UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOOD

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March 20, 2009
9:00 a.m.

USDA Cafeteria
(Conference Room)
1400 Independence Avenue, S.W.
Washington, D.C.

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I-N-D-E-X

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

(9:00 a.m.)

DR. GOLDMAN: Good morning, everyone. If I could get your attention please. Are we okay over there? Good.

Good morning again. I'm David Goldman. I'm the Assistant Administrator at FSIS for the Office of Public Health Science, and I am pleased to welcome the members of NACMCF, the Committee from 2007 through 2009, in their last plenary meeting and very important work ahead of us today to hopefully adopt two reports.

I also serve in addition to my job as an Assistant Administrator, I'm the Agency's liaison to NACMCF. So I've been to quite a few of the meetings, not the Subcommittee meetings but the plenary meetings, and have gotten to know some of the members quite well.

Today, I am going to chair the meeting with the assistance of Janice Oliver who will Co-Chair if necessary, and I am here in place of Ron Hicks, who is our Acting Deputy Under Secretary for Food Safety at USDA and, in that role, would be the NACMCF

Chair. He is unable to be with us today, does send his regards to the Committee and his thanks for your work.

As I said, this is the final plenary session. This Committee actually expires on Monday, and I'll challenge the group here a little bit. If we don't finish today, we can finish on Monday.

(Laughter.)

DR. GOLDMAN: I don't think that'll be necessary.

I want to highlight the fact that this Committee here and, for those who are from the public, the Committee seated at the table has really done exceptional work with respect to food safety. If the Committee successfully adopts the two reports that I mentioned a minute ago, this group will have completed four reports, which is quite an accomplishment. These reports include response to the questions posed by the FDA and National Marine Fisheries Service regarding Determination of Cooking Parameters for Safe Seafood for Consumers and the report called Assessment of Food as a Source of

Exposure to *Mycobacterium avium* subspecies *paratuberculosis*. If we successfully adopt the two reports today, these two will be added to this list and make the four I mentioned a minute ago.

These two reports are Parameters for Inoculated Pack/Challenge Study Protocols and Determination of the Most Appropriate Technologies for the Food Safety and Inspection Service to Adopt in Performing Routine and Baseline Microbiological Analyses.

On behalf of all of the sponsoring agencies of NACMCF, which include not only USDA's FSIS but the Department of Health and Human Services, Food and Drug Administration, Centers for Disease Control and Prevention, and the U.S. Department of Commerce's National Marine Fisheries Service, and the U.S. Department of Defense's Veterinary Service Activity, I want to sincerely thank all the members of this Committee for the valuable guidance and recommendations you've provided to each of the sponsoring agencies and the stakeholders on behalf of microbiological safety of foods. We recognize

your valuable service and commitment to food safety and public health.

At this point, I'd like to turn the floor over to Ms. Janice Oliver of the Food and Drug Administration who is the Deputy Director for Operations at CFSAN. Janice.

MS. OLIVER: Thanks, David. Good morning, and again I'd like to welcome all of the NACMCF members and our guests to this meeting. I'm sitting in today for Dr. Sundlof, who is unable to be here because he's at another obligation, but he sends his regards, and he wishes that the meeting be very productive.

I'm delighted to be here, and I really do understand the importance of NACMCF and the contributions of the Committee and that you've made to the federal agencies over the years.

I've served as the past Vice-Chair of the Committee and during that time worked on many valuable issues to Food and Drug, including those dealing with sprouts and with juice.

I especially wanted to be here today to

hear the work of the Subcommittee on the parameters for determining the inoculated pack and challenge study protocols. FDA put the charge forward to NACMCF to focus on an area where we needed some scientific guidance, and food establishments rely on these studies to determine time/temperature controls for a specific product, and it's important for the food establishments, but it's also important for the regulatory agencies who review these challenge studies.

We have a goal to have this report finalized within the next few weeks so we can actually put a link to it in our 2009 Food Code.

Once again, thank you very much for being here and thank you also, on my behalf and FDA's behalf, for serving on this Committee and all the contributions that you've made.

Now I'd like to turn it back to Dr. Goldman. David.

DR. GOLDMAN: Okay. Thank you, Janice. Before we move on to our agenda and to Gerri with some very important administrative comments, I want

to mention the FSIS charge that the New Technologies Group has been working on for about 18 months or so where they have developed some guidance and recommendations for FSIS to consider for improving testing methods for pathogens and indicator organisms.

This project really has some far reaching implications and applications, not only within FSIS, but, I would submit, across other agencies in the Federal Government and any entity that's working on food safety.

We've received quite a bit of feedback during this effort and look forward to hearing the details of this project that Uday Dessai will walk us through a little bit later this morning.

I also want to mention that I was at a meeting yesterday hosted by FDA and hosted, in fact, by the Acting Commissioner for FDA, who's informally charged a group of scientists across the Federal Government with looking at new technologies for *Salmonella* protection in particular. He's very interested in that on the heels of some *Salmonella*

outbreaks in FDA-regulated commodities.

The reason I mention this is that this charge that FSIS gave to NACMCF, and again we hope will be adopted today, kind of echoed some of the themes I heard yesterday. That meeting was quite amazing in that we had some very smart scientists from the DoD, from HHS, FDA and CDC, from the Department of Homeland Security and from USDA, and including even our partners at ARS within USDA. And this group of people I think demonstrated to me in that meeting that a federal interagency effort can be successful even when informally charged. People came in from across the country for this meeting yesterday even though it's not been formally designated, and the effort there and the preview that Dr. Dessai gave to this group was well received. So you can know that the work that you've done in that Subcommittee in particular has already had an impact on this broader interagency effort I mentioned. So I think it fits very nicely with the theme of increasing interagency work on scientific issues.

At this point, we want to formally introduce anyone from the public who's here to observe the meeting to the Committee members. So I will ask for each of the Committee members to introduce yourselves and your agency or affiliation, if you would, and we'll go to my left, or start over here with John Sofos.

DR. SOFOS: I'm John Sofos from Colorado State University.

DR. HARRIS: Linda Harris from the University of California at Davis.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

DR. MAZZOTTA: Alejandro Mazzotta with Campbell's Soup Company.

DR. WESLEY: Irene Wesley, U.S. Department of Agriculture, Agricultural Research Service, National Animal Disease Center, Ames, Iowa.

DR. MADDEN: Joe Madden, Neogen Corporation, Lansing, Michigan.

DR. KNABEL: Steve Knabel, Penn State University.

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

DR. FREIER: Tim Freier with Cargill in Minneapolis.

MS. KOWALCYK: Barbara Kowalcyk with Center for Foodborne Illness, Research and Prevention.

DR. JAHNCKE: Mike Jahncke with Virginia Tech.

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

MR. GARRETT: Spencer Garrett with the National Oceanic and Atmospheric Administration's National Marines Fisheries Service.

DR. ZINK: Don Zink with the Food and Drug Administration's Center for Food Safety and Applied Nutrition.

MS. SCOTT: Jenny Scott, Grocery Manufacturers Association.

DR. ENGELJOHN: Dan Engeljohn with USDA's Food Safety and Inspection Service.

DR. BUNNING: Kelly Bunning with FDA, Center for Food Safety and Applied Nutrition.

DR. KASE: Julie Kase, formerly with the North Carolina State Laboratory of Public Health, currently with the FDA CFSAN.

DR. HILL: Walt Hill, Institute for Environmental Health, University of Washington, Seattle.

DR. BROOKS: Scott Brooks, Yum! Brands.

DR. COOK: Peggy Cook, Safe Foods Corporation.

DR. ADES: Gary Ades, G & L Consulting Group.

COL. STEVENSON: Tim Stevenson, DoD Veterinary Service Activity.

DR. JACKSON: LeeAnne Jackson, FDA, Center for Food Safety and Applied Nutrition. I'm the FDA Liaison to the Executive Committee.

MS. RANSOM: Gerri Ransom, Food Safety and Inspection Service and NACMCF Executive Secretary.

DR. MBANDI: Evelyne Mbandi, Food Safety and Inspection Service, Microbiology Division.

DR. DESSAI: Uday Dessai, USDA, Food Safety and Inspection Service.

DR. MENG: Jianghong Meng, University of Maryland.

DR. GOLDMAN: We have one piece of business that's left over from last evening. We had a reception to honor the outgoing members of NACMCF, and one of the outgoing members was not able to be at the reception last night but is here this morning, and I think we want to especially appreciate the fact that Lee-Ann Jaykus was here earlier in the week, had to return home, and came back this morning to finish out the work. We really appreciate you in doing that, but we also want to present you with the Certificate of Appreciation from the USDA and a small token of our appreciation. So, Dr. Jaykus, thank you very much.

(Applause.)

DR. GOLDMAN: Okay. At this point, we'll move to Gerri Ransom who will have several announcements for you.

MS. RANSOM: Okay. Good morning. I wanted to join Dr. Goldman and Ms. Oliver in welcoming our guests and members today. I have a few business

items to mention regarding NACMCF.

The current charter is available on the FSIS website, and it is current through June 5, 2010, and as Dr. Goldman already mentioned, this NACMCF membership runs through March 23, 2009. And importantly I wanted to mention the process to establish the membership for the next NACMCF term has been ongoing.

Ultimately, the Secretary will be appointing 30 members to NACMCF to serve for the next two-year term. We were targeting that a new Committee would be in place with little lag time after March 23rd. However, it turns out we are operating on a bit of a delay with the processing of the new 2009 - 2011 membership. It has been on hold as the new Administration has been reviewing all advisory committees, but I am happy to report that things are moving again and our Committee paperwork and approvals are being worked on at this moment. I'm hesitant to make a prediction about when the next appointed Committee might come to be, but I will say, that if all goes smoothly, perhaps

appointments could occur in June.

Now I've mentioned this before, but I wanted to give a quick status report on the two final reports that this Committee has completed. Dr. Goldman has mentioned those. The Seafood Cook Report was published in the June issue of the Journal of Food Protection, and it is also on our FSIS website, and the *Mycobacterium avium* subspecies *paratuberculosis* or MAP Report, we've been working on that quite extensively. It has been reformatted and it is ready to be submitted to the Journal of Food Protection for publishing.

However, before we send the document to the journal, and also being prompted by a suggestion by a Committee member who was present for the adoption of this document, we are making an assessment whether new references need to be added to this paper. We have asked NACMCF members to consider these new references which you have before you, and so far the response has been favorable. And at this point, I would like Dr. Don Zink, who chaired that Subcommittee, to say a few words.

DR. ZINK: Thank you. The Subcommittee felt like it would be a good idea to update this document. MAP is such a fast moving field that we felt that these 19 references printed on this sheet before you should be reviewed and, if they're appropriate, included in the document.

In going over the references preliminarily, there's nothing in these references that changes the conclusion of the document we wrote. However, we think it would be valuable to have that document reflect the most recent and relevant references. So this would be the plan, and we'll go through the document if you concur and insert these references where appropriate.

Would anyone like to make any comments or observations on this? Joe.

DR. MADDEN: Yeah, I fully agree that the document should be updated, but there should be an amendment added or something saying that these references were added after the full Committee approved the report, something to reflect that they were added after the full Committee did approve it,

I think.

DR. ZINK: I think we can do that, yeah. I think that's appropriate. If nothing else, I'll pass it back to Gerri.

MS. RANSOM: Do we have a target date for completion and adding the references? Do you have an estimate?

DR. ZINK: Yeah, I think we can do this within a couple of weeks. I'd like to see this move just as fast as we can, and so we'll give it a really high priority.

MS. RANSOM: Okay. Sounds good.

Moving on, I wanted to mention since we are targeting the closing out of the current projects, I wanted to talk about the next work charges to be brought before the 2009 - 2011 Committee. Today we will be hearing about one new charge from Dr. Tim Stevenson of the Department of Defense who will provide us with the details on this charge on microbiological criteria.

An additional charge in preparation is one on the control of foodborne norovirus. This joint

agency charge on norovirus control is very close to being final, but we are waiting for the release of a FDA risk profile to see if any adjustments need to be made to the charge based on any new information that may be in this FDA report.

Moving on, I'll mention a few items of protocol today. I think we've all figured out how to work these microphones by pressing the button, but I do want to mention as we've done in the past, if you'd like to participate in discussions today, please take your name card and set it vertically and our Chair will call on you.

Also please remember to state your name and affiliation for the record each time you're addressing the Committee as this session is being recorded to create a transcript. And Karen has prompted me to remind everyone, and we're finding out that BlackBerrys and cell phones are interfering with the recording today. So if you could, could you please turn off your BlackBerrys. Unless it's absolutely essential that you have them on, put them under the table but being on the table is especially

bad.

Okay. Another thing I wanted to mention which I should have mentioned first maybe is that the restroom, the location of the restrooms. If you go outside to your right and you're looking at the hallway, the ladies' room is to the right and the men's room is about a mile down to your left.

(Laughter.)

MS. RANSOM: Now I wanted to mention for any guests wishing to make public comment, we ask that you please register with us where we have a sign-up sheet, and that will be out front. Each registrant will have 10 minutes for their remarks.

I also want to point out to our guests that we have a table out front which you probably already have seen that has copies of the documents that will be discussed today and some other materials. And I do want to mention at this point, if there's anybody in the room who needs a copy of either of the documents that are going to be discussed today, that would be the Inoculated Pack or the New Technologies, raise your hand and Michelle over

there in the corner by the light switch, with the big pile, will help you out. And that goes for Committee members, too, if you didn't bring your copies. So just raise your hand, and Michelle will help us out.

Okay. One additional and final item I need to mention to you today is that as soon as you're able, and this is pretty standard, please fill out your travel expense sheets for your reimbursement for travel to this meeting and provide the information to Karen Thomas-Sharp, and I wanted to say my apologies for recent delays in reimbursements that occurred with the change in our fiscal year, combined with the switching over to a new electronic system. But I am happy to report there is good news here because the reimbursement process really now is streamlined. So I think you'll find delays won't be happening again. So if you have any questions on this or need assistance, please do see Karen.

And at this point, I'm going to wish everyone a good meeting and get back to Dr. Goldman.

DR. GOLDMAN: Okay. Thank you, Gerri. Let

me just pause a minute and see if there are any questions for Gerri or Karen or anybody else who is staffing the Committee. Most of you are veterans and kind of know the ropes here.

(No response.)

DR. GOLDMAN: We have a very full agenda, and the agenda has already changed, only slightly. We're aware that some members of the Committee have flights mid-afternoon or so or late afternoon and need to depart obviously to make those flights in time, and we do need a certain number of Committee members present to adopt the reports that we're going to adopt or we hope to adopt today.

So we're going to deviate from the schedule that the members have in front of them and move the presentation of the work charge that was just mentioned by Dr. Stevenson to after the deliberations on the two reports. So that's the slight change there.

I guess the other thing I'd want to point out in terms of the agenda is that we've allotted two hours to each Subcommittee's review of their

reports, and those of you who are veterans know that it's up to the Subcommittee Chair, but I think in both of these instances, the intention is for them to go page by page through the report, and a couple of ground rules for that process.

That page-by-page review is primarily for the members of the Committee who haven't been on the Subcommittee. Certainly Subcommittee members who need to register a point or make a point should feel free to do that, but again primarily that's for the other Committee members who have not already been a part of the Subcommittee deliberations to raise concerns or make points during that review process.

So as I mentioned, Dr. Stevenson will present after that.

The other consequence of this change is that we've moved lunch back hoping that will maybe spur our review of things. I think lunch is now going to be at 12:45. Is that right? Something like that.

Dr. Stevenson is the DoD's representative to the Executive Committee, and he will present a

DoD initiated charge, as Gerri has mentioned already, on the study of microbiological criteria as indicators of process control or insanitary conditions. This is an area of work that's very important to the Department of Defense, in order that they can ensure the safety of foods that are purchased outside of the U.S., in particular for military personnel.

First on today's agenda then we will still hear from the Inoculated Pack Subcommittee as it's listed on your agenda, and then later we will hear from Uday Dessai regarding the New Technologies Subcommittee. I guess we're overemphasizing the point that we're at a very important point for both of these works in that we hope to be able to adopt both of the reports through the action of the full Committee today.

I do want to point out that I'm aware that both of these Subcommittees have worked long hours. In fact, Uday Dessai told me yesterday that his Subcommittee in particular didn't want to take lunch breaks earlier in the week, and I think that's a

testament to the hard work and dedication of Committee members.

You'll hear as we go through both of these reports that there are many inherent complexities to the reports themselves. There was a lot of, I think, healthy debate about the right approach to take in the development of these reports, but in any case, the two NACMCF Subcommittees have worked diligently, and again on behalf of all of the sponsoring agencies, I want to express our appreciation for the hard work that you've put into these projects.

So now we will move to the real work of today's Committee, and we will start with Dr. Don Zink, from the Food and Drug Administration, to lead our discussion and review of the Inoculated Pack/Challenge Study Protocol paper. Don.

DR. ZINK: Thank you. I have to say I think that the extra time we spent on this document was really a great benefit. We were able to tighten it up quite a bit and had the luxury, if you will, of going over it, and then putting it down and going

over it again, which is always helpful. Even with that, it seemed down to the wire there for a time.

What I want to do first is give you some broad stroke impressions or summary of the changes that were made to the document.

First, you'll notice we added an abstract. This is necessary for publication in a peer-reviewed journal, but probably one of the most significant things was discussions and additions pertaining to the use of statistics.

I have to tell you that historically what was done in inoculated pack studies would fall under the heading of common practice by scientists. And, since one of the main target audiences of this document is food service operators, for example, it's difficult to statistically characterize and design a study using the statistical approach based on the variables that you can have in preparation of food, particularly in a kitchen setting.

And so historically these studies have been done by designing them on a worst-case scenario for each variable on the theory, and history has proved

this workable, on the theory that you'll never encounter a food that has the perfect alignment of worst case in every such variable. However, I think the comments we got on statistics were, you know, very appropriate and caused us to go back through the document and look at where statistical considerations needed to be included, and we've done that.

So the use and limitations portion of the document was modified to note that you have to balance the statistical validity with practicality. These studies are tremendously expensive, and we don't want to make them more so, but you do need to be consulting a competent statistician. And it was modified in several places to reflect where you particularly could benefit from consulting a statistician.

And it notes that sampling schemes for food microbiology experience, again as I've described to you, were done primarily on common practice and not solely on statistical design. I think it was necessary to make that clear to the readership, of

this philosophy, and frankly until we got the comments about the use of statistics, we hadn't really made it clear this philosophy of worst case scenario experimental design.

Some other edits to it was Appendix B, considerations for selecting a laboratory. The Committee appreciates and is very concerned that doing these kinds of studies is part art and part science. And probably the single most important thing you can do in getting one of these studies done correctly is to work with somebody who really knows what they're doing and has the facilities to do it right.

And there are many, many laboratories that are perfectly competent testing laboratories but not at all competent to do these kinds of studies, and some of the laboratories that are very competent to do these kinds of studies aren't your ISO accredited, certified testing laboratories. A lot of them are more university laboratories, and we tried to make changes in this appendix to reflect that, and we do hope people will read that and take

careful note of it.

We list questions you should pose in considering which laboratory or person to design and do these studies, and they're not listed in any order of importance. It would be hard to do that because of the variability in studies themselves. And a negative response to one or more of these questions doesn't necessarily disqualify a laboratory. Like I said, you could have a very competent university laboratory that doesn't participate in check sample programs, isn't an ISO accredited laboratory, but nonetheless is competent.

The most important considerations again are associated with qualifications of personnel, and we hope that comes through in the document.

With that, what I would like to do is begin the page-by-page review of the document. At the Committee's pleasure, if you would like to streamline the process, you can come to me with typographical type changes and grammatical type changes, and we can focus on the more substantive changes if that would be acceptable to everybody,

not that we have any typographical errors in here.

(Laughter.)

DR. ZINK: With that, I'll open it up for discussion of page 2.

(No response.)

DR. ZINK: All right. We'll move to page 3. Page 4. Page 5. Page 6. Page 7. Page 8. Page 9. Page 10. Page 11. Page 12. Page 13. Page 14.

Page 15. Lee-Ann.

DR. JAYKUS: Lee-Ann Jaykus, North Carolina State University. On line 618, since sometimes these markers are not necessarily extra-chromosomal, they can sometimes be integrated within the chromosome, I just suggest a minor wording change to extra-chromosomal elements such as plasmids or other genetic markers.

DR. ZINK: That language again was or other --

DR. JAYKUS: Other genetic markers.

DR. ZINK: Other genetic markers. Would you say other genetic markers or other genetic

elements?

DR. JAYKUS: I would say markers because if you look at like, you know, lux genes and things like those, those really are markers.

DR. ZINK: Is there any discussion of this? If not, we'll make the change. Is there any other comments on page 15?

(No response.)

DR. ZINK: Page 16. Page 17. Page 18. Page 19. Page 20. Page 21. Page 22. Page 23. Page 24. Jenny.

MS. SCOTT: Just a comment. I'd like to draw the Committee's attention to the sentence on lines 1023 through 1025. We had a lot of discussion about the fact that this document does not deal with how to address some of the issues that come up any time you do a challenge study. What do you do when you've got some widely disparate values? What do you do when one replicate of your experience is statistically different from the other two replicates?

And we really felt that there aren't rules

out there. This is a really large topic, and this was perhaps an area where the Executive Group could pose another charge to the Committee to look at some of the issues around this in the future.

DR. ZINK: Jenny's remarks, you know, remind me of the extensive discussion we had on this. One of the great debates that we had, one of the purposes of these studies, is determining whether or not a pathogen grows in a product, and you have inherent variability in microbiological counts even when done carefully, and that variability tends to increase as the duration of this study progresses. How big an increase is a statistically significant increase or is a truly biologically significant increase.

It was such a difficult issue that involved so many things that I don't think this Committee could possibly put clear solutions to it in this report without spending possibly another year and a half on the endeavor. And it was actually, rather than include this in the report as a recommendation, the Subcommittee wanted to recommend to the full

Committee and the Executive Board that we consider ways in which a document could be generated, that would be, we called it at one point of kind of a primer for the application of statistical and other interpretative tools, to microbiological methods. There's a huge need for this, and when is variability in counts too much as Jenny said, and what exactly constitutes a significant increase in numbers. This is even debated and discussed in Codex documents with a fair degree of uncertainty.

So we think that's a very important consideration, and NACMCF may or may not be the best way or the best place to do and get this information published, but it's, we think, very important.

Do we have any discussion on this point or recommendations from anyone else? Spencer.

MR. GARRETT: Spencer Garrett with NOAA Fisheries. Other than to say I totally agree with you, that I think the discipline of microbiology, I think we need to kind of get the statisticians and the microbiologists together and have a peaceful resolution on how we proceed. (Laughter.) Thank

you.

DR. ZINK: Barbara.

MS. KOWALCYK: I just want to reiterate what Spencer said and that I agree with the recommendation and I concur, and I'm glad to see that it was addressed in the document. Thank you.

DR. GOLDMAN: Just a comment. I understand exactly what you've said, both you and Jenny. The first sentence in that section has three references which might lead the reader to conclude that there is some guidance out there about how to interpret test results. I don't know these references. I think one of them was written by people in the room here or at least they're co-authors.

Does the Committee or Subcommittee have any concern about that, the way that section leads off the discussion about interpretation of results?

DR. ZINK: I think that -- no. We have put in there I think what we felt was available, but no one feels that there's a real go-to source that clearly lays all out the information that you need for these kinds of things. Okay.

DR. SCHAFFNER: Don Schaffner, Rutgers University. Yeah, just to reiterate that. Although the first sentence does kind of indicate that there are some references out there, if you read through the rest of the section, what the Subcommittee does in the rest of the section is really illustrate some different points of view, and I think that concluding, and we debated where this sentence was going to go. And, finally, we decided that this sentence needs to go at the end so that the person having read through the entire section realizes, hey, you know, there really is not consensus out here, and we wanted to lay out that lack of consensus for readers of the document but also point the way towards maybe some way we could get some consensus.

DR. ZINK: Jenny.

MS. SCOTT: I just wanted to point out that those three references in the first sentence are specifically addressing the point that in doing these studies, you need to have an expert microbiologist involved to do the interpretation.

It's just a key point that we tried to make throughout this document that it's absolutely essential that you have a microbiologist who's familiar with these studies and interpreting the results to make a determination of the significance.

DR. ZINK: Do we have any other discussion on page 24?

(No response.)

DR. ZINK: Page 25. Page 26. Page 27. Page 28. Page 29.

What we are left with in the document is what we would call our worksheets. We were charged with responding to specific examples. In essence, what we've done is created a document here that says how you would design a challenge study of one type or another, and then we were charged to take our work product and show how to use it for several specific examples.

And in getting into this, we decided that there was a need for a good deal of preliminary information.

Table 1 is a discussion of the expertise

you need, and it's followed by tables that provide assistance in selecting the proper challenge organisms and giving you some idea of the physical chemical parameters of a food that would possibly limit your choice of challenge organisms. And finally, we give some definitions, but getting into the actual worksheets themselves beginning on food product checklist on page 60.

So I'll begin with this section. Are there any comments on page 39?

(No response.)

DR. ZINK: Page 40. Page 41. Page 42. Page 43. Page 44. Page 45. Page 45. Page 46. Page 47. Page 48. Page 49.

Then beginning the -- oh, no, not yet.

Page 50. Page 51. Page 52. Page 53. Page 54. Page 55. Page 56. Page 57. Page 58. Page 59.

And then beginning the checklists themselves. Page 60. Page 61. Page 62. Page 63. Page 64. Page 65. Page 66. Page 67. Page 68. Page 69. Page 70.

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Page 101. Page 102. Page 103. Page 104. Page 105. Page 106. Page 107. Page 108. Page 109. Page 110.

Page 111. Page 112. Page 113. Page 114. Page 115. Page 116. Page 117. Page 118. Page 119. Page 120.

Page 121. Page 122. Page 123. Page 124. And page 125. And technically we have a bid on page 126.

Okay. Does anyone have any overarching comments they'd like to make about the document? Yes, Spencer.

MR. GARRETT: Again Spencer Garrett with

NOAA Fisheries. I want to commend the Subcommittee on finally ferreting out all this information and putting it together in one spot where people can find it. I think it's just a tremendous piece of work you all did, and it's going to have a wide, broad impact on teaching microbiology and doing challenge studies and so forth. So thanks from one microbiologist.

DR. ZINK: Thank you. Well, with that, that concludes -- oh, excuse me. Stephen.

DR. KNABEL: Steve Knabel from Penn State University. I just have a question, and maybe it's already covered in the document. FDA, as I understand it, sometimes looks for a process authority to make an evaluation on some of these things. Was that discussed in the document? And how is that going to integrate with this?

DR. ZINK: The only place we have used the phrase process authority was in connection with establishing thermal processes for low acid canned foods and acidified foods. The extension of that term to other areas has been discussed, and if I'm

not mistaken, there was some discussion about it in our early deliberations, but rather than create sort of an expanded role for the phrase process authority, we instead focused on the fact that it's necessary to find yourself a really experienced microbiologist that would be, you know, a suitable expert in this area.

If there's no further discussion, that concludes the Subcommittee's presentation to the Committee, and I'll turn it back to Dr. Goldman.

DR. GOLDMAN: All right. Thank you very much. And it was a nice review, and I think the fact that there were so few questions again is testament to the hard work that the Subcommittee did in kind of answering any possible questions up front.

At this point, with that review of the paper, we're at the point of accepting a motion to approve this document as has been slightly amended during the course of the review. Do I have a motion from a member?

DR. MAZZOTTA: I so move.

DR. GOLDMAN: Okay. Dr. Mazzotta is --

DR. JAYKUS: I'll second it.

DR. GOLDMAN: And Dr. Jaykus is seconding. All right. Any further discussion of this document?

(No response.)

DR. GOLDMAN: Anyone opposed to adoption of the document that we just reviewed?

(No response.)

DR. GOLDMAN: All right. Then the document has been adopted. Thank you very much. I feel like clapping.

(Applause.)

DR. GOLDMAN: Thanks again, Don. That was great. Very good.

DR. ZINK: It was all the Committee, certainly not me, and through the use of webinar, we vastly extended the number of hours we can expend on a project, and their forbearance is to be commended.

DR. GOLDMAN: Good. Well, my thanks to all of you. Boy, that just provided an extra hour and a half in the agenda. We will, however, take a 15-minute break now before we go to the next document.

I know we've only been at it for an hour, but we'll take a 15-minute break, and at 10:15, Dr. Dessai will lead us through the second document.

(Off the record.)

(On the record.)

DR. GOLDMAN: All right. Good morning again. I think we will resume our deliberations with the review of the second document, from the Subcommittee on the Determination of the Most Appropriate Technologies for the FSIS to Adopt in Performing Routine and Baseline Microbiological Analyses, and I'm going to turn it over to the Subcommittee Chair, Uday Dessai.

DR. DESSAI: Thank you, David. I'd like to take the podium for a little bit. It looks like this is a lull before the storm or what because the morning was quiet, quiet, and I heard a lot of chatter out there saying just wait.

(Laughter.)

DR. DESSAI: But I think we really had a very productive 18 some months on this Subcommittee, and I definitely want to read out the names of the

people who were part of this Subcommittee who, like David said, who even refused to take their lunch breaks and worked very hard and despite the difficulties, personal difficulties, made time and contributed to this effort.

We have Peggy Cook. Dean Cliver couldn't make it this time. We have Dan Engeljohn, Walt Hill, Lee-Ann Jaykus, Julie Ann Kase, Stephen Knabel, then Barbara Kowalcyk, Jianghong Meng, Angela Ruple who couldn't make it this time, and Rob Tauxe is here in D.C., and then he -- if the first Committee had taken longer time, probably Rob would have been here by the time we are ready to present the charge, but probably he'll come here a little later, Irene Wesley, then Kelly Bunning and Tim Freier. Tim Freier wasn't even there on the Subcommittee to start with, but then he made time and then he's contributed substantially, too.

So having said that, I will just give you an overview summary of the charge, not the whole charge, but the six items that we had on the charge, and then I will approach the charge.

We had six charge questions, and like we presented earlier, the charge was kind of I would say amorphous, very diffused and different questions, and the parts of those questions went to different places, and the charge was asking for everything. And the Subcommittee actually spent a whole lot of time to digest the charge and see how it can be best addressed, and there were various versions of how it could be addressed, but finally we decided to stick to the charge.

And these are the six questions here, most appropriate and promising technologies, advantages, disadvantages, then the major question was about cell viability and culture confirmation.

Then charge 3 covered sampling issues, right from site, size, location, rinse versus excision, and the method parameters.

Can SNP technology be applied for detection and process control and thereby its cost effectiveness and then timeliness, that was question number 4, which was quite difficult for the Subcommittee to really address without getting into

further details of subtyping.

Then the new technology was to be put in perspective with attribution risk profiles to model human illnesses. The Committee had little difficulty because this is a whole different area, but the Committee did answer the question.

Then issues with implementing the new technologies for FSIS testing, including research gaps. So this is the last part, which is very important. We have identified research gaps as well as there are recommendations to those research gaps, which is section five and six.

Now the approach to the Subcommittee, the rationale to basically deal with this task was top down, that is starting with what is FSIS' vision, then you have the mission, you have the goals, strategic goals, how they tie to food safety and how would changes in methodology tie to those goals, and that was discussed extensively by the Committee. And then you will see it scattered all over the report tying what we do in terms of technology or new technology adoption to the strategic goals and

whether it's public health goals or food safety objectives.

Then the Committee strongly felt that there needs to be a process, a global process, by which FSIS can have new methods presented through that process and they can be ready for adoption, and there should be criteria for that process. So the Committee spent quite some time, and a process has been developed as a guideline for FSIS, and details about that process leading to method validation and adoption have been described.

Response to the questions are contained in multiple sections like I said earlier, and those are identified in the table of contents where different questions are answered. We didn't specifically answer question 1, 2, 3, 4. They're in different sections as it goes with the flow of the document.

And here we have the background. In the background area we have federal food testing programs which covers different agencies. Then we have current methods and approaches. Then purposes for microbial testing at different federal agencies,

type of testing that is done, and then performance criteria currently used, and then we have emerging technologies and methods which are out there, which have been summarized. Considerations in choosing the methods, that has been kind of qualitative ranking or comparison of the methods. It was not quantitative. It was just saying that these methods, if these are the parameters, then these methods can be used for following purposes. And then we have considerations for choosing methods, process evaluation of methods, and then barriers and gaps like I said earlier, and recommendations.

So that's the overall flow of the document that you'll be looking through in a little bit.

From the document that you received some time ago, which was to be sent to us by the 12th, we didn't receive a whole lot of comments, but the comments that we had received, we have addressed those comments. And the Committee over this week was supposed to meet Monday, Tuesday but continued through yesterday, and what was done was there is not much substantive material that's been added or

changed. Things have been edited for fluency and for better flow between the sections and then sentences in places.

Also we did little effort on focusing and removing redundancies, which were seen in the document in many places. And I think the document reads good, in my opinion, at this point in time, and I will go through the document page by page like Don did.

I would -- yes.

DR. JAYKUS: Uday, I'm sorry to interrupt, but I did want to point out that on Monday, the Committee went through the recommendations and the concluding statements pretty extensively. So while the nature of them have not necessarily changed, that part of the document is substantially different than what you would have received two weeks ago.

DR. DESSAI: Thanks, Lee-Ann. Actually I had a summary of those recommendations here, but I thought as we go through the document, we'll come to it anyhow. Thank you.

All right. We start the review of the

document from page 1. Page 2. And 3. Page 4.

MR. GARRETT: Uday, I regret to taking you back to page 1.

DR. DESSAI: Okay. That's fine.

MR. GARRETT: Just the disclaimer, is this disclaimer statement going to remain on the document when it's final? If it is, I would suggest you say the U.S. Department of Agriculture and other NACMCF sponsoring agencies.

DR. DESSAI: Okay.

MR. GARRETT: If it's to remain. I recommend that it remain.

DR. DESSAI: Any other comments on page 1?

(No response.)

DR. DESSAI: Okay. We'll go to page 5. Page 6. Page 7. Page 8.

DR. GLASS: Kathy Glass --

DR. DESSAI: Yes, Kathy.

DR. GLASS: -- UW Madison. I'd like to make a suggestion for items in lines 30 and 31 which make reference specifically to foodborne infections and not the broad spectrum of foodborne illness,

because foodborne illness also will include those things that are intoxications, those that are going to be involved with consumption of preformed toxins. If we take a look at *Staphylococcus aureus* and *Clostridium botulinum*, those things also will have potential technologies that need to be of concern here --

DR. DESSAI: Okay.

DR. GLASS: -- and just to make that a broader review of making sure that people aren't confusing infections with those particular intoxications.

DR. DESSAI: Thank you, Kathy.

Pages 8 and 9. Pages 10 and 11. Pages 12 -- yes, David.

DR. GOLDMAN: Sorry. David Goldman, FSIS. Sorry, back to page 9. I just noticed this. On the healthy people table, the 2010 target for *Listeria* is actually 0.24. The footnote is correct that the target was changed from some number that I can't recall to 0.25 as a result of an Executive Order, but during the midcourse review for healthy people

2010, the target for 2010 was changed to 0.24. So there may need to be some further clarification in the footnote there.

DR. DESSAI: Change noted. Thanks, David.

Pages 10 and 11. 12 and 13. 14 and 15. 16 and 17. Page 18. Pages 19 and 20. Page 21. Pages 22 and 23. Pages 24 and 25.

Yes, Jenny.

MS. SCOTT: On page 24, on the in-process control, your last sentence says that it's likely that a number of emerging technologies might be applicable to monitoring and verifying process control. Are you intending to suggest here that there might be technologies that measure pathogens that could be used for process control, or is that for all organisms in general?

DR. DESSAI: This was all organisms in general for in-plant process control. You want this clarified?

(No response.)

DR. DESSAI: Thank you. Any comments on page 25?

(No response.)

DR. DESSAI: We move to 26 and 27. 28 and 29. Page 30. Pages 31 through 38. Page 39.

Pages 40 and 41. Pages 42 and 43. Pages 44, 45, 46 and 47.

Yes, LeeAnne.

DR. JACKSON: On page 46, Footnote F, just reading through it, it doesn't look to me like it reads correctly.

DR. DESSAI: Okay. What's that again?

DR. JACKSON: Okay. Footnote F, where it says enumeration (quantified) capability of an assay to provide enumerate the number of bacteria present.

DR. DESSAI: Okay. Okay.

DR. JACKSON: I'm not sure exactly what the intent is there, but I would suggest that you make it read whatever the appropriate way is --

DR. DESSAI: Okay.

DR. JACKSON: -- that you mean for it to read.

DR. DESSAI: We'll do that.

DR. ENGELJOHN: Uday, this is Engeljohn.

If we remove the word provide, I think that's the intent.

DR. DESSAI: Thanks, Dan. Any other comments of page 47? Pages 48 and 49. Page 50. Pages 51 through 56.

DR. DESSAI: Page 57. Pages 58 and 59.

Spencer.

MR. GARRETT: On the previous tables that we've gone through, on Table 5, we put the headers on each page so you don't have to -- my memory span is not that good. (Laughter.) Just put it on each page would be helpful.

DR. DESSAI: Okay.

MR. GARRETT: Thank you.

DR. DESSAI: Thank you, Spencer. So through 60, any comments?

(No response.)

DR. DESSAI: Page 61. Page 62. Pages 63, 64 and 65. Pages 66 and 67. Page 68. Page 69. Page 70. Page 71.

Yes, Jenny.

MS. SCOTT: In number 2, I suggest that we

be a little more formal than saying that the methods are not ready for primetime and say that they're maybe not ready for implementation.

DR. DESSAI: Okay. Okay. Noted. Thank you. Page 71, any other questions?

(No response.)

DR. DESSAI: Page 72. Page 73.

DR. MADDEN: Joe Madden. I have a procedural type of comment I think on item number 4. Has the Committee in the past recommended restructuring something, an organization type of thing, and I think it's kind of a policy issue here that we're dealing with as to who does what in USDA. And I'm just concerned, is this properly placed in this document? Just a comment that I wanted to bring up, and I'm specifically referring to page 73, item number 4.

DR. DESSAI: Joe, I'll give a little background here, and then I would want other members of the Subcommittee to come in because there was a lot of discussion on this issue, and as the Committee began to learn more about FSIS and how

FSIS conducts business, and then in the context of the other federal agencies who are doing similar business, the Subcommittee strongly felt that that component, the scientific component to be able to apply resources to those questions related to methods, method development, part of method development, not from scratch and then validation. Those are very, very important issues which can keep FSIS from not doing what they could be doing much better.

So the Committee came to this recommendation, and then I will have the other Subcommittee members to really weigh in here, and this was strongly felt by the Subcommittee.

DR. MADDEN: Joe Madden. I strongly agree with it, but I'm, you know, just questioning should it be placed in this document here? I totally agree with you.

DR. DESSAI: Okay.

DR. MADDEN: But it's just, should it be here?

DR. DESSAI: Subcommittee.

MR. GARRETT: Thank you, Mr. Chair. I think there are two points to make. One, that it is a policy issue without a doubt at least to me and, of course, a little bit further down, you know, it talks about the Inter Personnel Act and transferring personnel among the agencies, which goes on now frankly under that, but I think maybe if you just soften it a little bit, you're saying the Committee is concerned. Well, maybe that's soft enough.

(Laughter.)

MR. GARRETT: I'm not too sure we want to disagree. I think that we're also concerned with the current interpretation, something of that nature, or you'll find yourself in a policy war very, very quickly. And we've managed to keep policy considerations out of these types and kinds of documents. It's okay to recommend, you know, that that be addressed. That's one thing, but to say we're disagreeing with the current actions of a major federal agency is totally something different.

And so I would just say, you know, that it's not that we disagree. It's just that they're

concerned and let it go at that.

DR. DESSAI: Okay. Noted. Yes, Walt.

DR. HILL: Walt Hill. Spencer, then would you agree that in Section 4, that we just delete the sentence that starts on line 10? Would that be satisfactory?

DR. ZINK: Why don't you put in is also concerned.

MR. GARRETT: Yeah, or you could put it in is also concerned with the current interpretation. I don't mind leaving it in provided that it's not a direct policy implication, okay, that we're recommending a direct policy.

DR. DESSAI: Thank you.

MR. GARRETT: Or you could say recognizes, but I think is also concerned would give it -- I'm not for taking it out. I just want to make certain that it reflects the concern of the whole Committee. That's all.

DR. DESSAI: This statement has been changed a number of times (laughter) from different words and different weight on it to the current

state, and we will change it.

MR. GARRETT: Thank you.

DR. DESSAI: Any other comments on page 73?

MS. OLIVER: This is Janice Oliver.

DR. DESSAI: Janice.

MS. OLIVER: On that same paragraph, line 12, where it says this Committee recommends that FSIS immediately assess the source.

DR. DESSAI: Okay.

MS. OLIVER: I think that that's a little bit strong and the wording could be changed.

DR. DESSAI: Assess the need to conduct.

MS. OLIVER: Yeah.

DR. DESSAI: So drop the source.

MR. GARRETT: Why not just drop immediately.

DR. DESSAI: Okay. Thank you. As it stands, item 4, line 8 through 16 would read, "One of the alternatives is the Committee is concerned that FSIS has no clearly defined mandate and limited infrastructure for method development and validation activities to support its public health regulatory

program. Consequently, this Committee recommends that FSIS assess the need to conduct method development and validation and seek funding for this effort, including in-house facilities pertinent, and the organizational structure necessary for successful implementation of appropriate technologies that will allow the Agency to meet its public health goals." Yes, Barbara.

MS. KOWALCYK: I just wanted to clarify. I thought we agreed that we were going to retain the sentence, "This Committee is also concerned with the current interpretation that method development constitutes a research activity and therefore falls outside the FSIS mandate." So we were only going to change that. We were not going to delete that sentence but rather change disagrees to is also concerned.

DR. DESSAI: Concerned, okay. Okay. Okay. Noted. Thank you. Yes, LeeAnne.

DR. JACKSON: LeeAnne Jackson. On line 13, where it mentioned the need to seek funding for this effort, I'm not quite sure that that's an

appropriate piece of information that needs to be included in the scientific document, that we're recommending an agency then proceed forward with trying to request funding in order to deal with these types of efforts.

DR. DESSAI: Okay. We could delete that sentence.

MR. GARRETT: I would suggest not the sentence.

DR. ENGELJOHN: This is Engeljohn with FSIS, and I'd like us to try to find some alternative language, but I would insist as a representative of FSIS on the Committee that the statement needs to stay. I'd like the Committee to perhaps help find some alternative wording that's suitable.

MR. GARRETT: Seek resources.

DR. ENGELJOHN: Yes. This is Engeljohn, and I think seek resources would be an acceptable --

DR. DESSAI: Okay.

DR. ENGELJOHN: -- substitution.

DR. DESSAI: Seek resources will be okay.

DR. ENGELJOHN: Yes.

DR. DESSAI: Thank you, Dan. Any other comments on page 73?

DR. WESLEY: Could you read what the changes have been then to 4?

DR. DESSAI: Okay. All right. "The Committee is concerned that FSIS has no clearly defined mandate and limited infrastructure for method development and validation activities to support its public health regulatory program. This Committee is concerned with the current interpretation that method development constitutes a research activity and therefore falls outside the FSIS mandate. Consequently, this Committee recommends that FSIS seek resources for successful implementation of appropriate technologies that will allow the Agency to meet its public health goals." Yes, Barb.

MS. KOWALCYK: Uday, I thought we had agreed that in that last sentence that begins consequently on line 13, that the only two changes that we were going to make to that sentence were to

remove the word immediately and replace the word funding in line 13 with resources. Otherwise, the sentence will remain the same.

DR. DESSAI: Okay.

DR. MBANDI: Yeah, just what --

DR. DESSAI: That's the changes we have.

DR. MBANDI: Yes.

DR. DESSAI: Okay. Barb, the change is noted.

DR. MBANDI: Yes. So it says, "Consequently, this Committee recommends that FSIS assess the needs to conduct method development and validation and seek resources for this effort, including in-house," yeah.

DR. DESSAI: That stays?

DR. MBANDI: Yes.

DR. DESSAI: That stays. Okay. Okay. I thought the concern was on that wording, but this is fine. No more comments on 73? David.

DR. GOLDMAN: David Goldman, FSIS. Line 34, I'd just be interested in the discussion. That whole list of bullets says, for example, FSIS

should, and then the last bullet there it talks about negotiating CRADAs. That's completely new territory for FSIS, and I just wondered if you could elaborate on the discussion a little bit, something, you know, I typically think of ARS involved in.

DR. DESSAI: In the context of FSIS' limited ability to support its mission in terms of method development and validation, the Committee strongly felt that there are other mechanisms used by other federal agencies, or actively used by other federal agencies which could be very useful for FSIS, and that's what generated this list, and I will actually have anybody from our Subcommittee to add to this? Dan.

DR. ENGELJOHN: This is Engeljohn. Just to follow up, I would as well, and I could certainly use any supported statements from the rest of the Subcommittee, but FSIS was welcoming the push to think outside of the box that we normally think within and to find other strategies. And so it was intended to be worded to be a little more aggressive in its nature.

DR. DESSAI: Spencer.

MR. GARRETT: Thank you, Mr. Chairman. I can appreciate what Dan's indicating, but it just seems to me it would read much better if you would just seek cooperative agreement between FSIS and commercial method developers and just let it go at that, and that gives you the latitude outside the box you're looking for. If it's something else than that, then I would suggest again this is a policy recommendation.

DR. DESSAI: Okay. Kelly.

DR. BUNNING: Kelly Bunning, FDA CFSAN. If you'll go a www.fda.gov, you'll notice that there is a link to the CRADAs that FDA has, of which there are literally hundreds, and they are actually negotiated. They are legal agreements. They're all slightly different, although they work from a boilerplate, and so it's a very viable mechanism, and I don't really see why FSIS cannot also negotiate CRADAs with a commercial entity as identified by that extensive list.

DR. DESSAI: Lee-Ann.

DR. JAYKUS: Lee-Ann Jaykus, North Carolina State University. I'm just going to make a suggestion for a wording change on line, I guess it's 24. Instead of saying, for example, FSIS should, why don't we just say, for example, FSIS could.

DR. DESSAI: Okay. Noted. Don.

DR. ZINK: Thank you. Don Zink, FDA. Going back to that business with the CRADA, I think at this corner of the table, we were sensitive to the policy issues relative to the mandate of FSIS and whether or not it included research. We were thinking that, hey, you could just take that off the radar screen by saying negotiate cooperative agreements, whether you ultimately wind up calling them CRADAs or memorandum of understanding and agreement or whatever. You know, I think it would have the same effect and wouldn't draw attention to the policy question of whether or not there's a mandate for research.

DR. DESSAI: Thank you, Don. Kelly.

DR. BUNNING: I think you're right, but

cooperative agreements are actually a type of grant, and a CRADA is actually a very directed effort. So I think what we were trying to do was give them all the tools of the arsenal to be successful.

DR. DESSAI: So CRADA stays? Yes, Spencer.

MR. GARRETT: I understand what cooperative agreements are, and I think, and maybe I'm over-emphasizing this, but I think this is a lightning rod for policy. I understand what you're trying to do. Just say seek arrangements, whatever those arrangements are.

DR. ZINK: Agreements.

MR. GARRETT: Well, not -- yeah, not necessarily, but they can be negotiated. They can be cooperative agreements. They can be direct contracts. There's four or five different possibilities, but I'm not going to belabor the point, but I do think that it's a policy issue. Once you start slipping into policy issues, I mean we want science-based regulatory decisions, but once you start slipping into policy issues in a scientific committee such as this which, in fact,

has the scientific standing of only a Subcommittee, I think you have to be very, very careful how you, you know, words mean things which are actually --

DR. DESSAI: Thank you, Spencer. Kelly, if this sentence would read, "Negotiate cooperative research and development agreements and other --

DR. BUNNING: This is Kelly Bunning from FDA. I think there are several words we can use besides negotiate if that would --

DR. DESSAI: And I'm fine with that.

DR. BUNNING: -- develop cooperative or whatever.

DR. DESSAI: Okay.

DR. BUNNING: Would that be suitable?

DR. DESSAI: Thanks. It looks like page 73 was very hot. Yes, Irene.

DR. WESLEY: Could you read what's left on page 73, lines 34 and 35 then.

DR. DESSAI: Line 34 and 35. Develop cooperative research and development agreements, and I've taken off CRADA and temporarily I had put similar other arrangements between FSIS and

commercial method developers, and we'll refine this. Yes, Don.

DR. ZINK: You know, I think what you read off could be fine. I wouldn't capitalize cooperative research and development agreements, you know. That makes it a little more generic, I think.

DR. DESSAI: Okay.

DR. ZINK: Alternatively you can say develop cooperative arrangements, cooperative relationships if you wanted to even soften it more, but it's not a big issue to me either way.

DR. DESSAI: So the sentence then would read develop cooperative relationships between FSIS and commercial method developers.

MS. KOWALCYK: Uday.

DR. DESSAI: Yes, Barbara.

MS. KOWALCYK: I thought we had just agreed that we were going to leave the sentence as develop cooperative research and development agreements, lowercases rather than capitalized. So it would be a lowercase c, a lowercase r, d and a, and other agreements between FSIS and commercial method

developers.

DR. DESSAI: Spencer, that's fine with you?

MR. GARRETT: That's fine.

DR. DESSAI: Okay. Thanks, Barb. Page 73 again.

(No response.)

DR. DESSAI: Okay. Page 74. Jenny.

MS. SCOTT: Jenny Scott, GMA. In number 8, just before the bullets, you're talking about recommending broad-based multidisciplinary research efforts, and you say that recommendation could be achieved with a presidentially directed task force. And while that's true, do you want to restrict yourself to that? Should we not be a little broader? I mean couldn't the Secretary even direct such a task force, the food safety working group. There are lots of entities that might develop this.

DR. DESSAI: Well, this was again one of the items which was discussed extensively right from the Manhattan Project, two different ideas, and finally to get attention, I think Kelly can say a little more about this.

(Laughter.)

DR. KELLY: This is Kelly Bunning with FDA. I, you know, think this issue is really the number one recommendation that we have, the real issue with bringing new technologies to bear as sample prep, and we've been talking about it for so long, and we don't want to have a grant system, open-ended grant system where it's funded. What we really need to do -- and it's not just foods; it's any complex method. It's something that really goes across departments and agencies, and we know the technologies are really good if we had good sample prep. Almost all of the advanced technologies out there would actually interface with a good sample prep really well.

So the question becomes how do we tackle this really huge issue? And the reason why we settled on presidentially directed, because I was thinking in the back of my mind OSTP, which would be a good place to lead this directive, it could, as was suggested, be the Secretary of Department of Health and Human Services. When you look at the

broad disciplines that need to come together, it does fit that model.

DR. DESSAI: Okay. We have Spencer and then we have Jenny.

MR. GARRETT: Thank you, Mr. Chairman. Spencer Garrett with NOAA Fisheries. I'm certainly sensitive to the need, and I think the way to do this has just been indicated. It should be a recommendation that the matter be referred to the Executive Office of the President's Office of Science and Technology, and I think that would probably fly as a scientific recommendation, not just a presidentially directed task force. We've got plenty of those that are pretty busy right now. But if you put in the Executive Office of the President's OSTP --

DR. DESSAI: OSTP.

MR. GARRETT: -- then I think that's a legitimate recommendation.

DR. BUNNING: I concur.

DR. DESSAI: Jenny.

MS. SCOTT: Nothing.

DR. DESSAI: Okay. Any other comments on this? Like Kelly said, this was one of the most important --

DR. KASE: Oh, I would like to actually hear how the statement reads now, please.

DR. DESSAI: Okay. We've not framed the language for that. So --

MR. GARRETT: Mr. Chairman, it could be very simply, this recommendation could be achieved with a referral --

DR. DESSAI: Okay.

MR. GARRETT: -- to the Executive Office of the President's Office of Science and Technology Policy.

DR. DESSAI: Barb.

MS. KOWALCYK: Barbara Kowalcyk, CFI. I just have a quick clarification. Would that sentence then continue to develop a task force with broad expertise to plan and implement a collection to detection initiative? Or are you talking about eliminating the entire rest of the recommendation?

MR. GARRETT: In fact, if it inferred that

would happen, it has to happen, broad-based, but if you want to leave that, that's fine, but just get the president out of there.

DR. DESSAI: So we replace a presidentially directed task force to the referral to the Executive Office of the President's Office of Science, Technology and Policy.

MR. GARRETT: Office of Science and Technology Policy. There's no and.

DR. DESSAI: Science and Technology Policy.

MS. KOWALCYK: To appoint a task force.

MR. GARRETT: To appoint a working group would be the --

DR. DESSAI: To appoint a working group.

MR. GARRETT: And just leave the rest.

DR. DESSAI: To appoint a working group with broad expertise to plan and implement a collection to detection initiative to and then the bullets. Thank you. Thank you, Kelly. Thank you, Spencer. Irene.

DR. WESLEY: May I recommend that you put quotes around collection to detection? This was a

spinoff on Farm to Fork.

DR. DESSAI: Correct. Okay. Thank you. Any other comments on page 74?

MS. RANSOM: Gerri Ransom. I have a question. Line 4 on page 74, where it says some current and emerging detection platforms are quite good, does performance or something need to be put in there for clarification? What does quite good mean?

DR. DESSAI: We --

MR. GARRETT: Could the word suitable be used?

DR. DESSAI: We can replace that. Lee-Ann.

DR. JAYKUS: I would actually suggest changing it, some current detection and emerging platforms, something like show promising capabilities or show promising performance, because you can't really separate the major prep from the detection platform. So all we can really say at this point is that the platforms look promising.

DR. DESSAI: So some of the current and emerging detection platforms look promising.

DR. JAYKUS: Or are quite promising.

DR. DESSAI: Are quite promising. Quite promising. So good will be replaced by promising. Okay. Page 74.

(No response.)

DR. DESSAI: Page 75 through --

DR. SOFOS: John Sofos. Just an editorial type of reminder that the references will need to be completed before it's submitted for publication.

DR. DESSAI: Okay. Thank you. That takes us to page 75 to 83. Page 84, 85. 86, 87.

Yes, Spencer.

MR. GARRETT: Thank you, Mr. Chairman. The same comment on the need for table headers on all the pages.

DR. DESSAI: Okay, noted. Jenny.

MS. SCOTT: To go back to page 85 and the PR/HACCP. Is that intended to refer to the pathogen reduction HACCP regulation?

DR. DESSAI: Page 85.

MS. SCOTT: You're defining it as an adaptation of HACCP intending to achieve reduction,

but we don't really define what the PR stands for in that context.

DR. DESSAI: Okay. We'll do that. Okay. Thank you. Spencer.

MR. GARRETT: Not to delay, I'm not familiar with that term at all, PR/HACCP. I thought it was public relations.

(Laughter.)

MR. GARRETT: I mean and that's fine, but somebody tell me what is pathogen reduction HACCP.

DR. ENGELJOHN: This is Engeljohn with FSIS. The PR/HACCP, it is intended to refer to the pathogen reduction HACCP regulations that FSIS issued.

MR. GARRETT: Well, then I think it should definitively say that because there's other HACCP programs operated by other agencies.

DR. ENGELJOHN: We'll change the reference. In the context of the document, it actually is in reference to the FSIS procedures. We'll get that changed.

MR. GARRETT: That's great.

DR. DESSAI: Thanks, Spencer. Page 85 through 90 back again.

(No response.)

DR. DESSAI: There are no comments on the document.

DR. MADDEN: Joe Madden. Just on page 87, line 15, is that supposed to be beta hemolytic *Listeria*?

DR. DESSAI: Line 18.

DR. MADDEN: Line 15.

DR. DESSAI: Line 15. Okay. All right. Thank you. Thanks, Joe. Irene.

DR. WESLEY: Way back on page 9 -- excuse me -- yeah, page 9, line 15, we lost our reference to the FSIS strategic plan.

DR. DESSAI: Line 15, yes, we'll insert it.

DR. WESLEY: Okay.

DR. DESSAI: Line 15. Thank you, Irene.

DR. ENGELJOHN: This is Engeljohn. If I could, the reference to that is on page 15, line number 17. I think that's where we decided was the most appropriate place for it.

DR. DESSAI: 17. Okay. Irene, do you want the reference to be moved in this location?

DR. ENGELJOHN: No, the most appropriate place for it is on line 17, page number 15 where it is presently located.

DR. DESSAI: Okay. Thank you. Spencer.

MR. GARRETT: Thank you. Just on page 90, the last page, at the very bottom, there's a 3 and a 4. What's that all about?

DR. ZINK: Oh, I get it. Those are lines 1 and 2, 3 and 4. They don't count the table as lines.

MR. GARRETT: Oh, I see. Okay. That's kind of new to us because there was nothing there, you know, just 3 and 4.

DR. DESSAI: Any other comments on the document? Am I asking for trouble?

MR. GARRETT: Again, as I said earlier, I think you all did a fantastic job. It's really worthwhile.

DR. DESSAI: Thank you.

(Applause.)

DR. DESSAI: We're not done yet. Lee-Ann.

DR. JAYKUS: Lee-Ann Jaykus, North Carolina State University. I just wanted to formally thank Dr. Peter Feng (of FDA) who was incredibly helpful in this task.

DR. DESSAI: Thank you. I just wanted to mention at this point, and we can clap again, we had a lot of experts that we had invited from other agencies, and we did invite about I think some 20 experts from across the country to come and tell us what are the newest technologies that they have out there. And we also had folks who are internal to FSIS. So many people have contributed to this effort, and Peter Feng's contribution just really stands out for his time and what he did for this Committee. He could not make it today because he is busy in the lab, but we do appreciate everyone's contributions here, and then once again I want to mention that the Subcommittee has worked week after week, through the webinar approach as well as through the week, to get this document here this week. No lunch.

(Laughter.)

DR. DESSAI: So I really appreciate the humongous efforts the Committee did this week and got the document here because we weren't quite sure to start with whether we would get here today. Thank you.

(Applause.)

DR. GOLDMAN: Very well. There was a lot of discussion during the review of this document, and there were changes recommended and noted by the Subcommittee Chair, and I want to ensure that the Committee as a whole agrees that what you heard and what we wrote down is going to be sufficient. I think we'll still end up re-circulating this. Is that right or no? We're done. So this is your last chance to -- okay. So if everyone's okay with that, we will now seek a motion to adopt this document with the changes as noted.

DR. WESLEY: I so move.

DR. GOLDMAN: Irene Wesley has made the motion.

DR. JAHNCKE: Second.

DR. GOLDMAN: Michael Jahncke has seconded. Any disagreement or dissension from adoption of this document?

(No response.)

DR. GOLDMAN: Seeing none, the document is adopted. Thank you.

(Applause.)

DR. GOLDMAN: Well, thank you all. We have two pieces of business left before you can all go home. So we have a decision. Does anyone need a break right at the moment?

(No response.)

DR. GOLDMAN: The two items we have left are the presentation of the work charge from Dr. Stevenson, and the last thing would be any public comments. So far, we have no one registered to make a public comment, but we will solicit at the very end.

Should we move ahead then?

(No response.)

DR. GOLDMAN: Okay. I'll turn it over now to Tim Stevenson.

COL. STEVENSON: All right. That's great. Let's roll with this. I had some help with the slides on the full sentences, but I did add in a few pictures which, from my academic background, we always loved to look at the pictures anyway.

So just to frame this a little bit on what the charge is for and how it will interact with what we do in the Department of Defense, the Veterinary Service works with all the other branches of the Service, the Army, the Marines, the Navy, and the Air Force, for their food safety needs outside the installation. Now, once it's delivered in through the gate, each branch of the Service has their own preventive medicine and other aspects that work with Food Safety, but outside the fence, especially overseas, the Army Veterinary Service is entrusted with that. So the work that you do will benefit not only the Army green, but all the branches of the Service.

A couple of pictures, just to keep us focused on who we're serving. Some of you, I know, have been in uniform and served in uniform. Others

of you may have family members, as you see on the bottom right, spouses or even children of military. I don't think any of us have been that person, but we've all been related to the military, and those that don't have those relationships, certainly know someone who has served in the uniformed services.

So we're asking for the National Advisory Committee to help us with our food safety initiatives, to protect and preserve the food supply of these men and women that are serving our country in uniform. And I've just been able to work with the Committee about a year and a half and have been so impressed with the level of expertise that is in this room, the expertise and experience, it just boggles my mind. I mean I feel like I've stayed at a Holiday Inn Express and spent some time with you guys. And so we're asking for your help to make our food supply as it can be.

Our food does come from around the world. Those of us living in the States are certainly more and more attuned to that with some of the outbreaks we've had recently with our global food supply

coming to the United States, but in the military, we're often consuming the food overseas, and you see some of the countries represented here where we have food supplies and where we have maybe some military personnel assigned. And so some of those areas of the world don't have the same cultures and some of the same standards in food safety that we have, certainly not across the board.

And so we try to pick out those processors, food processors that can attain the level of safety that we need to ensure the safety and well-being of our men and women in the services and then screen out those maybe that don't meet the rigorous standard of food safety like we've come to expect.

Three background slides. I'm sorry I'm finished with the pictures. So those of you that are wiser than I can engage now, and there are even some complete sentences I think on these, but background, the bedrock and the cornerstone of our food safety system is our audit program. We have auditors who are veterinarians and food safety experts. Some of those are not veterinarians, but

they're trained and they have expertise and background in food science and technology, and they do audits on some of our suppliers that sell food to the military.

We don't have the resources to audit every food supplier, you know. Crackers, we don't do an audit on the company producing crackers, but we focus on more potentially hazardous foods and do audits on those establishments. And one of the needs that has surfaced for this charge, this micro charge and the study for the group that we're asking is the auditors go into companies around the world and they see in these companies, in some cases microbial standards, and you think, where did they get that? It just doesn't merge with some of the scientific thought processes and the scientific norms and some of the standards that we have come to expect in the United States.

When our auditors are in the company doing the audit, in the absence of a clear reference standard, maybe one that this Committee could give us guidance on, then the auditor is in between a

rock and a hard place, and how does he sort of advise the food processor that the standard that he has might have some room for improvement. So this would be maybe something that our auditors could point toward when they are in countries around the world, they're looking at food processors, and they see microbial standards that maybe don't coincide with what we've come to expect in the United States.

In the absence, in some of those areas, we don't have clear standards of the United States that we could point to and say, for this particular commodity, these are some standards that you could consider, and in the absence of those, DoD has looked to industry. We have looked to federal agencies, scrubbing the literature, looking for all sorts of gleaning, the food safety community, to establish some of our own standards that again we didn't make up but we drew from many sources.

And if this Committee would look at those and give us some insight on the veracity and the applicability of those documents that we have, those standards that we have and how they might apply to

different food commodities, that would be especially useful for us.

And again, our perspective is global. We may be buying food and commodities from many parts of the world, and I think as we look at some of the spinoffs of this charge, and the work that this Committee does will help not only DoD, but as our food supply is so globally connected now, that the standards that this group comes up with I think will help us in the U.S. as we deal with international and global food markets as well.

Next background slide, some of the microstandards, and I'd ask you to consider that maybe at different points along production, from maybe the raw material, if there was a standard, and many of our companies would have a standard for accepting raw materials, and then they may have another standard later for finished product and then maybe at the end of shelf life, then we may be looking at a different milestone or target for some of those indicator organisms as well. And so again, looking at those points along the line.

We've talked about certificates of conformance and product acceptance. I think we have some industry representatives here and on the Committee. I think this may be helpful for them as well. Again, our auditors run into that when they look and they're doing an audit with a company, and they have an acceptance criteria, and many of those times, maybe they're well-intentioned, but we don't think they're getting the most value from their certificates of conformance, what they've written into the contract and what -- yeah, there's a micro test, but maybe it's not the most applicable and appropriate test for that raw material for their acceptance criteria. So we could point them to some advice maybe from this Committee on different commodities and which indicators might be most helpful for acceptance of raw materials.

And then again, indicators have historically looked at insanitary indicators that might show the process is out of control and that really we're not trying to test in safety. I think, you know, in years past, before we had refined food

processing systems, many times we tried to test in safety, we in the food safety community at large. That's not our goal, but our goal is to find microbial testing concepts and procedures and identify those that may be helpful for looking at the whole system, to find out when the system is out of kilter, something out of control, and then using indicators that might raise our level of concern maybe, and it could be tied to audit frequency. It could be tied to additional testing. It could be tied to a lot of different follow-on actions but using an indicator to look at process control and give us some increased level of suspicion. Or, in the other case, when things are good, that it would indicate good control along the food processing parameters.

And again, the second bullet, trying to harmonize what maybe has been published by a lot of private organizations, federal agencies, international standards, looking at some of those to harmonize those in some regard.

And so, again that takes us back to our

plea to ask for the brain power and wealth of experience in this room to help us refine our policies and give us some advice and guidance on the most applicable uses of microbial criteria.

So we've got one slide per question and the charge, and there are five questions.

The first one sort of points to and asks for a little bit of a roadmap. The DoD really is not in the process, the Department of Defense, of designing a microbiological criteria, but this could be a standard that we point our auditors to and we point our companies to that provide us. Like I say, some of these microbial standards that are applied and put into practice in different companies, and you look at it and you're like, well, where in the world did that come from, what plant did that come from?

And so this roadmap that we're asking for would be a way to codify maybe a more scientific approach to developing standards for different commodities. And so we've asked that sort of an overarching premise on how one would develop a

microbiological criteria, maybe for different points along the food processing chain and continuum.

Let me just go ahead and ask if there are questions on question 1. We've got five questions total. I think it would be fine to address questions as we go along rather than at the end, at this point of the presentation. Any questions on question 1, sort of the roadmap? How would one establish microbiological criterion?

(No response.)

COL. STEVENSON: Okay. Question 2 looks at various indicator organisms that have been used in the past, primarily to indicate insanitary conditions or poor process control, in looking at those, and again some of these are thrown out for the group's rigorous debate during the next times that the Committee gets together, the Subcommittee works on these. These have been used for various commodities. And so we'd like you to look at these at least as examples and say maybe they tend to apply or maybe they wouldn't apply as appropriately for certain commodities. So we'd like for you to

provide us some advice in those regards.

And then how might the level change between different commodities? So if one designed a process in a microbiological criterion, and we've asked for that advice in question 1, if one were designed along those lines, would something designed for poultry, would it also apply maybe to ground beef, or do you have to start over at ground zero? Would tuna salad be typical to ham salad? And so provide some advice there on different commodities and how these indicators might apply.

Questions on question 2? Yes, sir.

DR. KNABEL: Steve Knabel from Penn State University. One of the problems in using microorganisms as process control indicators is that they're so heterogeneously distributed in foods.

COL. STEVENSON: Yes.

DR. KNABEL: Is there any thought to actually adding some type of biomarker to foods before the process and then measure the decrease in that biomarker with time so that you can get something that's more uniformly distributed in the

food and actually gives you a better indication of the process control itself?

COL. STEVENSON: See, there's already been value from this group. Those are the kinds of ideas that we would like the Subcommittee to work through, and we've put these down as some examples, but the last column I think in the chart that is offered to you, are there other types of indicators that we should be considering? As technology develops, as our food processing systems develop, are there things like that, or phages and things like that, that maybe should be considered in the food industry? So I would welcome those types of thoughts and review from the Committee. Yes, ma'am.

DR. WESLEY: Irene Wesley, Ames, Iowa. I just had a question. This is assuming that if there is a company that you're looking potentially as a provider, that your standards would be equivalent to those in the prevailing country? Are you trying to look for harmonization?

COL. STEVENSON: We're in a unique situation as a buyer of products, not as a

regulatory agency. As a buyer, we can establish contracts and say these are the standards that we require, and so those standards, it may be some of these indicators often don't lend themselves directly to a purchasing standard, so to speak, especially when you're talking about indicator organisms, but what we have done in the past and what the group could discuss is, well, but looking at how does that affect our audit system? And give us some ideas about the confidence that we could have in the food processing system. So if some of these indicators were used and they're above a standard or we show a wide variety of results with some of these indicators, that would maybe increase our index of suspicion and we might do audits more frequently. Some of these products might not have exemption. We might go back and do more audits, a more thorough audit, things of this nature.

So we could have standards, and many times we have those type of standards in purchasing documents for pathogens, no *Salmonella* or *Salmonella*'s absent in a 25 gram sample, *E. coli*

O157, for those pathogens, those tend to be easier to put into contracting language that says we're going to exclude that type of thing, but we can have a standard of indictor organisms that ties in with our audit system. And if we go in to some countries and this happens, Dr. Wesley, where we go into countries and their standards are two or three logs higher than ours, and so then we work with the company, we look at what's actually in their process, and many times they may have a standard that's written in that they're going to have, for example, 6 log or 7 log, but actually what they're producing is 3 or 4 log. And so we would ask them to consider, if they want to do business with the Department of Defense, to lower their standard to what we consider an acceptable level, sort of tighten their processing conditions.

Sir, Dr. Zink.

DR. ZINK: Don Zink, FDA. I do think you're in kind of a unique situation, and as you usually think about micro criteria, you have some criteria above that, it's not acceptable. Below

that, it's acceptable, and you may have a three class plan wherein the middle you're uncertain, and accept or reject decisions have been made that way. There's some peril to that, and there's some difficulty with that, but in your situation, I think if we approached developing criteria for certain products produced by certain processes, that that could be an additional arrow in your quiver --

COL. STEVENSON: Yes.

DR. ZINK: -- in deciding whether or not you've got a potentially problem producer or not. I hate to try to get into the area where we write criteria that the world might interpret as accept or reject criteria.

COL. STEVENSON: Uh-huh.

DR. ZINK: But I have some pretty good insight into what some of your inspectors have to deal with in various countries and, you know, I think there's probably some good we could do with this.

COL. STEVENSON: Great.

DR. ZINK: And particularly since, correct

me if I'm wrong, you have a very large dataset where you've been doing this and collecting data for some time. I don't know how accessible or searchable it is, but --

COL. STEVENSON: Yes. Yes, sir. And we would try to make those available to the Committee as best we can; any way we see those data can help.

We have two primary laboratories, one in Europe and one in San Antonio, that has done extensive testing through the years. A lot of that again is focused on validating the system process. We do some pathogen testing as well, but focused on validating the system and raising our index of suspicion when we see indicators that the process is out of control.

Okay. All right. Question 3 gets into our ready-to-eat products, meat and poultry, and again looking at how different processes may vary between products and, in particular, ground beef, trimmings, ground beef products, how would it differ certainly between the ready-to-eat product. We may be looking at totally different indicators than we would in a

raw product or at different parts of the process. Again back to maybe certificates of conformance, initial product inspection, what would be prudent for companies, and as DoD works with companies around the world, what would be prudent if we could point them to a document like this that says for raw materials, you might want to consider this and again provide them some guidance. In many cases, what we see is maybe the parameters they're looking at aren't as scientifically valid as they could be, and as appropriate, as applicable, to provide them the best bang for the buck. Okay. Question 3. Okay. Ma'am.

DR. GLASS: Kathy Glass, UW Madison. I notice that most of these things are refrigerated type foods. Are there any other kinds of things that you need to take into consideration for some of the shelf stable items, particularly in light of some of our recent issues with shelf stable items?

COL. STEVENSON: We certainly wouldn't paint the Committee into a corner if there were some advice on some of these low moisture foods and

things such as what we're dealing with now with peanut products and things like that. The things that we've added, we wanted to be sure that we got some feedback on these particular commodities. That's where we've worked the most especially with microbial standards, but this wouldn't be a totally exclusive list. So if there's some guidance from the Committee, based on current issues or issues that may surface before the Committee is through with this work, we would welcome that as well.

Question 4, potential indicators, various points along the process, and again produce is one of those products, and bagged produce would be a refrigerated product as was mentioned in the last question, but are there some other parameters that we should consider at various points along the process? Again, primarily refrigerated, potentially hazardous foods, but it could also be low moisture foods or other areas of concern.

And this sort of opens it up, the question of are there other potential indicators such as Dr. Knabel asked earlier, phages, other types of

things that the Committee could recommend that we pursue in the future?

Last question, question number 5, looks at the old statistical issues. So that seems to be the question du jour of the day, and something that seems to be an area ripe for the picking, so to speak, and for consensus by the group, but as we develop these criteria, what type of sampling plans might go along with them, and what are the shortcomings of some of those sampling programs? So again not trying to test safety into a product, but looking at process control, indicators of process control, and the importance of statistical analysis as that ties in. Okay. Yes, ma'am.

MS. KOWALCYK: Barb Kowalcyk, CFI. I'm very impressed with the work charge, and I'm glad to see that question 5 is included. I just wanted to clarify that you're talking about statistical sampling plans, and this would not just include sampling in a laboratory setting but also sampling in the field.

COL. STEVENSON: Correct.

MS. KOWALCYK: I just wanted to clarify that.

COL. STEVENSON: Yes, yes. Samples taken from various points along the process.

MS. KOWALCYK: Okay. I also had a more general comment.

COL. STEVENSON: Yes.

MS. KOWALCYK: I can see that this charge would be applicable outside of DoD, also with USDA or FSIS and FDA, and I was wondering was that considered when bringing this charge before the Committee?

COL. STEVENSON: Sir.

DR. ENGELJOHN: This is Engeljohn with FSIS. I would say at least from the perspective of FSIS, we definitely saw an opportunity here for it to inform FSIS about the programs that we have. So we certainly were looking at this charge in terms of a broader perspective as well, specific to what's being asked, but also in light of how it could actually expand to that use that we actually have.

COL. STEVENSON: Spencer.

MR. GARRETT: Spencer Garrett, NOAA Fisheries. Yes, there are broader applications, but you have to remember, as Don Zink just indicated earlier, that this is a new twist for this Committee because most of the time we're looking at, you know, the science supporting regulatory actions, okay, and then there's a whole lot of scientific questions that you ask about that, and certainly statistical sampling plans and the performance characteristics and so forth are very important in that, very important in this as well.

But the point is here, the U.S. military or the Department of Defense is probably the third or fourth largest institutional purchaser of foods in the United States for food service, and because of that, one of their major difficulties is just buying food. I mean anybody that's ever been involved with this, and I have, years ago, I mean it's hard to get the supplier, the select supplier programs, dah, dah, dah, dah, dah, but again I want to point out that what you're asking is all going to be included, but this is a different type twist because now we're

dealing with the purchasing of food, trying to have microbiological criteria and other criteria. I mean we might develop a risk potential index for around the world or something, who knows.

COL. STEVENSON: Uh-huh.

MR. GARRETT: But it's a different twist, but it certainly has broad applicability for everybody.

COL. STEVENSON: Yes. Great. My last slide -- oh, a little bit for the Committee, a little bit on how it was recommended that the Subcommittee approach this. I worked very closely, and I'll go ahead and thank Spencer Garrett from NOAA Fisheries. He has graciously accepted to be the Chair of the Subcommittee, and the Board has recommended him for that, and we really look forward to his fantastic leadership and experience that he has in this area, and again working with the National Advisory Committee for many years, extremely well suited for this.

And these are some of the comments that we've worked with him on ways that he'd like to

approach this as a Subcommittee, first taking some of the work that's already been done by numerous agencies and organizations as you see listed, not an exhaustive list but certainly a starting point that the Committee would look at, look at some of the good work that's already been done and see where some of those guidances may have diverged, look at different areas and find the areas, maybe the gaps that are missing between those various agencies.

And then review and lay aside to compare the current DoD standards, which again have been gleaned from many of these agencies, and look at the appropriateness of those, good, bad, indifferent, give us some advice on how maybe the ones we're using now could best be used for various commodities and maybe ones that are maybe not as appropriate for this particular commodity. So give us some of your expertise in that area.

And then lastly, just looking at the charge questions, because again we did want specific feedback on those indicators that we've put forward in the charge, but we've not limited you to that, so

you can certainly add other criteria, indicator organisms as based on the wisdom and experience of the group.

So my last slide brings us to questions. Are there some questions about the overall nature of the charge that you would like to ask? Sir.

DR. TAUXE: Bob Tauxe at CDC. It's a very interesting charge, and I guess a question that I had was the extent to which DoD has in-house laboratory capacity or who would have perhaps contract audits with laboratory capacity and that laboratory approaches would be integral to this, not just a paper, you know, a paper limit or a paper description of a criterion.

COL. STEVENSON: Okay. Was there a particular question? I'm sorry.

DR. TAUXE: Well, you know, for example, if, you know, in the process of developing a criterion, is there the capacity within DoD if we were to suggest a certain number of laboratory steps be involved in the development of a criterion, is there a laboratory capacity to do that?

COL. STEVENSON: Some of that could be done by DoD. It just depends on the agencies. Most of our food, as I say, is procured off the installation. There's some food preparation on the installation, and so in that regard, DoD may be developing our own testing parameters based on the guidance of this group, but in most respects, it's done off the installation. The company, as we look at the quality history record of the company, as we do the audits, the advice of this Committee, our auditors could share with the processors that we're working with, especially in foreign countries where we see some microbiological criteria that maybe aren't as appropriate and scientifically based we we'd like them to be, and so they could be working with the company.

We do a significant amount of testing within our laboratories. Our processors that we bought food from also have testing programs. So it would be a combination really of those, and based on the guidance of this group, the most applicable indicator organisms for particular commodities,

that's probably where our limited laboratory testing -- because it's not an inexhaustible resource as, you know, where would we best focus our efforts.

DR. TAUXE: Thank you. I had one other question --

COL. STEVENSON: Yes, sir.

DR. TAUXE: -- which there is obvious interest in the application or consideration in some of our regulatory agencies to this, but it strikes me that many of our large private food companies confront this issue on a daily basis in their operations around the world, and I would hope it would be of interest and value to them as well.

COL. STEVENSON: I agree. I think the applicability to this charge is very broad in the value indeed.

Are there other questions? I know that there will be a lot of questions and debate when this goes to Subcommittee, but this at least gives you an overview, and again, I want to thank Spencer Garrett for agreeing to be the Chairman for this Subcommittee, full faith and confidence, and again,

thank you all for your service and being willing to share your expertise and wisdom.

I don't know if everybody saw our little friend here on the slide. So then we've got the question, you know, with this protein source. I don't know if this is a USDA product or FDA product, but I'll leave you with that thought and turn it back to the chair.

(Laughter.)

DR. GOLDMAN: Does everyone see the frog? Well, thank you, Dr. Stevenson. Thank you for leading us through that proposed charge. It sounds like there's a lot for this Committee to think about and wrestle with, and I think the point about the applicability beyond DoD is going to be a very important consideration for the Committee as well.

We're at the point now where I am to ask if there is anyone from the public who would like to make a comment?

(No response.)

DR. GOLDMAN: All right. I don't think we had anybody who signed up outside.

So I'm going to turn this back to Gerri for just a minute to kind of wrap up any administrative issues, and then we'll be ready to close I think.

MS. RANSOM: Okay. The first thing I'm going to do is pass the floor to my boss, Uday, who is going to briefly make a statement, and he just remembered what it was.

DR. DESSAI: This is to particularly appreciate and acknowledge the support in managing this NTSC effort of many people, especially Evelyne Mbandi who is being heroic in this effort which really made it possible for us to get to this point.

(Applause.)

DR. DESSAI: Thank you, Gerri.

MS. RANSOM: Thank you, Uday. I wanted to just say a word about the next NACMCF Committee, the 2009 - 2011 Committee. When members are appointed by the Secretary, we will have a press release out, getting the word out, and I also, I will be phoning each new appointed member to let them know they're on the Committee. So we'll keep our fingers crossed for June, and we'll go with that.

And I wanted to congratulate this Committee for your success. You do now have four adopted documents, four major pieces of work. So thank you for that. And I want to say you've been a fantastic bunch to work with.

Good luck to you in your future food safety endeavors, and I'm glad some of you may be coming back to us to serve another term. So thank you.

(Applause.)

DR. GOLDMAN: Any last comments from anyone for the good of the whole?

(No response.)

DR. GOLDMAN: Okay. I want to add my thanks and especially to the departing members. As I said earlier, we recognized them last night and added Lee-Ann's recognition today. It really takes a lot of time, as you all know very well, and we appreciate, the sponsoring agencies really appreciate this. So with that, I now call the meeting adjourned. (Whereupon, the meeting was concluded.)