

**USDA FOOD SAFETY AND INSPECTION SERVICE
Plenary Meeting Hearing on 09/24/2024**

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

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4 NATIONAL ADVISORY COMMITTEE ON
5 MICROBIOLOGICAL CRITERIA FOR FOODS (NACMCF)

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7 TUESDAY,
8 SEPTEMBER 24, 2024

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

14 MEMBERS PRESENT:

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

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

5

EXECUTIVE COMMITTEE MEMBERS PRESENT:

6

EMILIO ESTEBAN, Chair, Under Secretary for Food
Safety, USDA

7

DONALD PRATER, Vice Chair, Acting Director,
8 Under Secretary For Food Safety and
Applied Nutrition, U.S. Food and Drug
9 Administration (FDA)

8

10 KIS ROBERTSON-HALE, Deputy Assistant
Administrator, OPHS, FSIS

9

11 MEGIN NICHOLS, Deputy Director, Division of
Foodborne, Waterborne, and Environmental
12 Diseases, National Center for Emerging and
Zoonotic Infectious Diseases, Centers for
Disease Control and Prevention

10

13 ERIC OLSON, NACMCF FDA Center for Food Safety
and Applied Nutrition (CFSAN) Liaison

11

14 JON BELL, Director, National Seafood Inspection
Lab, National Oceanic & Atmospheric
15 Administration, Department of Commerce

12

16 USDA STAFF PRESENT:

17 KRISTAL SOUTHERN, Designated Federal Officer,
Food Safety and Inspection Service (FSIS)

16

18 JOHN JAROSH, Deputy Director, Microbiological
and Chemical Hazards Staff, Office of
19 Public Health Science, Food Safety and
Inspection Service

17

20 EVELYNE MBANDI, Director, Microbiological and
Chemical Hazards Staff, Office of Public
21 Health Science, Food Safety and Inspection
Service

18

22 BRYCE MERRILL, OPHS, FSIS

19

23 GLENN TILLMAN, Biological Information
Specialist, OPHS, FSIS

20

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

5 ALSO PRESENT:

6 MARCUS CRUZ, ASL Interpreter
7 STEVE FOLEY, FDA
8 WENDY MCMAHON, FDA
9 BETHANY PEACOCK, ASL Interpreter
10 ALISON RILEY, FDA
11 BEN WARREN, FDA CFSAN

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1	A-G-E-N-D-A	
2	Call Meeting to Order and Roll Call	
3	Dr. Kristal Southern, Designated Federal Officer.	5
4	Introductory Remarks	
5	Dr. J. Emilio Esteban.14
	Dr. Donald Prater.17
6	Update: Cronobacter spp. in Powdered Infant Formula Charge	
7	Drs. Elisabetta Lambertini and Abby Snyder.27
8		
9	Public Comment - Cronobacter spp. in Powdered Infant Formula.	N/A
10	Update: Genomics Charge (FSIS)	
11	Drs. KatieRose McCullough and Vik Dutta.49
12	Public Comment - Genomics.93
13	Closing Remarks	
14	Dr. J. Emilio Esteban.96
15	Adjourn	
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1 P-R-O-C-E-E-D-I-N-G-S

2 10:05 a.m.

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

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

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

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

24 So NACMCF is a federal advisory
25 committee that provides impartial scientific

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

9 The programs of other federal agencies
10 concerned with food safety including the Centers
11 for Disease Control and Prevention, the
12 Department of Commerce National Marine Fishery
13 Service and the Department of Defense Veterinary
14 Services also benefit from NACMCF work. NACMCF
15 members are appointed by the Secretary of
16 Agriculture through a rigorous process that helps
17 us to ensure that membership is fairly balanced
18 and can support the functions to be performed.
19 Committee members are chosen based on their
20 expertise in microbiology, risk assessment,
21 public health, food science and other relevant
22 disciplines in order to obtain the scientific
23 perspective, experience and point of view of all
24 stakeholders.

25 It is an honor to be appointed to

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

13 This is a hybrid meeting and with the
14 exception of our committee members and designated
15 speakers, our online attendees' microphones are
16 automatically muted when you logged in and you
17 will not have the ability to use your camera
18 during the meeting. A sign language interpreter
19 will be present for the duration of the meeting
20 and, in addition, closed captions can be enabled
21 by clicking the closed caption or CC bubble in
22 the bottom left of your screen.

23 If during registration you indicated
24 that you wish to provide oral comments and
25 confirmed your intent to do so via email with the

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

5 Lastly, the chat feature is available
6 for all attendees. Any comments made in the chat
7 will be shared with the committee after today's
8 meeting and attendees may also submit written
9 comments according to the options and directions
10 outlined in the Federal Register notice
11 announcing this meeting. These comments will
12 also be shared with the committee when they
13 become available.

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

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

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

4 DR. ESTEBAN: Present.

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

11 DR. PRATER: Present.

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

17 DR. ROBERTSON-HALE: Present.

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

22 DR. OLSON: Present.

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

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1 Nichols.

2 DR. NICHOLS: Present.

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

7 DR. BELL: Present.

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

12 (No audible response.)

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

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

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

4 We'll start with Dr. Bisha.

5 DR. BISHA: Here.

6 DR. SOUTHERN: Dr. Carleton from the
7 CDC.

8 DR. CARLETON: Present.

9 DR. SOUTHERN: Dr. Carlson.

10 DR. CARLSON: Here.

11 DR. SOUTHERN: Dr. Cetin-Karaca.

12 DR. CETIN-KARACA: Here.

13 DR. SOUTHERN: Dr. Chapman.

14 DR. CHAPMAN: Here.

15 DR. SOUTHERN: Dr. Dutta.

16 DR. DUTTA: Here.

17 DR. SOUTHERN: Dr. Feng.

18 DR. FENG: Here.

19 DR. SOUTHERN: Dr. Figgs.

20 DR. FIGGS: Here.

21 DR. SOUTHERN: Dr. Goldman.

22 DR. GOLDMAN: Here.

23 DR. SOUTHERN: Dr. Hansen.

24 DR. HANSEN: Here.

25 DR. SOUTHERN: Dr. Havelaar.

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1 DR. HAVELAAR: Here.

2 DR. SOUTHERN: Ms. Kause from FSIS.

3 MS. KAUSE: Here.

4 DR. SOUTHERN: Dr. Khaksar.

5 DR. KHAKSAR: Here.

6 DR. SOUTHERN: Dr. Lambertini. Dr.

7 Lambertini is on her way. And Ms. Lynn.

8 MS. LYNN: Here.

9 DR. SOUTHERN: Dr. McCullough.

10 DR. MCCULLOUGH: Present.

11 DR. SOUTHERN: Dr. Mello.

12 DR. MELLO: Here.

13 DR. SOUTHERN: Dr. Pradhan.

14 DR. PRADHAN: Here.

15 DR. SOUTHERN: Mr. Rana.

16 MR. RANA: Yes, here.

17 DR. SOUTHERN: Dr. Sanchez-Plata.

18 DR. SANCHEZ-PLATA: Here.

19 DR. SOUTHERN: Dr. Schill.

20 DR. SCHILL: Present.

21 DR. SOUTHERN: Dr. Shariat.

22 DR. SHARIAT: Present.

23 DR. SOUTHERN: Dr. Snyder.

24 DR. SNYDER: Here.

25 DR. SOUTHERN: Dr. Teplitski.

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1 DR. TEPLITSKI: Here.

2 DR. SOUTHERN: Dr. Wang.

3 DR. WANG: Here.

4 DR. SOUTHERN: Dr. Warren.

5 DR. WARREN: Present.

6 DR. SOUTHERN: And Dr. Yehualaeshet.

7 DR. YEHUALAESHET: Present.

8 DR. SOUTHERN: So those are our
9 members who are present here in the room and for
10 online attendees that may not have heard, we have
11 everyone present, except Dr. Lambertini, who we
12 have awareness is on her way.

13 Now, to our committee members joining
14 online. When your name is called, please unmute
15 and announce yourself by stating here or present.
16 Lieutenant Colonel Kubat.

17 (No audible response.)

18 DR. SOUTHERN: Okay. Dr. Moorman.

19 (No audible response.)

20 DR. SOUTHERN: And Dr. Warobo.

21 (No audible response.)

22 DR. SOUTHERN: Thank you. So, hearing
23 none, I recognize that we have 26 committee
24 members present at this time, which meets quorum
25 and I now call this meeting to order.

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

6 DR. ESTEBAN: Good morning.

7 (Chorus of good morning.)

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

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

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

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

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

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

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

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

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

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

18 (Laughter.)

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

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

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

13 DR. SOUTHERN: Yes.

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

17 (Laughter.)

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

20 DR. SOUTHERN: Thank you.

21 (Applause.)

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

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

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

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

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

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

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

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

1 Foods Program but for our agency in general.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 As you may recall, the work group is

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

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

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

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

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

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

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

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

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

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

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

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

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

25 To sort of wrap up the updates from

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

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

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

25 This group is not conducting a

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

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

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

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

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

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

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

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

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

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

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

19 (Applause.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 DR. SOUTHERN: Absolutely.

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

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

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

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

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

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

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

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

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

1 were positive for Cronobacter sakazakii, but
2 certain categories were much higher. For
3 example, grains, baked goods and flours, almost
4 26 percent were positive, nuts and nut butters 10
5 percent were positive, and also 10 percent of
6 seeds, sprouts and beans were tested.

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

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

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

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

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

1 considered. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 DR. SOUTHERN: What was the --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 We're also working with the National

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

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

1 globally.

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

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

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

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

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

18 And then, the frequency and severity
19 of illness and the patient outcomes. So, not
20 only how many people are getting sick, but how
21 sick are those people getting with what and for
22 what further complications or health outcomes is
23 something that is both important in component
24 1(a) and 1(c) that we'll talk about a little bit
25 later. Those different epidemiologic criteria,

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

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

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

1 something that the group thought was important.

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

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

25 And then the identification of the

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

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

22 Then, finally, rounding up in question
23 1, which is the portion C, which is where we've
24 talked about the genes for each of those
25 pathogens that are already known. So we've

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

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

23 I'll pass it over to Dr. Dutta.

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

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

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

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

1 to come up with as recommendations.

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

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

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

1 working with them.

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

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

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

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

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

16 Now having said that, there are
17 efforts at the AOAC, I'm giving you an example
18 here, where there have been certain criteria that
19 have been put together by the accreditation
20 bodies to home in on what these methods, the
21 genomics-based methods, should look like, what
22 are the criteria for that. So there is that
23 level of guidance that is out there, but as far
24
25 as methods are concerned, we did not see any one

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

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

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

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

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

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

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

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

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

24 (Applause.)

25 DR. SOUTHERN: And, again, another

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

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

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

21 DR. ESTEBAN: I am always thinking.

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

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

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

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

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

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

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

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

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

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

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

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

25 But I do think that there's going to

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

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

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

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

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

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

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

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

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

25 I will not go into mathematics right

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

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

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

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

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

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

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

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

1 right, go for it.

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

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

25 Back to my first question for this

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

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

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

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

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

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

19
20 And that early insight may be able to
21 further reduce the gap, if there is anything to
22 what is it that we are linking the organism to.
23 Now, in some cases, it's obvious that the one is
24 going on, right, it's clear, but in routine
25 sporadic cases, you know, we don't know how good

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

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

13 (Laughter.)

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

1 a plate?

2 DR. HAVELAAR: This is Aries Havelaar.
3 Picking up on the point that Dr. Dutta makes, I
4 recently read a paper from the UK looking at the
5 diversity of Campylobacter in poultry meats and
6 their summary conclusion is that you would need
7 to test up to 87 isolates per sample to detect
8 95 percent of the observed genotype sequence
9 diversity, so I think the point that you made
10 that we're based on one or two or three colonies
11 and they are typically the most rapidly growing,
12 the most easily culturable, not necessarily the
13 most dangerous types, so we've always been
14 looking through, like, a clouded set of mirrors
15 to what's happening in any food sample. I think
16 this is something that we really need to address
17 in our discussion, which methods are most able to
18 identify the full diversity. Culture methods are
19 very limited by just the nature of the amount of
20 work, maybe the novel genomic methods may harness
21 further.

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

1 and I think that's simplifying it.

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

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

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

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

25 DR. SOUTHERN: And we can, because I

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

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

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

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

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

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

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

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

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

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

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

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

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

23 DR. SOUTHERN: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

25 It wasn't that long ago that we were

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

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

25 So, I appreciate all the work that the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (Applause.)

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

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

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C E R T I F I C A T E

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



Court Reporter

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