

1

01:00:00,330 --> 01:00:01,830

Good afternoon, everyone.

2

01:00:02,530 --> 01:00:07,470

Welcome to the National Advisory Committee on Microbiological Criteria  
for

3

01:00:07,470 --> 01:00:12,290

Foods for NACMCF Subcommittee Debrief and Closeout Session.

4

01:00:12,730 --> 01:00:15,950

My name again is Dr. Krystal Southern.

5

01:00:16,210 --> 01:00:19,250

I serve as the designated federal officer for NACMCF and

6

01:00:19,250 --> 01:00:21,110

the director of the NACMCF Secretariat.

7

01:00:21,850 --> 01:00:24,630

The purpose of this meeting is for the committee to

8

01:00:24,630 --> 01:00:28,490

provide updates on their accomplishments and findings from the work

9

01:00:28,490 --> 01:00:31,650

they did this week to address the Food and Drug

10

01:00:31,650 --> 01:00:36,610

Administration's charge on Cronobacter species and powdered infant  
formula and

11

01:00:36,610 --> 01:00:40,010

the USDA Food Safety and Inspection Service charge on Genomics.

12

01:00:42,530 --> 01:00:46,930

So I just want to welcome everyone again this week

13

01:00:46,930 --> 01:00:48,730

if you're joining for the second time.

14

01:00:49,430 --> 01:00:53,090

NACMCF is a federal advisory committee that provides impartial scientific

15

01:00:53,090 --> 01:00:56,890

advice and recommendations to the U.S. Department of Agriculture

16

01:00:56,890 --> 01:01:01,990

and other government agencies on public health issues relative to

17

01:01:01,990 --> 01:01:04,410

the safety and wholesomeness of the U.S. food supply.

18

01:01:05,090 --> 01:01:09,030

More information about the committee, the members, the current charges,

19

01:01:09,250 --> 01:01:12,650

and past reports can be found by scanning the QR

20

01:01:12,650 --> 01:01:15,090

code on the screen which will take you to the

21

01:01:15,090 --> 01:01:15,930

NACMCF webpage.

22

01:01:17,510 --> 01:01:22,050

For those that joined the

23

01:01:22,050 --> 01:01:25,870

plenary on Tuesday, these housekeeping reminders will be familiar.

24

01:01:26,170 --> 01:01:29,330

But first, I want to remind everyone that this meeting

25

01:01:29,330 --> 01:01:33,750

is being recorded and FSIS will post the recording and

26

01:01:33,750 --> 01:01:37,570

transcripts when they become available on the NACMCF webpage which

27

01:01:37,570 --> 01:01:39,130  
is on the FSIS website.

28

01:01:39,930 --> 01:01:43,870  
For our online attendees, your microphones are automatically muted when

29

01:01:43,870 --> 01:01:46,170  
you logged in and you will not have the ability

30

01:01:46,170 --> 01:01:48,510  
to use your camera during the meeting.

31

01:01:48,990 --> 01:01:51,910  
For our in-person attendees, we request that you use

32

01:01:51,910 --> 01:01:55,290  
a microphone when speaking because as we saw on Tuesday,

33

01:01:55,550 --> 01:01:58,770  
if you're not using a microphone then our online attendees

34

01:01:58,770 --> 01:01:59,850  
cannot hear us.

35

01:02:00,710 --> 01:02:04,490  
Closed captions can be enabled by clicking the closed caption

36

01:02:04,490 --> 01:02:10,170  
or CC bubble in the bottom left of your screen.

37

01:02:10,250 --> 01:02:10,650

38

01:02:11,030 --> 01:02:13,710  
And as you can see, we also have ASL interpreter

39

01:02:13,710 --> 01:02:16,070  
available for the duration of the meeting.

40

01:02:16,750 --> 01:02:20,390  
There is no formal public comment period scheduled for this

41

01:02:20,390 --> 01:02:23,570

Meeting, but the chat feature is available for our virtual

42

01:02:23,570 --> 01:02:24,130

attendees.

43

01:02:24,850 --> 01:02:27,030

Any comments made in the chat will be shared with

44

01:02:27,030 --> 01:02:28,590

the committee after today's meeting.

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01:02:29,210 --> 01:02:33,390

In addition, attendees may submit written comments according to the

46

01:02:33,390 --> 01:02:38,010

options and directions outlined in the Federal Register Notice announcing

47

01:02:38,010 --> 01:02:38,690

this meeting.

48

01:02:39,110 --> 01:02:41,870

These comments will also be shared with the committee when

49

01:02:41,870 --> 01:02:43,030

they become available.

50

01:02:44,290 --> 01:02:47,850

So we'll now proceed to taking a roll call.

51

01:02:48,350 --> 01:02:50,730

I acknowledge that we do have some members of our

52

01:02:50,730 --> 01:02:53,050

Executive Committee joining us online.

53

01:02:53,410 --> 01:03:02,330

I have Dr. Donald Prater who is the NACMCF

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01:03:02,330 --> 01:03:03,330

Vice-Chair, my apologies.

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01:03:03,970 --> 01:03:07,050

And then also Dr. Denise Eblen who is the FSIS

56

01:03:07,050 --> 01:03:11,890

liaison for NACMCF and also Dr. Eric Olson who's the

57

01:03:11,890 --> 01:03:14,910

FDA liaison for NACMCF.

58

01:03:15,210 --> 01:03:18,770

Do I have any other Executive Committee members that are

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01:03:18,770 --> 01:03:23,770

joining online that have not made

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01:03:23,770 --> 01:03:24,850

their presence known?

61

01:03:29,120 --> 01:03:29,800

Okay.

62

01:03:30,320 --> 01:03:33,800

And I acknowledge the members that we have online and

63

01:03:33,800 --> 01:03:37,120

we do not have any Executive Committee members present in

64

01:03:37,120 --> 01:03:37,540

the room.

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01:03:37,680 --> 01:03:41,460

We'll now move on to a roll call of our

66

01:03:41,460 --> 01:03:43,760

members that are present.

67

01:03:44,440 --> 01:03:48,960

And again, for our online attendees, you may not hear

68

01:03:48,960 --> 01:03:51,240  
them say here or present because they won't have a

69

01:03:51,240 --> 01:03:53,620  
mic in front of them, but we'll acknowledge the count

70

01:03:53,620 --> 01:03:58,540  
at the end of the roll call.

71

01:03:58,680 --> 01:04:04,740  
So in alphabetical order we'll start with Dr. Bisha,

72

01:04:05,040 --> 01:04:14,940  
Dr. Carleton, Dr. Carlson, Dr. Cetin-Karaca, Dr. Chapman,

73

01:04:15,060 --> 01:04:25,360  
Dr. Dutta, and Dr. Feng, Dr. Figgs, Dr. Goldman,

74

01:04:25,480 --> 01:04:35,400  
Dr. Hansen, Dr. Havelaar, Ms. Kause, Dr. Khaksar, Lieutenant Colonel

75

01:04:35,400 --> 01:04:45,340  
Kubat, not present, Dr. Lambertini, Ms. Lynn,

76

01:04:45,460 --> 01:04:55,080  
Dr. McCullough, Dr. Mello, Dr. Moorman,

77

01:04:55,220 --> 01:05:04,280  
Dr. Pradhan, Mr. Rana, and Dr. Sanchez-Plata,

78

01:05:05,460 --> 01:05:15,520  
Dr. Schill, Dr. Shariat, not present, Dr. Snyder,

79

01:05:15,680 --> 01:05:24,580  
Dr. Teplitski, not present, Dr. Wang, and Dr. Warren,

80

01:05:25,000 --> 01:05:33,600  
not present, Dr. Yehualaeshet, and oh, Dr. Worobo, not present.

81

01:05:33,880 --> 01:05:35,380

So a little bit out of order.

82

01:05:36,100 --> 01:05:40,340

I recognize I believe that was 24 of 30 committee

83

01:05:40,340 --> 01:05:44,000

members present which meets quorum and I call this meeting

84

01:05:44,000 --> 01:05:44,680

to order.

85

01:05:49,260 --> 01:05:53,320

We will now begin the update starting with the Cronobacter

86

01:05:53,320 --> 01:05:55,960

in Powdered Infant Formula Subcommittee.

87

01:05:56,240 --> 01:06:00,940

This subcommittee is led by our members, Dr. Elisabetta Lambertini

88

01:06:00,940 --> 01:06:02,480

and Dr. Abby Snyder.

89

01:06:02,820 --> 01:06:05,740

Welcome, Drs. Lambertini and Snyder.

90

01:06:08,840 --> 01:06:09,580

Thank you.

91

01:06:09,680 --> 01:06:11,740

So we're just going to share a brief update about

92

01:06:11,740 --> 01:06:14,980

the work that the three work groups in our subcommittee

93

01:06:14,980 --> 01:06:15,860

did this week.

94

01:06:16,400 --> 01:06:19,660

I'm going to start off by sharing the report out

95

01:06:19,660 --> 01:06:21,840

for work group four and then I'm going to kick

96

01:06:21,840 --> 01:06:24,920

it over to Elisabetta for the updates for the work

97

01:06:24,920 --> 01:06:26,320

groups for questions two and three.

98

01:06:26,860 --> 01:06:30,800

So Q4, that is the charge that concerns risk communication,

99

01:06:31,220 --> 01:06:33,100

the charge question that concerns risk communication.

100

01:06:33,760 --> 01:06:36,920

You may remember that that group is addressing the question

101

01:06:36,920 --> 01:06:38,200

in three bins.

102

01:06:38,740 --> 01:06:43,380

The first bin is the topic that concerns what content,

103

01:06:43,520 --> 01:06:45,440

so the what of what should be included in the

104

01:06:45,440 --> 01:06:50,060

risk messaging, the second piece is the importance of reaching

105

01:06:50,060 --> 01:06:54,480

very targeted specific audiences, so the who of the risk

106

01:06:54,480 --> 01:06:58,660

messaging, and then the third piece is mechanisms for best

107

01:06:58,660 --> 01:07:02,200

reaching and motivating those audiences, so the how component of

108

01:07:02,200 --> 01:07:02,380



that.

109

01:07:02,700 --> 01:07:06,120

So in terms of an administrative update, this group has

110

01:07:06,120 --> 01:07:10,440

a rough draft developed for their response to this charge

111

01:07:10,440 --> 01:07:14,660

and is now in the process of refining and vetting

112

01:07:14,660 --> 01:07:16,160

those very specific recommendations.

113

01:07:17,060 --> 01:07:20,420

That work group also heard from subject matter experts this

114

01:07:20,420 --> 01:07:24,260

week from Abbott who spoke to the group specifically on

115

01:07:24,260 --> 01:07:28,380

the topic of hot water use in reconstitution of powdered

116

01:07:28,380 --> 01:07:33,480

infant formula and that conversation centered a lot around the

117

01:07:33,480 --> 01:07:35,960

need for additional research to fill in the gaps on

118

01:07:35,960 --> 01:07:41,140

topics to ensure consistent Cronobacterian activation while protecting nutrients and

119

01:07:41,140 --> 01:07:42,760

preventing burns from consumers.

120

01:07:43,600 --> 01:07:48,960

And so from that, that subject matter expert group provided

121

01:07:48,960 --> 01:07:54,580

some insights into attributes that are particularly important in those

122

01:07:54,580 --> 01:07:58,300

analyses which may not have been addressed in the existing

123

01:07:58,300 --> 01:08:01,980

literature, so even things like where that formula is in

124

01:08:01,980 --> 01:08:05,760

its shelf life as well as particular nutrient components and

125

01:08:05,760 --> 01:08:08,440

different types of formulas that would be especially sensitive to

126

01:08:08,440 --> 01:08:08,660

heat.

127

01:08:09,460 --> 01:08:12,420

So some of the work group's findings thus far, I

128

01:08:12,420 --> 01:08:13,440

think we have two to share.

129

01:08:13,580 --> 01:08:17,260

The first is that there's lots of variability in recommendations

130

01:08:17,260 --> 01:08:23,340

related to handling instructions among groups like CDC and WHO

131

01:08:23,340 --> 01:08:27,380

and even the instructions on labels for PIF products.

132

01:08:27,700 --> 01:08:32,200

The second finding is that there's a lack of data

133

01:08:32,200 --> 01:08:34,820

on actual handling practices, right, I alluded to that research

134

01:08:34,820 --> 01:08:38,940

gap before, but what research does exist suggests that it's

135

01:08:38,940 --> 01:08:43,000  
inconsistent and confusing messaging, at least as being reported by

136  
01:08:43,000 --> 01:08:43,780  
caregivers themselves.

137  
01:08:44,280 --> 01:08:47,120  
So the committee is working on drafting kind of incipient

138  
01:08:47,120 --> 01:08:49,400  
recommendations around some of the following topics.

139  
01:08:49,740 --> 01:08:54,760  
One is the need for transparent collaboration among stakeholder groups,

140  
01:08:54,900 --> 01:09:00,640  
so that includes obviously FDA, USDA, CDC, AAP, INCA, and

141  
01:09:00,640 --> 01:09:06,620  
individual PIF manufacturer companies with caregivers to create guidance  
information.

142  
01:09:07,280 --> 01:09:11,060  
The second relates to the importance of water heating and

143  
01:09:11,060 --> 01:09:14,840  
the potential for in-home contamination that may occur from

144  
01:09:14,840 --> 01:09:16,700  
cross-contamination with the environment.

145  
01:09:17,560 --> 01:09:21,160  
The third is that caregiver messaging should take the form

146  
01:09:21,160 --> 01:09:26,420  
of a risk communication frame and address different audiences, so

147  
01:09:26,420 --> 01:09:30,840  
parent, guardian, healthcare providers, childcare facilities differently.

148  
01:09:31,380 --> 01:09:33,340

And then the fourth is that social media and peer

149

01:09:33,340 --> 01:09:36,540

groups are going to be trusted and key groups for

150

01:09:36,540 --> 01:09:39,360

getting this information into the hands of the caregivers that

151

01:09:39,360 --> 01:09:39,600

matter.

152

01:09:39,900 --> 01:09:41,680

So that's just a summary of kind of where we

153

01:09:41,680 --> 01:09:43,420

are and how much further we are after this week

154

01:09:43,420 --> 01:09:44,360

of in-person meetings.

155

01:09:44,420 --> 01:09:44,800

Elisabetta.

156

01:09:47,400 --> 01:09:51,860

So I'll provide an update for Q2 and Q4.

157

01:09:52,660 --> 01:09:57,120

So overall, we made very good progress, so I'm very

158

01:09:57,120 --> 01:09:58,360

happy of where we are.

159

01:09:59,000 --> 01:10:02,280

For Q2, it's a question that deals with pathogen and

160

01:10:02,280 --> 01:10:04,300

host characteristics that contribute to risk.

161

01:10:04,860 --> 01:10:08,940

The drafting of the responses is underway for both on

162

01:10:08,940 --> 01:10:11,060  
the hazard front and on the host front.

163

01:10:11,700 --> 01:10:15,180  
We also cross-pollinated across working groups and a bit

164

01:10:15,180 --> 01:10:20,060  
with the genomic group to make sure that our questions

165

01:10:20,060 --> 01:10:22,000  
are well-connected and comprehensive.

166

01:10:23,080 --> 01:10:27,000  
We identified the need for additional SMEs in addition to

167

01:10:27,000 --> 01:10:29,760  
what we see in the literature to help address questions,

168

01:10:29,980 --> 01:10:34,720  
in particular, defining high-risk populations as well as defining

169

01:10:34,720 --> 01:10:36,440  
some of the host factors.

170

01:10:36,840 --> 01:10:40,480  
And we have identified experts from CDC that are going

171

01:10:40,480 --> 01:10:41,440  
to help us with this.

172

01:10:42,180 --> 01:10:46,220  
So a couple of snippets from the evidence that we've

173

01:10:46,220 --> 01:10:49,540  
been discussing on the front of hazard factors.

174

01:10:49,880 --> 01:10:55,540  
What we identified and are evaluating evidence on is osmotic

175

01:10:55,540 --> 01:11:01,380

stress tolerance, desiccation resistance, thermal stress tolerance,  
acidic stress tolerance,

176

01:11:01,820 --> 01:11:05,960

biofilm formation, virulence factor, and detection assays.

177

01:11:06,700 --> 01:11:09,740

You can see some parallels with the genomic, so we

178

01:11:09,740 --> 01:11:14,220

probably need to cross-pollinate before the charge is over.

179

01:11:14,880 --> 01:11:20,020

On host factors, we have seen this.

180

01:11:20,160 --> 01:11:22,580

We talked a bit in the beginning of these three

181

01:11:22,580 --> 01:11:28,240

days, confirmed that the age-specific vulnerabilities, that we see

182

01:11:28,240 --> 01:11:32,000

the impact of immunocompromising conditions and comorbidity.

183

01:11:32,860 --> 01:11:36,020

We see that Cronobacter affects all age groups.

184

01:11:36,980 --> 01:11:41,020

Majority of cases actually in adults, but neonates and infants

185

01:11:41,020 --> 01:11:43,620

are at higher risk of severe consequences.

186

01:11:44,560 --> 01:11:50,820

It is still uncertain if immunocompromised or immunocompromising  
conditions and

187

01:11:50,820 --> 01:11:55,280

comorbidities are the driving factors of infection and its severity.

188

01:11:55,980 --> 01:11:59,940

And the reported occurrence of these conditions are not frequent

189

01:11:59,940 --> 01:12:04,440

in documented cases, so it's hard to connect these factors

190

01:12:04,440 --> 01:12:06,260

to Cronobacter infection.

191

01:12:08,660 --> 01:12:15,060

For question three, Cronobacter control in pig production, we also

192

01:12:15,060 --> 01:12:18,020

made good progress in all the sections.

193

01:12:19,020 --> 01:12:25,480

And overall, our answer will contain recommendations for best practices

194

01:12:26,420 --> 01:12:29,340

that we think should be followed, and we highlight areas

195

01:12:29,340 --> 01:12:32,440

where enhanced attention seems needed.

196

01:12:33,080 --> 01:12:39,440

So, the structure of the answer already outlines what we

197

01:12:39,440 --> 01:12:40,920

think are these key areas.

198

01:12:41,480 --> 01:12:44,180

I'll briefly go through some of them.

199

01:12:45,100 --> 01:12:49,040

So, in terms of ingredients, we evaluated the risk associated

200

01:12:49,040 --> 01:12:50,780

with ingredients used in dry blending.

201

01:12:51,640 --> 01:12:55,580

Several heat-sensitive ingredients exist, as we know.

202

01:12:55,860 --> 01:13:01,640

They're commonly dry blended, and we focus on the sensitive

203

01:13:01,640 --> 01:13:02,480

ingredients.

204

01:13:03,280 --> 01:13:08,900

We think that selected few require special attention because of

205

01:13:08,900 --> 01:13:11,740

the high prevalence of Cronobacter that has been observed.

206

01:13:12,480 --> 01:13:14,000

Starches is one example.

207

01:13:15,040 --> 01:13:18,040

And we are working on finalizing recommendations on the key

208

01:13:18,040 --> 01:13:22,460

elements that manufacturers should consider when making decisions on where

209

01:13:22,460 --> 01:13:27,680

to source ingredients, especially dry blend ingredients, including if the

210

01:13:27,680 --> 01:13:30,920

ingredient undergoes a validated kill step and how that is

211

01:13:30,920 --> 01:13:31,520

demonstrated.

212

01:13:32,880 --> 01:13:35,480

And another aspect that we're keeping in mind for both

213

01:13:35,480 --> 01:13:39,100

ingredients and PIF is ensuring that any technology that is

214

01:13:39,100 --> 01:13:44,480

used to reduce contaminants do not reduce nutritional quality.

215



01:13:45,160 --> 01:13:47,700  
So, I'll touch on this.

216  
01:13:47,860 --> 01:13:52,240  
The SMEs are also helping us to understand these aspects

217  
01:13:52,240 --> 01:13:57,120  
of nutritional quality and maintaining the functional specs of formula.

218  
01:13:58,780 --> 01:14:04,880  
In terms of zoning and equipment design, we assess what

219  
01:14:04,880 --> 01:14:09,120  
is required, what the industry is doing, and what is

220  
01:14:09,120 --> 01:14:09,500  
needed.

221  
01:14:09,800 --> 01:14:13,200  
So, the report will include a summary of the recommended

222  
01:14:13,200 --> 01:14:17,060  
key practices in this area, which include, for example, which

223  
01:14:17,060 --> 01:14:21,520  
standards exist and the movement of air, personnel, materials from

224  
01:14:21,520 --> 01:14:24,200  
low and medium hygiene to high hygiene zones.

225  
01:14:25,040 --> 01:14:27,500  
We had a good discussion on the challenges of retrofitting

226  
01:14:27,500 --> 01:14:34,760  
these new protocols to older plants that were designed before

227  
01:14:34,760 --> 01:14:37,820  
the new plants, as well as mitigation strategies.

228  
01:14:38,020 --> 01:14:40,780  
So, based on this discussion, we are inviting a couple

229

01:14:40,780 --> 01:14:44,980  
of more SMEs from the industry to talk about equipment

230

01:14:44,980 --> 01:14:45,400  
design.

231

01:14:46,860 --> 01:14:52,020  
On sanitation, we acknowledge that wet cleaning is a well

232

01:14:52,020 --> 01:14:53,600  
-established process in the industry.

233

01:14:54,340 --> 01:14:58,140  
However, attention is needed on the equipment that handles dry

234

01:14:58,140 --> 01:15:01,520  
product, that is either equipment that is cleaned out of

235

01:15:01,520 --> 01:15:04,580  
place or that is clean in place, such as spray

236

01:15:04,580 --> 01:15:05,080  
dryers.

237

01:15:05,640 --> 01:15:08,980  
So, drying is key, and it's an area that we

238

01:15:08,980 --> 01:15:10,200  
think requires more attention.

239

01:15:11,020 --> 01:15:16,680  
So, we are reviewing the approaches for drying and what

240

01:15:16,680 --> 01:15:19,820  
new technologies may be available or becoming available.

241

01:15:20,880 --> 01:15:24,000  
On this point, also, the utility of dry cleaning as

242

01:15:24,000 --> 01:15:27,440

a response to a positive to a contamination event has

243

01:15:27,440 --> 01:15:30,880

been challenged, leading to the need to explore alternative approaches,

244

01:15:31,020 --> 01:15:33,520

including non-thermal or chemical treatments.

245

01:15:35,060 --> 01:15:36,520

A couple of more points.

246

01:15:37,080 --> 01:15:40,940

In terms of process control, we took into account that

247

01:15:40,940 --> 01:15:44,860

the industry relies on well-established processes, such as pasteurization.

248

01:15:45,680 --> 01:15:49,160

However, there is an opportunity to explore and validate alternative

249

01:15:49,160 --> 01:15:51,580

treatments, such as non-thermal technology.

250

01:15:52,300 --> 01:15:57,920

So, alternative technology keeps coming up in several of the

251

01:15:57,920 --> 01:15:59,060

points that we're looking at.

252

01:16:00,220 --> 01:16:04,240

We are engaged SMEs from the industry on this point

253

01:16:04,240 --> 01:16:09,040

as well, in particular on production practices and barriers for

254

01:16:09,040 --> 01:16:11,380

adoption of alternative approaches.

255

01:16:13,340 --> 01:16:14,360

Two more.

256

01:16:14,600 --> 01:16:19,780

On environmental monitoring, Cronobacter testing should always be performed in

257

01:16:19,780 --> 01:16:22,840

high-risk areas and cannot be replaced with other tests.

258

01:16:22,920 --> 01:16:29,100

That's a formula recommendation that we feel like we can

259

01:16:29,100 --> 01:16:30,800

start sharing and receiving.

260

01:16:32,020 --> 01:16:33,120

EBE, E.coli,

261

01:16:33,120 --> 01:16:37,180

Salmonella testing should be used in complementary fashion only.

262

01:16:38,780 --> 01:16:45,980

Last, to conduct risk root cause investigations, we recommend using

263

01:16:45,980 --> 01:16:50,960

whole genome sequencing (WGS) and we recognize the need to

264

01:16:50,960 --> 01:16:55,420

define criteria for when it is beneficial to use WGS

265

01:16:55,420 --> 01:17:00,940

versus what other source tracking techniques could be acceptable in

266

01:17:00,940 --> 01:17:01,780

other situations.

267

01:17:02,460 --> 01:17:05,140

So, in the draft, in the report, we will provide

268

01:17:05,140 --> 01:17:11,119

recommendations to develop these criteria to both finished product and

269

01:17:11,119 --> 01:17:13,180

positive environmental swabs.

270

01:17:15,420 --> 01:17:18,859

As we are developing a set criteria recommendation to determine

271

01:17:18,859 --> 01:17:23,800

the procedures for halting product or disposing of product following

272

01:17:23,800 --> 01:17:28,480

a positive event associated with the root cause analysis.

273

01:17:29,620 --> 01:17:31,760

So, I think that is all.

274

01:17:31,940 --> 01:17:34,240

As you can see, we did a lot of discussion

275

01:17:34,240 --> 01:17:37,820

and we identified a couple of more points that we

276

01:17:37,820 --> 01:17:38,460

want to add.

277

01:17:39,400 --> 01:17:39,900

That is all.

278

01:17:40,080 --> 01:17:40,420

Thank you.

279

01:17:40,560 --> 01:17:44,880

The next steps is to aim for a first full

280

01:17:44,880 --> 01:17:47,600

draft to circulate internally in November.

281

01:17:48,080 --> 01:17:48,460

Thank you.

282

01:17:55,530 --> 01:17:57,310  
Thank you very much.

283  
01:17:59,020 --> 01:18:04,120  
Thank you very much, Drs. Lambertini and Snyder, our co

284  
01:18:04,120 --> 01:18:07,220  
-chairs for the Cronobacter Subcommittee.

285  
01:18:08,240 --> 01:18:13,960  
So, we will have a very, you know, if there

286  
01:18:13,960 --> 01:18:19,080  
are questions or comments from our Executive Committee members that

287  
01:18:19,080 --> 01:18:25,040  
are online, you can go ahead and unmute yourself and

288  
01:18:25,040 --> 01:18:32,060  
feel free to also use your camera to address the

289  
01:18:32,060 --> 01:18:34,280  
Committee on that update for the work that they've done

290  
01:18:34,280 --> 01:18:34,800  
for the week.

291  
01:18:35,080 --> 01:18:38,260  
If we have any questions or comments from our Executive

292  
01:18:38,260 --> 01:18:39,840  
Committee members that are online.

293  
01:18:51,190 --> 01:18:55,370  
I think Dr. Prater is trying to speak.

294  
01:18:55,890 --> 01:18:58,610  
I'm trying to come on camera and unmute.

295  
01:18:58,730 --> 01:18:59,250

Can you hear me?

296

01:18:59,870 --> 01:19:01,790

Yes, we can hear you loud and clear.

297

01:19:01,970 --> 01:19:02,370

Thank you.

298

01:19:02,430 --> 01:19:03,690

Okay, thank you so much.

299

01:19:03,930 --> 01:19:06,450

I don't have any specific questions.

300

01:19:06,590 --> 01:19:10,070

It was very interesting to hear the updates and very

301

01:19:10,070 --> 01:19:13,650

grateful to the work of the Subcommittee and in particular,

302

01:19:13,890 --> 01:19:16,530

the leadership of Dr. Lambertini and Dr. Snyder.

303

01:19:17,290 --> 01:19:21,330

We'll be anxious to hear more about that in the

304

01:19:21,330 --> 01:19:24,670

report, but it sounds like a lot of progress was

305

01:19:24,670 --> 01:19:25,430

made this week.

306

01:19:25,550 --> 01:19:29,930

So, really appreciate that and happy to listen to questions

307

01:19:29,930 --> 01:19:31,070

that others might have.

308

01:19:33,270 --> 01:19:34,530

Thank you, Dr. Prater.

309

01:19:35,130 --> 01:19:36,390  
Krystal, this is Emilio.

310

01:19:36,430 --> 01:19:37,490  
Can you hear me?

311

01:19:37,950 --> 01:19:38,270  
Hello.

312

01:19:39,530 --> 01:19:40,790  
Dr. Esteban, go ahead.

313

01:19:41,110 --> 01:19:44,650  
Yes, I'm not going to be on camera because I'm

314

01:19:44,650 --> 01:19:46,850  
in the middle of a meeting here in Arkansas, but

315

01:19:46,850 --> 01:19:48,850  
I wanted to thank the Committee for the work they've

316

01:19:48,850 --> 01:19:51,030  
done over the last few months.

317

01:19:51,790 --> 01:19:55,730  
Things are very touchy subject and they've addressed a lot

318

01:19:55,730 --> 01:19:59,690  
of the questions and I look forward to reading the

319

01:19:59,690 --> 01:20:03,170  
conclusions of recommendations and see how we can move forward.

320

01:20:03,510 --> 01:20:05,850  
So, thank you very much and great leadership.

321

01:20:06,010 --> 01:20:06,290  
Thank you.

322

01:20:07,870 --> 01:20:09,190



Thank you, Dr. Esteban.

323

01:20:09,290 --> 01:20:13,030  
I see Dr. Catlin has her hand up.

324

01:20:14,490 --> 01:20:17,090  
Go ahead, Michelle, you can unmute yourself.

325

01:20:17,110 --> 01:20:18,030  
I was hit by mistakes.

326

01:20:18,770 --> 01:20:20,410  
Oh, okay.

327

01:20:21,930 --> 01:20:24,550  
Yeah, it's kind of weird because the raise hand feature

328

01:20:24,550 --> 01:20:26,090  
is so close to reaction.

329

01:20:26,390 --> 01:20:29,410  
So, sometimes we'll see people want to give a hand

330

01:20:29,410 --> 01:20:31,430  
clap and they end up raising their hand.

331

01:20:31,510 --> 01:20:32,170  
Not a problem.

332

01:20:33,390 --> 01:20:33,670  
All right.

333

01:20:33,710 --> 01:20:39,690  
Are there any other Executive Committee members or other Committee

334

01:20:39,690 --> 01:20:44,290  
members that are online that wish to address the Committee

335

01:20:44,290 --> 01:20:46,330  
on the updates that were just presented?

336

01:20:50,180 --> 01:20:51,840

All right, not seeing any.

337

01:20:52,220 --> 01:20:56,580

And to our members in the room, do we have

338

01:20:56,580 --> 01:21:00,940

any questions or comments that you'd like to add on

339

01:21:00,940 --> 01:21:04,000

some of the discussion that happened this week or any

340

01:21:04,000 --> 01:21:06,540

questions or comments for the updates that were just provided?

341

01:21:10,310 --> 01:21:11,590

Seeing none.

342

01:21:11,930 --> 01:21:12,770

Oh, we got one.

343

01:21:12,890 --> 01:21:13,690

There we go.

344

01:21:14,050 --> 01:21:14,370

Go ahead, Janell.

345

01:21:14,450 --> 01:21:15,850

Shantel, will bring you the mic.

346

01:21:18,490 --> 01:21:21,350

Hi, this is Janell Kause of the United States Department

347

01:21:21,350 --> 01:21:23,790

of Agriculture's Food Safety Inspection Service.

348

01:21:24,550 --> 01:21:28,070

Dr. Lambertini, you talked about a crosswalk on the genomics.

349

01:21:28,570 --> 01:21:31,550

Can you elaborate a little further on what you anticipate?

350

01:21:37,540 --> 01:21:37,860

Thank you.

351

01:21:37,880 --> 01:21:40,220

We don't have a comprehensive list, but we've seen a

352

01:21:40,220 --> 01:21:42,340

couple of areas of overlap.

353

01:21:42,660 --> 01:21:47,640

The most clear one is on virulence factors.

354

01:21:47,800 --> 01:21:57,100

So, question two, host-pathogen interaction and Cronobacter factors that

355

01:21:57,100 --> 01:21:59,980

contribute to risk or modulate risk.

356

01:22:00,540 --> 01:22:03,300

And I think from that is, I talked to some

357

01:22:03,300 --> 01:22:09,740

of the genomics charge that are focusing on that aspect

358

01:22:09,740 --> 01:22:10,920

in a more general fashion.

359

01:22:11,360 --> 01:22:14,720

So, it looks like what we are looking at could

360

01:22:14,720 --> 01:22:18,520

provide a case study, possibly, to your answer.

361

01:22:19,040 --> 01:22:23,380

And we should compare notes on what are the genetic

362

01:22:23,380 --> 01:22:26,780

elements of importance or virulence and all the lists that

363

01:22:26,780 --> 01:22:27,860  
we've been going through.

364

01:22:28,760 --> 01:22:30,300  
Are we seeing the same thing?

365

01:22:30,560 --> 01:22:34,500  
Is the same type of, not the genetic elements because

366

01:22:34,500 --> 01:22:39,480  
they're specific to Cronobacter, but the type of phenotype that

367

01:22:39,480 --> 01:22:41,120  
we are looking at?

368

01:22:42,520 --> 01:22:46,540  
And does what we see here match with your classification?

369

01:22:47,400 --> 01:22:48,320  
Do you see any?

370

01:22:50,580 --> 01:22:52,340  
I don't have any other specifics.

371

01:22:52,540 --> 01:22:55,260  
It's just, at some point, the entire committee will review

372

01:22:55,260 --> 01:22:57,900  
each other's work, and that might be a place for

373

01:22:57,900 --> 01:22:59,980  
the genomics committee to send special attention.

374

01:23:01,680 --> 01:23:05,880  
Actually, also in Q3, we're talking about use of WGS

375

01:23:05,880 --> 01:23:11,860  
in root cause analysis and process control during feed production.

376

01:23:12,700 --> 01:23:15,240

So, that's another area where we would welcome your thoughts.

377

01:23:19,540 --> 01:23:20,340

Thank you.

378

01:23:21,160 --> 01:23:28,080

And are there other questions or comments in the room

379

01:23:28,080 --> 01:23:28,900

on Cronobacter?

380

01:23:30,380 --> 01:23:31,400

All right.

381

01:23:34,070 --> 01:23:36,970

So, we're going to go ahead, then, and move on

382

01:23:37,530 --> 01:23:42,510

to the next update, and that will be an update

383

01:23:42,510 --> 01:23:45,590

from our Genomic subcommittee.

384

01:23:46,070 --> 01:23:51,390

And the subcommittee, this subcommittee is co-led by Drs.

385

01:23:51,390 --> 01:23:56,050

Vik Dutta and KatieRose McCullough, and they will provide

386

01:23:56,050 --> 01:23:59,670

progress updates on the committee's work to address the Genomics

387

01:23:59,670 --> 01:24:00,290

charge.

388

01:24:00,430 --> 01:24:02,610

So, welcome, Drs. Dutta and McCullough.

389

01:24:07,850 --> 01:24:09,090

Thank you, Dr. Southern.

390

01:24:10,190 --> 01:24:11,210

Good afternoon, everyone.

391

01:24:12,490 --> 01:24:17,250

So, as you know, the Genomics committee have been working

392

01:24:17,250 --> 01:24:20,830

for the last couple of days, and just as we

393

01:24:20,830 --> 01:24:25,270

discussed, we started with buttoning up the concerns on Q1

394

01:24:25,270 --> 01:24:25,810

and Q2.

395

01:24:26,330 --> 01:24:30,670

It's more of just finishing up what was started already,

396

01:24:31,410 --> 01:24:35,190

and we feel good about what we have assigned in

397

01:24:35,190 --> 01:24:39,270

terms of the leftover work, and the goal is to

398

01:24:39,270 --> 01:24:41,810

have a decent draft by November.

399

01:24:42,330 --> 01:24:44,850

And so, we discussed that quite a bit, and at

400

01:24:44,850 --> 01:24:47,070

this point, we feel good about the progress we have

401

01:24:47,070 --> 01:24:48,930

made on Q1 and Q2.

402

01:24:49,370 --> 01:24:53,470

We also heard from SME, Dr. Eric Brown and Dr.

403

01:24:53,490 --> 01:24:57,650

Rachel Binet from FDA CFSAN, and they shared their genomics

404

01:24:57,650 --> 01:25:02,550

practices and what they're doing to help with the public

405

01:25:02,550 --> 01:25:05,290

health questions, similar to what we are trying to answer

406

01:25:05,290 --> 01:25:05,550

here.

407

01:25:06,390 --> 01:25:08,530

So, with that said, we did spend quite a bit

408

01:25:08,530 --> 01:25:10,190

of time, and I would say majority of the time,

409

01:25:10,190 --> 01:25:12,870

on Q3 and Q4.

410

01:25:13,330 --> 01:25:17,930

I will quickly provide a brief summary on Q3, and

411

01:25:17,930 --> 01:25:21,090

for our audience, just to kind of debrief really quick,

412

01:25:21,290 --> 01:25:25,550

Q3 was related to research gaps and the knowledge gaps

413

01:25:25,550 --> 01:25:28,850

as it relates to the Genomics charge, and Q4 is

414

01:25:28,850 --> 01:25:34,970

more related to strategic vision, which Dr. McCullough will debrief

415

01:25:34,970 --> 01:25:35,570

us in a minute.

416

01:25:36,150 --> 01:25:40,230

So, Q3 is divided into three parts, A, B, and

417

01:25:40,230 --> 01:25:40,450  
C.

418

01:25:40,930 --> 01:25:46,330  
For A, subcommittee, again, a lot of discussions.

419

01:25:46,650 --> 01:25:50,330  
We decided to focus on highlighting the research and the

420

01:25:50,330 --> 01:25:54,770  
knowledge gaps through the epidemiological triad model of infectious  
disease

421

01:25:54,770 --> 01:25:59,450  
causation as a core, and the idea is to discuss

422

01:25:59,450 --> 01:26:04,810  
all four pathogens, Salmonella, Listeria, Mono, Stax, and Campylobacter,  
through

423

01:26:04,810 --> 01:26:08,930  
this, and therefore identify, you know, the factors that could

424

01:26:08,930 --> 01:26:11,570  
be related to host, the agent, and the exposure.

425

01:26:12,230 --> 01:26:16,470  
More specifically, we discussed the role that virulence gene variants

426

01:26:16,470 --> 01:26:21,110  
can play, the mechanistic model for host-pathogen interactions, using

427

01:26:21,110 --> 01:26:25,990  
the current genomes, so looking retrospectively and characterizing  
virulence genes

428

01:26:25,990 --> 01:26:29,330  
as we call them today, and see what impact, if

429

01:26:29,330 --> 01:26:33,070  
any, they can have on risk profiling, and then we



430

01:26:33,070 --> 01:26:36,670

also discussed what role can vaccines have as we are

431

01:26:36,670 --> 01:26:40,170

looking at the virulence genes, and then the impact of

432

01:26:40,170 --> 01:26:43,550

virulence if there is a modification in the definition of

433

01:26:43,550 --> 01:26:47,810

the virulence genes on the regulation surveillance system, and also

434

01:26:47,810 --> 01:26:51,170

the role that functional genomics can play in confirming some

435

01:26:51,170 --> 01:26:54,630

of the newly identified virulence genes.

436

01:26:55,230 --> 01:26:58,510

We also discussed metadata gaps that need to be researched,

437

01:26:58,890 --> 01:27:01,630

more specifically as it relates to sharing as well as

438

01:27:01,630 --> 01:27:07,210

the content, and then we also discussed increased exposure as

439

01:27:07,210 --> 01:27:12,210

a function of adaptive attributes, and within that, increased survival,

440

01:27:13,090 --> 01:27:16,130

just increased exposure because organisms are doing a better job

441

01:27:16,130 --> 01:27:20,430

through their adaptive mechanisms, and also in certain cases, like

442

01:27:20,430 --> 01:27:25,170

Dr. Brown indicated in his presentation, heightened virulence just because

443

01:27:25,170 --> 01:27:29,370

of the adaptations that the organisms are going throughout there.

444

01:27:29,990 --> 01:27:34,370

For 3B, we spent a lot of time on the

445

01:27:34,370 --> 01:27:38,170

test methods, and the idea was to define a criteria

446

01:27:38,170 --> 01:27:41,410

for a good lab test, and within that, we discussed,

447

01:27:41,590 --> 01:27:44,210

of course, the role of QPCR, which is an obvious

448

01:27:44,210 --> 01:27:49,750

immediate testing technology that's available, but then how can what

449

01:27:49,750 --> 01:27:51,910

is being done today in the labs can be enhanced

450

01:27:51,910 --> 01:27:55,610

with technologies like targeted amplicon sequencing, and you can almost

451

01:27:55,610 --> 01:27:57,670

see like a resolution path there, and then going all

452

01:27:57,670 --> 01:28:01,390

the way to WGS, and the committee agrees that there's

453

01:28:01,390 --> 01:28:04,550

a role for each one of these technologies that can

454

01:28:04,550 --> 01:28:08,030

be relevant to decision-making when it comes to public

455

01:28:08,030 --> 01:28:11,250

health, and we've kind of created a triad there as

456

01:28:11,250 --> 01:28:14,030

well, and we'll be discussing this as part of 3B.

457

01:28:14,750 --> 01:28:17,670

More specifically, we'll be talking about the pros and cons

458

01:28:17,670 --> 01:28:21,090

of each one of these technologies and provide detailed overview

459

01:28:21,090 --> 01:28:24,570

of various methods as it relates to specific pathogens.

460

01:28:25,310 --> 01:28:30,910

For 3C, we discussed the description of rep strains as

461

01:28:30,910 --> 01:28:32,390

CDC is describing them today.

462

01:28:32,830 --> 01:28:35,330

What are the factors, the criteria that are being used,

463

01:28:35,430 --> 01:28:37,450

and can we revisit them and see if there is

464

01:28:37,450 --> 01:28:41,870

a role for improvement, and then more specifically, as it

465

01:28:41,870 --> 01:28:45,330

relates to capturing metadata, one of the ideas that committee

466

01:28:45,890 --> 01:28:49,370

was indicating is to use unsupervised machine learning and then

467

01:28:49,370 --> 01:28:51,990

following it up manually as one of the ideas that

468

01:28:51,990 --> 01:28:54,210

could be used to improve the definition of, and then

469

01:28:54,210 --> 01:28:56,150

the factors that are used to define the rep strains,

470

01:28:56,770 --> 01:29:00,190

and then also look at the factors that would, excuse

471

01:29:00,190 --> 01:29:05,330

me, define the factors that can be looked beyond genetic

472

01:29:05,330 --> 01:29:06,910

relatedness.

473

01:29:07,670 --> 01:29:13,030

And finally, we also looked at the role of genomics

474

01:29:13,030 --> 01:29:17,630

as it relates to vaccine development, vaccine assay development.

475

01:29:18,130 --> 01:29:19,070

A couple of things there.

476

01:29:19,150 --> 01:29:22,610

The obvious one is using the technology like qPCR to

477

01:29:22,610 --> 01:29:26,210

develop vaccine assays, and one of the sort of ideas

478

01:29:26,210 --> 01:29:29,110

that kept coming up is the phased use of technology,

479

01:29:29,110 --> 01:29:31,670

similar to what I was describing between PCR, Target, and

480

01:29:31,670 --> 01:29:34,890

Amplicon, and WGS, and how can that be effectively used

481

01:29:34,890 --> 01:29:40,090

to not only develop new assays, but also monitor going

482

01:29:40,090 --> 01:29:42,210

forward the trends that are happening epidemiologically.

483

01:29:42,730 --> 01:29:46,410

More specifically, in this case, we wanted to stress the

484

01:29:46,410 --> 01:29:50,310

impact that vaccines can have on the ecology of these

485

01:29:50,310 --> 01:29:55,150

organisms, and maybe use this phased use of technology and

486

01:29:55,150 --> 01:29:59,110

the impact and studying the impact on surveillance to make

487

01:29:59,110 --> 01:29:59,730

it more efficient.

488

01:30:00,470 --> 01:30:04,690

We also defined a few more SMEs, subject matter experts

489

01:30:04,690 --> 01:30:09,130

that we need to hear from, and with that, one

490

01:30:09,130 --> 01:30:09,570

more thing.

491

01:30:09,950 --> 01:30:12,650

There was a general idea that we haven't really found

492

01:30:12,650 --> 01:30:14,690

a place to, quote, bucket them.

493

01:30:15,190 --> 01:30:18,970

One is the role of omics, the gaps with the

494

01:30:18,970 --> 01:30:21,910

attribution models, and then the genes that can be used

495

01:30:21,910 --> 01:30:22,550

predictors.

496

01:30:22,750 --> 01:30:25,350

These are the sort of floating topics that do not

497

01:30:25,350 --> 01:30:30,110

necessarily fit exactly into our framework as the genomic charge

498

01:30:30,110 --> 01:30:33,970

is concerned on question three, but we feel comfortable and

499

01:30:33,970 --> 01:30:36,930

confident that we will be using some of these things

500

01:30:36,930 --> 01:30:41,870

as we respond to these questions and subparts, and there's

501

01:30:41,870 --> 01:30:45,070

more that you can expect from us as the time

502

01:30:45,070 --> 01:30:45,430

goes by.

503

01:30:45,670 --> 01:30:47,930

So with that, I'm going to switch it over to

504

01:30:47,930 --> 01:30:49,710

Dr. McCullough to talk about strategic vision.

505

01:30:50,590 --> 01:30:51,110

Thank you.

506

01:30:53,770 --> 01:30:56,950

Thank you, Dr. Dutta, and I am thrilled to be

507

01:30:56,950 --> 01:30:58,950

able to come talk to you about the strategic vision.

508

01:30:59,110 --> 01:31:02,690

We started this morning having a very passionate and robust

509

01:31:02,690 --> 01:31:06,250

discussion about dreaming big and what the strategic vision would

510

01:31:06,250 --> 01:31:09,690

be to better utilize genomic sequencing and the use of

511

01:31:09,690 --> 01:31:14,590

genomics in the industry for FSI's regulated products, and again,

512

01:31:14,670 --> 01:31:18,050

I want to stress the excitement and passion for the

513

01:31:18,050 --> 01:31:20,610

group was so much so that we ruined Dr. Dutta's

514

01:31:20,610 --> 01:31:23,890

breakfast by having to have the banana that was passed

515

01:31:23,890 --> 01:31:24,070

around.

516

01:31:24,170 --> 01:31:26,590

Only if you had the talking banana were you allowed

517

01:31:26,590 --> 01:31:29,270

to speak, because we just had everybody so excited to

518

01:31:29,270 --> 01:31:30,230

really weigh in here.

519

01:31:30,290 --> 01:31:32,390

So I think a lot of really good, exciting content

520

01:31:32,390 --> 01:31:33,550

to complement.

521

01:31:34,350 --> 01:31:37,270

So starting off question four really, again, was focused on

522

01:31:37,270 --> 01:31:40,670

the strategic vision based on risk management and questions and

523

01:31:40,670 --> 01:31:41,410

tools being deployed.

524

01:31:41,830 --> 01:31:45,870

How might genomics better inform FSI's and other regulatory agencies

525

01:31:45,870 --> 01:31:48,010

along the farm for continuum?

526

01:31:48,390 --> 01:31:49,990

So very broad, something very exciting.

527

01:31:50,390 --> 01:31:54,250

So for part A, how might regulatory agencies adjust sampling

528

01:31:54,250 --> 01:31:54,630

plans?

529

01:31:54,690 --> 01:31:57,570

There's a lot of discussion about the role of sampling

530

01:31:57,570 --> 01:31:58,670

and then why you're sampling.

531

01:31:58,790 --> 01:31:59,650

Is it for verification?

532

01:32:00,090 --> 01:32:01,570

Is it for something else?

533

01:32:02,010 --> 01:32:05,010

And so we discussed the role for exploratory programs really

534

01:32:05,010 --> 01:32:10,070

focused on upstream source and understanding the potential indicators that

535

01:32:10,070 --> 01:32:12,370

may be able to track better what is coming into

536

01:32:12,370 --> 01:32:17,150

establishments, and also the need for true baseline testing versus

537



01:32:17,150 --> 01:32:21,830  
verification sampling to better inform public health risk-based  
decisions.

538  
01:32:22,630 --> 01:32:25,550  
For portion B, which is focused on how genomics might

539  
01:32:25,550 --> 01:32:29,610  
be used to inform risk-based strategies, we focused on

540  
01:32:29,610 --> 01:32:32,690  
how to help determine the different stereotypes of concern, which

541  
01:32:32,690 --> 01:32:35,130  
is a big focus for all the different federal agencies,

542  
01:32:35,810 --> 01:32:38,770  
and maybe a global watch list based on the genes

543  
01:32:38,770 --> 01:32:41,890  
that are available with a sort of stoplight approach based

544  
01:32:41,890 --> 01:32:43,090  
on these genes that they have.

545  
01:32:43,170 --> 01:32:43,890  
You know, are you red?

546  
01:32:44,030 --> 01:32:44,550  
Are you yellow?

547  
01:32:44,630 --> 01:32:45,330  
Are you green?

548  
01:32:45,730 --> 01:32:47,970  
And how do we make those ...|how can that inform risk

549  
01:32:47,970 --> 01:32:50,330  
-based strategies that can be applied across the industry?

550  
01:32:51,070 --> 01:32:54,690

We discussed the further evaluation of virulent pathogens of concern

551

01:32:54,690 --> 01:32:57,530

and ranking them based on genes and which genes matter,

552

01:32:57,650 --> 01:32:59,790

and how does that combine with some of the work

553

01:32:59,790 --> 01:33:03,330

that's been done to classify stereotypes into those that are

554

01:33:03,330 --> 01:33:05,130

highly virulent or low virulent.

555

01:33:05,430 --> 01:33:08,790

Does the cell biology match those and match up with

556

01:33:08,790 --> 01:33:11,830

that stuff combined with that public health risk and what

557

01:33:11,830 --> 01:33:12,650

makes sense there?

558

01:33:12,650 --> 01:33:15,930

And that all of that genomic information really needs to

559

01:33:15,930 --> 01:33:18,590

be validated or tied back to what is a true

560

01:33:18,590 --> 01:33:19,190

hazard.

561

01:33:20,050 --> 01:33:23,170

For portion C, benefits and consideration of using genomic-based

562

01:33:23,170 --> 01:33:27,210

approaches to rank subtypes, we talked about how all evidence

563

01:33:27,210 --> 01:33:30,990

to rank these subtypes absolutely needs to be validated with

564

01:33:30,990 --> 01:33:32,510  
epidemiological information.

565

01:33:33,310 --> 01:33:36,450  
Sometimes there's this tenor of where if you have the

566

01:33:36,450 --> 01:33:38,830  
genomics or you have that information, there's a less need

567

01:33:38,830 --> 01:33:39,250  
for epi.

568

01:33:39,810 --> 01:33:43,330  
Our group really believes that that highlights the need, more

569

01:33:43,330 --> 01:33:45,850  
important and more accurate epi, and what can we do

570

01:33:45,850 --> 01:33:49,290  
to make those recommendations to empower the different public health

571

01:33:49,290 --> 01:33:52,250  
agencies out there to get better support to do better

572

01:33:52,250 --> 01:33:54,630  
epidemiology, including the state agencies out there?

573

01:33:55,150 --> 01:33:57,530  
We talked about how risk is not black and white.

574

01:33:57,590 --> 01:34:00,630  
It's really a continuum, and how can we help give

575

01:34:00,630 --> 01:34:03,810  
information out to industry and the public health agencies of

576

01:34:03,810 --> 01:34:06,350  
where do you draw that line on that continuum to

577

01:34:06,350 --> 01:34:07,630

make a risk-based decision?

578

01:34:08,409 --> 01:34:11,290

And then we talked about the alignment of different tools

579

01:34:11,290 --> 01:34:14,350

so that they're usable for all stakeholders and at multiple

580

01:34:14,350 --> 01:34:16,370

different education levels, right?

581

01:34:16,389 --> 01:34:18,830

We need to have it understandable and things that are

582

01:34:18,830 --> 01:34:19,010

usable.

583

01:34:19,150 --> 01:34:21,949

There's a tremendous amount of information that's already out there

584

01:34:21,949 --> 01:34:25,130

and available to genomics, but not always applicable and understandable

585

01:34:25,130 --> 01:34:25,790

for everybody.

586

01:34:25,929 --> 01:34:28,050

So how do we give that information in a more,

587

01:34:28,770 --> 01:34:32,730

in an easier to consume and applicable way across the

588

01:34:32,730 --> 01:34:33,130

industry?

589

01:34:33,489 --> 01:34:37,010

And then part D, which is how regulatory entities might

590

01:34:37,010 --> 01:34:40,590

interpret this genomic information to support regulatory action.

591

01:34:40,790 --> 01:34:43,190

So we talked about how there's multiple different types of

592

01:34:43,190 --> 01:34:44,650

regulatory action that's available.

593

01:34:44,929 --> 01:34:47,070

We spent a lot of time talking about where there's

594

01:34:47,070 --> 01:34:50,810

regulatory authority and where there's not regulatory authority and what

595

01:34:50,810 --> 01:34:53,690

recommendations we may need to make to address some of

596

01:34:53,690 --> 01:34:55,830

the gaps where regulatory authority might be.

597

01:34:56,290 --> 01:34:58,270

And some of that talked about the approaches that may

598

01:34:58,270 --> 01:35:01,710

need to look more closely at sources coming into establishments,

599

01:35:01,710 --> 01:35:02,470

so on-farm.

600

01:35:03,030 --> 01:35:06,710

And how do we, maybe we should recommend with that

601

01:35:06,710 --> 01:35:10,310

stoplight approach we talked about earlier, using that stoplight approach,

602

01:35:10,370 --> 01:35:13,230

can that guide what sort of regulatory actions may or

603

01:35:13,230 --> 01:35:14,610

may not need to be taken?

604

01:35:15,070 --> 01:35:18,110

And that again, there's a spectrum of regulatory actions which

605

01:35:18,110 --> 01:35:22,830

would be appropriate based on those stoplight indications we have.

606

01:35:22,830 --> 01:35:25,230

So like I said, very, very robust discussion.

607

01:35:25,690 --> 01:35:27,330

We also came up with a few things that really

608

01:35:27,330 --> 01:35:29,610

didn't fit into any of our parts that we added

609

01:35:29,610 --> 01:35:31,850

and decided it had to be part of this conversation.

610

01:35:32,530 --> 01:35:34,750

And so one of those is a big part of

611

01:35:34,750 --> 01:35:37,590

any time we're talking about genomics is data sharing.

612

01:35:38,190 --> 01:35:40,750

The gap that is where there may be data out

613

01:35:40,750 --> 01:35:43,430

there, not as much genomic information everybody thinks, but how

614

01:35:43,430 --> 01:35:46,610

do we get over legal concerns and considerations with sharing

615

01:35:46,610 --> 01:35:49,230

data really across different stakeholders?

616

01:35:49,570 --> 01:35:52,350

We talked about that information and education sharing.

617

01:35:52,490 --> 01:35:53,930

I kind of hinted at this a bit earlier.

618

01:35:54,050 --> 01:35:58,350

There's a lot of information out there that's available for

619

01:35:58,350 --> 01:36:01,090

people to use, but people don't know how to use

620

01:36:01,090 --> 01:36:01,290

it.

621

01:36:01,570 --> 01:36:04,610

So how do we better educate people and share that

622

01:36:04,610 --> 01:36:07,590

information so that they can use it into actionable ways?

623

01:36:08,070 --> 01:36:09,670

And this one I want to stress is our very

624

01:36:09,670 --> 01:36:12,530

much so dream big, is talk about is there a

625

01:36:12,530 --> 01:36:15,870

way we can come up with an indexing dashboard that

626

01:36:15,870 --> 01:36:19,410

people across the industry can use using genomics to better

627

01:36:19,410 --> 01:36:21,710

figure out or get a better indicator of where their

628

01:36:21,710 --> 01:36:25,070

risk is specifically for them, where that can help drive

629

01:36:25,070 --> 01:36:26,110

improvements for industry.

630

01:36:26,250 --> 01:36:27,730

So those are what we're going to be focusing on

631

01:36:27,730 --> 01:36:28,510

with question four.

632

01:36:28,730 --> 01:36:31,510

But I really, really strongly encourage the rest of our

633

01:36:31,510 --> 01:36:34,590

committee as we're discussing it and open it up here

634

01:36:34,590 --> 01:36:37,490

to questions to please participate and add to what

635

01:36:37,570 --> 01:36:38,470

Dr. Dutta and I presented.

636

01:36:38,650 --> 01:36:40,310

And I think I also want to say in closing,

637

01:36:40,910 --> 01:36:44,150

huge thanks to the USDA team, Dr. Southern and

638

01:36:44,250 --> 01:36:44,470

Dr. Tillman.

639

01:36:44,610 --> 01:36:46,610

I think at one time, he wanted to hogtie us

640

01:36:46,610 --> 01:36:48,210

all and keep us all quiet.

641

01:36:48,350 --> 01:36:50,150

He's been our handler for the past three days.

642

01:36:50,210 --> 01:36:52,110

We really sincerely appreciate you as well.



643

01:36:52,530 --> 01:36:54,570

And of course, Shantel and the entire USDA team, excellent

644

01:36:54,570 --> 01:36:54,890

job.

645

01:36:54,970 --> 01:36:58,290

We really appreciated and valued our time here together.

646

01:36:58,390 --> 01:36:59,030

So thank you.

647

01:37:05,710 --> 01:37:06,190

Wow.

648

01:37:06,950 --> 01:37:10,510

I didn't know that from the plenary it could get

649

01:37:10,510 --> 01:37:11,530

any better.

650

01:37:11,930 --> 01:37:12,990

It was such a great meeting.

651

01:37:13,630 --> 01:37:16,170

And then just watching you all work this week.

652

01:37:16,630 --> 01:37:20,210

And then even today, I'm sad that, you know, in

653

01:37:20,210 --> 01:37:22,610

a few moments, we're going to go our separate ways.

654

01:37:22,910 --> 01:37:26,610

Thank you all for just such great presentations and being

655

01:37:26,610 --> 01:37:29,410

so thoughtful and committed to the charges that have been

656

01:37:29,410 --> 01:37:30,170

placed before you.

657

01:37:30,310 --> 01:37:36,090

So thank you, Drs. Dutta and McCullough on that presentation

658

01:37:36,090 --> 01:37:36,770

for genomics.

659

01:37:37,470 --> 01:37:41,090

So we are going to, move on per usual

660

01:37:41,090 --> 01:37:43,630

NACMCF style, go ahead and open it up to our

661

01:37:43,630 --> 01:37:48,010

Executive Committee members who are all joining us online.

662

01:37:48,390 --> 01:37:51,470

You all should have the opportunity to unmute yourself and

663

01:37:51,470 --> 01:37:52,810

also choose to go on camera.

664

01:37:53,150 --> 01:37:58,250

If you have any questions or comments for the,

665

01:37:58,250 --> 01:38:03,510

for the committee on the genomics update and their

666

01:38:03,510 --> 01:38:04,530

next steps.

667

01:38:12,690 --> 01:38:14,170

I'm trying to raise my hand.

668

01:38:14,270 --> 01:38:14,710

Is it working?

669

01:38:17,090 --> 01:38:19,150

It's, I see that you've come off mute.

670

01:38:19,270 --> 01:38:20,430  
Go ahead, Dr. Esteban.

671  
01:38:20,850 --> 01:38:22,850  
I'll try to raise my hand, but anyway.

672  
01:38:24,430 --> 01:38:28,610  
As with the other subcommittee, most impressive work.

673  
01:38:30,730 --> 01:38:32,030  
Clearly, I'm biased.

674  
01:38:32,350 --> 01:38:35,210  
I really, really care about, not that I don't care

675  
01:38:35,210 --> 01:38:37,330  
about the other charge, but I care a lot about

676  
01:38:37,330 --> 01:38:39,350  
this one because of my direct impact on my job.

677  
01:38:42,750 --> 01:38:43,650  
I'm going to start.

678  
01:38:45,710 --> 01:38:48,470  
I'm glad that you guys were very passionate and open

679  
01:38:48,470 --> 01:38:50,030  
and communicating and everything.

680  
01:38:50,430 --> 01:38:51,730  
I didn't expect any less.

681  
01:38:52,170 --> 01:38:54,330  
So thank you for being so open.

682  
01:38:54,790 --> 01:38:56,930  
That's why we have these committees the way we have

683  
01:38:56,930 --> 01:38:59,890  
them, so people can come and feel free to engage

684

01:38:59,890 --> 01:39:00,650

and open up.

685

01:39:02,330 --> 01:39:05,970

I'm very curious to read the report to see what

686

01:39:05,970 --> 01:39:08,070

the clear pathway forward is.

687

01:39:10,150 --> 01:39:14,650

Obviously, we're not the only country in the world that's

688

01:39:14,650 --> 01:39:17,330

doing this, and so I'm curious to see how this

689

01:39:17,330 --> 01:39:19,590

matches with things that we've heard in other parts of

690

01:39:19,590 --> 01:39:19,910

the planet.

691

01:39:21,250 --> 01:39:25,110

I'm very, very curious as to the recommendations for the

692

01:39:25,110 --> 01:39:27,810

follow-ups that we will have from this.

693

01:39:28,470 --> 01:39:29,850

I know you're going to work on the report, and

694

01:39:29,850 --> 01:39:31,530

we're going to get to see it and do things

695

01:39:31,530 --> 01:39:33,990

like this, and you all have different parts that you're

696

01:39:33,990 --> 01:39:36,690

going to add to the report, and that's fine, but

697

01:39:36,690 --> 01:39:38,230  
I don't want to lose momentum.

698  
01:39:39,370 --> 01:39:43,650  
So within the context of NACMCF, or even if you

699  
01:39:43,650 --> 01:39:47,430  
want to remain within that context, I would love to

700  
01:39:47,430 --> 01:39:51,630  
hear your advice, input, or at least ideas on how

701  
01:39:51,630 --> 01:39:56,190  
do we keep this momentum going so we don't lose

702  
01:39:56,190 --> 01:39:59,170  
what we've gained through all this passion this week.

703  
01:40:00,990 --> 01:40:01,950  
I'm going to stop there.

704  
01:40:05,550 --> 01:40:09,810  
I look forward to reading our clear, concise thoughts forward

705  
01:40:09,810 --> 01:40:12,530  
to you, too, of what we think the action should

706  
01:40:12,530 --> 01:40:14,690  
be, because based on our conversation today, we've got a

707  
01:40:14,690 --> 01:40:18,230  
lot of different things you can implement, Dr. Esteban, but

708  
01:40:18,230 --> 01:40:21,190  
I think what came up by multiple different members, and

709  
01:40:21,190 --> 01:40:23,010  
I would pass the mic over to hear Dr. Adeta

710  
01:40:23,010 --> 01:40:26,550  
as well for his opinion and input, but there was

711

01:40:26,550 --> 01:40:29,510

a lot of discussions and questions about the same thing,

712

01:40:29,610 --> 01:40:31,670

and can we get together again in person?

713

01:40:32,550 --> 01:40:34,630

And so I know I hate saying that, so I'm

714

01:40:34,630 --> 01:40:38,630

looking at you, Krystal, and saying I'm so sorry, but

715

01:40:38,630 --> 01:40:43,490

really this sort of the gelling that we had together

716

01:40:43,490 --> 01:40:45,730

and the idea of flow of exchange I think was

717

01:40:45,730 --> 01:40:46,990

extraordinarily valuable.

718

01:40:47,450 --> 01:40:49,510

Our time here needs to be done, because we now

719

01:40:49,510 --> 01:40:51,650

need to go home and do research and get into

720

01:40:51,650 --> 01:40:56,190

the published literature, but the support that we could have

721

01:40:56,190 --> 01:41:00,050

to even come and do this again maybe early in

722

01:41:00,050 --> 01:41:02,330

the new year to say, okay, now we've done a

723

01:41:02,330 --> 01:41:03,730

little bit more of the work, how do we button

724

01:41:03,730 --> 01:41:07,470  
it up, I think would be extraordinarily valuable for us.

725  
01:41:08,330 --> 01:41:11,650  
I'll say if it was my decision, it's always going

726  
01:41:11,650 --> 01:41:12,350  
to be a yes.

727  
01:41:14,110 --> 01:41:15,130  
We know there's limitations.

728  
01:41:15,930 --> 01:41:17,990  
But I put that out there so that it's on

729  
01:41:17,990 --> 01:41:20,090  
the official record.

730  
01:41:20,090 --> 01:41:20,710  
There you go.

731  
01:41:21,130 --> 01:41:22,550  
Go ahead, Vik.

732  
01:41:24,530 --> 01:41:25,490  
This is Vik Dutta.

733  
01:41:25,670 --> 01:41:29,590  
So I don't have anything specific to add except just

734  
01:41:29,590 --> 01:41:32,550  
to kind of give you an outset and perspective of

735  
01:41:32,550 --> 01:41:34,450  
how committee has been doing its work.

736  
01:41:34,850 --> 01:41:37,430  
The amount of progress we made in the last two

737  
01:41:37,430 --> 01:41:40,390  
and a half days is light years ahead of what

738

01:41:40,390 --> 01:41:42,390  
we have been able to do over months, and I'm

739

01:41:42,390 --> 01:41:43,830  
seeing a lot of nods in the room.

740

01:41:44,850 --> 01:41:50,290  
And so that's how we would recommend, Dr. Esteban, to

741

01:41:50,290 --> 01:41:52,130  
answer your question, keep the momentum going.

742

01:41:52,650 --> 01:41:55,830  
Having said that, we have all, all of us have

743

01:41:55,830 --> 01:41:56,650  
our work cut out.

744

01:41:57,390 --> 01:42:00,390  
So it's not going to be a slowdown for us.

745

01:42:00,490 --> 01:42:04,490  
You may not see the work under the sort of

746

01:42:04,490 --> 01:42:05,390  
radar happening.

747

01:42:05,590 --> 01:42:09,550  
But, you know, hopefully, as we continue to move forward,

748

01:42:09,710 --> 01:42:13,470  
we'll be able to debrief you on more specifics that

749

01:42:13,470 --> 01:42:15,670  
the committee comes up with.

750

01:42:16,450 --> 01:42:16,790  
Yeah.

751



01:42:17,670 --> 01:42:19,830  
Real quick to add to, and I'm going to kind

752  
01:42:19,830 --> 01:42:21,550  
of toss it back to our group out a little

753  
01:42:21,550 --> 01:42:24,290  
bit, but you kind of mentioned some things that are

754  
01:42:24,290 --> 01:42:26,910  
being done globally, right?

755  
01:42:27,030 --> 01:42:28,370  
And saying how consistent.

756  
01:42:28,630 --> 01:42:29,950  
Oh, you know, that was a big part of the

757  
01:42:29,950 --> 01:42:31,010  
topic of conversation.

758  
01:42:31,230 --> 01:42:33,650  
We talked a lot about, well, this approach is being

759  
01:42:33,650 --> 01:42:36,510  
used by EFSA or over in the EU or New

760  
01:42:36,510 --> 01:42:38,870  
Zealand demoed this type of work in this area based

761  
01:42:38,870 --> 01:42:39,610  
on attribution.

762  
01:42:39,710 --> 01:42:41,270  
And so there was a lot of that type of

763  
01:42:41,270 --> 01:42:41,750  
discussion.

764  
01:42:41,750 --> 01:42:44,470  
So I want you to know that is in consideration

765

01:42:44,470 --> 01:42:49,090

and we look forward to incorporating and comparing contrasting pros

766

01:42:49,090 --> 01:42:52,150

and cons in our recommendations on how to move forward.

767

01:42:52,250 --> 01:42:54,730

Does anybody want to add anything to that global perspective?

768

01:42:55,050 --> 01:42:58,150

I'm looking obviously at you, Dr. Havelaar, because you bring

769

01:42:58,150 --> 01:43:01,090

such a great global vision as well.

770

01:43:03,690 --> 01:43:07,030

Well, I think that we're going to summarize this very

771

01:43:07,030 --> 01:43:07,290

well.

772

01:43:07,390 --> 01:43:09,570

There's a lot of things that we can learn from

773

01:43:09,570 --> 01:43:12,290

approaches in different parts of the world.

774

01:43:13,250 --> 01:43:15,550

I have had a lot of experience in Europe.

775

01:43:15,730 --> 01:43:18,110

Apparently I've been engaged with New Zealand a lot, so

776

01:43:18,110 --> 01:43:23,170

I'll be happy to share that information and discussion with

777

01:43:23,170 --> 01:43:26,350

people who know the US system better, see how that

778

01:43:26,350 --> 01:43:28,350  
can be applicable, what we can learn from that.

779  
01:43:28,470 --> 01:43:31,230  
But I think certainly, I mean, we talked also about

780  
01:43:31,230 --> 01:43:32,190  
global gene pools.

781  
01:43:32,190 --> 01:43:36,170  
The next AMR problem in the US is probably not

782  
01:43:36,170 --> 01:43:40,050  
going to come from being originating here.

783  
01:43:40,170 --> 01:43:41,990  
It may come from another area in the world where

784  
01:43:41,990 --> 01:43:45,030  
we know AMR and tuberculosis is much heavier than

785  
01:43:45,030 --> 01:43:45,330  
here.

786  
01:43:45,830 --> 01:43:47,710  
So we'll have to, that's I think the idea of

787  
01:43:47,710 --> 01:43:51,050  
the global watch list, what's emerging in Southeast Asia and

788  
01:43:51,050 --> 01:43:54,790  
other areas where we know that antibiotics are used both

789  
01:43:54,790 --> 01:43:58,430  
in human and animal medicine in a large degree.

790  
01:43:58,610 --> 01:44:01,770  
What's happening there and how much concern do we need

791  
01:44:01,770 --> 01:44:02,150  
to have?

792

01:44:02,270 --> 01:44:04,750

What should be on our watch list that might make

793

01:44:04,750 --> 01:44:07,390

it into our food supply and into our people?

794

01:44:12,200 --> 01:44:13,160

Thank you.

795

01:44:14,240 --> 01:44:17,900

I'm always in favor of trying to keep the momentum

796

01:44:17,900 --> 01:44:19,420

going by an in-person meeting.

797

01:44:20,260 --> 01:44:23,420

It's a lot of work to plan this, but this

798

01:44:23,420 --> 01:44:26,680

is now a couple times we've done this, at least

799

01:44:26,680 --> 01:44:28,540

since I've been the designated federal officer.

800

01:44:28,920 --> 01:44:31,740

And I agree, just watching you all work, I can

801

01:44:31,740 --> 01:44:32,860

see the difference.

802

01:44:33,220 --> 01:44:40,380

So hopefully, again, we'll have the magma fairies of ENR

803

01:44:40,380 --> 01:44:43,280

on our side.

804

01:44:43,380 --> 01:44:43,780

We'll see.

805

01:44:44,560 --> 01:44:47,540  
But we will also continue to do whatever we need

806  
01:44:47,540 --> 01:44:51,300  
to do to support the entire committee virtually so that

807  
01:44:51,300 --> 01:44:53,100  
we can certainly be successful.

808  
01:44:54,420 --> 01:44:58,320  
Are there any other questions or comments from our committee

809  
01:44:58,320 --> 01:45:00,960  
members or our Executive Committee members online?

810  
01:45:01,520 --> 01:45:03,160  
I see we have a hand in the back.

811  
01:45:05,100 --> 01:45:06,240  
Hey, David Goldman.

812  
01:45:07,200 --> 01:45:10,380  
Thank you for that very comprehensive genomics report.

813  
01:45:10,840 --> 01:45:12,820  
I have a question that kind of sits at the

814  
01:45:12,820 --> 01:45:16,620  
intersection of a very technical part of your work as

815  
01:45:16,620 --> 01:45:20,680  
well as the maybe question three, part three, having to

816  
01:45:20,680 --> 01:45:22,080  
do with the regulatory approach.

817  
01:45:22,920 --> 01:45:25,840  
And that is, based on what you've learned so far,

818  
01:45:26,100 --> 01:45:28,680  
and given that there are four pathogens of public health

819

01:45:28,680 --> 01:45:33,260

concern, do you think there's enough common understanding about virulence

820

01:45:33,260 --> 01:45:37,780

that we can come up with one sensible regulatory framework?

821

01:45:38,100 --> 01:45:41,240

Or based on what I know, for example, about STEC

822

01:45:41,240 --> 01:45:44,380

virulence and salmonella virulence, which are very different as I

823

01:45:44,380 --> 01:45:46,560

understand it, are we going to end up with four

824

01:45:46,560 --> 01:45:47,860

different sort of approaches?

825

01:45:48,140 --> 01:45:50,640

I mean, have you thought about that and how that's

826

01:45:50,640 --> 01:45:51,400

going to play out?

827

01:45:54,360 --> 01:45:56,180

Yes, we've had a little bit of that discussion.

828

01:45:56,360 --> 01:45:59,040

What I'll tell you is I wouldn't call them what's

829

01:45:59,040 --> 01:46:01,420

being considered four different regulatory approaches.

830

01:46:01,720 --> 01:46:07,080

Probably maybe four different definitions of what would be appropriate.

831

01:46:07,680 --> 01:46:10,100

You know, we really took a lot to focus on,

832

01:46:10,180 --> 01:46:11,660  
you know, we know a lot more about E.

833  
01:46:11,720 --> 01:46:15,960  
coli than we do about listeria, than we do about

834  
01:46:15,960 --> 01:46:17,460  
salmonella, than we do about campylobacter.

835  
01:46:17,560 --> 01:46:20,020  
We ranked them and said, what do we know about

836  
01:46:20,020 --> 01:46:21,960  
when it comes to those virulence genes and what do

837  
01:46:21,960 --> 01:46:22,700  
we not know?

838  
01:46:23,260 --> 01:46:25,600  
There's a lot of discussion, too, as if we take

839  
01:46:25,600 --> 01:46:28,020  
a gene-based approach, right, and we say, if it

840  
01:46:28,020 --> 01:46:31,840  
has these two or three things, then that's where the

841  
01:46:31,840 --> 01:46:33,700  
regulatory action may need to be taken.

842  
01:46:34,700 --> 01:46:36,880  
Do we catch other pathogens?

843  
01:46:36,920 --> 01:46:38,720  
Like, if you're doing that with E.

844  
01:46:38,800 --> 01:46:41,260  
coli, are we going to catch some Shigella and what

845  
01:46:41,260 --> 01:46:42,480  
kind of problems we have with that?

846

01:46:42,660 --> 01:46:44,220

So, those are things we're talking about.

847

01:46:44,300 --> 01:46:46,820

We don't have the answer or recommendation yet, but come

848

01:46:46,820 --> 01:46:49,020

back to us in a little bit, and hopefully we'll

849

01:46:49,020 --> 01:46:50,000

have more of a thought.

850

01:46:56,560 --> 01:46:58,700

Yeah, Dr. Goldman, the only thing I would add is

851

01:46:58,700 --> 01:47:01,260

we have to respect the biology of the organism, right?

852

01:47:01,360 --> 01:47:04,880

So, what we are, what we know and how we

853

01:47:04,880 --> 01:47:08,200

are, how our public health system is set up today

854

01:47:10,200 --> 01:47:11,740

is not ideal.

855

01:47:12,640 --> 01:47:15,020

And again, this is, I'm agreeing with Dr. McCulloch, just

856

01:47:15,020 --> 01:47:16,120

providing a different context.

857

01:47:16,980 --> 01:47:19,540

But at the same time, I don't think we should

858

01:47:19,540 --> 01:47:22,860

try to fit it into, you know, that narrow framework

859



01:47:22,860 --> 01:47:24,620  
because it really is diverse.

860  
01:47:24,860 --> 01:47:27,300  
And we spend a lot of time talking about exposure

861  
01:47:27,300 --> 01:47:30,180  
and host factors as it relates to the public health

862  
01:47:30,180 --> 01:47:31,440  
outcome and the clinical outcome.

863  
01:47:31,660 --> 01:47:34,720  
So, it likely will not change because that's just the

864  
01:47:34,720 --> 01:47:35,960  
way these organisms are.

865  
01:47:36,840 --> 01:47:39,800  
But having said that, closing gaps on what we are

866  
01:47:39,800 --> 01:47:41,880  
currently doing to what we could be doing, what we

867  
01:47:41,880 --> 01:47:44,680  
should be doing, is definitely going to be the focus

868  
01:47:44,680 --> 01:47:45,680  
for us going forward.

869  
01:47:48,080 --> 01:47:51,180  
And we have another question here.

870  
01:47:51,440 --> 01:47:52,040  
Oh, there's another.

871  
01:47:52,720 --> 01:47:55,620  
We also have, yeah, Dr. Prater has his hand up.

872  
01:47:56,000 --> 01:47:56,940  
Go ahead, please.

873

01:47:58,180 --> 01:47:59,400

Thanks, Dr. Southern.

874

01:47:59,460 --> 01:48:02,660

I just want to, on behalf of FDA, express my

875

01:48:02,660 --> 01:48:05,080

appreciation to the genomics subcommittee.

876

01:48:05,320 --> 01:48:08,820

So, the work that you're doing is quite valuable, not

877

01:48:08,820 --> 01:48:11,420

only to FSIS, but to us as well, and I'm

878

01:48:11,420 --> 01:48:12,920

sure other agencies.

879

01:48:13,980 --> 01:48:15,900

I wanted to echo some of the points that you

880

01:48:15,900 --> 01:48:17,920

made about international collaboration.

881

01:48:18,320 --> 01:48:21,520

We are talking with our counterparts in the EU and

882

01:48:21,520 --> 01:48:24,880

other places in the as well, trying to encourage them

883

01:48:24,880 --> 01:48:29,420

to, you know, share information through our genome tracker network.

884

01:48:29,800 --> 01:48:33,680

But we recognize that some of the value in information

885

01:48:33,680 --> 01:48:35,160

sharing comes with the metadata.

886

01:48:35,700 --> 01:48:39,200  
But that also is the place that faces some of

887  
01:48:39,200 --> 01:48:42,620  
the greatest challenges because that starts to include other types

888  
01:48:42,620 --> 01:48:43,260  
of information.

889  
01:48:43,480 --> 01:48:46,780  
So, in your report, if you have recommendations or things

890  
01:48:46,780 --> 01:48:51,480  
that would facilitate our ability to share data, genomic data,

891  
01:48:51,600 --> 01:48:56,280  
including metadata, that would be really helpful because we know

892  
01:48:56,280 --> 01:48:59,780  
that our industry colleagues have quite a lot of data.

893  
01:48:59,940 --> 01:49:04,140  
We know that other regulatory counterparts across the world have

894  
01:49:04,140 --> 01:49:04,380  
data.

895  
01:49:04,480 --> 01:49:06,840  
And I think real value here is when we can

896  
01:49:06,840 --> 01:49:09,980  
share this information and be able to use it.

897  
01:49:10,180 --> 01:49:12,200  
So, thank you very much for your work, and we're

898  
01:49:12,200 --> 01:49:13,200  
very grateful.

899  
01:49:20,360 --> 01:49:20,800  
Okay.

900

01:49:21,620 --> 01:49:24,120

Thank you very much, really.

901

01:49:24,300 --> 01:49:27,420

It's very interesting what we heard from the summary.

902

01:49:27,920 --> 01:49:34,280

There are a lot of things, particularly for Q group

903

01:49:34,280 --> 01:49:38,160

two, that is an important issue on viral risk factor,

904

01:49:38,260 --> 01:49:39,400

what we are doing, number one.

905

01:49:40,440 --> 01:49:41,860

I'm quite sure we can get a lot of help

906

01:49:41,860 --> 01:49:42,620

from you.

907

01:49:46,690 --> 01:49:47,170

Okay.

908

01:49:47,170 --> 01:49:48,150

Can you hear me now?

909

01:49:48,590 --> 01:49:49,050

Oh, sorry.

910

01:49:49,210 --> 01:49:49,410

Okay.

911

01:49:49,910 --> 01:49:50,130

Yeah.

912

01:49:50,430 --> 01:49:51,130

Thank you very much.

913

01:49:51,230 --> 01:49:51,330

Okay.

914

01:49:51,890 --> 01:49:53,830

In fact, I have two questions.

915

01:49:53,950 --> 01:49:56,390

One thing, you are using genomics.

916

01:49:56,710 --> 01:50:00,530

Now, what I saw from the literature, metabolomics is crossing

917

01:50:00,530 --> 01:50:01,950

the border on food safety.

918

01:50:02,710 --> 01:50:06,810

It's releasing a number of good information, which the other

919

01:50:06,810 --> 01:50:08,710

genomics part cannot do.

920

01:50:09,050 --> 01:50:12,310

So, do you think to consider that metabolomics as a

921

01:50:12,310 --> 01:50:13,970

part of your interest?

922

01:50:14,350 --> 01:50:15,450

That is a fast suggestion.

923

01:50:15,830 --> 01:50:19,070

Number two, one of the things we should recommend as

924

01:50:19,070 --> 01:50:21,510

a molecular detection technology, the PCR.

925

01:50:22,670 --> 01:50:25,770

I'm a little bit scared of using PCR as the

926

01:50:25,770 --> 01:50:31,130

only solution for the only parameter as a diagnostic modality,

927

01:50:31,830 --> 01:50:35,070

because particularly now we're not talking about diagnostic.

928

01:50:35,230 --> 01:50:37,510

Every diagnostic technique has a limitation.

929

01:50:39,250 --> 01:50:40,710

So, what do you think?

930

01:50:40,710 --> 01:50:45,550

I mean, particularly, PCR is detecting the genomics part of

931

01:50:45,550 --> 01:50:46,790

the bacteria.

932

01:50:47,070 --> 01:50:48,410

There is a viability issue.

933

01:50:49,630 --> 01:50:50,370

What do you think?

934

01:50:50,450 --> 01:50:54,330

Is there any means to approach that area?

935

01:50:54,710 --> 01:50:55,570

Thank you very much.

936

01:50:59,550 --> 01:51:01,090

Thank you, Dr. Yellowish.

937

01:51:02,910 --> 01:51:06,190

When you hold the mic, hold your hand up closer.

938

01:51:06,490 --> 01:51:08,610

Yeah, for some reason, it's, yeah.

939

01:51:10,350 --> 01:51:10,870

Yeah.

940

01:51:13,030 --> 01:51:17,790

So, Dr. Teshome, both of those topics were heavily discussed.

941

01:51:19,430 --> 01:51:21,790

And then if you'd recall, I'm going to say like

942

01:51:21,790 --> 01:51:24,090

a little side comment, you know, and this has come

943

01:51:24,090 --> 01:51:26,550

up multiple times, we have to stay practical.

944

01:51:27,350 --> 01:51:32,030

And proteomics, metabolomics are excellent tools, but they're excellent research

945

01:51:32,030 --> 01:51:32,470

tools.

946

01:51:33,270 --> 01:51:36,530

Having said that, we did discuss that there are certain

947

01:51:36,530 --> 01:51:44,070

virulence determinants or adaptation, adaptive genes that, you know, we

948

01:51:44,070 --> 01:51:47,330

see those trends happening on the genomic side, but we

949

01:51:47,330 --> 01:51:50,190

don't know if they're having an implication as it relates

950

01:51:50,190 --> 01:51:53,310

to clinical outcomes or public health in general.

951

01:51:53,750 --> 01:51:56,530

And so, there is a role for confirmation, and that's

952

01:51:56,530 --> 01:51:59,690  
where we captured it in the research gaps, that we

953  
01:51:59,690 --> 01:52:02,810  
probably need to do a better job understanding as it

954  
01:52:02,810 --> 01:52:07,850  
relates to the regulatory actions and framework, what role can

955  
01:52:07,850 --> 01:52:09,530  
these technologies play, if at all.

956  
01:52:09,810 --> 01:52:13,390  
So, we gave ourselves some space to really take a

957  
01:52:13,390 --> 01:52:14,930  
deep dive and understand that.

958  
01:52:16,030 --> 01:52:18,430  
As far as the PCR is concerned, we fully agree.

959  
01:52:18,810 --> 01:52:23,550  
And that's why we are looking into technologies that are

960  
01:52:23,550 --> 01:52:27,330  
beyond PCR for a couple of reasons you mentioned here.

961  
01:52:27,450 --> 01:52:31,670  
You know, it's not comprehensive, and there's the live dead

962  
01:52:31,670 --> 01:52:32,110  
issues.

963  
01:52:32,750 --> 01:52:35,110  
And so, again, we gave ourselves plenty of room to

964  
01:52:35,110 --> 01:52:40,130  
discuss different chemistries that could define the live versus dead,

965  
01:52:40,230 --> 01:52:40,450  
you know.



966

01:52:40,510 --> 01:52:42,930

And then we also defined that PCRs and the pros

967

01:52:42,930 --> 01:52:46,730

and cons of what we are, when we do develop

968

01:52:46,730 --> 01:52:49,510

a PCR for whatever attribute.

969

01:52:50,050 --> 01:52:53,110

We understand, we as in, I'm talking with the collective

970

01:52:53,110 --> 01:52:55,650

public health community, that it's not a perfect solution.

971

01:52:56,510 --> 01:52:59,170

And one example of that is we spent a lot

972

01:52:59,170 --> 01:53:03,550

of time discussing targeted amplicon sequencing or targeted NGSs.

973

01:53:03,710 --> 01:53:06,830

You know, it's kind of like an evolving field to

974

01:53:06,830 --> 01:53:08,610

see if we could deploy that.

975

01:53:08,810 --> 01:53:12,510

I'm talking about like in our recommendations as a go

976

01:53:12,510 --> 01:53:15,290

-between, without going to all the way to WGS, as

977

01:53:15,290 --> 01:53:17,050

a tool that could be used more routinely.

978

01:53:17,230 --> 01:53:21,670

I'm putting air quotes here, as an alternative to overcome

979

01:53:21,670 --> 01:53:25,890  
some of these resolution issues, single gene limitations, and so

980  
01:53:25,890 --> 01:53:26,330  
on and so forth.

981  
01:53:26,910 --> 01:53:29,570  
And then those technologies also overcome the live versus dead

982  
01:53:29,570 --> 01:53:29,970  
as well.

983  
01:53:30,050 --> 01:53:32,090  
So, again, the goal is to capture as much as

984  
01:53:32,090 --> 01:53:35,350  
we can about these technologies and how they can be

985  
01:53:35,350 --> 01:53:38,030  
put together and maybe do some brainstorming along the way.

986  
01:53:38,430 --> 01:53:40,670  
So, yes, we are considering both of those.

987  
01:53:41,170 --> 01:53:41,350  
Thank you.

988  
01:53:42,330 --> 01:53:42,890  
Great.

989  
01:53:43,790 --> 01:53:44,670  
All right.

990  
01:53:46,070 --> 01:53:47,470  
I'm looking at the time.

991  
01:53:47,710 --> 01:53:51,010  
And once again, we have found ourselves in a discussion

992  
01:53:51,010 --> 01:53:52,730  
that I hate to end.

993

01:53:54,070 --> 01:53:56,310

But we do want to be mindful of the time.

994

01:53:56,690 --> 01:54:00,590

So, this does bring us to, not only to the

995

01:54:00,590 --> 01:54:03,010

end of our agenda, but also to the end of

996

01:54:03,010 --> 01:54:05,710

our week together in person with the committee.

997

01:54:05,910 --> 01:54:08,790

As you mentioned, you guys now have your marching orders

998

01:54:08,790 --> 01:54:11,450

to go back and make some more things happen.

999

01:54:11,710 --> 01:54:13,950

And then so that when we come back together, we'll

1000

01:54:13,950 --> 01:54:15,250

have even more progress.

1001

01:54:16,030 --> 01:54:16,710

I'm really excited.

1002

01:54:16,850 --> 01:54:19,650

And I've really had enjoyed the opportunity to get to

1003

01:54:19,650 --> 01:54:23,010

know and interact with each and every one of you

1004

01:54:23,010 --> 01:54:24,070

this week.

1005

01:54:24,470 --> 01:54:27,010

And again, I do see firsthand your commitment to the

1006

01:54:27,010 --> 01:54:27,350  
charges.

1007

01:54:27,350 --> 01:54:31,510  
And we are incredibly grateful, not only as USDA, but

1008

01:54:31,510 --> 01:54:38,170  
as NACMCF, which comprises USDA, FDA, CDC, Department of Defense,

1009

01:54:38,250 --> 01:54:41,830  
Veterinary Services, as well as NOAA National Marine Fishery Service.

1010

01:54:42,610 --> 01:54:45,970  
So, just a reminder for those out in the public

1011

01:54:45,970 --> 01:54:48,550  
world that are not already sitting here at this table

1012

01:54:48,550 --> 01:54:51,630  
as a member, if you want to one day nominate

1013

01:54:51,630 --> 01:54:55,550  
yourself or another person who you think would be a

1014

01:54:55,550 --> 01:54:58,830  
great NACMCF member, our nomination open period is coming up

1015

01:54:58,830 --> 01:54:59,170  
soon.

1016

01:54:59,290 --> 01:55:01,010  
I don't have an exact date for that.

1017

01:55:01,090 --> 01:55:03,170  
But in the next month or in the next couple

1018

01:55:03,170 --> 01:55:05,930  
of months, please be on the lookout for that nomination

1019

01:55:05,930 --> 01:55:11,050

open period announcement in our federal register and constituent update

1020

01:55:11,050 --> 01:55:16,590

and also maybe some social media outlets like LinkedIn, the

1021

01:55:16,590 --> 01:55:18,330

USDA FSIS LinkedIn.

1022

01:55:19,090 --> 01:55:22,190

So, I want to thank the NACMCF members and also

1023

01:55:22,190 --> 01:55:25,370

our subject matter experts that have been alluded to in

1024

01:55:25,370 --> 01:55:25,950

the presentations.

1025

01:55:27,110 --> 01:55:29,730

We've had some subject matter experts even come to us

1026

01:55:29,730 --> 01:55:32,450

just this week after the discussion at the plenary and

1027

01:55:32,450 --> 01:55:35,770

say, I might have some information that would be helpful

1028

01:55:35,770 --> 01:55:36,850

to your committee.

1029

01:55:37,090 --> 01:55:39,290

If that's you and you're out there and you think

1030

01:55:39,290 --> 01:55:41,650

that you might have some information that's helpful to the

1031

01:55:41,650 --> 01:55:44,550

work that they're doing, especially where some of the knowledge

1032

01:55:44,550 --> 01:55:47,230

gaps were mentioned, please don't hesitate to reach out to

1033

01:55:47,230 --> 01:55:51,730

myself, Dr. Krystal Southern, at NACMCF, that's

1034

01:55:51,730 --> 01:55:58,530

N-A-C-M-C-F, at USDA.gov. And so,

1035

01:55:58,690 --> 01:56:01,470

I do want to also thank our Executive Committee for

1036

01:56:01,470 --> 01:56:02,470

your support and leadership.

1037

01:56:03,390 --> 01:56:06,910

And especially, there aren't many ways I can ever say

1038

01:56:06,910 --> 01:56:09,090

thank you, but to the NACMCF Secretariat, these are the

1039

01:56:09,090 --> 01:56:13,370

volunteers from our individual staffs that have been helping to

1040

01:56:13,370 --> 01:56:17,590

just even escort our committee members, our visitors around the

1041

01:56:17,590 --> 01:56:19,730

building, just even things like that.

1042

01:56:19,750 --> 01:56:22,430

And just making sure you all have a comfortable space

1043

01:56:22,430 --> 01:56:25,090

to conduct your work without many challenges.

1044

01:56:25,930 --> 01:56:29,830

And especially, a special thank you to our advisory committee

1045

01:56:29,830 --> 01:56:33,910

specialist, Mrs. Shantel Williams, who remains off camera, but is

1046

01:56:33,910 --> 01:56:37,090

always in the background helping me and to make everything

1047

01:56:37,090 --> 01:56:37,770

go smoothly.

1048

01:56:38,410 --> 01:56:41,130

So, with that, I want to now turn it over

1049

01:56:41,130 --> 01:56:46,950

to the USDA FSIS Undersecretary for Food Safety and our

1050

01:56:46,950 --> 01:56:51,450

NACMCF Chair to officially close us out, Dr. Emilio Esteban.

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01:56:52,690 --> 01:56:53,570

Thank you, Krystal.

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01:56:53,870 --> 01:56:57,010

And I'm sure that my speechwriter had drafted closing remarks

1053

01:56:57,010 --> 01:56:59,130

for me, but since I'm not there, I have no

1054

01:56:59,130 --> 01:56:59,770

clue what to say.

1055

01:57:00,110 --> 01:57:01,890

So, I'm going to go ad lib, as usual.

1056

01:57:04,750 --> 01:57:08,790

I can't thank the committee enough for the advice you

1057

01:57:08,790 --> 01:57:09,170

give us.

1058

01:57:09,610 --> 01:57:10,990

We really take it to heart.

1059

01:57:11,310 --> 01:57:15,730

We really believe that your advice sets the path for

1060

01:57:15,730 --> 01:57:16,490  
what we want to do.

1061

01:57:17,470 --> 01:57:19,510  
And not only the path, but it's also the foundation

1062

01:57:19,510 --> 01:57:21,670  
for the next steps that we take.

1063

01:57:22,330 --> 01:57:25,310  
So, the work you've done this week is phenomenal.

1064

01:57:26,350 --> 01:57:30,250  
We expect to see or hope to see the next

1065

01:57:30,250 --> 01:57:31,670  
iterations of this.

1066

01:57:32,430 --> 01:57:34,890  
And you have my word that I will try to

1067

01:57:34,890 --> 01:57:40,790  
find the resources so that the engagement is physical, not

1068

01:57:40,790 --> 01:57:41,690  
just virtual.

1069

01:57:42,330 --> 01:57:45,030  
So, I can promise that I'm going to make every

1070

01:57:45,030 --> 01:57:50,770  
effort to find those resources, because there's nothing like sitting

1071

01:57:50,770 --> 01:57:52,370  
around the table and passing a banana.

1072

01:57:52,950 --> 01:57:54,170  
That has to be awesome.

1073



01:57:55,870 --> 01:57:58,030  
So, that's it.

1074  
01:57:58,510 --> 01:57:59,510  
Thank you very much.

1075  
01:58:00,730 --> 01:58:03,910  
I'm apologizing for not being there in person, but I

1076  
01:58:03,910 --> 01:58:06,410  
had to deal with other things outside of the capital

1077  
01:58:06,410 --> 01:58:06,710  
area.

1078  
01:58:08,410 --> 01:58:11,650  
Perhaps Dr. Prater would like to also offer some closing

1079  
01:58:11,650 --> 01:58:12,050  
remarks.

1080  
01:58:13,450 --> 01:58:13,970  
Yes, please.

1081  
01:58:14,110 --> 01:58:14,990  
Go ahead, Dr. Prater.

1082  
01:58:21,780 --> 01:58:25,780  
Well, thank you very much to all the committee members

1083  
01:58:25,780 --> 01:58:29,780  
that have really helped us and will help us as

1084  
01:58:29,780 --> 01:58:31,060  
you develop your report.

1085  
01:58:31,680 --> 01:58:33,100  
This is exciting work.

1086  
01:58:33,240 --> 01:58:35,660  
I mean, you all are really on the cusp of

1087

01:58:35,660 --> 01:58:39,340

addressing some of the most complex public health challenges of

1088

01:58:39,340 --> 01:58:39,900

our time.

1089

01:58:40,620 --> 01:58:44,680

Genomics has such a wonderful opportunity to be able to

1090

01:58:44,680 --> 01:58:46,600

inform our work as we go forward.

1091

01:58:47,200 --> 01:58:51,780

Cronobacter in Powdered Infant Formula is certainly a recent challenge

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01:58:51,780 --> 01:58:55,860

and one that is much more complex, I think, as

1093

01:58:55,860 --> 01:58:58,500

we get to look into it further.

1094

01:58:58,840 --> 01:59:03,120

But the ability to get your advice, your wisdom, your

1095

01:59:03,120 --> 01:59:06,440

good thinking, to draw on the subject matter experts and

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01:59:06,440 --> 01:59:09,960

your professional contacts really helps us a lot, and we

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01:59:09,960 --> 01:59:11,900

are ever grateful for what you're doing.

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01:59:12,240 --> 01:59:15,520

Sincere thanks to Dr. Southern and also to the Executive

1099

01:59:15,520 --> 01:59:18,280

Secretary that has organized this meeting.

1100

01:59:18,400 --> 01:59:20,440  
It sounds like it was a really terrific week.

1101  
01:59:20,540 --> 01:59:21,760  
So, thank you all very much.

1102  
01:59:23,240 --> 01:59:24,100  
Thank you.

1103  
01:59:24,600 --> 01:59:29,200  
So, thank you very much, Drs. Esteban and Dr. Prater,

1104  
01:59:29,400 --> 01:59:32,200  
again, for your leadership as the NACMCF Chair and

1105  
01:59:32,200 --> 01:59:32,520  
Vice-Chair.

1106  
01:59:33,100 --> 01:59:36,800  
We have completed the purpose of today's NACMCF debrief meeting,

1107  
01:59:36,800 --> 01:59:38,080  
and meetings this week.

1108  
01:59:38,140 --> 01:59:39,440  
We now stand adjourned.

1109  
01:59:39,760 --> 01:59:42,700  
I wish you all safe travels to wherever your destination

1110  
01:59:42,700 --> 01:59:43,300  
may be.

1111  
01:59:43,440 --> 01:59:45,520  
And if you're joining us online, I also hope that

1112  
01:59:45,520 --> 01:59:48,780  
you're keeping dry and also safe.

1113  
01:59:49,020 --> 01:59:50,900

And with that, we now stand adjourned.

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01:59:51,000 --> 01:59:51,540

Thank you, everyone.

1115

01:59:51,700 --> 01:59:52,940

Have a good rest of the day.