected identification of serotypes of public health concern and is there strain selection bias introduced by these methods? How should pathogen characteristics derived from whole genome sequencing, such as serotype, virulence, and antimicrobial resistance, be considered in the development of microbiological criteria? And lastly, [inaudible 00:23:58] is needed to organize the charge into three different groups?

We are going to include the impact of salmonella in poultry on public health, and these are going to be questions one and four, the role of [inaudible 00:24:28] at pre-harvest and post-harvest for process control, methodologies for detection, which are going to be questioned six, seven, and eight. The charge did not specifically request an evaluation of efficacy of various treatment [inaudible 00:24:43] did briefly discuss practices that may affect change. At this point, I would like to hand this over to my co-chair, Elisabetta, who will then walk us through questions one through five.

Elisabetta Lambertini:

Thank you, Kathy. And I had a little glitch in the audio, so please stop me if it is on my end. So I will summarize questions and after each question, we'll have a couple of minutes for the committee to express their comments. Kathy will show the document, but yeah, don't try to read, but I will refer the pages for each question. So starting with question one, this is page nine through 21 and figures one and two in the appendix. The charge question is can we assess the public health impact, for example, reduction in salmonellosis, of controlling specific salmonella serotypes and/or amounts, levels in poultry products? What types of approaches could we use? So the committee addressed this question in two parts. Part one addresses how to predict the public health impact of hypothetical changes in salmonella control strategies in poultry, prior to their implementation. The committee found that quantitative microbial risk assessment methods can be effectively used to estimate reductions in salmonella [inaudible 00:26:13] resulting from the implementation of microbiological criteria, in poultry products and associated risk control measures.

Question one, reviewed the range of published risk based models, which while not assessing all possible processes stages where MCs could be set, provide both evidence on potential impacts of [inaudible 00:26:34] and templates for further risk assessment studies. You can see this in table one. Question one also reviews key parameters involved in characterizing and modeling MCs, depending on the level of detail targeted. And these parameters can serve as a reference for other questions in the document. Assessing the impact MC based on prevalence level and sub type using QMRA may also benefit from incorporating emerging omics methodologies to classify virulence while acknowledging data quality and availability issues. Part two, address how to assess effectiveness of the standards once they are implemented, so looking back retrospectively. We found that several types of public health surveillance data are available that can support assessing the efficacy of standards in reducing salmonellosis, these are reviewed in table three.

Allowing for some year to year variability, case based serotypes and genotype based surveillance is likely to detect important changes, such as within five years of full implantation. We'll now ask for comments from the committee and subject matter expert on question one. These comments are being recorded in the transcript from the meeting and feel free to also write comments in the chat. I don't hear any comments, so I think we can move to the next question. I would say that we are grouping question one and four together. So question four is the only one out of order, as they both refer to public health impacts. So question four, you can find it in pages 22 to 28 and figures three and four in the appendix. The charge question is 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 salmonella serotypes of greatest public health concern associated with specific poultry products. I won't read the three sub questions right now.

Several approaches have been used to attribute human salmonellosis to specific foods and sources. These include case control studies, analysis of reported foodborne outbreaks and most recently, source attribution based on whole genome sequence genotyping. Attribution based on outbreak data and genotype both give the greatest weight to data from the most recent years. Like attribution based on reported outbreak, genotype based attribution indicates that poultry is the leading source of human salmonellosis. The effectiveness of a prevention strategy that serogroups or serotype targets, should be evaluated annually with case based surveillance. Changes in the attribution model would likely take several years to be observed. The most current data should be used for all analysis, but the number of years to be included depends on the rate at which new information is added obviously. Combining data from several recent years in a trend model, [inaudible 00:30:06] effects of single annual preservation, such as large outbreaks.

Targeted interventional strategists in the industry are expected to affect predominant serotypes found to be associated with human illness. It is not [inaudible 00:30:21] if other strains will become predominant in the future, hence any serotype specific control measure should be reevaluated in approximately five years interval or as allowed by data. We will now ask for comments from the committee and subject matter experts for question four. Thank you. I don't hear any comment and of course we have some time at the end as well, so we'll move on to question two. Question two can be found on pages 29 to 36 and figures five, six and seven, and also in appendix B. Charge question is, what types of microbiological criteria could be established to encourage control of salmonella pre-harvest, that is in live birds on farm? Should FSIS consider qualitative microbiological criteria for control of the presence of salmonella in a flock when they're presented for slaughter? How could FSIS use these criteria to address salmonella serotypes most frequently associated with human illness? And what industry data would provide evidence of controls?

Now in considering possible MC or testing programs to encourage salmonella control at pre-harvest, the following points emerge. Now we know that US producers voluntarily implement several salmonella control practices on farms and use qualitative testing to monitor effectiveness of management in breeder flocks actually [inaudible 00:32:10] and transfer. This approach has resulted in lower prevalence on chilled carcasses but not resulted in fewer illnesses associated with poultry. Multiple routes of contamination have been observed and no single control measure has been found to be effective in controlling salmonella on farms. Hence, farms should be incentivized to apply a multi barrier approach that combines the suite of best practices and include testing or using testing information at multiple points to inform farm management operation. Qualitative salmonella testing of breeder flocks and feed is recommended to control these important entry routes. Testing of flocks for salmonella prior to slaughter, from a couple of weeks prior to immediately before slaughter, could inform management actions to reduce the level of contamination in the flock or cross-contamination with other flocks, such as transport consideration, remediation of houses or mitigation strategies in downstream processing.

This information could also inform longer term management actions on the farm and the risk assessment approach can be used to compare the potential impact of different approaches and parameters. So we're not tasked to developing the risk assessment, but we recognize that, as discussed question one, the methods exist to determine the impact of different combination of testing and feeds and their parameters. This test could be complimented by testing for the presence of high concern serovars, which could trigger a different control protocol. Wherever we recognize that complex patterns of serovar occurrence are likely to complicate interpretation and enhanced actionability. In terms of serovar specific control measures, vaccines are likely the only serovar specific control strategy at pre-

harvest, but will not eliminate also salmonella from flock. We present a case study on Sweden to illustrate an approach not focused on specific serovars in question two, while other case studies focusing on a set of serovars are illustrated in question four.

Overall the committee found that substantially more data and analysis are needed to assess the effect of pre-harvest control measures on salmonella prevalence or levels in serovars. This information would support actionable microbiology criteria, able to verify and inform process control on farms. And this information would also improve the ability of risk models to estimate impacts and enhance the cost effectiveness of control actions. Thank you. We'll now for comments from committee and subject matter experts on question two. Thank you.

Sonya Roberts:

This is Sonya Roberts. I would like to address the idea that Sweden is very different from the United States in [inaudible 00:35:26] but when you look at the size of a barn and a number of barns you can have on a farm, you find it very similar and this is addressed in the appendix. Thank you.

Elisabetta Lambertini:

Thank you, Sonya. Yeah, indeed, appendix B illustrates parameters related to this case study.

Sonya Roberts:

It was table five.

Elisabetta Lambertini:

Any other comments? All right, let's move on to question three and five. So I will summarize question three and five together since they were deemed to be very related by the committee and then we'll open for comments on both. Charge question for question three is what types of microbiological criteria could be established for poultry carcasses, parts and comminuted products prior to applying interventions and after interventions, considering current technology? Could the quantity of salmonella or quantity of microbiological indicator organisms such as APC be used? What are the key parameters that need to be considered and what data analysis techniques could be used? So how would this criteria be linked to human illness? And question five focuses more specific on indicator organism, asking, there is a documented correlation between the reduction in the quantity of APC between carcasses and finished products and the occurrence of salmonella in finished product for beef, pork and poultry. How might this information be used to set microbiological criteria to assess process pathogen control in poultry?

So the committee found that enumeration of salmonella and not serotype specific with a set threshold concentration could be used to identify highly contaminated lots to be diverted for further processing. Removing or treating product lots that are contaminated at higher levels is expected to reduce consumer exposure. This may even be more important for comminuted, for mechanically separated products for a high degree of handling and mixing can [inaudible 00:38:09] salmonella through a large batch. The specific threshold and other MC parameters will need to be determined, used in risk assessment approaches as discussed in question one. A quantitative MC can also be used to assess the performance or process control of an establishment over a certain time period, and in information that could be complimentary to current performance standards. Hence, the quantitative MC could also be associated with risk mitigation actions at establishment level, in addition to mitigation actions on a lot.

In all cases, the public health impact of an MC is tied to the actual effective implementation of risk mitigation actions, voluntarily or by enforcement. As mentioned in question one, concentration based approaches relies on the availability of testing protocols able to reliably detect and quantify salmonella at the concentrations observed at the considered processing stage. For finished products, for example, the vast majority of samples show very low concentrations below 0.1 CFUs per gram. Other key parameters to consider we're also applying in question one.

Now on question five more specifically, but following logically in the reasoning of question three, the committee found that indicator organisms such as aerobic plate counts, APC, or [inaudible 00:39:36] may be useful for process control. For example, to verify that an intervention step has been effectively applied, such as an antimicrobial [inaudible 00:39:45] or to assess trends over time in an establishment in conjunction with process management. However, in regards to MCs, several unpublished studies and data derive primarily at this point for personal communication from university and industry, only a couple are published, suggest a very weak or no correlation between levels of indicator organisms and presence or levels of salmonella post chill. There is little evidence supporting a correlation and while absence of evidence is not evidence of absence, at this time, MC based on indicator organism, does not seem supported. We know the research needs in question nine. I'll now pause for comments on question three and five. Thank you. If you have any clarification questions, this is a very short summary, feel free to post those as well.

Kathy Glass:

I don't see any hands up.

Elisabetta Lambertini:

All right, if there are no comments at this time, I will pass the microphone back to Kathy for question six through nine. Thank you.

Kathy Glass:

All right, thank you. So question six is going to be handled on pages 46 through 47 and on table six and seven, and the question is what rapid methods and technologies are available for the quantification of salmonella and how should FSIS make the best use of these methods? The committee reviewed the information that was available and noted that in recent years, methods have been developed for using quantitative PCR for enumerating salmonella in poultry. Two of these methods that are described in table six, have been validated by AOAC performance test methods certification for enumeration of salmonella in 2021 and 2022. Other enumeration assays that have been developed or expected to be commercialized in the near future, are shown on table seven. FSIS can consider the validation status of each method and concentration levels used in validation and hence the method ability to detect pathogen concentrations commonly observed in poultry. An enumeration assay should also be considered in the context of the sampling protocol, including number and frequency of samples collected in relationship to product flow rate, as discussed in question one.

Are there any comments from the committee or subject matter experts that need to be addressed in the final document for question six? I see no hands up, so then we will turn to question seven, which is found on page 48 and 50. This question was, are there particular approaches that would result in selective identification of serotypes of public health concern? For example, are there approaches to mitigate a potential strain selection bias introduced by the laboratory method and if needed, what type of research could be conducted to ensure performance characteristics of current lab methods, such as enrichment, incubation, pre-screening, do not result in a biased serotype detection? As the committee

reviewed the response, the answer reviewed biases that could be introduced by selective and non-selective culture media, isolation practices and shifts in serotype abundance during enrichment. Approaches that seek to characterize salmonella after detection and isolation include culture-based serotyping and molecular approaches such as amplicon sequencing and DNA microarrays. Methods for qualitative culture independent detection of multiple targets, such as using multiplex PCR assays to detect specific serotypes of concern are commercially available.

And these are noted on table seven, that provides some details of these methods. A study on salmonella using novel molecular assays is being conducted by USDA agriculture research service, others are expected to be developed. Compared to culture based serotyping, these molecular methods should avoid the biases associated with characterizing culture isolates if their detection limit is sufficiently low. In addition, the group decided to refer to question four that also reviewed salmonella characterization approaches for human specimens. With that, are there any comments from the committee and subject matter experts that need to be addressed in the final document for question seven?

I see no hands up at this point. Then we will proceed to question eight, which can be found on pages 50 and 51. This question is how should pathogen characteristics derive from whole genome sequencing, specifically serotype, virulence, antimicrobial resistance, be considered in the development of microbiological criteria? Numerous studies support that whole genome sequencing is a critical element in establishing microbiological criteria for salmonella. The greatest value of whole genome sequencing is in differentiating salmonella with high public health relevance from salmonella with limited public health relevance. Whole genome sequencing can define serotype, predict antimicrobial resistant profiles and offer insight into virulence capacity of an isolate. Recent analysis showed that commonly associated serovars are [inaudible 00:46:37], this underscores that serotype alone cannot define the relative virulence potential of a strain.

There are limitations to whole genome sequencing to characterize virulence. First, there is a need to expand the database of sequence isolates associated with illness. Second, there is currently no agreed upon definition of virulence in terms of genes presence or absence in those profiles that can reliably predicts severity of disease. Host interactions further complicate the ability to predict virulence. There is potential for whole genome sequence data to be incorporated into quantitative microbial risk assessment, but it is currently limited by lack of standardization and assembly processing and integration of whole genome sequence and metadata. Overall, WGS subtyping adds significant discriminatory power that can be used to aid epidemiological investigations and trace back studies. Are there any comments from the committee or subject matter expert that need to be addressed in the final document for question eight?

With that, we will proceed to question nine, which is going to look at research gaps. So what research is needed to support FSIS new salmonella strategies in term of setting microbiological criteria? And in this particular case, the committee identified substantial number of data gaps that could affect the responses to the agency and these are outlined on pages 52 to 54. They include specific gaps that are going to be identified for each individual question. Due to the extensive data gaps identified by the committee, the agency should reevaluate this document in three to five years after appropriate data has been collected and risk assessments are complete. Are there any additional comments or data gaps that the subcommittee members and subject matter experts would like to include in the final document?

So without any additional questions, we will then take a look at the recommendations provided by the committees that are found starting on page four. And these are going to be once again fairly extensive. One would be to collect appropriate data to refine food attribution models to determine which form of raw poultry, in other words, are they further processed versus parts versus whole carcasses and food handler practices that contribute most to salmonellosis associated with chicken and poultry products,

that would help to define where we should be focusing our efforts. Expand systematic FSIS sampling for salmonella levels, prevalence and subtypes on poultry pre-harvest, as well as post-harvest and prioritize the ground poultry products, mechanically recovered poultry meat, tenders and breaded stuffed raw poultry products to identify salmonella levels and evolution of predominant serotypes. Incentivize industry to deposit data that would be non punitive on levels of indicator organisms and salmonella prevalence, concentration and serotypes found at various stages of processing. That includes the pre-harvest through the final product, along with practices that can mitigate contamination.

Compare the serotypes frequently that are isolated from patients with those that are isolated from poultry products to determine if salmonella strategies used by industry are effective against all salmonella equally, or selecting for specific serotypes. Develop and validate quantitative testing methods to determine if and how testing a processing scheduling can reduce the likelihood that carcasses and parts with higher levels of salmonella that are most capable of causing illness are released into commerce. Consider changes to the performance standards based on enumeration of salmonella in the product, rather than prevalence of salmonella alone or on serotype found. Complete risk assessments for chicken and poultry to assess public health impacts of different risk based salmonella control strategies.

Incentivize industry to universally implement robust salmonella mitigation programs and qualitative salmonella testing at the breeder, hatchery, grow out and transport levels. And eliminate conditions in houses that harbor and transmit salmonella by implementation of known and validated mitigation strategies. And lastly, due to the extent of extensive data gaps identified by the committee, the agency should reevaluate this document in three to five years after appropriate data has been collected and risk assessments are complete. Are there any questions or comments that need to be addressed regarding the recommendations? Hearing none and seeing no hands up, I'd like to turn this back over to John.

John Jarosh:

Thank you, Dr. Glass and Dr. Lambertini, for leading the discussion today. Now we will proceed to the first public comment period. This public comment period will be for receiving comments on the report, enhancing salmonella control in poultry products. Each person making public comments will be provided three minutes to make their comments and then the event producer will move on to the next person in the queue. The event producer will let you know when you have 30 seconds remaining, so that you can start wrapping up your comments. If you are scheduled to make a public comment, at this time you may want to raise your hand to help the event producer locate you. I will now hand things over to the event producer to receive public comments.

Speaker 28:

Thank you, John. All right. Looks like, according to my list, the first person on my list who is currently logged in is Ashley Peterson. So Ashley, I'm going to go ahead and unmute you now. Please remember to click on the popup that has appeared, to make sure you are unmuted.

Ashley Peterson:

Perfect. Can you hear me?

Speaker 28:

Yes, I can. Go ahead.

Ashley Peterson:

Thank you. I'm Ashley Peterson with the National Chicken Council. We appreciate the advisory committees measured approach on the topic of salmonella in poultry, and overall, support many of the recommendations in the report. Specifically, we appreciate the acknowledgement that there are extensive data gaps, the need to complete risk assessments and the emphasis on a risk based approach to food safety. We too believe there is a need to redefine food attribution models and suggest that consumption patterns be considered as part of this approach. This highlights the need for improved data collection reporting and consistency and that live bird exposure should not be included in food attribution models. We agree that there should be an expansion of FSIS sampling to include chicken parts, comminuted chicken and source material used in the manufacturing of not ready to eat stuffed chicken products, not the finished product.

This information should be used to determine risk profiles for each, instead of an establishing an adulterant status for salmonella regarding MSC only product that does not receive a lethality step should be eligible for sampling. However, as pre harvest sampling is outside of the agency's jurisdiction, we do not support its inclusion and recommendation two. NCC agrees that an anonymized non punitive data depository would be valuable. Sharing data with the agency must not result in regulatory enforcement action and must be completely voluntary. All data submitted would need to meet [inaudible 00:55:51] exemption three. NCC supports consideration of performance standards based off enumeration of salmonella rather than prevalence, and we suggest that a baseline be performed and through a risk assessment, determine which products may have the greatest impact on public health. This is a more scientifically valid and risk based approach than the current enforceable final products standard contemplated in the salmonella framework.

The agency may consider relying on previous experience with LM control and ready to eat products and classify establishments based on different alternatives used to control salmonella and raw poultry, while recognizing that salmonella is not an adulterant per se in raw poultry. For years, the industry has implemented a multi hurdle approach focused on the continual reduction of salmonella from farm to fork, executing robust vaccination, biosecurity, sanitation, and other effective programs. These programs are distinctive to each complex depending on their unique challenges. There are no validated mitigation strategies pre-harvest and what may seem effective on one farm may not be on another. We suggest that the advisory committee develop a list of data gaps and research needs and work collaboratively with ARS and industry to help address recommendations in four, five and [inaudible 00:57:03].

Food safety is a top priority for the broiler industry and we support changes in food safety regulations that are based on sound science, robust data, and are demonstrated to positively impact public health. This approach is reflected in many of the committee's recommendation. First, gather data, then analyze the data to understand what it tells us, finally, propose policy informed by that data. We appreciate the opportunity to provide comment today and look forward to continued meaningful dialogue with the advisory committee and FSIS. Thank you.

Speaker 28:

Thank you, Ashley. We'll go to the next person on my list. Mitzi Baum, please go ahead.

Mitzi Baum:

Thank you. This is Mitzi Baum, with Stop Foodborne Illness. Stop Foodborne Illness is the voice for state food and we support pre-harvest controls, requiring incoming flocks to be tested as part of a

comprehensive farm to table approach. This control is in alignment with FSISs 2013 salmonella action plan to minimize poultry hazards. Application of supply chain principles for live animals is consistent with existing [inaudible 00:58:16] framework. It's not prescriptive, rather it's a step in the process to identify and control hazards in raw materials, in this case, incoming flocks. Current performance standards are unenforceable and allows poultry contaminated with harmful salmonella to be put into commerce. This is evidenced by CDC statistics of 1.35 million illnesses, 26,500 hospitalizations and 420 deaths each year due to this pathogen.

According to [inaudible 00:58:47], 20% of these illnesses, hospitalizations, and deaths are attributable to salmonella in poultry. Currently adulterated product is receiving the USDA mark of inspection and it's a mark that evokes trust for consumers. This mark should be meaningful. However, if consumers understood that they are spending their hard earned dollars on products that aren't safe, we'd be having a different discussion. We need to focus on enforceable finished product standards, focus on the serotypes that are known to cause human illness. Stop applauds USDA and NACMCF for engaging in this process. This, as with all food, and food safety issues, should be focused on public health outcome, of providing safe food for consumers with current science driving the process. Thank you.

Speaker 28:

Thank you. All right, we're going to go to the next person on my list, Anastacia Larkin, please click on the popup to allow yourself to be unmuted, and then you have three minutes to speak, don't forget to introduce yourself when you get started. Anastacia, please click on the popup to allow yourself to be unmuted. All right, then we'll go to the next person on my list. Art Lona, please click on the popup to allow yourself to be unmuted and then you'll have three minutes to speak.

Art Lona:

Hello, this is Art Lona with Creative Systems out of San Antonio. We created a device, a high intensity pulse UV system. Really appreciate the opportunity and everything you guys are doing to make our food chains safe. One thing I just wanted to make a comment, that I did not get a copy of the report, not sure if we were supposed to, as an attendee, but it's something that I would like to get if possible, I've sent an email too, so we can absorb this information in more detail. So from our end, we just want to understand the different serotypes so that we can focus our technology to eliminate those. So any help on gaining access to the report and understanding a little further would be appreciated.

Speaker 28:

All right, thank you, Art. I will go to the next person on my list, Angie Siemens. Let me go ahead and unmute you. Click on the popup to allow yourself to be unmuted and then you'll have three minutes to speak. Please be sure to introduce yourself before you get started.

Angie Siemens:

Yes, Dr. Angie Siemens with Cargill Incorporated. First I want to thank the NACMCF subcommittee for their due diligence in completing this important salmonella review, especially in the abbreviated time that you were given allotted to complete the review. I'm going to technical question or technical comment and then a process comment with this. I did see in your Q2 summary that you stated that more data should be analyzed before deciding whether qualitative or quantitative measures should be used. I very much agree with that. However, I don't know that the documentation throughout the comments in Q2 really support. You've got on page 31, line 12, it suggested that qualitative salmonella measures may be more appropriate, and then it comes back on page 36, on line 14, 17 states that

quantitative salmonella testing is likely to offer the most actionable information. I believe that the committee or subcommittee should take a look at the differential or conclude that even in the body of the response to Q2, that it may not be appropriate to recommend either one of those given the data gaps that exist, which is where your summary actually went.

So trying to make sure that the document supports the ultimate summary. I also have a question on relative to the approval of the document, with a number of data gaps that are available. Not sure if the intent is to approve the document today, but I struggle with approving it with the amount of data gaps that are available. And is it appropriate not to review this document as recommended in three to five years? There's substantial number of contracts that are out on various research projects that should be completed in a shorter amount of time and that could influence the recommendations of this committee. And I would hate for that data not to be available through the advisory committee review to the agency in making this such an important regulatory proposal [inaudible 01:04:31]. I certainly appreciate what the committee has done, I will supply these comments in writing and thank you.

Speaker 28:

And thank you for your comments. And that is everyone on my list. I will give Anastacia Larkin one more opportunity just in case. Go ahead and just tried to unmute you, so please click on the popup to unmute yourself and then you'll have three minutes to speak.

Anastacia Larkin:

Hello, Anastacia Larkin Cogle Foods. Thank you for providing me the opportunity, sorry I was having issues with my microphone, to speak. But I just wanted to thank everyone for coming together and putting together this proposal. But I really have to agree with most of the people in the industry, that we need more data here. And this is coming from a further processor standpoint, we're very concerned about a finished product standard and we really look forward to seeing some more data. Thank you.

Speaker 28:

And thank you. And that's everyone on my list. Back to John.

John Jarosh:

Thank you to all the commenters who are participating in today's meeting. We have put a link to the report in the chat and we can work on following up to send that to your emails that we have in the registration. We'll now proceed with a vote on adoption of the report. If the report is adopted, it will be on condition of finalizing the report to address the items discussed by the committee today and additional grammatical errors if identified, with consideration given to the oral and chat comments made at today's meeting and consideration of the written comments received as described in the Federal Register Notice announcing this meeting. We will first attempt to adopt the report by acclamation. If this fails, we'll proceed directly to a roll call vote. Is there a motion to adopt the report entitled, Response to Questions Posed by the Food Safety Inspection Service, Enhancing Salmonella Control in Poultry Products?

Jim Dickson:

Jim Dixon, so moved.

John Jarosh:

Is there a second?

Haley Oliver:

Haley Oliver, second.

John Jarosh:

All in favor of adopting the report entitled, Responses to Questions Posed by the Food Safety Inspection Service Enhancing Salmonella Control in Poultry Products, signify in the affirmative.

Group:

Aye.

John Jarosh:

Okay. Anyone opposed to adopting the report entitled, Responses to Questions Posed by the Food Safety Inspection Service, Enhancing Salmonella Control in Poultry Products, signify by saying no. Hearing none, Deputy Secretary Eskin, as the Chair of NACMCF, Dr. Mayne, as the Vice Chair of NACMCF, the report, Responses to Questions Posed by the Food Safety and Inspection Service, Enhancing Salmonella Control in Poultry Products, has now been adopted by the NACMCF committee, pending finalization to address items discussed by the committee today and additional grammatical errors if identified, with consideration given to oral and chat comments made at today's meeting and consideration of written comments received as described in the Federal Register Notice announcing this meeting.

Sandra Eskin:

Thank you John and the committee and subcommittee.

John Jarosh:

So the next item on this agenda, we'll now proceed to Dr. Benjamin Warren from the Food and Drug Administration. He will issue a new work charge to the committee on *Cronobacter* species in powdered infant formula. If members of the committee have questions or comments, please hold them to the end of the presentation. Dr. Warren promises it's a short presentation, so he'll provide some time at the end if you have questions on it. Dr. Warren, when you're ready, you can go ahead and start.

Benjamin Warren:

Thank you John, and good morning everyone. In the next slide, as John indicated, I'm going to review some brief background on *Cronobacter* in powdered infant formula and then issue a charge to the committee that the FDA has prepared. So *Cronobacter* species are motile gram-negative, rod-shaped opportunistic pathogens of the family Enterobacteriaceae, that can cause foodborne illness, primarily among infants less than two months old, but also in immunocompromised adults. *Cronobacter* are widely distributed, they've previously been isolated from various environments, such as in home and in the food manufacturing environment. They've been isolated from various foods in addition to powdered infant formula, these would include things like cheeses, meats, and vegetables. They've been isolated from animals and insects such as rats and flies. And of course, they've also been isolated in clinical sources from folks that have been infected by *Cronobacter*. Although several species of *Cronobacter* may be capable of causing diseases in humans, *Cronobacter sakazakii* is the one most often associated with

illness. Yet the lack of mandatory national disease reporting for *Cronobacter* makes this challenging to draw definitive conclusions.

Cronobacter typically manifests in infants that have other issues, such as those that were born premature, or those with weakened immune systems, although full term infants without underlying conditions have also experienced invasive *Cronobacter* infections. Infections in infants younger than 12 months can be very deadly. Case fatality rates can range anywhere from 10 to 80% in these infections. *Cronobacter* has been reported to survive for as long as two years in low moisture foods, and this includes powdered infant formula. Contaminated powdered infant formula has been previously associated with some *Cronobacter* infections among infants, with the organism being isolated from not only the powdered infant formula in its dry form, but also the rehydrated infant formula, as well as utensils that were used to prepare or administer the infant formula, such as bottles.

In late 2021, and earlier this year, a series of *Cronobacter* illnesses among infants in the US was associated with feeding powdered infant formula produced by a specific manufacturer at one facility. FDA inspection of the suspected manufacturing facility revealed the presence of *Cronobacter* in multiple locations within the production environment, as well as other conditions unsuitable for producing powdered infant formula. This led to the manufacturer initiating a voluntary nationwide recall and the temporary shutdown of the plant. Both of these were major contributing factors to the infant formula shortage experienced across the US in 2022. These findings have raised questions about control measures for *Cronobacter* on dry processing environments and the extent of corrective actions when *Cronobacter* is found in the processing environment or product samples.

As you heard, Dr. Mayne mention in her opening remarks in this meeting, the FDA released this morning a draft strategy to prevent *Cronobacter* illnesses associated with powdered infant formula. FDA has identified expertise within this committee as uniquely positioned to provide impartial scientific advice that may be used to inform further development of this strategy. Therefore, FDA is seeking advice from NACMCF on addressing knowledge gaps and key issues related to *Cronobacter* in four specific areas. And I'll use the next few slides to review these four areas and the core questions associated with them.

So the first question, FDA recognizes that given the timing, there are a number of members on the committee who their terms will be coming to completion in September, 2023. So FDA is issuing four charge questions, however, we're asking that this first question be delivered in September, 2023, which coincides with the terms of these respective committee members. This first question, what is the current prevalence and level of *Cronobacter* contamination in powdered infant formula in the US market? What is known about *Cronobacter* in other foods in the home environment, and the frequency with which these foods and environmental sources contribute to human infections?

The remainder of the questions, questions two, three, and four, FDA is giving a deliverable of November, 2024 to allow time for the recruitment of new members to the committee and the continuation of work through the full term. The second question, what factors, for example, virulence factors, host factors, dose of exposure, place an infant at greater risk for *Cronobacter* infection and serious adverse health consequences or death? Question three, what food safety management practices, for example, facility and equipment design, hygienic zoning and packaging, preventive controls, verification activities, should manufacturers of powdered infant formula employ to further reduce the risk of *Cronobacter* contamination of formula for the production environment?

Excuse me. And then the last question, also delivered in November, 2024, is 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? FDA would like to thank NACMCF and the members of the subcommittee in advance for taking this charge and lending your expertise toward

preventing cronobacter illnesses associated with powdered infant formula. At this time, this concludes our slides. I'll turn it back over to John.

John Jarosh:

So do any of the committee members or executive committee have any comments or questions for Dr. Warren? I don't see any hands raised or anybody jumping in, so thank you, Dr. Warren. The NACMCF secretary will help you out however you need to, to address this important charge for FDA. We'll now proceed with to the second public comment period. The second public comment period will be for receiving comments on the new work charge, cronobacter species in powdered infant formula. Each person making public comments will be provided three minutes to make their comments, and then the event producer will move on to the next person in the queue. The event producer will let you know when you have 30 seconds remaining in your time, so that you can start wrapping up your comments. If you're scheduled to make a public comment at this time, you may raise your hand to help the event producer locate you. I'll now hand things over to the event producer to receive public comments.

Speaker 28:

Thank you. We're going to go to the first person on my list, Ben Jones. Ben, I have unmuted you. Please click on the popup that just appeared, to allow yourself to be unmuted in order to make your comments. Again, you have three minutes. Please remember to introduce yourself before you get started.

Ben Jones:

Yeah, well, I appreciate the time, however, and I'm Ben Jones with Malcolm Corporation, Director of Operations Quality, but I do not actually have any comments at this time. And I appreciate the various entities involved with improving food safety mitigation for this very important product in our market. But I don't have any additional comments. Thank you.

Speaker 28:

Thank you. All right, then we'll go to the next person on my list, Mitzi.

Mitzi Baum:

Thank you. It is a fact that cronobacter sakazakii is a dangerous pathogen and it is exceedingly dangerous for infants. According to the CDC, infants who become infected by cronobacter sakazakii, have up to an 80% mortality rate as shown on the slide. In the most recent outbreak, of the four confirmed cases, two infants died. Stop Foodborne Illness, the voice for safe food, would like to thank cronobacter and the FDA for highlighting the need for additional research on cronobacter. Cronobacter is not a new pathogen. The first documented case of cronobacter in the US was in 1979. Since 1979, there have been many reported infant deaths associated with cronobacter in powdered infant formula, including the deaths of twin boys shortly after birth, while still in the hospital. The lethality of cronobacter to infants is documented but not well researched. But regardless of the research, the documentation and high mortality rate of infants infected with cronobacter sakazakii, should be enough for consumers expect this issue to receive an urgent response.

In the spring, Commissioner Califf stated that if cronobacter had been reportable, the most recent outbreak could have been identified sooner, and that was also referenced in the slides just shown. This could have prevented additional illnesses and removed contaminated powdered infant formula from the

shelves. When discussing having *Cronobacter* on the reportable list, Stop has been receiving a response of *Cronobacter* is rare. Our response is, so is botulism and it's on the reportable list. This is not acceptable to consumers. Stop Foodborne Illness currently has a [change.org](https://www.change.org) petition to have *Cronobacter sakazakii* added to the reportable disease list. There are almost 1,100 signatures and it's growing daily. We've been calling upon the Council of State and Territorial Epidemiologists, CDC and FDA to take action on this issue since March, with no response. CST has received email, snail mail, and phone calls with no response. One infant death attributable to this pathogen should be enough. We can and must do more to protect the most vulnerable. Thank you.

Speaker 28:

Thank you. Go to the next person on my list, that would be Art Lona.

Art Lona:

Hello, yes, I have no comment during this session on this period. Thank you.

Speaker 28:

Okay, thank you. All right. And that is everyone on my list that is currently logged in. I'll turn things back over to John.

John Jarosh:

Thank you to all the commenters for participating in today's meeting. I will now proceed to the next item on the agenda, which is to provide a brief update on the committee work addressing questions posed by the Food and Drug Administration on *Cyclospora cayentanensis*. On November 17th, 2021, the Food and Drug Administration issued a work charge to the committee seeking information on factors that can contribute to the *Cyclospora cayentanensis* contamination of domestically grown and imported produce, and is seeking recommendations for developing an effective prevention and management strategy. At this time, the *Cyclospora* subcommittee, which is co-led by Dr. Max Teplitski and Dr. Peggy Cook, is close to having a rough draft on the report in some areas and in a couple areas, they still need more information. One of these areas that they're seeking more information on is testing methods and their current use. So when the subcommittee is ready, we will be reaching out to some of the testing laboratories that have the capability for *Cyclospora*, to see what methods they're using and how they are working to identify *Cyclospora*.

The *Cyclospora* subcommittee is currently on track to complete their work in order to hold a plenary meeting to discuss and vote to adopt the report, in August of 2023. On my screen, here's just a brief overview of what their timeline looks like. They do plan to have a first draft on April 1st or around April 1st, for the subcommittee to start reviewing, and then they hope to have a full committee review start on July 1st, 2023. And as we move closer to the month of August in 2023, will begin the process of scheduling a date for their plenary meeting and that will be announced in a Federal Register Notice. Are there any questions from the executive committee or members of the committee on the *Cyclospora* charge that I can try to address?

Susan Mayne:

So no questions, but FDA thanks the subcommittee for their work on this and we look forward to seeing the progress made. So thank you to the subcommittee.

John Jarosh:

On behalf of the subcommittee, you're welcome. So before we conclude today's meeting, I'd like to make everyone aware that the current cronobacter appointment terms end in September, 2023. Dr. Warren alluded to this in his presentation of the cronobacter in powdered infant formula charge. 15 of the current members will be term limited, so we'll be announcing a call for nominations to fill these upcoming vacancies in the Federal Register in the next couple of months. If you are interested in nominating someone to serve as an appointed member of NACMCF, or if you wish to serve, you can self nominate. The requirements will be posted in the Federal Register Notice and are available on the NACMCF webpage on the FSIS website. To navigate to the NACMCF webpage, select the policy tab on the main FSIS website and then select advisory committees and that will lead you to the NACMCF webpage.

Committee members serve two year terms and they can be reappointed for one additional term. Former members are eligible for repeat service after one term of non-service service. Members of the committee will be chosen on their expertise in microbiology, risk assessment, epidemiology, public health, food science, and other relevant disciplines in order to obtain the scientific perspective, expertise, experience, and a point of view from all stakeholders. I'm certain that FSIS and one of the other federal partners will have a new charge for the next NACMCF term, starting at the end of September, 2023. But we heard from the Food and Drug Administration today that the cronobacter species in powdered infant formula charge will carry over to the next NACMCF term. So if there are individuals with related experience, it would be a good opportunity to consider either nominating someone you know or nominating yourself to serve on NACMCF when that announcement for nominations comes out.

I want to say thank you to the executive committee for supporting NACMCF, I want to thank all the committee members of NACMCF for the work that you put in, the subject matter experts for consulting with the committee and helping them get the information that they need to answer the questions that are posed to them. And I want to thank the members of the public for contributing to and supporting NACMCF. And a special thanks to the NACMCF Secretariat, Dr. Evelyn Mbandi, Ms. Leslie Good, Mr. Bryce Merrill and Dr. Susie Hammonds. I appreciate your efforts and energy invested in supporting NACMCF. We have completed the purpose of today's NACMCF plenary meeting, we now stand adjourned. Thank you all and have a wonderful day.

Speaker 28:

That concludes today's conference. Thank you for using event services. You may now disconnect.