UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOODS

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PLENARY SESSION

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August 7, 2018
10:00 a.m.

Patriots Plaza III
355 E Street, SW
First Floor Auditorium
Washington, D.C. 20024

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I-N-D-E-X

I-N-D-E-X

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

(8:15 a.m.)

DR. CARTER: Thank you. If you don't know who I am by now, I'm Mark Carter. I'm the DFO. I'm an employee of FSIS. I work for the Office of Public Health Science, and next on our agenda, we're going to hear some remarks from FSIS and FDA.

And I'm going to introduce my Assistant Administrator, Captain Kis Robertson Hale, and she'll be representing our NACMCF Chair, who is Carmen Rottenberg. As I mentioned before, she can't be here with us today.

CAPT. HALE: Good morning, everyone.

DR. CARTER: Try pressing the button.

CAPT. HALE: Good morning and welcome, everyone. It's great to see everyone, and a lot of work has gone into this. So first off, I want to thank the planners for getting us started off to a great meeting.

I'm Kis Robertson Hale. I'm the Deputy Assistant Administrator of the Office of Public Health Science for FSIS. And I'm representing Carmen Rottenberg, our Acting Deputy Under Secretary for Food Safety and the current Chair for NACMCF. She cannot be here today.

To my left is Dr. Mickey Parish, who is the Director of Senior Science Advisor Staff at FDA's Center for Food Safety and Nutrition, CFSAN, and he is filling in today for our NACMCF Vice Chair, Dr. Susan Mayne who also could not attend today.

So this meeting is our plenary meeting for 2018. It's a very important meeting as the Committee is coming together to deliberate on recommendations regarding *Salmonella* control strategies in poultry, as well as virulence factors and attributes that define foodborne Shiga toxin-producing *E. coli* as severe human pathogens from FSIS and FDA, respectively.

Our goal today is for NACMCF to adopt final recommendations for FSIS and FDA by the close of this meeting.

Our two subcommittees worked very intensely on these projects for the last couple of years, so that we could provide this very useful food safety information to both Agencies. On behalf of USDA Food Safety and Inspection Service, FDA and CDC within the Department of Health and Human Sciences, the National Marine Fisheries Services, U.S. Department of Commerce and Veterinary Service Activity at the U.S. Department of Defense, we thank each of you for lending your expertise to this project, and we especially recognize

Subcommittee members and assisting experts for their commitment and hard work that went to the projects. We also commend the entire NACMCF team for their monumental efforts important projects.

At FSIS, we work really hard to advance a science-based public health data driven public health agenda. As the public health agency responsible for ensuring the safety of meat, poultry, processed egg products, as well as Siluriformes products, increasing *Salmonella* illnesses is one of our top most priorities.

However, *Salmonella* still remains a major public health problem and an important cause of illnesses from FSIS regulated products, and poultry, in particular, remains a commodity that's associated with the largest proportion of *Salmonella* illnesses.

So in the Agency, we've taken a number of actions to decrease *Salmonella* illnesses from the products we regulate including poultry. And those actions align to our 5-year strategic plan which is on the web and includes a goal of decreasing illnesses and a goal of modernizing regulations and our inspection procedures based on how we operate as an Agency.

Each year we lay out the specific activities

we plan to accomplish. We post those on our website, and those represent our annual plans.

One way we try to ensure that we are modernizing our policies and inspection systems is by incorporating the best available science into our decisions as an Agency.

FSIS is continuing to use science and risk assessments to develop policies and regulations that will protect the public's health by decreasing foodborne illnesses. And to do so, we make sure we have at our fingertips the most current science in our implementing state of the art data analysis and risk assessment.

Also to that end, we are also reaching out to our research partners and external advisors to ensure we have the necessary information to help us solve the public health problems that we are regularly confronted with.

So looking ahead, controlling *Salmonella* will likely take a multi-pronged approach with a combination of approaches on farm, at the establishment and beyond, and we will continue to work with our partner agencies, researchers and industry, many of whom are here today, to control *Salmonella* in poultry.

Likewise, I'm certain that the FDA is looking forward to receiving the Committee's recommendations on virulence factors and attributes that define STEC as severe human pathogens.

In conclusion, I again thank everyone who has served on NACMCF and for your work on these projects. You serve an important advisory role, and your contributions really do help us built a better food safety system. Thank so much for your time and your dedication to the food safety and public health, and I really look forward to the discussion here today.

Now I'll turn the floor over to Dr. Mickey Parish, the Director of the Senior Science Advisor Staff at CFSAN and our representative for the NACMCF Vice Chair.

DR. PARISH: Thank you, Kis. I would like to join you in the comments that you've made today to welcome everyone. Welcome to your Nation's capital. We appreciate your time and effort and your dedication that you're willing to put a not insignificant amount of time for the next 2 years into these efforts.

I would like to acknowledge not just FDA and FSIS, but also CDC, DoD, NOAA, for their strong support of NACMCF in the past and continuing strong

support of NACMCF in the future, and also the NACMCF Executive Secretariat, Karen, Mark and others who have made this possible. It takes a lot of work and effort to pull together administratively, using Government regulations to make sure that we can meet together as a group of experts.

So we have two new charges to address. I think both of them are quite important. Obviously the use of water, of recycled water in meat processing is a critical concerning as is the FDA charge on process controls and addressing products and their use in microbiological criteria.

So we look forward to your response in 2 years, and we look forward to the adoption of two products that were produced in the last cycle.

So I would like to recognize Alison O'Brien and Carolyn Hovde, for their work, Gary Acuff and Guy Loneragan for their work on those charges and thank you for that, for what you've done.

I would also like to recognize coming up, Peggy Cook and Omar Oyarzabal for the work that they're going to do in leading one of the subcommittees and also Kathy Glass and Laurie Post for their work that they have agreed to do in leading the FDA subcommittee.

In addition to Committee members, you'll notice that there will be technical advisors available for use of the subcommittees. FDA has provided a number of technical advisors. It may be possible to bring in other technical advisors for the use from outside, perhaps academia, as needed, and we would encourage you to do that if you reach an impasse where you need some additional information.

Please feel free to ask. We're happy to help provide that information as necessary and to try to twist a few arms of our friends in academia or industry to get them to help if necessary.

We have a broad community of experts here, academia, industry, federal government, state government, as well as consumer group and we are very happy to have everyone's input.

For FDA, I just wanted to point out the importance of preventive controls and potential for product testing and it's impact as a verification tool, remains an incredibly important aspect of FSMA. We wrote the charge with a very specific concern in mind, and we have a number of questions there. We understand that the Subcommittee when they read the charge and they see the questions, may have some additional questions themselves about what was our

intent.

So with that in mind, Jenny Scott will be representing FDA as the FDA member of the Committee. She'll be on the Subcommittee, and we will have additional FDA personnel available to help answer any questions and provide input.

So I served on this committee two cycles ago myself as the FDA member. It was highly memorable experience. That was the DoD charge on micro criteria, had a great time. I learned to love this building. You come down here and spend 2 or 3 days with people that you don't see but every once in a while. The food trucks are wonderful. The food trucks outside here are wonderful. There are good restaurants nearby as well, and you'll learn to have a soft spot in your heart for coming here and working together on this Committee.

So thank you again for your efforts and your efforts in the past as well as the efforts you're going to put into this, in the next few years and we look for, as Kis said, to your reports to the Agencies in the future.

So with that, I'll turn it back over to Mark, I believe, for continuing with the agenda.

DR. CARTER: Thank you, Mickey. Thank you,

Kis. All right.

Next on the agenda is a roll call. So this is the official part of the meeting. We need everyone to state their name, everyone who's here, to state their name and affiliation, and this is for the record. This goes on the public record for the NACMCF minutes for our meeting. So I will start.

I'm Mark Carter, and I'm with FSIS. You'll need to press the button on your microphone when you speak.

MS. SCOTT: Good morning. I'm Jenny Scott. I'm with FDA's Center for Food Safety and Applied Nutrition.

DR. DIEZ: Hi, Francisco Diez, Center for Food Safety, University of Georgia.

DR. MELTON-CELSA: Good morning. I'm Angela Melton-Celsa. I'm with Uniformed Services University.

MS. McMAHON: Wendy McMahon with Silliker.

DR. EIFERT: Joe Eifert, Virginia Tech, Food Science and Technology.

DR. ZAGMUTT: Francisco Zagmutt, Epix Analytics in Fort Collins, Colorado.

DR. LEWANDOWSKI: Patty Lewandowski, Florida Department of Health.

DR. DICKSON: Jim Dickson, Iowa State

University.

DR. TAUXE: Rob Tauxe, Centers for Disease Control and Prevention.

DR. MBANDI: Evelyne Mbandi, FSIS.

DR. LIANG: Art Liang -- oh, excuse me.

CAPT. HALE: Kis Robertson Hale, FSIS.

DR. PARISH: Yeah, Mickey Parish, FDA.

DR. LIANG: Art Liang, CDC. I'm a member of the Executive Committee.

COL HANFELT: Margery Hanfelt, Department of Defense, Veterinary Services.

DR. WILMA: Alisa Wilma, Department of Defense, Veterinary Services.

DR. ELLIOTT: Phil Elliott, Kellogg Company.

DR. OLIVER: Haley Oliver, Food Science, Purdue University.

MS. DAVIS: De Ann Davis, Church Brothers Farms.

DR. ACUFF: Gary Acuff, Texas A&M University.

DR. HOVDE: Hi, everyone. Carolyn Hovde, University of Idaho.

DR. COOK: Petty Cook, Tristrata Group.

MR. ASMUS: Aaron Asmus, Hormel Foods.

DR. TRINETTA: Valentina Trinetta, Kansas

State University.

DR. KOOHMARAIE: Mohammad Koohmaraie, IEH Laboratories.

MS. COFFMAN: Vanessa Coffman, The Keep Antibiotics Working Coalition.

MR. RUBY: John Ruby, Church & Dwight, Animal Production.

DR. KOTTAPALLI: Bala Kottapalli, ConAgra Brands.

DR. PETRAN: I'm Ruth Petran with EcoLab.

DR. STILLWELL: Scott Stillwell, Tyson Foods.

MS. RUPLE: Angela Ruple, NOAA Fisheries.

DR. JAYKUS: Lee-Ann Jaykus, North Carolina State University.

DR. OYARZABAL: Omar Oyarzabal, University of Vermont.

DR. GLASS: Kathy Glass, University of Wisconsin-Madison.

DR. POST: Laurie Post, Deibel Laboratories.

DR. CARTER: Let's continue with the next group behind.

MR. JONES: William Jones, FDA.

MR. DAVIDSON: Gordon Davidson, FDA.

MS. ZERKE: Maria Zerke, FDA.

MS. SILVA: -- Silva, FDA.

MS. HANNON: Bertha Hannon, FDA.

UNIDENTIFIED SPEAKER: Sorry. I'm just a member of the public. I didn't know I was supposed to sit over there.

DR. CARTER: You don't have to sit anywhere special, but we do need to know -- we need to know your name and affiliation, please.

MR. HALL: Sorry. Mark Hall, USDA.

JAMES: James --

MS. HARKLESS: Rita Harkless, Perdue Foods.

DR. CARTER: And over here?

MR. PARSONS: Grant Parsons -- Perdue.

DOLLY: Dolly Abu --

MR. WHEELHOUSE: Carl Wheelhouse, Natural Technologies.

DR. CARTER: Okay.

MR. ALLARD: Marc Allard, FDA.

MS. WALKER: Kimberly Walker, American Society for Microbiology.

MR. FLOOD: Lee Flood, R&S --

KATIE: Katie -- American Native --

MS. COOK: Shannon Cook, DGMA.

MS. DELTA: Alma Delta, TMA.

UNIDENTIFIED SPEAKER: I'm (Indiscernible).

DR. CARTER: I'm sorry. What's your affiliation?

UNIDENTIFIED SPEAKER: I have no affiliation.

DR. CARTER: Okay. Just public?

UNIDENTIFIED SPEAKER: Yes.

DR. PETERSON: Ashley Peterson, National Chicken Council.

MS. MASTERS: Barb Masters, Keystone Foods.

DR. BOOREN: Betsy Booren, OFW Law.

MR. BOWERS: John Bowers, FDA.

DR. FENG: Peter Feng, FDA.

DR. CARTER: Is there anyone who has not yet introduced themselves?

(No response.)

DR. CARTER: Okay. Thank you. So next, before we begin the program in earnest, I have a few business announcements. The four documents we're going to discuss today are all available on the FSIS website. They're also available in hard copies. If you are a member of the Committee, you should have copies of all the documents at your station. So the reports are the thick ones that are stapled together and the charges I believe are in the notebooks. And if you are not a Committee member, there are hard

copies that are available outside. If you didn't pick them up yet, they're out on the countertop on your way in, and you may want to read along as the reports are reviewed.

Okay. As I mentioned earlier, the current NACMCF Charter expires February 3, 2019. The Charter is also available for review on the FSIS website. Very soon, we'll be begin the process to renew the charter so that it renews prior to expiration.

This is a public meeting, and so we have time for public comments. We look forward to input from the public and please note that we are soliciting only comments related to the *Salmonella* control strategies in poultry and the STEC lab reports that we're discussing today. We're not asking for comments beyond the scope of the NACMCF draft reports being discussed today.

For guests wishing to make public comment please come to the microphone, repeat your name and affiliation for the record, before making a comment and please limit your comments to 5 minutes.

Lastly, the Subcommittee chairs, members and assisting experts worked extremely hard on these projects, everyone really stepped up to the plate to make it happen. I want to say many thanks for your

efforts on these reports, and especially to the assisting experts.

So next on our agenda is Dr. Gary Acuff who was our *Salmonella* Subcommittee co-chair who will present the draft document on Controlling *Salmonella* in Poultry for adoption. He will go through the report, and then we will take brief comments. If you have comments that you need to make during the report, Committee members can contribute comments as we go along. Again we're not going to change the report, but we'll just submit a report with your comments as an addition. So if at any given point in the report review, you feel you obliged to make a comment, please interrupt and you may make your comments. Dr. Acuff.

DR. ACUFF: Thank you, Mark. So our Subcommittee was chaired by Dr. Guy Loneragan and I was co-chair. Guy could not be here today. So I agreed to run through the report.

We have received comments from most of the Subcommittee members on the final draft, and we've also received comments from new Committee members, Drs. Eifert, Zagmutt, Scott and Glass. So we have all those comments also.

So our intent at this point is to make final changes to the document but they're for the most part

minor and the report will probably stand as it is at this point.

So going through what we have so far, the report is in response to the questions posed by the USDA, FSIS, regarding poultry, *Salmonella* in poultry. We had six questions that were provided to the Subcommittee, and the organization of the document is -- we have an executive summary where we provided very brief responses to the questions, and then were not asked for a recommendations section, but we did that anyway because we couldn't help ourselves.

So we provided our recommendations and then we did an introduction, talked about all of the questions in detail, and then you can see in Section 4, we answered each question in detail with quite an extensive discussion.

So I need to go through -- we need to go through each page and ask if there are comments. Is that -- if I turned on the microphone, you could to respond to me.

(Laughter.)

DR. ACUFF: All right. So if anyone has comments, then I think what we'll do is go through the document a page at a time and if you have anything you want to address, then speak up, and we'll make note.

Is that correct?

Okay. So starting with -- well, let's move past the executive summary to the recommendations. So that will be page 5. Any comments on page 5? On page 6, those are all recommendations.

(No response.)

DR. ACUFF: All right. So the then introduction begins on page 7. The specific charge was on page 8. And then discussion of our first answering the charge on page 9. We basically broke question up into question 1 and 2, and then questions 3, 4 and 5, we broke into working groups, and then we all -- the Subcommittee all came back together to answer question 6.

All right. So responses to each of the questions begins on page 10. The first question was, what criteria defines *Salmonella* that are highly virulent to humans? Are markers serotype specific? And then there was a subquestion, what tools are available for continuing to identify the most virulent foodborne salmonellae?

So any comments, questions about page 10, page 11, page 12 or 13? If anyone behind has a question, just speak up and I'll stop. Page 14.

(No response.)

DR. ACUFF: All right. So page 15, question 2 was, where does *Salmonella* reside inside and on the surface of poultry and how do those populations of bacteria contribute to food contamination? The sub questions were, discuss locations, persistence and resistance to interventions. And then discuss the latest information on the ecology of *Salmonella* within or on poultry regarding the gut, cloaca, bone marrow, the heart, skin follicles/skin surfaces, lymphatic system, immune evasion and other. Discuss strategies to mitigate risk factors at these locations.

So that answer then is on the rest of page 15, 16. Comments on page 17, page 18, page 19, 20, page 21, 22, page 23, 24, page 25? Dr. Scott.

MS. SCOTT: I know we've submitted comments, but I just want to point out that this document will be read by people who are not familiar with FSIS' performance standards, testing procedures and terms like set base sampling and moving window need to be explained in this document.

DR. ACUFF: Correct. Yes. Yeah, we will -- we've developed some text to address that. So we'll definitely cover that in the final document. Thank you.

Okay. Finishing, 25, 26.

(No response.)

DR. ACUFF: Question 3 was in two parts. Question 3, Part A was, would removing flocks of highly *Salmonella*-contaminated birds entering the slaughter plant reduce foodborne illnesses in humans? What are important considerations to arriving at a threshold level, looking at prevalence or load, of *Salmonella* associated with incoming birds that would necessitate additional control steps in the food safety system or HACCP plan?

Our answer to that is on page 27. Any comments there?

(No response.)

DR. ACUFF: Page 28, Part B of that question was, what are they key considerations or steps for an alternative processing scenario if the threshold level is exceeded?

(No response.)

DR. ACUFF: And then Question 4 on page 29, what should raw poultry establishments consider when determining the appropriate level of *Salmonella*, or threshold, that would necessitate additional control steps in the food safety system or HACCP plan?

And then the Committee's response is there on page 29. Any comments on page 29 or 30, page 31,

page 32?

(No response.)

DR. ACUFF: On page 33, we have question 5. As informed by questions 3 and 4, what methods are best suited to measure pathogen levels on animals and in product more rapidly than current tests?

That response is on the bottom of page 33. Any comments or questions on 33, 34?

(No response.)

DR. ACUFF: Also there is a Part B to question 5 on page 35. That is, what is a sampling scenario that would enable an establishment to test incoming birds and product for a threshold *Salmonella* level and have a result in a timely manner so that processing can proceed as appropriate?

Our response is there on page 35. Any comments? Page 36. Comments on page 37?

(No response.)

DR. ACUFF: All right. Question 6, the last question, considering the farm-to-the-table continuum for poultry, what are the top three focus points, control measures or best practices, that would be compatible with industry-wide practices, which could be addressed or implemented to achieve the highest rte of reduction of *Salmonella* with regard to both

foodborne illnesses and on product?

So the Subcommittee actually in typical fashion, instead of identifying three focus points, we identified four answers, because we couldn't limit ourselves to three. So you see the four answers there, and they continue on through page 37. Any comment on page 38, page 39 and page 41?

DR. COFFMAN: Hi, this is Vanessa Coffman. I have a question on page 41, and maybe this is a question for Karen and the group. So we're talking about consumers and what we're going to do to address the consumer role in food safety. And I'm wondering how we're going to communicate these documents to the public at large, you know, nobody going to go from the general community into the general purpose section to read the full document. I'm not sure as to what we're going to do to communicate to the consumer.

DR. ACUFF: So I know it will be posted on the FSIS webpage and Federal Food Protection. I assume that also food safety organizations will pick up that document and help us summarize it but, Evelyn, maybe you can respond to that.

DR. MBANDI: This is Evelyn Mbandi, FSIS. That's correct. We're going to post the report on the web. We will have a constituent update announcing the

availability of this document and hopefully more people will have access to the document in addition to publishing in JFP.

DR. COFFMAN: Okay. So that constituent update is a press release?

DR. MBANDI: Yes, that is correct. We create a press release.

DR. COFFMAN: Okay.

DR. ACUFF: All right. So we have -- in addition to that, we have a three pages, page 53, of references. I'm sure we all read those carefully. Actually the Subcommittee has. But any comments on the references and then that will complete the document?

(No response.)

DR. ACUFF: All right. So speaking on behalf of Dr. Loneragan, the Chair, we appreciate all of the comments that we did receive. There were some very thoughtful and helpful comments. So we will address those. Most of them were minor, just some things that we need to elaborate on, but we will address all of those and take care of in the final document.

DR. CARTER: Thank you, Dr. Acuff.

I'll receive the final report from the

Subcommittee. We will post this on the FSIS website and submit it for publication by the journal of food protection.

The Committee would now like to invite public comments on the *Salmonella* control. Please be reminded that we're soliciting comments only related to this project and the document that Dr. Acuff just discussed.

Again, if you wish to make a public comment, please come to the microphone and repeat your name and affiliation for the record before making a comment.

Are there any public comments? Going once. Going twice.

(No response.)

DR. CARTER: Very well. We'd like to move to adopt this document. And do we have a motion from the Committee members to adopt this as final with the changes as described?

DR. KOOHMARAIE: I'll make a motion.

DR. OYARZABAL: Second.

DR. CARTER: Very well. That is Dr. Koohmaraie's motion to be approved. And second from Omar.

I would propose to approve this as unanimous by acclamation. Is there any dissent? Any dissent

among the Committee?

(No response.)

DR. CARTER: Then it's approved unanimously. Thank you.

And thank you, Dr. Acuff, for your work on the Subcommittee. It is much appreciated. Congratulations on adoption of the document.

Next on our agenda is Dr. Carolyn Hovde Bahach. Our FDA Subcommittee Co-Chair will present for adoption the draft document on virulence factors and attributes that define STEC as severe human pathogens. She will go through the report, and we'll take comments as we go along.

DR. HOVDE: Thank you, Mark, and thank you to everyone who worked on this document. I think we can feel very proud of what we've created. This document is 163 pages long, and so we're not going to go through it exactly page by page but more in groups of pages.

The Chair of this group, of course, was Dr. Alison O'Brien, and I was Co-Chair.

Everyone on the Committee has read and submitted typographical changes and very good, what I would call minor changes that improve the clarity of the document.

Just as the previous document, we start with an executive summary, and that goes from page 1 through page 4.

If there are any comments on the executive summary, please make them now.

(No response.)

DR. HOVDE: There's also on pages 5 through 9, the executive summary of the charge, and what can be found in these pages are the specific questions that we addressed and in bold are the chapters that address each of the charges, and I think for clarity, that will be easy to follow. So that's pages 1 through or through page 9. Comments?

(No response.)

DR. HOVDE: We then have an overview and introduction, the steps of pathogenesis, the prevention detection and surveillance, and then we begin with chapter 1 on page 14, clinical and epidemiologic features of STEC. In that chapter, we covered descriptive epidemiology, surveillance of infections, incidents of serotypes, clinical features and we have incorporated summaries throughout the document. The first summary is on page 16. Comments thus far?

(No response.)

DR. HOVDE: We then talked about the burden of health, I'm sorry, the burden of illness, international burden, and trends and incidence, change in incidence, attributes of health burden and food sources. And there's a summary of that on page 24. Yes, comment.

DR. GLASS: Kathy Glass, UW-Madison. One thing with the C.4 attribution by case-control studies, I think it would be useful if we could include where the failures occurred. For example, they have sliced delicatessen meat as being a risk factor with *E. coli* O157, to identify whether or not this was an occurrence that deli recontamination is a risk factor versus failures in cooking as a risk factor would be I think very useful to put in there.

DR. HOVDE: Where is this?

DR. GLASS: With C.4 from line --

DR. HOVDE: 507?

DR. GLASS: -- 509 specifically --

DR. HOVDE: 509.

Dr. GLASS: -- and 507.

DR. HOVDE: And would that distinction be in the references?

UNIDENTIFIED SPEAKER: It should be referenced.

DR. HOVDE: Yeah, the reference is at the end of that line. I guess I'm asking back to you. But your suggestion is to have specific language in the sentence. Is that correct?

DR. GLASS: Say that again?

DR. HOVDE: Is your suggestion to change the sentence specifically to add your comment --

DR. GLASS: To clarify -- yes.

DR. HOVDE: -- in the sentence, not just the fact that the references could lead someone to that understanding.

DR. GLASS: Yes, to clarify where the failure occurred.

DR. HOVDE: Very good. Further comments about that sentence?

DR. KOOHMARAIE: Well, most of --

DR. CARTER: Please state your name and affiliation.

DR. KOOHMARAIE: Mohammad Koohmaraie, IEH Laboratories, and I was on this Subcommittee. I was just making a comment that the comment that was just made with regard to --

DR. TAUXE: This is Bob Tauxe. The comment on the comment, we'd have to go back and look at the three references that are mentioned here, 93, 194 and

258, but small case control studies comparing exposures of patients in population controls, if I were talking to a patient about what they ate, how would they know whether the sausage or whatever was undercooked or under processed? They would just know they ate processed meat. So that essentially may not have been available to the study. We can go back and look.

DR. HOVDE: Other comments about this?

(No response.)

DR. HOVDE: Okay. Going forward, prevalence on page 25, comments of STEC in cattle, we went through virulence and putative virulence genes of STEC in cattle, prevalence of STEC in food, prevalence in produce, prevalence in beef and dairy products, and that we have an overall chapter summary on page 29. Comments here?

(No response.)

DR. HOVDE: Chapter 2, we talked about virulence profiles and pathogenesis of STEC, talking about serotypes associated with human illness, virulence factors that include colonization factors, all the way to summarize that area on page 35. Comments?

(No response.)

DR. HOVDE: We then talked about Shiga toxin, phage coding of the toxin, summarized that on page 41; talked about other toxins, acid tolerance, approaches to predicting the capacity of STEC to cause severe illness, models to predict virulence, summarized that and animal models and summarized that. The overall chapter 2 summary is on page 47. Comments on these?

(No response.)

DR. HOVDE: Chapter 3 discusses methods to detect and characterize STEC, starting at the bottom of page 47. We did an overview of the protocols used by USDA FSIS, FDA or in clinical settings. We talked about advantages and disadvantages of these methods. On page 55, we did an overview of protocols currently used in the food industry for the detection of STEC, detection of virulence genes and serotype, the advantages and limitations, new and developing high throughput methods on page 61, limitation procedures, PCR, biosensor, microarray, high-throughput methods, genomic clusters and lineages, list prediction, DNA sequencing, transcriptomics and preteomics. And we summarized this chapter on page 70 and 71.

Comments on this section please?

(No response.)

DR. HOVDE: We have Chapter 4, gaps and recommendations, on page 72, 73 through 78, and tables and figures that go through page 99.

Comments on this material?

(No response.)

DR. HOVDE: We've included an appendix with case studies on page 100. On page 106, an appendix that lists the acronyms that were used.

Comments on those appendices?

(No response.)

DR. HOVDE: We've come to the references that start on page 114 to the end of the document.

Comments on the references?

(No response.)

DR. CARTER: Thank you, Dr. Hovde. If there are no further comments for Dr. Hovde, I'd like to personally apologize for a break of protocol. The last time I was in front of you, I usurped the floor from the Committee Chair, which is represented by Captain Kis Robertson Hale, and she should be the one who is actually administering the approval process. Would you like me to do it for the second one?

CAPT. HALE: No, I can do it, but -- thank you. It's no big deal.

So we'll see if there's any public comments

before we move.

(No response.)

CAPT. HALE: All right. Hearing none, we'd like to move to adopt this document. Can I get a motion from the Committee to adopt this document as final?

DR. ACUFF: Motion to approve.

CAPT. HALE: Do I have a second?

DR. DIEZ-GONZALEZ: Second.

DR. CARTER: Will you please state your name for the record?

CAPT. HALE: Can you state your name for the record? State your name for the record.

DR. ACUFF: Gary Acuff, Texas A&M.

DR. DIEZ-GONZALEZ: Francisco Diez-Gonzalez, University of Georgia.

CAPT. HALE: Thank you. So the vote was unanimous acceptance, approval?

(No response.)

CAPT. HALE: Okay. Thank you.

Thank you, Carolyn. We really appreciate the work that the Subcommittee did on this. So great job. So what are our next steps then for this?

DR. CARTER: So the Subcommittee will incorporate the comments into the final report, and

then pass it up to the NACMCF. And then upon receipt of the final report, we will list it on the FSIS website and submit it for publication. Jenny.

MS. SCOTT: Just a comment. I want to thank the Committee for an excellent report and the timeliness of it. The CODEX Committee on food hygiene is about to move forward in taking that new work under control of STEC, and this information will be very helpful as we develop our project documents and move forward. Thank you.

DR. CARTER: Very good. Are there any public comments on the reports that were presented today?

(No response.)

DR. CARTER: So I need to see what time it is. Our agenda has us going through fairly late in the day but -- that maybe we would just move on, since everybody's here, and then maybe we'll be able --

CAPT. HALE: Do you want to move to presenting the charges then? Is that the plan?

DR. CARTER: Okay.

CAPT. HALE: Okay. So let's do that. Mark, you want to tee that up.

DR. CARTER: Thank you, Kis. FSIS has prepared charges for the new NACMCF, and our next

agenda item is presentation of the new charges.

The FDA charges will be presented first by Dr. Jenny Scott.

MS. SCOTT: Thank you, and for the record, there's no doctor.

I'm going to present the charge on microbiological testing by industry of ready-to-eat foods under FDA's jurisdiction for pathogens, or appropriate indicator organisms, as a verification of preventive controls.

In 2015, FDA published a final rule under FSMA, the FDA Food Safety Modernization Act, on preventive controls for human food. Facilities are required to conduct hazard analysis and implement of any controls for hazards identified as requiring them. These provision controls must be monitored and verified and corrective actions taken when they're not properly implemented.

Verification activities for preventive controls from microbial hazards include product testing for a pathogen or appropriate indicator organism as appropriate to the food the facility and the nature of the control of the facility's food safety system under a flexibility clause. So industry asked us to put flexibility in our approach and we did

so.

Moreover because of the flexibility that FDA provided in the rule, there's a lack of clarity by industry and by FDA investigators as to when such testing is appropriate.

So FDA is seeking advice from NACMCF on the utility and necessity of industry testing of ready-to-eat food for pathogens, or indicator organisms, and the criteria the industry could apply in determining what, if any, microbial testing is appropriate for verifying pathogen control for ready-to-eat foods produced by a facility.

Such advice should include specifics on tests for microorganism or microorganisms, the sampling plan that should be used, the type of test, that is presence or absence or enumeration, the frequency of such testing, interpretation of results and actions to take when such testing indicates a loss of control.

We're also requesting advice from NACMCF on the use by industry of enzymatic indicators of application of heat-based processes, such as alkaline phosphatase for pasteurization of milk, and whether there are situations where verification testing of products by industry would not be necessary if there's

evidence that appropriate treatment was applied.

The charge includes a list of food categories of concern, and asks specific questions, for example, about the principles and criteria a company should apply in selecting the test microorganism and frequency testing and the results that would indicate a loss of process control.

Are there any questions?

(No response.)

DR. CARTER: Thank you, Jenny.

The Subcommittee members will have plenty of opportunity for in depth discussion of the charge.

Next, we will hear from Bill Shaw who will present the FSIS charge. Do you have slides?

DR. SHAW: Yes. Okay. So Jenny is a lot quicker than I am. I'm really excited to talk about this charge, and I hope that those of the Subcommittee will find it enjoyable. You know, it's not the typical FSIS charge of late, yet it is a totally an inclusive USDA charge.

This charge is about food safety, modernization and new technology, which are the core focuses of FSIS right now, but it also includes agricultural conservation, protection of the environment, sustainability and some intentional

requisites for flexibility.

So a charge like this has a lot of moving parts, and I hope that I can give you some of the contacts and ideas that you will then hone into and focus on over the next couple of days. In giving you some thoughts on, you know, options of current water use, future water use concerns, Agency actions that we could potentially take, and then, you know, appropriate charges --

And, of course, my staff and I will be around this week, and we'll be here to answer questions and help out as we go along.

So when it comes to water, we tend to take it for granted in all aspects of our lives including food processing. It's just always there. We've come to NACMCF over the years about pathogens, interventions, passive, validation and the list goes on, and now it's water.

The various regulations around water within the FSIS regulatory structure haven't really been updated since the 1990s. Our policies may be leading to more water usage than is necessary in this current time.

We would like you to help us evaluate that

and give us advice on the technological improvement available to form our policies around water.

This is just a look at water consumption, and you see the black pieces of pie are, you know, what we consider domestic and commercial water by usage, not used in processing. And although it's not the largest usage of water within, you know, the consumption in the United States, it's still sizable at 8 percent of the total water consumption used for this purpose. So it's something that can have benefits if we look at usage. There's an opportunity there.

Regardless of where you are on the climate change situation, there's some trends in weather that are showing impact from the availability of clean and inexpensive water. Water is becoming more expensive.

I personally was sort of brought to this issue a few years ago in what many call the mini dustbowl. So a few years ago, there was a pretty wide drought in the area just east of where the original dustbowl was. And being in my position at FSIS, looking at new technologies and regulatory waivers, and that's sort of what my staff manages, a number of establishments came to us from that region sort of saying, okay, we may have to look at some alternatives

to water reconditioning or getting water or what's open to us? We see that your regs and your policies, you know, may be difficult for us.

And ultimately those establishments at that time, you know, with the economic pressures, chose to reduce production dates, rather than implement additional technology.

But that was at that time. Industry has continued to talk about this area, and if we have another one, I don't think that would be their choice again based on the things that we've talked about. And at that time, you know, I'm a food microbiologist. So I really hadn't really thought about largely, you know, water treatment systems and all of that sort of thing, but since then, we, within our staff, we've started to educate ourselves.

And a tour that the Subcommittee will take later to DC waters is one that I took my staff on, and I think you'll find it really interesting. And we've learned a lot and I think it's time for us then, you know, to ask you for your thoughts.

Okay. So this next one, I know this sort of looks at the last couple of years when we've had some drought issues. And if you take nothing from these slides, but look at the red and the orange and the

brown, those are areas, in 2012 and 2014, where there were water drought areas that affected the United States. If you look at those areas of the country, they're where our plants are for FSIS. They're where we are at. And so it just further shows that water is something you need to start thinking about if we haven't thought about it before.

You know, there are potential actions that our Agency can take. I believe there are opportunities for FSIS to start now in thinking about coming innovations in food processing when it comes to water and have the knowledge and regulatory infrastructure ready to go.

I think NACMCF, as in the past, has the technical expertise to assist us in preparing for these innovations, many of which are happening around the world and I believe economic pressures as well as consumer pressures will bring them to the United States.

You'll have a speaker later from the industry who will speak to that in particular, and what the challenges are to them and what they're thinking about.

So getting to the charge itself, we're requesting guidance from NACMCF to address

alternatives to current water usage, whether it adds information about practices, that industry can take, that can help us inform guidance that we provide to industry and it could potentially inform us on some rulemaking ideas.

I draw your attention in particular to our sanitation regs, and this Subcommittee I'm sure will spend a lot of time thinking about 416.2, and especially 2(g)(4) which has a very interesting wording in there that, you know, technology today might not make that necessary anymore. And so I hope the group will talk in depth about that.

So getting to the questions, and we have plenty of questions. And it shows how water impacts everything that has to do with food processing in one way or the other.

So our first question really centers around what are the current water usage practices for slaughterhouses and processors? Where can water be conserved? And, what are some alternative water sources? And that gets into reconditioning and treatment and those various technologies.

And then question 2, what are available technological strategies for water? How can you recycle by reclaiming, reconditioning and reusing?

I had this weird pipedream that this sort of led to this charge is that is a full closed water system reasonable as an ultimate goal? Can a large slaughter plant be just off the water grid basically? And so is that possible?

There are current strategies that many establishments use about drainage and collection of used water, physical filtration, grease traps, HACCP storage and sedimentation, chlorine treatments, but then there are newer technologies that get into the world of reverse osmosis, you know, nanofiltration, ultrafiltration, activated carbon, advanced oxidation. We've got chemical coagulation and electrocoagulation to deal with blood. Constructed wetlands, often we refer to them as lagoons, that are aerobic and anaerobic lagoons in succession. We've got gamma radiation or UV light. So there are lots of options that could potentially impact food processing.

Question 3, what are the common contaminants of concern in water? So what are the metrics we can use to determine if these technologies in number 2 are comparable to typical potable water sources today? What are the metrics we need to be concerned about when evaluating these treatment programs?

And one of our biggest regulatory hurdles,

and I want the Subcommittee to especially spend some time looking again at that 416.2(g)(4), because it has in there, you know, provisions for using reconditioned water but then there's that what we call the rinse requirement. And so if these newer technologies can really take us back, is that necessary any more? In some of these systems, maybe the rinse isn't necessary and we can go back and sort of foster industry in removing these directions because they don't still have to have those rinses again. So think about that.

And then question 4, how do residual contaminants in establishment water affect high quality and safety? So this moves to sort of like are there and whether this is from reconditioned systems or water that's coming into establishments today, based on, you know, metrics and requirements of water, can there be contaminants left that can impact the uses of that water? The sort of easiest example is could metal ions or various contaminants impact the effectiveness of antimicrobial interventions? Is that possible? And so this question sort of wraps around that area.

Question 5, what are the best ways to assure and/or monitor quality and safety of alternative source water in FSIS regulated establishments? So if

we decide that this group of certain water treatment systems are possible, how do we monitor that, whether it's industry, whether it's us? What are the acceptable monitoring practices? Is there testing involved? What should we test for? Phosphorous, total nitrogen, organic carbon, metals such as lead. What should we be concerned about? And then what would be the frequency? So that's sort of what question 5 gets at.

Then question 6, so we moved in a little different direction with 6. Are there special considerations for foods that are produced entirely within water? We now have a whole new regulatory structure of Siluriformes fish, and so we didn't think we could ask a water charge without sort of addressing the considerations in that way for us.

And then question 7, flooding or runoff can contaminate animals and sources with human sewage and farm waste. What precautions should establishments take? DC water which when we take the trip, has an extensive canal system to deal with overflow. I hope that you pay particular attention to that and see how they work that system to take into account any sort of flooding.

And then also think about, so when a

municipal water source has a flooding occurrence or has an overflow, a backflow, they often, you know, put out a boil water recommendation. Sometimes those are precautionary when you talk to them, but how should establishments react to that? How should we as an Agency react to that?

And then question 8, finally, we get to water replacement. So as many of you know, our sanitation requirements are quite extensive, our regulatory requirements, and this results in often overnight sanitation shifts that use lots of water. And are there alternative procedures that can use less?

We know that there are places around the world that have alternate methods, and so what are those and how can we potentially incorporate them into our regulatory structure, into our guidance, into our food processing systems?

So that's it in a nutshell, all about water. I know you're used to having us give you things about pathogens and various things, but something a little different this time. Any questions?

DR. HOVDE: I have a question. This charge is exclusively towards slaughter processing plants, correct? Not of vegetable, other kinds of food,

activities?

DR. SHAW: No, and we did this on purpose. This is -- in the title of it we say water in animal slaughter and processing, because if you sort of delves directly into the regulatory structure of FSIS, and FDA has, assuming things in the pipeline, and they're working in this area on their sort of regulatory structure, and we don't want to impede on that. We don't want overlap that. We really want to focus on FSIS regulated slaughter plants and processing facilities, yes.

DR. HOVDE: Great. That sounds like a very easy charge. That zeros it right down.

DR. SHAW: I'm sure it does.

MS. SCOTT: Well, I just want to follow up on Carolyn's question. When you get to the fish, you talk about fish growing in water, but is the charge to the slaughtering of the fish that had been run in water or are you actually asking people to look at the growing waters for the fish?

DR. SHAW: Right. When it comes to fish, yes, the growing waters because we were given authority over that. So, yes, it's the ponds and then also water in the slaughter facility.

DR. ZAGMUTT: A follow-up question about

that. Francisco Zagmutt. If you're taking about fish, are we talking about only FSIS regulated fish, catfish or salmon as well?

DR. SHAW: Siluriformes. So, yes.

DR. ZAGMUTT: Okay.

MS. SCOTT: This seems to extend beyond microbiological contaminants. This is a microbiological committee but it is your attempt to deal with for example, chemical contaminants as well?

DR. SHAW: Well, especially when they impact microbiological issues. So especially when chemical contaminants can then either interact with the antimicrobial treatments that are used with that water, and so how they interact with each other.

But, yeah, I get what you're saying about, you know, this micro criteria for food, but we do believe that, you know, and we've seen that the chemistries of antimicrobial agents that are designed to kill microorganisms, they play a role in water and so we can't separate that them completely. But, yes, it should be a microbiological -- endeavor.

Yes, go ahead.

DR. PARISH: First of all, thank you very much for a very well thought out and interesting challenge for the Subcommittee. I think you did a

really nice job, and to your question regarding, you know, FDA policies and procedures related to water, to the extent that the Subcommittee's recommendations might be useful for FDA regulated facilities, we'll be very interested in seeing what the Subcommittee comes out with. I mean if it's helpful for FDA regulated plants, then we absolutely want to be open to seeing what the Subcommittee comes up with for that.

DR. SHAW: Yeah, we just didn't want to word our charge in such a say that the outcome has a bunch of regulatory and rulemaking things for FDA because we all know that you're immersed in your FSMA and you're moving forward --

(Laughter).

DR. SHAW: You know, being in an Agency that has to go through HACCP limitation, you have a -- and being part of that, you have a lot -- like I have a lot of -- I feel for the diverse complications and challenges that go along with implementing something like that, that is that big. And so I think that that's why we would like to stick to our establishments as much as possible with this charge.

DR. CARTER: Anything else?

(No response.)

DR. CARTER: Thank you, Dr. Shaw. And as I

said, the Committee will have plenty of opportunity to discuss the charges and what we decide to work on as a Subcommittee. Kis.

CAPT. HALE: So it looks like we're at the close of the Plenary by my account. Are there any other comments or anything before we look at wrapping things up?

(No response.)

CAPT. HALE: I would like to thank the two presenters of the charges and those that helped in developing them. I think the Subcommittees will have lots to think about and work on. So we will look forward to the work that transpires on that. Go ahead.

DR. HOVDE: I would like to make one quick comment, and that is to thank Dr. Angela Melton-Celsa who was in charge of our document from actually typing it to keeping track of everyone's comments, and she did a beautiful job, and I was remiss in not opening my session with acknowledging her. Thanks so much, Angela. We wouldn't have done it without you.

CAPT. HALE: Okay. Thank you. So I'll turn it over to you, Mark, to adjourn us.

DFR. CARTER: Thanks, Kis.

Before we adjourn, we'll be going to lunch

now, and it looks like it'll be a little bit more than an hour if we get back at 1:00. So it's 11:20. I propose that we come back at 1:00. That gives you a nice long lunchtime, and you'll have plenty of time this afternoon and when we come back, we'll be meeting as Subcommittees and not doing a Plenary.

Is Karen here to tell us which meeting rooms we'll be using? Do you happen to know, Ellen?

All right. We'll figure that out in the next hour and a half, and when you come back, you can come back to this general area, and we'll have the Subcommittee meetings promptly in nearby smaller rooms.

I now call this meeting adjourned. Thank you.

(Whereupon, at 1:21 p.m., the meeting was concluded.)

C E R T I F I C A T E

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

NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS
PLENARY SESSION
Washington, D.C.
August 7, 2018

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

TOM BOWMAN, Reporter
FREE STATE REPORTING, INC.