UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA

FOR FOODS

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PLENARY SESSION

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FRIDAY,

SEPTEMBER 22, 2006

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The meeting convened in the Conference Room of the USDA Cafeteria, 1400 Independence Avenue, S.W., Washington, D.C., at 8:30 a.m., Robert E. Brackett, Ph.D., VICE-CHAIRPERSON, presiding.

EXECUTIVE COMMITTEE MEMBERS PRESENT:
ROBERT E. BRACKETT, Ph.D., Vice-Chairperson
LEEANNE JACKSON, Ph.D., FDA Liaison
BRADFORD W. HILDABRAND, D.V.M., M.V.P.M, Defense
Department Liaison
DAVID GOLDMAN, M.D., M.P.H., FSIS Liaison
GERRI RANSOM, M.S., Executive Secretariat
KAREN THOMAS-SHARP, Advisory Committee Specialist

COMMITTEE MEMBERS PRESENT:

DR. GARY ADES
DR. LARRY BEUCHAT
DR. KATHRYN BOOR
DR. SCOTT BROOKS
DR. PEGGY COOK
DR. DANIEL ENGELJOHN
MR. SPENCER GARRETT
DR. LINDA HARRIS
DR. WALT HILL
DR. MICHAEL JAHNCKE
DR. LEE-ANN JAYKUS
LTC. ROBIN KING
MS. BARBARA KOWALCYK
DR. JOSEPH MADDEN
DR. ALEJANDRO MAZZOTTA
DR. ANN MARIE McNAMARA
DR. JIANGHONG MENG
DR. DALE MORSE
MS. ANGELA RUPLE
DR. DONALD SCHAFFNER
MS. VIRGINIA(JENNY)SCOTT
DR. JOHN SOFOS
DR. STERLING THOMPSON
DR. IRENE WESLEY
DR. DONALD ZINK

MEETING PARTICIPANT PRESENT:

DR. JIM WITHEE

C O N T E N T S

P R O C E E D I N G S

(8:33 a.m.)

VICE-CHAIRPERSON BRACKETT: Well, good morning, everybody, and welcome, and I'd like to welcome all of our members, as well as our guests to this final plenary session of the 2004 - 2006 National Advisory Committee on Microbiological Criteria for Foods.

I am Dr. Robert Brackett, and I'm the Vice-Chair of the Committee and the Director of FDA's Center for Food Safety and Applied Nutrition.

Unfortunately our Chair, Dr. Richard Raymond, who is the Under Secretary for Food Safety at USDA, is unable to be here today due to another obligation, and he does send his sincere regrets that he cannot be here for this meeting.

As most of you know, the plenary session brings to a close the current two-year cycle of this Committee that began on September 23rd, 2004. The Chair and I want to

mention that our 2004-2006 Committee has been extremely productive in assisting our participating food safety agencies with a variety of typically complex food safety issues, and our members have provided an invaluable service in lending their expertise to our nation's food safety programs, and we are appreciative of that.

(In 2004 through 2006) The Committee is to be commended for their hard work and sound scientific advice provided in the reports, and for the important role that they played in helping provide us with a scientific foundation, very important, for regulations and programs aimed at reducing foodborne diseases and also enhancing general public health in the United States.

Preventing and reducing foodborne illnesses is a continuing challenge, and the reports that this Committee adopts are a vital part of our success in these areas. These reports provide us with the latest information

and serve as guidance and as part of our basis for science-based decision making in the regulatory agencies.

On behalf of the full Committee and the federal agencies that sponsor NACMCF, I would like to thank each of you for your service on the 2004-2006 Committee and the valuable time that you have given in support of the activities of this Committee.

At this time I think what we'd like to do is go around the table and have the Committee members introduce themselves and state their affiliations, please. And I guess we'll start over with Dr. Thompson.

DR. THOMPSON: (Speaking from an unmiked location.) (Hershey Foods Corporation)

DR. MENG: Jianghong Meng, University of Maryland.

DR. MORSE: Dale Morse, New York State Department of Health.

LTC. KING: Robin King, Department of Defense.

DR. BEUCHAT: Larry Beuchat, University of Georgia.

DR. MADDEN: Joseph Madden, Neogen Corporation.

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

DR. MAZZOTTA: Alejandro Mazzotta with McDonald's Corporation.

DR. McNAMARA: Ann Marie McNamara with Silliker, Inc.

DR. HILL: Walt Hill, Institute for Environmental Health.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority (STOP).

DR. JAHNCKE: Michael Jahncke, Virginia Tech.

DR. BROOKS: Scott Brooks, Food Safety Net Services.

DR. HARRIS: Linda Harris, University of California, Davis.

MR. GARRETT: Spencer Garrett, NOAA Fisheries, and on my immediate left is my

special assistant Emille Cole, also with NOAA Fisheries.

MS. RUPLE: Angela Ruple, also of NOAA Fisheries.

DR. ADES: Gary Ades, EHA Consulting.

DR. BOOR: Kathryn Boor, Cornell University.

DR. COOK: Peggy Cook, Safe Foods Corporation.

DR. SCHAFFNER: Don Schaffner, Rutgers, the State University of New Jersey.

DR. SOFOS: John Sofos, Colorado State University.

DR. WESLEY: Irene Wesley, Agriculture Research Service, National Animal Disease Center, Ames, Iowa.

DR. ENGELJOHN: Dan Engeljohn, U.S. Department of Agriculture, Food Safety and Inspection Service.

DR. JACKSON: LeeAnne Jackson, Food and Drug Administration, Center for Food

Safety and Applied Nutrition.

MS. RANSOM: Gerri Ransom, Food Safety Inspection Service.

DR. GOLDMAN: David Goldman, the Office of Public Health Science at the Food Safety and Inspection Service.

LTC. HILDABRAND: Brad Hildabrand, Department of Defense, Veterinary Service.

VICE-CHAIRPERSON BRACKETT: Dr. Zink just joined us. Name and affiliation, please.

DR. ZINK: Don Zink, Food and Drug Administration, Center for Food Safety and Applied Nutrition.

VICE-CHAIRPERSON BRACKETT: Okay. I think we've gotten everybody here.

Okay. At this time I'd like to turn the floor over to Gerri Ransom, our Executive Secretary, who can provide you with some additional information for the day.

MS. RANSOM: Good morning and, again, welcome. As always, please let Karen

and I know if you need any assistance and we'll get something for you if you need it.

We've already figured out how to work the microphones, but just push the button until you see the red ring and that will tell you it's on.

Just a quick reminder on some meeting procedure for today. When you'd like to speak, please take your name card and set it vertically. That will alert Dr. Brackett to call on you.

I wanted to mention for any guests wishing to make public comment, we ask that you please register with our folks out front. Public commenters will each have ten minutes for remarks.

I also want to point out to our guests that we have a table out front where you can find copies of NACMCF documents. So feel free to take copies of what interests you, and any guests who would like to distribute materials, please also see our

folks out front on that.

Related to NACMCF business I have a few updates for us. Regarding this Committee's two completed reports, that is, the report on the Analytical Utilities of *Campylobacter* Methodologies, that report has recently been posted on FSIS Website, and it has been accepted for publication by the Journal of Food Protection. So we'll see that published soon.

The other report, Response to the Questions Posed by the FSIS Regarding Consumer Guidelines for the Safe Cooking of Poultry Products, is also up on our Website. That's posted as a draft document. It has recently been accepted for publication in the Journal of Food Protection. So very soon we'll put the final version on the Web as well.

Now, as Dr. Brackett mentioned, the scientific advice provided by NACMCF plays an important role in strengthening sponsoring agencies' food safety programs. The

Campylobacter and poultry cook reports I just mentioned are a perfect example of this.

The *Campylobacter* report is being used extensively by our baseline study design teams who have been developing upcoming microbiological baseline studies for broilers (young chickens), and turkeys, respectively. This report is being heavily relied upon to assist us in selecting and validating a *Campylobacter* protocol.

We are also using the report for study design issues, including sampling plans, and this report is going to help us with future baselines as well where there's a *Campylobacter* testing component.

The poultry cook report was quite timely for the agency because we had to consider immediate recommendations related to a current outbreak associated with raw breaded poultry product, the type addressed in this report. There was also an urgent need for FSIS to convey safe poultry cooking procedures

to consumers and industry regarding avian influenza virus.

The agency used this report to support new labeling policy for raw breaded poultry products. The report's focus on the need for validating cooking instructions for consumers was vitally important information. This report is also serving as an important resource document for FSIS inspectors and the industry.

Now, as Dr. Brackett indicated, this Committee's two-year term is coming to an end, and it expires actually tomorrow, September 23rd, 2006. Now, the majority of our current members are eligible to return for another term, but new work charges will dictate what specific expertise is needed for the next Committee.

A notice soliciting nominations for membership on the next Committee term was published in the Federal Register on August 23rd. This notice has a 30-day open period

where we are collecting resumes on nominees. Copies of this notice are available out front.

A similar notice actually published in June, but this more recent notice contains some revisions, and if you look at the notice, it explains what these revisions are.

Anyone who applied to the June notice does not have to reapply to the August notice.

Upon the close of our nominations notice, the NACMCF Executive Committee will evaluate resumes received and make recommendations to the Secretary of Agriculture on appointees for the next NACMCF term.

Ultimately the Secretary of Agriculture will appoint 30 members to NACMCF to serve for the next two-year term. So we do have a process to go through, but I anticipate in early 2007 the new Committee will be in place and will be making plans for our next

meetings.

I'm happy to report that NACMCF was rechartered on August 3rd, 2006. This renewed charter is available on the FSIS Website. It's current through August 3rd, 2008, and I anticipate that a Federal Register notice will publish very soon on this.

Just a couple of administrative notes. Please check that your contact information in the meeting book if it's in need of any updates and let us know.

Very importantly, please fill out your travel expense sheets for your reimbursement for travel to this meeting and provide them with required receipts to Karen as soon as possible. This is very important this time around because we're approaching the end of our fiscal year. So it's critical that Karen receives your information.

I wanted to echo what Dr. Brackett said about this Committee being very hard working. I can verify this. I've seen

members just this week postponing lunch and dinner in order to get work done. We've got a very dedicated group of folks. We've seen people from other subcommittees volunteering to help the current working subcommittees. You guys have been a fabulous group, very enjoyable to work with. I thank you for this.

And with that I'll now turn the floor over to Dr. Brackett.

VICE-CHAIRPERSON BRACKETT: Thank you, Gerri.

Moving on, I'm pleased to report that our subcommittees have made some remarkable progress during this week, short week that it was, and the subcommittees include the Subcommittee on Determination of Cooking Parameters for Safe Seafood for Consumers, which was chaired by Mr. Spencer Garrett; and, secondly, the Subcommittee on Assessment of the Food Safety Importance of *Mycobacterium avium* subspecies *paratuberculosis*, chaired by Dr. Acheson. He

was unable to be here. So we had LeeAnne Jackson and Don Zink assisting in that Subcommittee this week.

Dr. Acheson's MAP group only recently began work during our March meetings this year, and the group has heard from a number of subject matter experts, and we're grateful for their willingness to share their expertise and for their participation in these subcommittee meetings and sessions.

I would now like to call on Dr. Don Zink of FDA, who is a member of the Subcommittee, to provide us with an update on the activities.

Don.

DR. ZINK: The Subcommittee has completed a review of almost 150 current publications in the scientific literature. There's still some more literature that this Subcommittee is accessing and evaluating, but after this review of literature, during this meeting the Subcommittee began to outline its

answers to the questions and began to write a report answering these questions.

I should add that the Subcommittee began its work by dividing itself in two, with one group addressing Questions No. 1 and 2 and part of Question 5, and another group addressing Question 3, which is efficacy of current methods for the detection of MAP, and these two groups are working independently and will then combine their reports.

I should also like to especially thank the outside experts that have been assisting the Subcommittee: Dr. Roy Radcliff of the Marshfield Clinic, and Dr. Michael Collins of the University Of Wisconsin School Of Veterinary Medicine. They've been extremely helpful to the Subcommittee.

Thank you.

VICE-CHAIRPERSON BRACKETT: Thank you, Don.

Do we have any other comments from any of the members of the Subcommittee for the

general good?

(No response.)

VICE-CHAIRPERSON BRACKETT: Okay. Thanks.

Spencer.

MR. GARRETT: Thank you, Mr. Chairman.

Let me begin by thanking the members of the Subcommittee, and I really didn't mean it when I said the floggings will continue until the report is finished. So I don't want you to think that I really meant that.

But we did quite a bit of work. The report that we have before us, there's actually three sections to the report, and the report -- would you like me to go through the report now? Is that --

VICE-CHAIRPERSON BRACKETT: I think you could have a summary of the report. We did have some discussion about the reports as well. Does everybody have a copy of the

report? That's the first thing because we can get you copies if you don't.

Some of the members of the general Committee have asked questions, and so I would like before we begin the report ask if there are any comments from the members.

MS. KOWALCYK: Yes, there is. This is Barbara Kowalcyk.

I'm just a little -- this is a very important document, and we received it last night about six o'clock and I would like to have more time to review it before we get really involved in discussing it and voting on it just because it's very important.

And I would, therefore, move that we postpone any major discussion until the next meeting.

VICE-CHAIRPERSON BRACKETT: Okay. Barbara has made a motion that we actually postpone this for further review. Do we have any seconds or discussion about this? Does anybody want to second what Barbara has

proposed here?

DR. SCHAFFNER: Second.

VICE-CHAIRPERSON BRACKETT: Okay. The second was Don Schaffner.

And, by the way, please make sure that you say your names and your affiliations for our transcriber here as well.

Okay. Any discussion about the proposal? It has been seconded to continue review of this document through the next session. Any other discussion about this?

MR. GARRETT: Mr. Chair, just let me ask Barbara. I think maybe we might want to go through the report, not certainly not adopt it, but go through it.

MS. KOWALCYK: Right. No, I have no problem with that. I just don't want to get into a major discussion about it since I didn't receive it until about six o'clock last night and didn't really have sufficient time to go through it thoroughly.

So before we went down any road of

major discussion, I just wanted to make sure you were aware.

MR. GARRETT: No, that's certainly fine, but we will go through the report, and then I think maybe what we might want to do is then after we finish going through the report, then have a timeline for any other comments to be sent to us, say, like November 1st or something, you know, whatever the date is.

MS. KOWALCYK: I think that's completely agreeable.

VICE-CHAIRPERSON BRACKETT: Okay. Thank you.

Let me just say here I have to leave because of an urgent matter, and so in my absence I've asked Dr. David Goldman to take over and continue on as chairing this meeting.

Thanks.

MR. GARRETT: With that then, I'll continue my remarks relative to the report in general, and then we'll go through it

essentially page by page if there are any comments to be made, again, with the record showing that we'll accept written comments until such date we decide after we go through the report.

As I started to indicate before, the report actually is comprised of three sections, and there's only two sections here. For example, the body of the report is contained from pages 1 to 33, and then there is an appendix, which are pages 34 through 40, and then also, the third part, which is missing which we still have to do, which we did not have time to do, merely actually lists the references. The references are noted in the text, but we haven't listed the references in the report, and we have to do that as well.

So the little extra time will help us all, I think. Okay?

And I'd just like to start on the first page. We spelled microbiological wrong twice. I think we got it right now. Any

comments on the first page?

The second page is the table of contents.

The third page is the introduction. You begin to see the references coming in now, and the list of references will be completed.

The fourth page -- and if I'm going too fast, somebody slow me down. Yeah? Yes, ma'am.

DR. WESLEY: I had a question on Line 117.

DR. GOLDMAN: Irene, please remember to identify yourself for the transcriptionist.

DR. WESLEY: Sure. Irene Wesley.

MR. GARRETT: Yes. Please go forward with your question.

DR. WESLEY: Excuse me?

MR. GARRETT: Ask your question.

DR. WESLEY: Okay, all right. I think you meant sanitation practices.

MR. GARRETT: Yes, the insertion is to insert the word "sanitation" between the words "harvest" and "practices" on Line 117.

DR. WESLEY: Yes. Something was a little bit amuck.

MR. GARRETT: So noted. Any more on page 4?

Page 5?

Page 6? I would point out that we actually reordered the order of the questions, which we do quite frequently in these documents just for ease of flow, and it makes the Committee work go easier.

Page 7. And on page 7, we begin answering the first question.

Page 8.

Page 9.

Page 10. I might point out that as we were looking at the documents, we obviously looked not only at scientific articles and technical articles, but also what I refer to as popular articles, like recipe

books and recipe Websites.

Page 11, and as you can see, there are numerous types and kinds of cooking methods for seafoods.

Page 12, and this table is actually showing the advantages and the limitations and a few comments relative to those methods.

Page 13.

Page 14.

Page 15, which brings us to Question 2 on page 16.

Page 17.

Page 18.

Page 19.

DR. MORSE: Question, comment. Dale Morse, New York State Health Department.

Looking at this and the table on 17, the category of unknown is very large, but I believe there are several papers that have looked in particular at shellfish-related outbreaks and showing that a number of them

would fit criteria for virus, norovirus type outbreaks, and it seems like there could be some mention of that.

They basically may not have definitive diagnoses, but they've looked at criteria, such as individuals have -- the symptoms they have, low rate of fever, high rate of vomiting. They have negative bacterial cultures, and the incubation and duration is comparable to viral-like outbreaks.

And then in some years where people have looked at multiple outbreaks more thoroughly with extensive testing have shown the majority of them related to noroviruses where they have done testing.

So it seems like there needs to be a greater description of the probable association with noroviruses, and it seems like that could be emphasized.

MR. GARRETT: Very well, Dr. Jaykus.

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

I agree with Dale. I think that's an excellent suggestion, and as a member of the subcommittee, I'll take care of drafting that.

MR. GARRETT: Thank you very much for those comments, both of those comments.

Do you have some more comments, Dale or Lee-Ann? Your little flags are at half mast there.

(Laughter.)

MR. GARRETT: Here's one. Thank you, Lynn.

DR. WESLEY: I had a comment on Lines 383 to about 385. Irene Wesley, USDA.

Lines 383 to 385, I would recommend that that statement be strengthened by including data to show there is an increase.

MR. GARRETT: Very well. Noted. Do you actually have the reference or are you

just merely suggesting we seek out the reference? Very well.

Page 20.

DR. MORSE: Dale Morse, New York.

Just coming back to 19 again, I'm going to mention this later on, but it's again an important role of *Vibrio vulnificus*. Even though it has been rare, the illnesses are very severe with people with blood stream infections having up to 50 percent mortality.

So I was going to mention it should be listed later on in the description of viruses, but it doesn't even appear in the table I notice in terms of outbreaks, but it is a very important pathogen for shellfish. So perhaps that should be mentioned here as well as sort of background information.

MR. GARRETT: So if I could paraphrase that, just strengthen the VV issue, argument or description. "Description" is a better word.

Very well. Page 20.

Page 21. Which brings us to our Question No. 4 on Line 446.

Page 22. Irene.

DR. WESLEY: Irene Wesley, USDA.

I would like to recommend that Lines 478 to 480, "there is no single temperature," that that statement be bolded.

MR. GARRETT: Are there any other Committee comments on that?

DR. SCHAFFNER: Yes, Don Schaffner, Rutgers University.

A comment on that general section. While I appreciate what you guys are trying to do with this sentence, the charge doesn't say anything about palatability, and what I'm wondering is can you share with us some of your discussions, and maybe this is not the place or time. But I'm concerned that the charge doesn't address palatability, but you've said we can't come up with an answer because it would result in an impalatable product.

Yet you sort of hint that you could theoretically come up with this temperature, and it still might be useful to come up with that temperature and then say, "But this will result in an unpalatable product in these circumstances."

MR. GARRETT: I believe in Question 5 that statement is actually made. The point is made in a different question. It is also made in the recommendations or the conclusions, rather.

It wasn't specifically in the charge. I mean, we intuitively kind of figured out that you still have to sell the product or you have to cook the product, and there's a difference between commercial cooking and ready-to-eat foods which have extended refrigerated shelf life versus, if you would, home cooking where the shelf life can be reasonably expected to be much less.

So does any other Committee member want to go further than that or try to

recapture the discussion? Or maybe we should go through Question 5 and if it's not answered there, then we'll come back to it.

I mean, obviously there is a single temperature. You could can all seafood. So I mean, it goes from that extreme down to trying to have some sort of palatable product.

I don't know if I'm making sense or not, but that essentially recaps our discussion. Any more on -- I'm sorry. Lee-Ann, yes.

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

I think what's critical in that sentence is all cooked fishery products, no single temperature that would inactivate pathogens in all products because it's product dependent, both the target pathogen and the temperature may be product dependent.

So keep that in mind. I think Spencer's point is that we do go into greater

detail later on in the narrative for Question 5 regarding that.

MR. GARRETT: Thank you for that, Lee-Ann. You might want to knock your little thing down there.

Twenty-three.

Twenty-four.

Twenty-five. Dale.

DR. MORSE: Dale Morse, New York.

Again, I've only reviewed this briefly. I don't know if there was discussion in the Subcommittee about, again, the importance of the *Vibrio* infections and *Vibrio vulnificus* and whether any recommendations at all can be made for safe cooking because it wasn't clear to me.

One, it seems like maybe there should be a separate paragraph about the importance of this pathogen, and it's my understanding that because of the inability to sort of recommend a safe temperature to cook it, that's why the recommendations are made

that immunocompromised individuals not consume this product raw, and I believe California has actually taken action to, I think, ban or restrict selling of shellfish from certain waters during certain times of the year.

So it seems like it should be at least addressed in the text. So did the Committee think that there was -- I know the charges for *Vibrio* talks about 122 degrees Fahrenheit for five minutes. Was that considered a safe level if somebody cooked at that level, or what is the product like after that much cooking? Was there discussion about this, and did other people think there should be more attention to this organism?

MR. GARRETT: Of course, *Vibrio* are fairly sensitive to heat. There's two points I think we need to make. One is our charge was with cooked seafood, and we can certainly put in, if you would like, if the Committee would like, we can put in a separate paragraph about *Vibrio vulnificus*.

Those illnesses, to my knowledge, I don't think there has been an illness due to cooked seafood, has there? Aren't they all raw?

So we did not really address raw seafood, sushi and so forth. But I think your point is well made, that we need to put something in here about *Vibrio vulnificus*, and we can do that in a separate paragraph.

Does that seem -- Dan?

DR. ENGELJOHN: Engeljohn with FSIS.

On page 23, you identified the log reduction for *Listeria*. Then on page 25 -- sorry. I should have started that way. Page 25 you give the time-temperatures for *Salmonella* as the target pathogen, and I was just wondering if it would be helpful to list what we think the expected log reduction for *Salmonella* is here. I think that would provide some useful information to industry.

MR. GARRETT: So you're

suggesting, as I understand it, to give the expected log reduction in the text relative to the table. We can do that.

Twenty-six. I'm sorry. Irene again.

DR. WESLEY: Irene Wesley, ARS.

On page 25, Line 552 through 553, I would recommend that you elaborate on the results of the prevalance studies that have been done on European shellfish.

And also, in the table -- excuse me?

MR. GARRETT: To what purpose? Just merely to -- I'm trying to get the context.

DR. WESLEY: I think that you have given the data for U.S. and to state similar environmental prevalence studies, I think that sort of leads to what the results of those studies were. I would say more for completion.

MR. GARRETT: Very well. I'm just

trying to get the context.

DR. WESLEY: And then I had another comment on 25 that's more of a clerical suggestion. In Table 5, for consistency, I would recommend, for example, on the time-temperature column that the abbreviation for minutes be either m-i-n, which is acceptable, or m-i-n-s, but just be consistent.

And similarly, over in the products category, for consistency again the word "homogenate" should be either capitalized or not capitalized.

MR. GARRETT: So noted.

Page 26.

Twenty-seven. Irene.

DR. WESLEY: Irene Wesley, ARS.

I would recommend that since the Z-value is defined, that D-value for ease of reading also be redefined.

I had a second --

MR. GARRETT: Yes, ma'am. Go

ahead.

DR. WESLEY: -- recommendation or question. The last citation for imitation crabmeat cites Mazzotta unpublished data. Is there -- my understanding was that data that are included in these reports should be peer reviewed or at least accessible.

DR. MAZZOTTA: The data is published. So I don't know if you want to cite the published paper.

MR. GARRETT: Yes, if we could have that publication.

John.

DR. SOFOS: The D-value is not defined in the table because it is defined in the text where the table is cited.

MR. GARRETT: Irene, is that satisfactory?

DR. WESLEY: I'm thinking that in terms of ease of reading, that the reader, therefore, has to go back into the text. Just for convenience, if it's there it's a little

bit easier to get the drift of where you're going with it.

MR. GARRETT: Very well. My off button did that.

Yes, Scott.

DR. BROOKS: This is just a point of editorial. I think we just missed a decimal point, but on Table 6, page 26, under lobster, the Z-value, it should be 5.0 C. degrees. So in case people were wondering which one was right.

(Laughter.)

MR. GARRETT: As they say, good catch.

Page 28. Irene.

DR. WESLEY: Line 585. Again, for convenience of the reader, this is the first time in this document that the abbreviations HAV have been used, although Hepatitis A virus is used in its entirety in other portions f the text.

MR. GARRETT: We'll check the

document. I believe that the first time it's used, it's spelled out and then the abbreviation put in parentheses after that. That's what it was supposed to be.

PARTICIPANT: Yes.

MR. GARRETT: Okay. Thank you. We'll check that. Thanks. Another good catch.

Dale.

DR. MORSE: Just a question for my own information. I know that the temperatures given sort of describe the internal temperature. For the layperson, how do you measure that when you're cooking it and did any of these papers look at how you could practically look at steaming at a certain temperature for a certain time frame? Are people supposed to measure the internal temperature while they're cooking?

Was there any sort of more practical guidance in any of the literature?

MR. GARRETT: Lee-Ann?

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

No, there is not more practical guidance in the literature. All of the studies that have been reported have been kind of set up in a laboratory and, you know, measured internal temperature in that manner.

So that's the answer to your question.

MR. GARRETT: Linda.

DR. HARRIS: I believe that in Table 6 you may have made an error in your Z-value. Z-values are not in degrees Fahrenheit, but they are Fahrenheit degrees, and so it appears that you may have just translated degrees Fahrenheit into degrees Celsius, and that's not correct.

So you'll have to go back, I think, and have a look at these calculations in the Celsius or go back to the original reference to see what was done here.

MR. GARRETT: So noted.

Donald.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

This is a comment back to Lee-Ann in response to Dale's question. Should one of the recommendations coming out of this Subcommittee then be that when people do studies in the laboratory that people be encouraged to look at real cooking conditions to see if there's a correlation or to see if we could put some more science behind this?

MR. GARRETT: That's an excellent suggestion. Let's wait until we get to the recommendations and let's bring that up again.

Lee-Ann.

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

Actually those studies, there have been studies done to that effect like grilling steaming, things like that. They are old studies. They're from the '70s, but we could certainly note those in this section.

MR. GARRETT: Linda. Oh.

This brings me to page 29.

Thirty. Oh, I'm sorry. Lee-Ann. I had the 1,000 yard stare there.

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

Before we leave this Question No. 5, and this actually goes back to one of Don Schaffner's initial questions or initial queries. I think it might be worthwhile somewhere to put a table that lists the categories of the commodities and the pathogens that really are of concern in those specific commodities because then I think it's much easier for the reader to understand what might be the most resistent pathogen in each different commodity.

MR. GARRETT: So then the suggestion is in Question No. 5, craft a new table indicating each commodity and pathogen of concern for each commodity. Yeah, great. A good idea.

Don.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

And, in fact, if you're going to do that and then you're going to recommend temperatures, I would suggest that on page 22 where you first respond to Question 5 say that although no single temperature could be determined, there is a table coming up that's going to recommend on a specific basis that so that the people don't read that paragraph and say, "Oh, well, then I'm not going to read the rest of the document."

MR. GARRETT: Good point. Lee-Ann.

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

I think that will also help with this issue of, you know, vibrios in molluscan shellfish because they're not highlighted from a heat standpoint because they would be killed very easily, you know, were the other

pathogens the target.

MR. GARRETT: Larry.

DR. BEUCHAT: Building on Lee-Ann's suggestion, would there be any value in listing seafoods relative to certain pathogens that might be more likely to be present that originated from various regions of the world or even coastal areas of the U.S.?

I don't know if this could be done easily, but for the purpose of importation of some seafood items, some entirely imported versus others that are not, are there differences in probability of prevalence of certain pathogens? I think there is.

And would that information be valuable also as part of this table that Lee-Ann has suggested?

MR. GARRETT: Which ones do you think, where that information exists?

(Laughter.)

DR. BEUCHAT: I'm not a seafood person

MR. GARRETT: Let me remind everybody --

DR. BEUCHAT: -- perhaps also some of the serotypes of *Salmonella*, not only enteric or pathogenic, for example.

MR. GARRETT: Let me remind everyone that we import 80 percent of the seafood we consume in the United States.

DR. BEUCHAT: The parasite issue, perhaps also viruses. I don't know.

MR. GARRETT: I take your point. It's just I'm not sure that we can do it. That's my point. We can certainly take another look at it.

Some years ago I published a risk potential index that actually did -- this is long before -- that we actually used an assessment or we called it an evaluation tool like that, but it's very complicated. When you glaze seafood, you actually analyze the glaze not the seafood. You have to chip the ice off, things like that, but we can take a

look at that, sure.

Twenty-nine.

Thirty. Oh, Don, I'm sorry.

DR. SCHAFFNER: That's okay. Don Schaffner, Rutgers University.

On the response to Question 6, I'm curious whether the Subcommittee debated whether -- it's not clear to me from reading this whether additional research is needed or whether no amount of research will ever clarify this issue, and I would hope that the Subcommittee would come -- if more research is needed, again, maybe that needs to be in recommendations, but it just wasn't clear to me, you know, whether anymore information would help it.

Certainly if more information would help, then that should be a recommendation.

MR. GARRETT: Would any Subcommittee member like to comment on that?

I don't think we need anymore

research on the drunken crabs that we looked at. I see from where you're coming, and there's certainly a difference even in ceviche where there's commercially prepared by people that actually can control the pH versus, you know, in the home. I'm just not certain more research is needed, frankly. We're trying to make a strong case that, you know, you pay your money and you take your choice.

Joe.

DR. MADDEN: Joseph Madden.

I was a member of the Subcommittee, and I kind of looked at that question as well, and it came to my mind how are we going to have a citizen check the pH, for example, on ceviche to make it 2.5 or below, and I struggled with that, too, the same thing.

But I don't know how we can accomplish that.

Thank you.

MR. GARRETT: Lee-Ann.

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

Again, this is the whole commodity specific area. I mean, it has definitely been studied in molluscan shellfish with vibrios, particularly alcohol and organic acids. so there is some data, but again, I tend to agree with Joe that it's such a specific area that I think it's going to be hard to do substantial research with individual commodities.

MR. GARRETT: Thirty-one -- oh, I'm sorry. Scott.

DR. BROOKS: Scott Brooks with Food Safety Net Services.

Just a note on that question. On Line 643, we talk about there being a paucity of data regarding the efficacy of novel methods. It essentially implies that if a good researcher came up with something out there, they certainly could do some research to answer it.

I wouldn't be opposed to adding a

recommendation in there, but it wouldn't be maybe as weighted as some of our other recommendations.

MR. GARRETT: Let's just wait until we get to the recommendations. Then we'll sort it out then.

Thirty-one. Oh, Dale. I'm sorry.

DR. MORSE: I just had another comment on page 30 under the seventh number. This may be covered by putting more background information earlier in the text about the epidemiology and risks from shellfish and *Vibrio vulnificus*, but just this section starts out that advisories currently exist and recommendations on consuming only properly cooked. It doesn't give the background of why, such as, you know, immunocompromised individuals are at high risk for certain infections such as *Vibrio*.

So perhaps, you know, emphasizing what the risks are first, that's the reason why there are advisories. So just more

background of the risk that is posed to these individuals.

MR. GARRETT: So what I'm noting here then, Dale, would be more background on who the subpopulations at risk are and what those risks, in fact, are for those subpopulations. Does that get the point?

DR. MORSE: Yes, it would just be the question asked, should there be, you know, any special advice, and so you need to start off with the sentence that immunocompromised are at higher risk. Several studies have demonstrated that they can be at high risk and, therefore, you know, advisories have been made, since there's background why there's advisories, and there's a reason for this.

MR. GARRETT: Larry.

DR. BEUCHAT: Larry Beuchat, University of Georgia.

I don't want to belabor the point on the consumer methods for preparing seafood, but I remember you might want to consider

referencing a paper published by Oliver and his group several years ago now demonstrating that the use of cocktail sauce was not the answer to eliminating vibrios. I believe it was on oysters, just to strengthen this --

MR. GARRETT: Tabasco sauce, I think, but again, gentlemen, this is not a document on raw fish. I think we have to keep that in the back of our mind. We kind of had those discussions, but we really were not asked to produce a document on eating raw foods, and most of the discussion that we're taking even in terms of the advisories relate to raw molluscan shellfish.

And I might point out actually that there's a little over 3,000 advisories for fishery problems. I think it's around 3,400 now. You can go on the EPA Website and take a look. Most of those are chemical advisories.

Thirty-one.

Should we recognize him? Yeah,

Dan's got one.

DR. ENGELJOHN: Engeljohn with USDA.

On the seventh bullet related to *Listeria*, I'm concerned that the bullet or recommendation implies that it's better to undercook the product than to cook it for safety.

And so if you go back to page 23, it says the reason why, this 6-D for *Listeria* might not be appropriate for consumers, and the response was because the types and numbers of bacterial pathogens might not be present as they are on the commercially distributed or manufactured seafood.

So it gives the reason that the micro levels are different and are of different types, and that's the reason why, and I really don't think it would be good to imply that it's better to undercook it so that it's palatable than to cook it until it's safe.

MR. GARRETT: Are you suggesting that we explain the reason why here or are you saying that we should reduce the phrase "and could result in overcooking"?

DR. ENGELJOHN: I think that because I think people will tend to go to the conclusions to try to get a synopsis of what you're dealing with it would be better to just use the wording that you had back on page 23 and add in "due to types and numbers of bacterial pathogens that might be present on commercially distributed or manufactured seafood." It seems to me that would provide the clarity as to why. It's the same wording from page 23.

MR. GARRETT: So noted. Any more on page 31? Don.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

In the bullet point below that, I think you might be missing the word "not." You say, "This recommended cooking time-

temperature may be practical for consumers." That contradicts what I think you said earlier in the text.

MR. GARRETT: Another good catch just like that missed decimal point.

Thirty-two. Dan.

DR. ENGELJOHN: Yes. Engeljohn with USDA.

As a follow-up to my previous comment on page 20 or on page 31 about the *Listeria*, because it's not explained in the paper, do we know what the level of contamination is on the consumer ready products so that we could provide guidance as to what the appropriate log reduction from *Listeria* would be on the consumer products?

So I guess the question is: is there a data need for knowing what the contamination level is on consumer ready product that's different than that for the commercially distributed product and the reason why you're saying 6-log reduction from

Listeria is necessary there?

Perhaps if we knew what the level of contamination was on the consumer ready product you would have more guidance to give as to what the appropriate level would be. I'm just asking the question because I don't know.

MR. GARRETT: As I recall the discussions, there are several points to make. One is that the level and the pathogens are very commodity-specific.

Two, there often times is not much known. So therefore, when you're doing thermal times, that you have to use a surrogate organism, and I think that was my understanding.

John, do you want to add to that or correct me if I'm incorrect?

DR. SOFOS: Yes, Sofos.

Also for the commercially prepared 6-D reduction products, we need to consider that those have a shelf life and should be

distributed, sold, while the consumers were not expecting a long storage of leftovers, but pretty much quick consumption.

So the 6-D reduction may be also needed to take care of potential growth during storage.

MR. GARRETT: I think what Dan may be recommending is that -- and this goes back, I think, to perhaps what Don was pointing out in some of his recommendations -- that there is a research need to better describe what could reasonably and usually be expected on the consumer prepared seafoods, the raw materials that the consumer is going to have.

Is that agreeable? And we'll note that and put it in?

John still. No, Scott.

DR. BROOKS: Scott Brooks, Food Safety Net Services.

Just to point out maybe a partial answer to the question, on page 37 in the appendix, we actually do list the *Listeria*

monocytogenes risk assessment, expected contamination levels.

MR. GARRETT: Lee-Ann first and then Dale.

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

Line 703 should be *Salmonella enterica* species, not Enteritidis.

MR. GARRETT: Another good catch.

Dale.

DR. MORSE: Dale Morse, New York.

It may be already in the last bullet, but I'm thinking about the earlier discussion about, you know, the cooking methods and needing to get the guidance into practical cooking guidance, like back to shellfish instead of the internal temperature, because it seems like the Committee should make this recommendation that there needs to be specific cooking methods, including, you know, practical or something that focuses on you've got to be able to have something, you

know, steaming it at what temperature for what time or something rather than just the internal temperature. Otherwise you have to have thermometers that measure that.

So try to look at a way to emphasize the importance of developing practical guidelines for the consumer to be able to follow that is scientifically safe.

MR. GARRETT: How about in Line 710 we got rid of both and we just said "provide practical, safe, and palatable products for consumers"?

That last recommendation is a dual statement that addresses both the cooking procedures, as well as what the target organisms are. So I think that's about as far as you can go, and that is a big research item.

Lee-Ann.

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

If I could just suggest ending

that was "provide both safe and palatable products to consumers and practical guidance to consumers to attain this," or something, something worded in that means.

MR. GARRETT: "And practical guidance for consumers," something like that, yeah.

LTC. KING: Robin King, Department of Defense Veterinary Services.

I was going to go back to the bullet that starts on Line 698 again. Looking at that it seems to me that's not really a recommendation. It's just a repeat of the conclusion above, and I know there was some talk about that earlier. Was the final conclusion that there was going to be a recommendation made about either the target organism, L. mono, or, you know, to relook if there's something else that can be done for seafood products?

MR. GARRETT: Well, I think earlier in the text it was indicated that the

current guidance in the food code, which was based on *Salmonella enterica*, which is essentially a 3-D cook, I think that is referenced in the text.

What do you recommend that we do here?

LTC. KING: Well, I think something needs to be added to either make a recommendation to refer either to earlier text or to add text to make this a recommendation. To me as I read it, it's really just another conclusion.

MR. GARRETT: So either refer to the earlier text or add sufficiently to make this a recommendation, yeah. Very good.

Don, I promised I'd come back now. Have we incorporated sufficient research recommendations or would you like to add some?

DR. SCHAFFNER: No, I think we're good.

MR. GARRETT: Okay. Any other academician, I mean, I know there's others in

the house -- but is there any other academician who wishes to add a recommendation or anybody on the Committee? Dan.

DR. ENGELJOHN: Just because, again, it's my lack of understanding about seafood and fish, but on the bullets, I think they begin like on Line 700, the one about *Salmonella*. There the bullet advises that the *Salmonella* should be the target organism and that should be followed, but if you go back to page 25, the information that you're referring to is to seafood, but to some specific seafoods.

Because I do think that people do tend to read conclusions and recommendations. I'm just curious as to whether or not the bullet should be more explicit as to which seafood products, *Salmonella*, should be the target organism.

MR. GARRETT: I think I'm not an expert on the Food Code by a shot. We have some around here. If I'm not mistaken, the

Food Code -- how is that worded? Scott, you're kind of an expert on the seafood code. How is that? It covers seafoods and other foods as well. It's not just seafoods, is it?

DR. BROOKS: You're talking Section 3401 in the Food Code?

MR. GARRETT: I don't know what I'm -- I don't know what.

(Laughter.)

DR. BROOKS: I was having a cite problem.

MR. GARRETT: See what I mean? He's kind of an expert.

DR. BROOKS: I apologize. I was having a sidebar, but you're talking about the cooking and the D-values for *Salmonella*? Yeah, and there is very little information specifically on seafoods in the Food Code. In the public health reasons for 3-401, it makes an inference. It says because the expected contamination levels are limited on the interior of the seafood, that this would be

adequate for destruction of the *Salmonella* on the exterior surface of the seafood.

There is a paucity of data in that as well though.

MR. GARRETT: Thank you.

So I think perhaps with that information, Don, that very well might be a recommendation, but Lee-Ann first and then --

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

I was just going to agree with Dan. I mean certainly molluscan shellfish needs to be pulled out of that.

DR. ENGELJOHN: I was just going to verify that. This is Engeljohn.

That the reference in the Food Code does refer to fish, not just seafood, and I know there's a difference. I'm sure there is.

(Laughter.)

DR. ENGELJOHN: But because it does right above that in page 23 talk about

molluscan shellfish and the fact that there's a limited amount of data, I just think it would be better to be more clear here in these recommendations and conclusions.

MR. GARRETT: So noted, and just in the interest of transparency, let the record show that I don't know much about poultry --

(Laughter.)

MR. GARRETT: -- as it relates to cooking, but I was a poultry pathologist for *Charles Pfizer* for five years in one of their laboratories. So I know the inside of the chickens. I just don't know much about the outsides of them.

Irene.

DR. WESLEY: Irene Wesley, ARS.

Line 697 on page 32, I think you folks want to assure the microbial safety of seafoods.

MR. GARRETT: On page 32, 697?

DR. WESLEY: Yes.

MR. GARRETT: I think we may have to run that by Walt Hill.

PARTICIPANT: (Speaking from an unmiked location.)

MR. GARRETT: That's a little sidebar humor going on in the Subcommittee there.

But certainly a point well taken. Do you have some more, Irene?

See, I get to do that all the time.

Thirty-three.

Now, then what we did actually is to give more clarifying or more information in the appendix, commonly done in many documents such as this, Codex and so forth. Still has the same force and stature as the text itself, by the way.

So I'll start going through the references, and if anybody wants to add anything or give us some advice on any changes, please feel free.

Page 34. Irene.

DR. WESLEY: I'm going to recommend that at Line 734 that you actually put in the D-value for Campy to show how low it is.

MR. GARRETT: Should we do that for all of them or just Campy?

DR. WESLEY: I'm just looking at page 34.

MR. GARRETT: Okay, okay. Any more on page 34?

Thirty-five. Dan or Don, rather.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

If we're going alphabetically, *Salmonella* would be next, and *Salmonella* is missing. I'm wondering if there's a reason why the Subcommittee has not included *Salmonella*.

MR. GARRETT: Yeah, the reason it's missing is it was originally in the appendix, and what we did was a short write-up

and so we just put it in the text. That's the only reason it's missing.

DR. SCHAFFNER: And then just as a follow-up question, it looks like you started off this list alphabetically and then somewhere in the middle of the list it's not alphabetical. If you have a logic for why you had it the way it is, I'd be happy to hear it, but otherwise I'd suggest you pick some system for organizing it and then stick to it.

MR. GARRETT: We'll so note that we need to put this alphabetically. How would that be? Once we took *Salmonella* out, everything fell apart. Ordinarily this would have been done, but we were actually moving very quick on this one.

DR. COOK: Spencer, Peggy Cook, Safe Foods.

I would really recommend that you put *Salmonella* back in that since you're listing pathogens.

MR. GARRETT: Should we put it in

word for word what we have in the text or should we put some more descriptive information? We probably ought to put some more descriptive information about *Salmonella*.

I would turn to John Sofos to help with that. John, if you don't mind. Okay?

Irene.

DR. WESLEY: If *Salmonella* goes back in, which I think is superb, I would recommend that *Listeria* also be popped in there somewhere.

PARTICIPANTS: It is.

MR. GARRETT: It is.

Thirty-six.

Thirty-seven.

Thirty-eight. Dale.

DR. MORSE: It's a small point. You know, several times in the text the term "food handlers" is used. I guess a preference for "food workers" instead of "food handlers," for states like New York that have regulations against direct handling of food that could be

then consumed without cooking. So the preference is to not reinforce the message that should be bare hand contact with food. So sort of a JACUS-H term (phonetic), a preference to use the term "food worker" rather than "food handler" throughout.

MR. GARRETT: Use the term what?

DR. MORSE: Food worker.

MR. GARRETT: Food workers. Okay. Remember I'm from Mississippi. Gambling is outlawed in our state constitution. So we renamed it gaming, and we're doing well.

Point well taken though.

Jenny.

MS. SCOTT: Jenny Scott, Food Products Association.

It seems to me that there are a lot of food workers that don't actually handle food and this could be problematic. Can we come up with a different solution that would address Dale's concern as well as deal with that, and then consumers that handle food that

aren't workers?

MR. GARRETT: Linda.

DR. HARRIS: Well, I would just ask. It seems to me that you can handle food with tongs or you can handle food with gloves on. You know, I understand the issue is no direct contact, bare hand contact, but aren't they still food handlers when you're separated from direct contact with the food?

MR. GARRETT: Dale, I'm taken with the argument to the contrary. This is not a regulation we're writing here.

DR. MORSE: Right. Of course, anybody could handle food, even all the way so that it would cover workers anyway.

MR. GARRETT: Yeah. I think food handling is a usual and customary term used, you know, in CODEX documents and international documents, FAO documents. I think we had better stick with a popular notation. I think we'd be on a little bit better ground for understanding at least.

Larry.

DR. BEUCHAT: Larry Beuchat, University of Georgia.

Just a question out of curiosity more or less. *Plesiomonas* is not on the screen at all. Is that not now or has it ever been really considered a foodborne pathogen? I'm just curious. It's not listed here.

MR. GARRETT: Joe.

DR. MADDEN: Joe Madden, Neogen Corporation.

I think what we tried to do, Larry, was to take and look at what was reported in outbreaks in the CDC, and those were the ones that we were addressing, and there were no cases of *Plesiomonas shigelloides* reported.

There were?

PARTICIPANT: Yes.

DR. MADDEN: Okay. There were some. I'm sorry. Take it back.

MR. GARRETT: I've done some

things I wish I could take back.

(Laughter.)

MR. GARRETT: No, I think it's a point well taken. If it's right, we ought to put something in there.

Thirty-nine.

Forty. Don.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

It's not clear to me what lethal rate means in this table, and I'm wondering if you can provide some units or some clarification. It's not a commonly used term, at least not one I'm familiar with.

MR. GARRETT: Would any Subcommittee member like to address that for him? Jenny.

MS. SCOTT: Jenny Scott, FPA.

I think we need a little bit more information with respect to this table, putting it into context. There's no descriptor here where it comes from. We have

the information where it originates from, in addition to being in the hazards and controls guidance, and to Don's point, yeah, we ought to provide some explanation for the lethal rate.

MR. GARRETT: Could I rely on you to grab something and submit it to us?

Any more comments on page 40?

DR. SCHAFFNER: Just a minor typo. *monocytogenes* is not capitalized.

MR. GARRETT: Linda picked that up for me.

Ladies and gentlemen, we've gone through the document, albeit rather rapidly. What we would like to do now, I think, is if there are any other comments, we'd like to be provided those comments in writing to -- oh, I'm sorry, Irene.

DR. WESLEY: I had just a couple of thoughts. On page 40, and it sort of goes also back into 39 -- Irene Wesley, ARS. Excuse me.

Helminths, I'm going to assume because I don't know the data, are probably not as important as a risk in seafoods as, say, bacteria or viruses, and somewhere I'd like to recommend to the Committee that they perhaps provide some risk numbers so that the helminths can be categorized as either high, low or medium in comparison to the bacterial and viral agents.

Then over on page 40, Lines 910 to 911 --

MR. GARRETT: Well, let me stop you right there just a minute. Certainly do what you want to do, but I'm wondering why you want to do it. I mean, helminths are -- I mean, *Anisakis*, for example, certainly does not rise to the risk of some bacterial pathogens, but nonetheless it is reported by CDC.

DR. WESLEY: But I'm wondering in terms of priority.

MR. GARRETT: Well, that's what --

DR. WESLEY: Importance.

MR. GARRETT: That's why I wanted to know. Once you start, we were not asked to do a risk assessment or prioritization of risk. Once we start with one, then where do you stop? I think that was the concern of the Subcommittee.

DR. WESLEY: Okay.

MR. GARRETT: That's the problem. Certainly it's not -- and, again, most of those cases are, again, from eating raw fish.

DR. WESLEY: Then I had a question on Lines 910 and 911. I'm a little concerned about the references based on the 1979 and 1982 publication in terms of recency. You know, supermarkets I'm going to assume have changed a lot in the last couple of years.

MR. GARRETT: These were actually done on the fish themselves. I mean, the worm is going to still be there. The *Anisakis* -- in fact, I believe one was FDA did a study. Joe, you might be able to help me out. It was

done back years and years and years ago looking for *Diphyllobothrium latum*, which is the broad fish tapeworm, in wild salmon, and I think the sample size was over 1,000, and they didn't find any, but they found *Anisakis* in every fillet.

So I think that data -- I mean, that data is still there. I don't think anything has changed to get the worm out of the wild fish is what I'm trying to say.

DR. WESLEY: Then one final comment --

MR. GARRETT: Yeah, sure.

DR. WESLEY: -- on Line 916 or is that 915 and a half? I'm going to assume that the number in parentheses is degrees Centigrade.

MR. GARRETT: Okay. Jenny.

MS. SCOTT: Jenny Scott, FPA.

Just to Irene's point, could we add a sentence at the end of Line 911 that says, "No more recent data are available"?

MR. GARRETT: Jenny, I apologize. I didn't -- I was taking care of an administrative matter.

MS. SCOTT: Just as an administrative matter, could we add a sentence at the end of 911 that says, "No more recent data are available" to address Irene's concern?

MR. GARRETT: Yeah, we'll check that to make certain that's true, too.

Okay. Then what I would like to do then if it's possible, if there are any other comments that people would like to make, I would like for you to forward those comments using this document, and when you make your comment, please indicate the page number and the line number, and forward those comments to Gerri Ransom, and then she'll get them to us, and then we'll look at them and incorporate them or talk to the Subcommittee by phone and, you know, hash it out.

I think one of the things, if I'm

not mistaken, Gerri, we actually could do this -- well, I don't guess we could. I was thinking we could actually adopt this report by phone, but we really can't because some members are going off and new members are coming on.

So we'll have it ready for formal passage at the next --

MS. RANSOM: Okay, yeah. We'll look at the logistics of the format of the meeting that we'll get it adopted at.

MR. GARRETT: Yeah.

MS. RANSOM: We might wait until the next meeting.

MR. GARRETT: Yeah, whatever. Okay.

MS. RANSOM: And did you have a deadline, Spencer, on those comments?

MR. GARRETT: I would kind of like November 1. That gives everybody plenty of time to look at it.

Boy, that was a definitive pop if

I ever heard one. What a pen.

So I again thank you for participating in this exercise. I again thank the Subcommittee for their hard work, and it's really fun to be associated with a team like you folks.

Thank you very much.

DR. GOLDMAN: Okay. Thank you very much, Spencer.

I want to add my thanks to you and your subcommittee and your staff for bringing this document to the full Committee today and to the Committee for beginning pretty substantive discussion as well as the group edit that we always do very well, I think, and assist the Subcommittee as well in producing a good final document.

So we have an assignment now for the full Committee to bring any additional comments back to the Subcommittee through Gerri Ransom by November 1st, and I think we will be poised then to have the full final

document ready for adoption at the first plenary session of the next Committee. So I think that's the way we'll be able to handle that.

I'm sorry. Scott.

DR. BROOKS: Scott Brooks, Food Safety Net Services.

Maybe it's my parliamentary background or something, but just a point of parliamentary order. We did have a motion that was seconded earlier. I think we kind of went on past it, but probably just to close the books, we should probably take a vote on it or something or withdraw it.

DR. GOLDMAN: Thanks for that reminder. I noted that in a sidebar. Yes, we did have a motion to not adopt this report by the full Committee today and to have some further time for discussion and comment, and that motion was seconded.

I think we saw some head nods, but can we get the assent of the entire Committee

to adopt that motion?

Is there anyone opposed to that then?

MS. RANSOM: Can we review who did the first and second motion?

MS. KOWALCYK: Barbara Kowalcyk from Safe Tables.

I did the first motion.

DR. SCHAFFNER: And Don Schaffner seconded.

DR. GOLDMAN: Okay. Thank you.

Okay. Thanks, again.

If you look at your agenda, we are at a break. So we will do that, but before we do, I just want to review briefly what's coming up. After the break we'll have the presentation of two draft charges to the Committee. Both of them will be in the form of draft charges, which indicates that the presenters and the agencies that are sponsoring them would like for the Committee to help them refine the charges to the extent

that the Committee feels it's necessary.

The other thing I want to note is that you heard from Jenny Scott, but she entered the Committee meeting during our discussion on that subcommittee report. So we want to welcome Jenny Scott from Food Products Association to the meeting.

We missed one very important thing. Since it is break time, to remind you about where the restrooms are for those who are not familiar with the building. If you exit the doors right out this way, the men's room is down to the left a fair piece down the corridor there, and the women's room is just to the right, I think, out that exit there.

So we are ahead of time, as is somewhat customary to the plenary session, but we will take our break. We'll give you 20 minutes for a break, and we'll reconvene at that time, unless there are any comments at this point from anyone else.

So we'll reconvene at, say, 10:25.

Thank you.

(Whereupon, the foregoing matter went off the record at 10:06 a.m. and went back on the record at 10:33 a.m.)

DR. GOLDMAN: Before we move to our draft work charges, Gerri Ransom has a couple more administrative announcements.

MS. RANSOM: Okay. I just wanted to give you the reminder to please turn in your annual ethics training certificates to Karen or myself before you leave today or speak to us if there's a problem with that, but please turn those in.

Also, Karen has reemphasized to me that it is very important to get your travel information into her for reimbursement due to the end of our fiscal year. So there's our second reminder on that.

And also, for members of the public we did check out front. No one signed up for public comment. So if you do want to make a public comment, please sign up outside

at the table.

Thanks.

DR. GOLDMAN: Okay. Thank you, Gerri.

One other small point on the agenda. There is a break scheduled after the draft work charges. We will forego that break unless there is a particular need, and we'll let individual members take a break if they need to in the interest of moving the agenda along and perhaps adjourning early, as I expect we'll be able to do.

So we now have a draft work charge that will be presented by Don Zink from the FDA. He will present a draft charge on inoculated pack challenge study protocols.

FDA, just to reiterate has brought this charge forward to the full Committee for their input, their guidance and clarification on issues that are surrounding setting up such challenge studies. This is an area I think we'll all agree is of critical importance to

public health.

With that, Don.

DR. ZINK: Okay. Thank you very much.

As you think about this charge, put yourself in the place mentally of either a state, local, or federal regulator who must review the results of the challenge study, or of a laboratory manager who must design a challenge study that is going to be appropriate and will receive favorable regulatory review.

By way of further background, the primary customer, if you will, of these sorts of inoculated pack or challenge study protocols are restaurant and retail food store industry. They routinely do these things or contract to have these done to determine whether a specific food requires time-temperature control for safety, and by that I mean must the food be kept refrigerated or must the shelf life of the food be limited.

Can they get a waiver from refrigeration or shelf life requirements, in other words?

When laboratory testing is used to support this, the data is usually submitted to a state or local agency or directly to the FDA in the form of a variance application for approval. I think it is safe to say that having looked at a number of these over the years, there is quite a bit of variability in the quality and adequacy of these studies that are submitted.

The submitter is responsible to insure that the study is appropriate for the food and pathogen of concern, and that all of the necessary elements are in the study that will make it a valid design and present a conclusion that you can have confidence in.

Now, for your information, the definition of potentially hazardous food or a food that requires time-temperature control for safety was amended in the 2005 FDA Food Code. Previously the code set pH limits or

water activity limits, and now the food code actually gives you two tables, and these two tables, one is for organisms that produce heat resistant spores. The other is for organisms that are vegetative organism, referring to the pathogen of concern.

And the tables are conservative, but they now consider the interaction of pH and water activity, which actually made it a little bit easier to get some of those foods where you have an interaction of pH and the water activity in the appropriate ranges approved without the need to do these kinds of challenge studies.

Nevertheless, quite a few challenge studies are still done.

The charge then is, because of the very large number of questions that come about in how to design these studies; when you consider the diversity of food products that are out there, a lot of them ethnic foods and manners of preparation, et cetera, it's really

almost any -- it's very hard to come up with a protocol or even a family of protocols where you have a one size fits all that you can say simply, "Here. Use this method and it will be fine."

So what's really being asked for here is, if you will, the strategic principles and elements that have to go into designing and conducting these kinds of studies.

The first is what are the appropriate criteria that must be considered for an inoculated pack or challenge study to determine if a food requires time-temperature control for safety. For example, the pathogen of concern, are there any particular strains that should be selected or avoided?

Are surrogate organisms appropriate? How many strains? What level of inoculation should be used? Incubation temperatures, the duration of the study, food product physical properties, et cetera.

By food product physical

properties, if you're trying to validate a food that has a particular pH or water activity, then you obviously need to be sure that you test that pH and water activity. Believe it or not, not everybody does, or you should at least pick a range or a conservative value.

For example, that's what we're after there.

There's a growing number of mathematical models and database type models, and what would be the appropriate use of these and under what conditions can they be a substitute for inoculated pack or challenge studies, and of the ones currently available, which ones are most suitable for use and what are the limitations?

Oftentimes a retailer, take for example the case of an assortment of baked pies or of filled pastry, for example. You can imagine how expensive it is to do these studies for the regulated industry, and often

times these are not large firms.

What are the limitations for applying the results of inoculated pack or challenge studies on one food to another similar food?

Of the existing inoculated pack/challenge study protocols, there are several published, for example, American Baking Association, NSF International, and perhaps others. Which are most suitable for application to a wide variety of foods? And what are the limitations of these protocols? Are there existing protocols that are appropriate for specific food-pathogen pairs?

We often see that firms who have knowledge of these protocols don't really know what foods they can and cannot be used with, and they may inappropriately pick one of these protocols and use it.

Ultimately we think that a decision tree can be developed. This is something like a dichotomous tree that will

aid one in going through the design of an appropriate inoculated pack/challenge study. We would like the Committee to develop such a decision tree and then demonstrate the utility of the tree with a kind of a desktop exercise using a meat filled puffed pastry, cheese pizza, chopped lettuce, cheese, and lemon meringue pie, for example. These are typical of some of the kinds of things we see come before us.

And finally, identify the basic knowledge, skills and education, training, experience, and abilities necessary for a multi-disciplinary work group or individual to be qualified to design, conduct, and evaluate an inoculated pack/challenge study.

We're often asked who out there is competent to do these, and how do I know that they're competent to do these, and it's not an easy question to answer. It certainly requires someone with some detailed expertise, and this is what we're after here, is some

sort of insightful statement as to what sorts of talents and skills are required to do this.

With that, I open it up to any questions.

DR. GOLDMAN: Spencer.

MR. GARRETT: Thank you, Don.

Just an observation, perhaps a recommendation that this Committee for seafoods actually did something very similar to this a number of years ago, and you're a new Committee. You might want to review that document from two different perspectives.

One, while you're doing it, do you think it's still current?

But then, two, there may be some things in there that might be useful in terms of for botulinum the cocktail strains we use and so forth and so on. Just a recommendation.

DR. ZINK: I believe we also did something like this last year when we considered the -- what was the name of that

report?

PARTICIPANT: Shelf Life.

DR. ZINK: Oh, yeah, Shelf Life. We put something in there as an appendix, which is probably also relevant.

Yes, Gary.

DR. ADES: First, I'd like to applaud the fact that you're getting this charge. I mean, it's badly needed in the industry. From several previous jobs that I've had, we've needed it desperately.

I would ask whether this could be expanded to take a look at the need that the processors have for challenge studies because we are continually, when I was in the processing end of this business, being asked to validate interventions, and we are constantly challenged, in essence, to try to find somebody to do this, especially with the fact that we really wanted to have real life conditions. So we needed to have pilot plant size equipment to test it on, and we kept

running into situations where we couldn't get the equipment. The whole idea of how to inoculate was questionable because it just didn't make any sense the way things were inoculated. It wasn't real life.

And this was especially true when we came into the *Listeria* directive because we were using postpasteurization, and we wanted to validate the postpasteurization. And every kind of protocol we saw didn't work, and we finally had to design our own and ended up putting pilot plant equipment in Wisconsin in a lab's parking lot and doing it in January, which really wasn't a whole bunch of fun.

DR. ZINK: That was the BSL-III parking lot, right?

DR. ADES: Yeah. We had lots of the parking lots filled up out there.

(Laughter.)

DR. ADES: But I would suggest or just make the suggestion that this would be extraordinarily valuable to the entire

processing industry if we could put together some protocols, some ideas, and some decision trees in ways that people could look at this.

It's sorely needed out there, and there is really very few people providing any guidance or advice.

DR. ZINK: I guess when we drafted this we were primarily thinking about our Food Code needs, but your question is a good one. I'd open it up to the whole Committee.

How different do you think -- if we develop this for the need as it's stated here primarily in the retail area, how different do you think those protocols would be from meeting the needs of the processed food industry?

Gary.

DR. ADES: Yeah, I've been in both ends of this thing, and I don't think they're going to be very different at all. I think they're just going to be a lot of the same base-type of information, and there's going to

be some variation, processor versus food service operations.

But I think that there's going to be a lot of the same thought process involved and a lot of the basic criteria of selection of individuals to do at the same types of thing. So I think there are an awful lot of similarities.

DR. ZINK: Scott.

DR. BROOKS: Scott Brooks with Food Safety Net Services.

I would agree. I think in the food processing industry the only thing they would add onto it, and it would probably be in the same decision tree would just be a lot of the quality parameters that they would be looking for, shelf life for non-safety reasons. But I would concur.

DR. ZINK: I guess if there's no further questions -- oh, excuse me. Don.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

As someone who is on the IFT panel that drafted the first report, I'm a little puzzled because except for point six, I thought we addressed in that report one through five. Now, I think it would be great to take another crack at this, to have a larger number of people take a look at it.

What would be very helpful to me would be if the agency could identify in the context of the IFT report specifically what's there that's not sufficient so that we don't spend time here at NACMCF reinventing the wheel, and that we focus on adding onto the work that was already done by the IFT panel.

DR. ZINK: I think it's a question of detail and audience. What we're looking to come out of this is a document that, for example, a regulatory in the state or local level can sit down with, someone who may not even be a microbiologist or have a great deal of experience in microbiology and judge the adequacy of a design and the merits of the

conclusion from it.

I see the IFT report was a kind of a top level scholarly document, not that we don't want this work to be scholarly, but it has to be a front line kind of document that's usable in that context.

DR. SCHAFFNER: And thank you. Don Schaffner, Rutgers, again.

That's a very helpful clarification because one of the things that we were specifically forbidden to do in the IFT panel was to talk about implementation and practicality. We were asked to write a scientific document. So that's a very, very helpful clarification.

Thank you.

DR. ZINK: Spencer.

MR. GARRETT: Thank you.

Spencer Garrett with NOAA Fisheries.

I would add to both what Scott and Gary has said. I think if you're including

processes, it wouldn't be that sufficiently different. Of course, there will be nuances in the commodities and the pathogens, of course.

Are you including seafoods in this?

DR. ZINK: There's no limitation on it.

MR. GARRETT: Great.

DR. ZINK: We get all sorts of requests. Actually seafoods are one of them. You know, with I guess --

MR. GARRETT: No, no. That's fine. I would certainly support the inclusion of seafood.

DR. ZINK: I'm thinking cold smoked salmon and some of those other things, yeah.

MR. GARRETT: Yeah, that's fine.

DR. ZINK: Alejandro.

DR. MAZZOTTA: Don, since his Question 6 is the one that is important, it

seems like it is targeting the training and education that the person designing the study needs to have, and since this is going to be submitted to local and state regulatory agencies, should we consider there also the communication or education that local health departments and officials should have to interpret those data?

DR. ZINK: Well, that's a good point. That's a tough one, too. You don't always have that kind of skill set in a reviewer.

I think that should be addressed by the Committee. It's a good point. Certainly whoever reviews this is going to have to have a certain level of competency in order to determine whether or not even if they have a detailed guide in front of them, whether or not, in fact, the report they're looking at meets that. So that's a good point. I'll put that down.

Okay. Spencer, did you have

something?

MR. GARRETT: Yeah, upon reflection I was just thinking that perhaps since you're including seafood, and I certainly support that, why don't you add one more thing to your decision tree and use a fishery product as well?

DR. ZINK: Use fishery? Okay.

MR. GARRETT: Yeah. I think you'll get broader utility that way.

DR. ZINK: Okay. Irene.

DR. WESLEY: Irene Wesley, ARS.

I had a question for you, Don. Is part of the preparation for this Committee going to involve the chair procuring documents or models from the industry, for example, on the decision trees to see what they have?

DR. ZINK: Yes, I think we would do that. I think we could easily provide you with the models and the links and previous efforts in this regard, ABA, NSF, the IFT report. Sure.

If no further comments, I'll turn it back to you.

DR. MAZZOTTA: Don, one more question. Alejandro Mazzotta with McDonald's Corporation.

Is this something that eventually will be brought to the Conference of Food Protection, something that will be included in the Food Code or in the future? You can think about, well, how is this going to be managed in the future.

DR. ZINK: I am not that expert with what would or would not go in with the Food Code, but I think that certainly at a very minimum this effort would want to be introduced and discussed at length at the conference. I mean, that's clearly the people that need to know what we're doing and why and buy into it.

As to whether or not it could be published in the Food Code, that's an interesting question, you know. Certainly I

guess it could be.

Okay. Thank you.

DR. GOLDMAN: Thank you, Don.

With this draft charge, what we would like to do is if there are any additional comments that you would like to have considered by FDA and refining this work charge, please get those comments to Gerri Ransom, and she will get them disseminated to those at FDA who will be working on this charge, and the intention would be that we bring a formal charge to the next plenary session for acceptance by the Committee. Is that okay?

All right, good.

MS. RANSOM: November 1st will work for this as well.

DR. GOLDMAN: Okay. Thank you.

All right. We will move now to the next draft work charge, and representing FSIS will be Jim Withee. Jim Withee is a Fellow with the American Association for the

Advancement of Science. He is on assignment to FSIS. He is beginning the second year of his fellowship with the Risk Assessment Division in FSIS.

This charge is to help the agency and other interested parties to develop the most appropriate technologies for the agency and other regulatory agencies to adopt in performing routine and baseline microbiological analyses.

FSIS is seeking comments on how to best construct this charge, and I think hopefully everybody has a copy of it. I think it's in your book, and there's some on the table as well.

The goal of this project is to yield the most useful information to FSIS and others in the public health community regarding technologies that can be used to improve food safety testing.

So with that, Jim Withee. Thank you.

DR. WITHEE: Thank you, David.

Yes, I just want to say at the outset I really want to thank Gerri Ransom and Uday for inviting me to give this presentation. It's a topic that's very dear to my heart because in my background of molecular biology, my knowledge of molecular biology and genetics runs deep, and my knowledge of food safety and public health is still fairly shallow. So keep that in mind.

But it's a really exciting time to be reevaluating technologies for foodborne pathogen testing. Several years ago FSIS adopted PCR-based assays as a screening methodology for detecting pathogens and made great gains in the speed and specificity of their tests.

And since that time our understanding of the organisms' genomes and our ability to detect sequence differences has just made leaps and bounds in terms of cost and time and the scope of data you can

collect.

So David already did a really good job summarizing the charge, but I wanted to reiterate it here and make a couple of points.

What we're discussing here are the most appropriate technologies for FSIS, and I have just briefly 15 or 20 minutes of background to bring people up to speed on what FSIS wants from the microbial analysis, what kind of data we might want in the future, and what are our standards right now for the assays that are in place.

And there's an ominous addition to the charge in that FSIS expects the charge will be a long term project. I'd like to focus a little bit on that, too, because it's a very broad charge, and I think part of the task here will be to really prioritize, separate, break it down into small parts.

And then again, what we're really going to talk about here are most appropriate technologies, and that's what I want to give a

little background into.

So this is an overview of the background just for the next 15 minutes, and I want to make clear that I think these things go best as a dialogue. So please interrupt, tap your desk, raise your hand, and comment and ask questions at any time as I'm going over some of these topics.

First, we're going to talk briefly about microbial analysis at FSIS, and that just includes the programs where we collect data currently, as well as how that data is applied at FSIS in their food safety mission and the methods that are in place at labs right now. Okay? So this is what is.

I'm going to talk about important analysis parameters, and by that I mean what should an assay -- what kind of parameters should an assay have to be effective. Okay?

And these are some of the parameters that I think are of importance to FSIS, and we'll talk about not only what these

parameters are and why they're important, but how the assays that we have in place are meeting that right now.

So that can become kind of the standard. It has to be this or better, right? Because this is what we've got now.

And then considerations. These are just interesting topics to consider when you're looking over technologies, and I've only picked a few because we don't want to sit in here for days, right? But I think some interesting topics to address are how data is acquired and transferred so that it can be aggregated and analyzed and applied.

What type of feature are you going to detect? And I have just a brief thought about protecting DNA features versus protein.

Another really important topic for the upcoming years, I believe, in microbe detection is going to be serotype versus genotype, and I have some brief thoughts on that. And I think it's a really interesting

topic.

And then, finally, technologies are apt to be applied in different environments, particularly in the future, and I think there are different needs within in-plant technologies versus laboratory methodologies, and also potentially in the future the way we test and baseline studies versus the regulatory testing requirements.

And then we have the charge question. These are looming up, of course, as the most important part.

So what do we do now? This is sort of the 50,000 foot kindergarten view. FSIS basically has two programs where they acquire most of their microbial data. We have regulatory sampling, and there are the national baseline studies.

And I know everybody is familiar with this, but I just want to get people thinking in context.

So of course, the regulatory

programs are where FSIS samples product from federally inspected establishments. Baseline studies really are formulated to determine the national or nationwide prevalence of a particular pathogen in particular products, and they are pretty different.

So regulatory data is primarily applied at FSIS for verification of safety and for regulatory actions. There are other applications, too. I mean, I only list a few. I don't even know a comprehensive list, but of course, recall looms large with regulatory data, and plant corrective actions if adulterated product is found, and then other applications. So this is the way this analysis is used.

Now, the baseline data is used pretty differently. A primary use within FSIS would be setting performance standards for regulatory purposes. So we can keep that in mind, but also it really forms the foundation of most of the science-based programs and

policies and risk analysis at FSIS. This is how we find out the nationwide prevalence of pathogens in our products.

And when you think about the baseline studies that FSIS does, they're really important. I mean, I really believe this. There are many stakeholders who depend on the baseline studies for information, and I just listed a few here: industry, academics, and all kinds of public health agencies, state and local, FDA, CDC.

FSIS is uniquely positioned to collect samples all over the country in all of these establishments in a way that basically nobody else is in the U.S.

So in the end though we don't want to lose sight of the fact that both these programs, of course, are important because they merge to give us increased food safety, and that is the overlying theme here with our testing programs.

So what about the laboratory

methodology? I want to describe now what's actually happening in FSIS labs when they do regulatory testing. And most of this information I gleaned because I'm actually now working out in Alameda at the Western Lab and from Emilio Esteban and John Rivera (of FSIS) out there, I was able to get an in depth look at how they actually analyzed samples, and I think this is really a useful starting point. If you're going to consider changes, you've got to know what's in place now.

So here's a pathogen I'm bringing down. It's going to be *E. coli* 0157. All of the testing protocols are similar, but different, and I'm not going to discuss the differences so much as lay out a typical protocol for 0157 and then we can look at a time line and expenses and specificity and so forth.

So here's our pathogen. On day one the sample shows up at the lab. Okay? And there's a 24-hour enrichment step where

you use a culture condition that's specific for the pathogen you want to assay.

On the second day there's a batch PCR screen for three loci in the bacteria. Okay? And based on the outcome of this screen, which is actually very rapid and very effective -- we'll talk about it in a moment -- the screen itself only takes about four hours and only one hour of that is hands on time.

Based on the output of that screen if the same is negative, it's considered negative and it's discarded. If it's positive, then there's a whole series of confirmatory tests that take place, and most of these look at antigens on the surface of the bacteria using specific antibodies, and you know, metabolic properties and biochemical properties in growth type assays. It's a very extensive confirmation process. There are many assays that get done.

So that's days three to five, and

after that it's sent on for further characterization. Okay? This means serotype, antimicrobial resistance, and in many cases PFGE patterns.

Now, I just want to bring up the fact to emphasize I should test for multiple pathogens, and now I've brought in *Listeria* and *Salmonella*, right? And each of these undergoes a similar process, but they have to be done independently because all of the steps, the enrichment, the PCR screen, the confirmatory testing, everything is specific to the pathogen of interest.

So if you want to test for three pathogens in one product, you have to do three completely separate protocols, and the time frames are similar, although 0157 is actually faster than *Salmonella* or *Listeria* for technical reasons.

So I just want to bring up a subtle point now looking at this slide. The first is the enrichment step, the 24-hour

step, is probably a great place where you could save time. The PCR assay is already really fast and really effective, but having to enrich for the bacteria for 24 hours is killing that first day. Otherwise you'd have results in four hours, right, in a fantasy world? So that's a good place to look at sort of targeting the assay.

I don't know if people can see the screen. It's kind of dimmed out.

The second thing is -- so that brings us down now. We've skipped a day because we're not enriching anymore. So we're able to skip that step.

The second thing is we're able to use technologies to test for all three bugs in parallel in the same assay because you are lacking the specific enrichment step. Then you collapse this thing laterally.

So now we've saved resources and time in a three-fold way, right? Not only are we skipping the enrichment step. We are

testing for all three pathogens in one sample at the same time on the first day.

It's my opinion after looking at this step for several months that there are technologies available if they were chosen correctly that would allow you to do this. In some cases, you might have to make some compromises in terms of sensitivity, but we can talk about that in a moment. So just keep that in mind.

I think that vertically eliminating that first day and collapsing the assay into a more multiplexed form are great places to look at.

Okay. So what kind of parameters are important in our analysis, right? And there are many, but I just picked these three quantities because I think they cover some of the more important aspects:

Time and expense. Can you make it faster? Can you make it cheaper?

Sensitivity and specificity of the

assay.

And in the scope of the analysis, how much data do you get from the sample? What do you learn about it?

So it's briefly to show what's important about these analyses and where FSIS is with them.

DR. WESLEY: Can I ask a question?

DR. WITHEE: Yes.

DR. WESLEY: Irene Wesley, ARS.

Are sensitivity and specificity okay?

Could you define selectivity? Is that bias in the enrichment?

DR. WITHEE: Yeah, and actually, you know, when I discuss this, I'm only going to talk about sensitivity and specificity, but I think selectivity would refer to false positives.

Let me push on with the discussion. I'm sorry about that. Actually, yeah. Exclusivity and inclusivity, when I

discuss this I'm going to talk just in terms of sensitivity and specificity and talk about specificity in terms of positives, percentage of positives identified and negatives identified.

So time of analysis, why is it important? It really impacts at least three things that happen in FSIS situations. The time for analysis of a sample is important for the response time in an outbreak, for product recalls, and in test and hold situations when a product is being tested in industry.

And I think it is fairly obvious. I'm just bringing the point up though that when you reduce the time for analysis you're going to speed up all of these processes as well, which is a good thing.

And where are we now? I already showed the methodology, but I think it's useful to show it on this time line.

Day one, sample arrives. Between day two and three you get screen results

depending on the pathogen. For 0157 it's on day two. For *Listeria*, it's a little longer.

Between days three and five you have a presumptive positive. This is based on partial confirmation and a positive outcome from the screen.

And then between days five and eight, depending on the pathogen, you get a final positive.

From there, after day eight, the samples are sent on for further characterization, and this includes the serotyping, antimicrobial resistance, and PFGE patterns.

In terms of expense, these were numbers that the chief microbiologist at the Western Lab worked up and was kind enough to tell me, first, you know, why is it important, right?

Microbial analysis is really at the heart of a lot of what FSIS does, and they spend a large amount of resources and time

testing a lot of samples every year to support policies and regulations.

So, you know, increasing your cost effectiveness here or your public health benefit for dollar in this area at FSIS would be an impact just because of the scope and the importance of the problem.

So where are we now? It's about 88 to $98 a sample depending on the pathogen, and this does not include the further characterization. This just includes the final result.

So now I apologize for that, Irene, for the confusion there. Some of these terms honestly were new to me, too, but I think we have got good definitions here with sensitivity and specificity, and it includes selectivity.

The sensitivity will be the percent of true positives that a test identifies, and what's related to this and what I'll discuss about the assays that are in

place now, of course, is the limit of detection that has to be considered here, which can be reported in colony forming units per gram or whatever in your sample.

And there's specificity, which can be defined as the percent of true negatives that a test identifies, and this is related to positive predictive value and negative predictive value.

So I just put together this little diagram showing sensitivity and specificity. If you have a pail and it's full of yellow marbles and down in that pail are a few red square marbles, right, there can be a tradeoff between sensitivity and specificity in some assays depending on how they detect.

So an assay, for instance, that had a very high sensitivity but a very low specificity would find all three red squares in this case, but it would also identify wrongly several yellow marbles. Okay?

Conversely, an assay that had the

opposite properties that had a very high specificity and low sensitivity, it would only find red squares, but it wouldn't do as good a job at detecting all of them in this pail.

So right now FSIS scores very high. Regulatory testing is really aimed at optimizing these parameters. In talking to them, the PCR screen alone has almost 100 percent sensitivity and specificity. It's a very sensitive assay, and it's very specific. It's well over 99 percent of the positives are confirmed with confirmatory testing.

And limit of detection is very low. It's one colony forming unit per 25 grams, which I consider to be very good.

So what about the scope? What do you learn at FSIS when you analyze a sample? I think this becomes important, too, because as FSIS is bringing more science into the policies, more risk analysis into their regulations, different kinds of data are being required.

This is what we're collecting currently. Definitely you get genus and species. So I just put some examples here, *Salmonella, Listeria, E. coli*.

We also don't carry this out ourselves, and we will show this in a second, but serotype information is collected on FSIS samples, too. So for *E. coli* that includes just looking for 0157, but for *Salmonella* it's very extensive.

Antibiotic resistance, information on the samples is collected by ARS, and PFGE patterns are done for some microbes, for some samples routinely and for others only in particular situations, but this is kind of the scope of data that can be collected about a sample.

So now I want to just bring up a few considerations and then we'll start introducing the charge questions and hopefully have some good discussions surrounding the choices here.

The first kind of consideration you can have is with data acquisition and transfer. Then we'll talk DNA versus protein, genotypes and serotypes, and some different applications.

So I brought this map of the United States, and I realized from the plan on the way here I was trying to look at the acquisition and I have a hard time finding Iowa on a map, but I did get it figured out. My geography is also weak. See how you guys would do on this right now, probably better than me.

I brought up this is a situation that would happen at the Western Lab. Okay? And this is how we acquire our data. It's kind of fun.

So there's Emilio at the Western Lab in Alameda in California, and say he gets in a sample of poultry and he confirms that it's *Salmonella*. So he's shouting it out from there, right?

One thing that has to happen is it's going to get sent to NVSL to be serotyped. Okay? And NVSL is going to shout back, "It's Heidelberg," and this is an extensive process that's going to require a fair amount of time and expense and antibodies which have to in most cases be produced in the animals and so forth.

But he's not done yet, right? Because he also -- don't want to take out DSL -- he needs more. So he's also going to send it to ARS, and they're going to do antibiotic resistance testing on it using growth assays. Okay? And ARS is down there in Athens, Georgia, and they're going to shout back, "Gentamicin," right? That's the resistance they found in it.

But he's still not done. He's going to send it out to the FSIS Eastern Lab where they're going to do a PFGE test on it, and they're just going to shout back with a bunch of "damns" because that's what the PFGE

results look like.

So you can see that -- and this is just one scenario. PFGE could be done in other places, and depending on the sample type things could be different, but it's not an atypical scenario. Okay?

So there's four labs collaborating to collect the different types of information, all using different types of technologies.

So what about the data transfer and aggregation? So now we have these four spots, right? And they're all on the screen twirling, and they've all got important information about a single sample with a unique identifier. Okay?

And in the middle of this thing we have our sophisticated food safety experts sitting at their computer, and they want to access all of the information about a particular sample, right?

So our food safety expert, she wants to be able to say, "Look. Sample ID,

you know, 10,410 AB. What was the antibiotic resistance? What was the PFGE pattern? What was the microbes found in it? How many microbes were found in it? Serotypes," et cetera, right?

This is what has to happen, and it does happen, but as far as I know, there's not an automated system where all of this information is reported to a single database for repository so that it can be easily aggregated and searched in an effective way.

And I think that's one more thing to look at when we're looking at new technologies. This will not require Star Wars. I know the computer technology is not the limiting factor here. I'm not going to pretend I understand what is because I don't, but this would be nice.

Currently this data is aggregated all the time and searched effectively, but it takes human power, and our risk analysis in the middle there is too small for that.

So now I want to bring up another consideration, which is detecting features of the microbe, and I have some considerations here of DNA versus protein that are very shallow because I didn't want to eat up a lot of time, but come out to California and have a beer with me, and we can go on and on, right? But I think this is interesting.

And put out this diagram which again are hard to see. On the right is a ribbon structure of a protein. So that's going to be our protein column. On the left is a double helix representing our nucleic acids. The protein is a ribbon structure of RAS, which is a nice and famous structure and has nothing to do with bacteria, but it will do.

So here's my final just like one word take. I don't want to list too much. I believe what you'll find as you look at the technologies is that currently, and this I think will be changing over time, but

currently relative to protein, DNA detection assays are going to excel at detecting a huge scope of information, very affordably and very accurately. You're going to be able to look at many, many, many traits within the bacteria relatively cheaply compared to analyzing many, many, many, many proteins present. Okay?

On the other hand, I think with current technologies, you're going to find that protein detection is going to have at least two advantages. They tend to be faster because the kinetics of protein binding can be very specific. Because the protein binding can be very specific, the kinetics are very rapid relative to DNA hybridization or amplification. Okay? A lot of protein detection technologies are very rapid. They really are real time.

And they also demonstrate expression of a trait, and it had been brought up to me before, well, if you detect a genetic trait in a food product, how do you know it's

actually being expressed. Is it really a threat just because the gene is present?

I have my own take on that, but finding the protein definitely demonstrates the final product of the gene has been produced, right?

These are just a couple of things to think about and comment on as you're looking over these.

What about genotype versus serotype? I think this is going to be very important. We're already in the midst of a very important shift here potentially, and again, I just put up two figures. On the left is an actual sequence readout of DNA, and on the right is a cartoon of a cell expressing some antigens on the surface, and I put it up because you can see the obvious complexity of the genetic information versus the single protein antigen represented on the surface of the bacteria.

My main point here is that when

you detect the genotype of an organism, you learn a lot more about it that's relevant to its pathogenicity than you do when you detect one or two antigens on the surface and call that the subtype.

And, in fact, genomic studies over and over are beginning to find in these bacteria that there's more genetic variation within some serotypes than between them, right? It's not necessarily the most meaningful way to classify bacteria anymore even though it has done us in good stead up to now.

And some other considerations. In addition to the fact that detecting the genotype delivers a lot more detailed information about the organism, it also is apt to cost less and be faster. Raising antibodies is an expensive process, especially if they're raised and harvested from animals, and in addition it's timely.

So now I just want to finish up

here with one more final consideration, which is the specificity of the applications to the technology. Okay? So I want people to consider as we're looking over technologies the charge is very broad. There could be applications that are within plants versus the laboratory. This is one distinction. And in this case in the lab you don't have time to really do a detailed analysis, right?

Whereas in plant, I think you're going to detect fewer quantities with small devices that are extremely rugged. Okay? So they may have a very limited range of detection, but they're going to work rapidly, and they're going to be able to withstand field conditions, whereas in lab testing is where you're going to really gain your detailed information about products and have a more extensive analysis of them.

Likewise, I think there's opportunity when you're comparing data from national baseline studies with the uses of

regulatory data to utilize slightly different technologies that have gives and takes in some of the parameters we talked about.

The amount of confirmatory testing that goes into confirming a positive for regulatory purposes is extensive, and it's probably important for regulation, but I'm wondering if it might not be worth considering doing baseline studies where you collect a large scope of data to inform, you know, science-based policies and risk models, but you sacrifice some of the confirmatory testing.

So there may be a little more uncertainty hovering around the data, but you're going to have a lot more of it to populate some of these decision making policies.

And then finally, the last bit I want to bring up here, and then I'm finished up and we'll go through the charges, is, you know, the final consideration, of course, is

balancing public health with the burden of resources, and so I put this scale in here, and on one side we have public health. On the other side we have FSIS resources and the burden to industry.

When you're considering technologies for use in the FSIS environment, I think this is the balance that you're trying to keep in mind.

So that's kind of a lot and people are quiet, but are there any questions on the background before we move to the charges here?

Okay. So the first charge -- yes. Oh, I'm sorry.

DR. BEUCHAT: Larry Beuchat.

Under the important analysis parameters, you did not list the criterion to be able to determine or distinguish dead from living cells or byproducts that may be toxic to humans. Is this a given in the approach that the FSIS is taking?

DR. WITHEE: Do you know what?

That's a really good point. So as I said, the considerations are a brief list, and I think in regulatory situations it's mandatory at this point that we determine there's a living organism in the product, and someone else can speak to this.

That's true, right? So, yes, I think that's an important consideration.

DR. BEUCHAT: So if you skip the enrichment and go directly to PCR, is that technique or some technique molecularly-based going to be able to tell you whether the cell is living or dead?

DR. WITHEE: There are some indications that some of them could. For instance, there are DNA binding dyes that are excluded by intact membranes that actually will affect the outcome of some of these assays.

In addition, I could envision and I was showing that first screen where we collapsed out the first day and then we

laterally collapsed it by bringing in the other organisms. I can envision that being still a first screen, and then you don't spend time to do the additional culturing and confirmatory tests until you get a positive, and you do it for only the pathogens that were present.

So those are some scenarios, but you know, you bring up a very good series of issues.

DR. MENG: Jianghong Meng, University of Maryland.

Is PCR sensitive enough to detect a pathogen without enrichment?

DR. WITHEE: So sensitive enough starts to begin the issue. Without getting into the lab and doing some pilots, I'm not sure just standing here how far down the limit of detection will drop, but I will say this. The way that PCR assay is run currently, it's probably not the very most sensitive way to detect and amplify specific loci.

In a minute here I'm going to talk about considering a larger scale genotyping type assay that would probably depend on detecting many, many loci and then using universal primers to amplify out the initial amplicons, which can increase the sensitivity in many cases.

So I think it could be a little better than the assays that are being used now in terms of the limit of detection with no enrichment, but I don't know how far down it could go until we get into the lab.

MR. GARRETT: Spencer Garrett, NOAA Fisheries.

Following on Larry's question, you responded that there's some indication relative to you may be able to segregate, if you would, or account for, even more importantly numerically account for the dead cells, but some indication and a definitive answer -- some indication is not a definitive answer.

So I guess my question is, just so I understand it, that what you're inferring is that the degree of sophistication of the technology at present cannot, in fact, do that from a regulatory perspective where we have microbiological numerical criteria relative to regulation.

DR. WITHEE: You know what? It's a really important issue, and I'm not going to stand up here and make a definitive call on that right now. I'm just going to be honest and say I have never worked with -- well --

MR. GARRETT: That's fair enough.

DR. WITHEE: Okay.

MR. GARRETT: But there are a lot of microbiologists around this table. Can anybody here answer my question in the affirmative?

The question is: is the technology that's under discussion, PCR, is the technology sufficiently sophisticated enough to segregate out the dead cells from

the live cells in cases where we have regulation premised upon the number of the bacteria?

DR. JAYKUS: Lee-Ann Jaykus, N.C. State University.

The answer is no. Basic PCR methods detect DNA only, and the literature is very clear that DNA is stable from dead cells and for very long periods of time.

You can potentially move to an RNA target which has some indication of viability depending upon the RNA target that you deal with, but the reality is that that's really tricky.

And so the take home message really is that the molecular -- and I'm sure that most of the people who work in this field would agree with this -- the molecular methods are more sophisticated than are the sample preparation methods that we have that can be applied prior to or pre-PCR screening.

MS. KOWALCYK: Barbara Kowalcyk,

Safe Tables Our Priority.

I have a question that may be not a dumb one, but from a public health standpoint, does it really matter whether there's live, for example, *E. coli* versus dead *E. coli*? Doesn't it indicate at some point that there was a contamination of the product, whether it was live or dead, and it just happens to have died? And isn't that useful information to help determine whether or not regulatory action needs to be taken or some improvement needs to be taken in the process in the plant?

DR. WITHEE: I agree. I will be quiet after this. I agree there is much use in detecting pathogenic traits in a sample, even without taking the further steps to verify whether or not it's currently alive in the sample. It tells you something about the sample that's important to know.

In addition, I just wanted to come back to the comment of is it impossible to use

a molecular technique to differentiate living cells versus dead cells based on detection of DNA traits. I think it is possible, and it's not just by using straight PCR. I tried to infer this, but there are DNA binding dyes that actually will inhibit the PCR reaction that don't have access to the DNA and intact cells.

So you have at least the ability to detect whether or not soluble material is intact with intact membranes.

DR. ZINK: I want to second what Lee-Ann said. I agree. The answer is no. You can't rely on PCR now to only detect living cells.

However, I have put this challenge to our scientists, and while they have not come to me with a method and a proof and validation, I think that there's a number of them that are now thinking along these lines of stratagems that would allow you to detect only living cells, and I think it remains to

be seen whether they'll achieve that goal, the one that satisfies all of the stakeholders involved.

To the question of is it important to know whether it is living or dead, I think when you're dealing with processed foods, yes, it is important to know whether it's living or dead. There are many microbial pathogens that are unavoidable. Indeed, this is why we process those foods.

And as a regulator, you do have to answer the question is this product safe, is this product adulterated, is there a living organism in here which has either survived the process or recontaminated the product.

But I also admit that there are situations where even detecting a dead organism can provide some useful information to history.

MR. GARRETT: And then just not to, in quotes, overcook this, I just want to point out the nature of my question was from a

regulatory perspective, and I certainly agree it's nice to have all of the information that you can get, but as you're doing your baseline surveys, when we talk about baseline surveys, we're going to have to account for that criterion, dead or alive, both ways, and then you may get erasure or something you can do.

But particularly in processed foods, I agree with Don that that's why we process them, to get rid of the pathogens.

MS. KOWALCYK: If I may, I would agree with you in the baseline surveys where you're ideally trying to find the prevalence of these bacteria in the food supply, but in a regulatory setting, of course, is it necessary?

Obviously there's something wrong with the process in the plant or whatever where there was contamination introduced into the food product. So it would be useful to know whether or not the bacteria -- even if there was dead bacteria introduced.

DR. GOLDMAN: Walt.

DR. McNAMARA: Ann Marie McNamara, Silliker Labs.

But to answer the question about, you know, dead versus live and is there something wrong with the process, you know, having dead cells after it has gone through a carcass wash says that the carcass wash is effective or pasteurization of milk says, you know, your pasteurization step was effective.

You know, having been a former regulator, you have to regulate based on live cells, and while I understand where you're coming from, you know, I think we have to be very cognizant of the statutes and the purpose of the baseline studies, et cetera, and the regulatory programs. Because what I would say to the Committee is this charge is just too big.

We can have this huge, esoteric discussion about all of the foibles of micro testing and what's coming up like

nanotechnology, but nanotechnology is not here. You know, do you want us to look at something that can be applicable in the next two years? Do you want us to focus on the MLG methods and give a recommendation of how they could be strengthened with current methodologies, or you know, do you want us to sit here and talk about future technology that might not be here for six years?

DR. GOLDMAN: If I may, Ann Marie, thank you for that comment. I think that you've raised some important considerations. I don't know if you're already reacting to the questions because we haven't gone through them yet --

(Laughter.)

DR. GOLDMAN: -- but, I mean, you may have read them, and I appreciate that, but I think we have recognized in trying to develop the charge that, as Jim pointed out, it is broad at least in its concept. We have actually anticipated there might be, as you

said, this would be a long term project that might be broken into parts, and some would have some short term applicability and, therefore, be more focused and others might be longer term and a little bit broader.

Our agency is certainly aware, as I think is the rest of the public health community, that, to use PulseNet as an example, they are looking out for the next generation. They have solidified our use of PFGE, but recognize that that's not the be all and end all in terms of detecting pathogens and using that particular aspect or trait or characteristic to detect pathogens and to match them with others. There are other subtyping methods that are necessary and useful for various purposes.

So our agency wants to make sure that we are aligned and in step with the rest of the public health community as they move forth with new technologies that will help us all better understand the relationships

between organisms and help us apply our regulations better.

So I appreciate your comments, and I hope that has addressed it a bit, and we will, I think, get to it a bit more with the questions and further discussion and your comments to help us refine the charge.

I think Walt was next.

DR. HILL: Thanks, David.

Walt Hill, USDA, retired.

I have several things. I think that the first thing that governs how you're going to look at laboratory methods is really what the data is going to be used for, and those are mostly policy questions, and without a clear understanding of what questions policy is asking, we can't really evaluate how methods are going to provide those answers.

And even though it said the charge is fairly broad, I think it's -- and I don't know if this needs to be incorporated or not because it would make it broader -- but there

are up front issues that need to be decided. For example, what is the basic study design?

Because if you have an ineffective study design no matter how good your laboratory methods are, you're going to get the wrong answers.

And secondly, what goes into your laboratory is as critical, if not more so, than what comes out. So if you have garbage in, garbage out, and that's the issue of sample collection.

And I think that those two issues, study design and sample collection, are integral toward increasing your confidence in the laboratory results, and you can have the fanciest nanotechnology sensor array of whatever. If you haven't addressed fully the implications of the design and sample collection, you're going to be misled.

Thank you.

DR. GOLDMAN: Thank you.

We had -- Robin King has been

waiting. Just a minute, and then we'll get to Barbara.

LTC. KING: Robin King, Department of Defense.

I guess I just kind of wanted to bring up the point that it was my understanding that some of the molecular methods like PCR and even immunocapture are very good and very fast, and I think we all agree with that, but as Lee-Ann pointed out earlier, some of our food matrices can affect those tests, and I wonder if perhaps we should be looking at methods of isolation so that once we get them to these machines, the testing will go faster.

DR. GOLDMAN: Thank you.

Barbara.

MS. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority.

I wanted to concur with Walt here. I've had a personal interest in the microbial testing that FSIS does for quite some time,

and it really is at the heart of HACCP, and it's very important.

And there has been several criticisms, myself included as well as other groups, of the design of both the regulatory sampling program and the microbiological baseline surveys, and certainly -- I was going to bring this up later -- but certainly looking at, you know, first clearly defining what you're hoping to achieve with these programs, you know, you have to ask the right question and design the study to answer that question and then make sure that you have good, solid, statistical methods that you're employing and sampling methods.

And I agree. I've used the term many times. Crap in gives you crap out. Garbage in gives you garbage out, and you know, you will limit the interpretability of your data if you don't carefully design these studies, and I would agree with Walt completely. You should almost take a step

back, take a look at what the basic premise for these studies is and what you're really trying to achieve, and then get into the laboratory methods and all of that kind of stuff.

DR. GOLDMAN: Thank you for that comment.

I think this Committee has advised FSIS previously about baseline studies in particular, and I think the Subcommittee charged finally with this work charge would be well advised to consult those previous reports and consider some of the things you're suggesting right now.

Are there any other comments or questions before we quickly run through the questions themselves? Okay, Irene.

DR. WESLEY: Irene Wesley, ARS, Ames, Iowa.

First of all, I want to commend FSIS for taking the initiative in this most exciting adventure. All right? It's forward

thinking. I think when you say to keep in step with, I would like to suggest that you take the lead as opposed to taking the step with.

The ideas that you have presented are right on target, and hopefully you've been able to interact with some of the ARS folks in the Albany area which I think are pursuing similar thought processes. So, again, congratulations to FSIS.

DR. WITHEE: I think I'd just like to comment on that. Obviously ARS will be an integral part of development and implementation of any technologies. That just makes a lot of sense.

And there are many sophisticated genomics projects going on in a lot of ARS facilities and I'm aware of a lot of them.

DR. GOLDMAN: That's a good point.

DR. WITHEE: And also Robin brought up the point about isolation of pathogens, from the specimen being important

to the testing, and I consider that to be part of the methodology, and it is a critical part, especially if you're going to move to start avoiding enrichment steps and cut off that first day.

DR. GOLDMAN: Why don't we run through the questions, and we'll just present the questions that we've drafted to this point, and of course seek any input you have now or later, up until November 1st.

DR. WITHEE: Absolutely, and that was a good discussion. Already we've incited a lot of thought here.

So in terms of what are the most appropriate technologies, I just brought in a couple of bubbles here. How would they be validated? Implementation models, i.e., are these technologies being used in other institutions that are similar or equivalent to FSIS?

The second question is a question that asks you to specifically consider a large

scale genotype assay. I think it's particularly relevant, and I showed in that first slide how you could collapse laterally the parallel testing protocols into one large multiplexed assay, and I really believe it's possible, but I believe it will not be done through DNA hybridization or by detecting the amplicon onto the way they currently are.

If you want to go for a massive genotyping assay or not massive, but a large scale multiplexing, I think you want to detect SNPs or single nucleotype polymorphisms, and such an assay -- and there are many being used commercially and in research -- are capable of identifying thousands of different loci in a sample very cheaply because adding additional features when you're working in these kind of high input systems is no more expensive than testing ten. Okay? If you can render ten or 50, you can do 1,000 in a single sample.

And since you're detecting SNPs, you can do a lot. You can get a lot more

data, and we can get it a lot faster. And so in some ways I'm just throwing these out. You could identify multiple pathogen species or strains in a single sample. It's very fast. It's very cost effective, and it's high throughput. So it's research efficient.

And in addition to identifying species and genus, you could also identify virulence factors, antibiotic resistance genes, and serotype equivalence through genovirus.

So how would this kind of thing work? This is cut from one of the slides I showed earlier where I was going over the methodology in place now, and you can see we've got our bacteria with the enrichment staff, a screen based on screening a few loci in the bacteria, confirmatory tests, and then it's sent off to several different laboratories for further characterization.

I would say that a large scale genotyping assay, if it's done properly could

potentially eliminate the enrichment step and it could replace what's happening now in the PCR screen and at least equivalence for a lot of what's happening in the further characterization just in terms of saving time and resources, and it can integrate all of the pathogens into a single assay, all of that information for them. Okay?

Because what we'll be able to do is from a single sample detect, for instance, 1,000 traits that you choose, which is more than enough to identify three species or four species of bacteria, give you some epi data in terms of important genotypic markers, give you a genovar, find important virulence factors, and so forth.

If you wanted live specimens at that point, you could go back and just culture or use antibodies to isolate for a very specific type of bacteria rather than doing it for all three every time, something like that to consider.

So SNPs I think are small genetic changes in general that can't be detected through direct hybridization are probably a good alternative here.

And in terms of detecting the amplicons in the largely multiplexed assay like this, you won't detect them by a simple labeling of just like one, two, three. You really need to bring them to universal matrix. So you'll use universal primers, which are just kick ass and specific, right? So you amplify the heck out of everything equivalently after the initial binding step where you query. Okay?

And maybe this makes more sense to someone with a molecular background than others, but all you need to know is you bring in primers that are much more effective than the ones that you're using to amplify directly off the genome right now.

And then so this is a three primer extension assay. It's very good at detecting

SNPs, which are single nucleotide polymorphisms, very small changes in DNA sequences that can distinguish fine differences.

Very high throughput. Within a single sample a lot of companies will offer a matrix that will allow you to do 1,000 SNPs in one well, in a 96-well plate. So you could run, you know, thousands in parallel by stacking 96 well plates.

And it's quantitative. I think it will be difficult. It's my opinion now, although you'd have to go into the lab. I think it would be difficult to come back and say, "Oh, it's this many CFUs of *Salmonella* Kentucky in the sample." But I think it will be very feasible to say there's ten times more Kentucky than Heidelberg in this sample, or there's 12 times more, you know, *Listeria monocytogenes* than *Listeria*-whatever. Okay?

Because relative differences, since it's all being amplified by the same

primers, you can actually get into a linear range, the reaction, and make relative comparisons which could be useful in some cases.

So are there questions about that before I move to the next charge?

Okay. So the third charge asks which of these technologies are applicable immediately and which for the future. There was a really poignant question brought up earlier. What are we being asked here? And I agree the charge is large and cumbersome taken as a whole.

So part of what can be done here is going over, and this is one of the first questions to consider: are you looking at long term applications or short term?

Ideally we want to do both, right? The agency needs to be looking into the future and into what can be done immediately and how they will merge. I know it's complicated, but the advantage to considering

them both up front is what you can implement things immediately that are going to merge well with what you implement later. Because when you buy infrastructure and train employees to implement a new technology, it's nice to have things that merge kind of seamlessly later rather than having to completely throw things in the dumpster, right, and start over?

So in some ways there is an advantage up front to thinking about what you want to do now and what you want to do in ten years and seeing if there's any way to set them up to flow well.

Enumeration is a huge issue at FSIS. I mean, it's not done typically, but it's discussed a lot because currently we get very good data on the prevalence of pathogens in regulatory and baseline type studies, but very little data is available on the load of the pathogens.

And of course, that's important

when assessing the risk for foodborne illness, not just the prevalance but how much of it is on a product.

So I think this is something that needs to be considered carefully. If you can add in enumeration in any way, it can be of great benefit.

Currently enumeration technologies require basically plating and counting. Those are the best and most solid ways, and they work. But they're time consuming.

DR. ENGELJOHN: Engeljohn with USDA.

I just wanted to point out one thing for the Committee to consider there is we did add the term "indicator organism" there because we're not just concerned with the pathogens. We are concerned with the indicators. Hopefully as we get fewer and fewer pathogens on the products it will be the process control that will tell us whether or not the conditions are such that the pathogens

may be there, but the indicators may be better for us to be looking at as a regulatory agency and use that information.

So it's important to consider more than just pathogens. Indicators that may not be pathogenic, but indicators are what we're looking at.

DR. WESLEY: Irene Wesley, ARS, Ames, Iowa.

Just to let the group know, as I'm sure you know, there are at least two commercial systems that are available for enumerating *Campylobacter* and *Salmonella* in turkey ceca, which is a really dirty matrix.

DR. WITHEE: And I actually don't know a lot about food science. I mean just briefly they work on optical density of cultures or how do they operate?

DR. WESLEY: They're PCR-based.

DR. WITHEE: They are? So they're extrapolating back from PCR amplicon levels to --

DR. WESLEY: It's a direct detection for campy with absolutely no enrichment, and for *Salmonella* we're extrapolating back.

DR. WITHEE: Excellent. I'd like to talk to you more about that afterwards actually. That's very interesting.

Thank you.

So this gets back. Remember I had the question about Iowa and Georgia and could I find them on the map, right? The type and format that the data is captured in is really important, and that's being considered in this charge.

I guess currently the data is captured, and I don't guess. It's true the data is currently captured from the BAX PCR assay, for instance, in a digital format where it's transferred directly to databases in-house in the labs where it's captured. It's more of that second part, to transfer an aggregation where it's actually sent to a

central repository that would need to be considered, and are we adopting technologies that readily lend themselves to being implemented in that kind of a database structure?

And of course, these large scale genotype assays or anything else that's high throughput like that is, because the final step is you put the plate into a reader, right? And everything is acquired digitally, and from there it can be sent in an automated fashion to anyone that should have access or put into a central repository or anything that seems most desirable there.

It's really the rear end of the question because once you capture the data, just like people talk about the front end, the data is no good if the sampling regime isn't set up properly.

The data is also no good if after it is captured it's not assembled properly.

And then finally, a really

important issue is human attribution, and so from our point of view when we're testing in meat and poultry products, what technologies are apt to give us the most information about human attribution?

And at least part of this is going to merge with what types of information is being obtained from clinical samples. What are you finding in diarrhea and vomit from patients? And what kinds of traits are they testing for and how can we actually match our products to those illnesses better?

And this like the enumeration is a real important topic for the present and future of FSIS. I think that this is a really important issue to address.

So that really is the final charge question. Yes.

MR. GARRETT: Two things. You couldn't hear me?

I want to build on Irene's comments. We certainly applaud also FSIS

taking this very advanced approach, and you know, we all know that the only thing in life that's inevitable is change and methods are going to change, and this is the wave of the future, without a doubt.

And I think it would be very helpful at least to me, but I think probably to all of the other Committee members. I believe you indicated we could have the same November 1st date to send in some comments to Gerri.

I think it would be very helpful if you would E-mail your presentation to everybody so that we can really quietly reflect about this a little bit. Without a doubt, this is where we're going, you know, and it would be very helpful for us to actually review it again and formulate our recommendations.

DR. WITHEE: Thank you.

We can E-mail it out to the members as well as post it on the NACMCF

Website.

Barbara.

DR. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority.

I would also like to really applaud and commend the agency for bringing this important topic to NACMCF.

I think Questions 5 and 6 are crucial. I wouldn't really -- and actually Question 6 in the document we received is different than Question 6 that's up there. I think that these are crucial front end questions.

In the document that I received, Question 6, "what technologies especially from those suitable for FSIS testing would provide the type of data useful in risk assessment attribution models for human illness, and what tests could assist in yielding data that would translate into risk profile for a given product operation?" which is different than what's up there.

These are really front end questions, and they really get back at the design of the study and statistical methods and data collection methods. And of course, I know the agency is working diligently towards a risk-based inspection model, and this certainly would go hand in hand with that.

I would hope that before we start tackling the technologies, which I believe are probably also very important, Questions 5 and 6 really need to be front end and really looked at at the same time. What are the purposes of these sampling programs, and how are you going to not only design the study? How are you going to collect the data and how does the agency have the appropriate information technology infrastructure to enable you to do that in the most efficient and expedient way?

But I do applaud the agency. I think this is an important topic, and I really look forward to working on it.

DR. GOLDMAN: Thank you. Thank you, Barbara.

I'm not sure who was next, Walt or Lee-Ann. Walt.

DR. HILL: Thank you. Walt Hill, USDA, retired.

It seems to me that a lot of the methods or a lot of the regulations are, in fact, method dependent. All of the baseline studies that were done in the '90s generated performance standards, and that's what the people are expected to make, and if we should by some good fortune of scientific advancement be able to develop more sensitive methods, what happens to those old performance standards and what's the regulatory apparatus that needs to be in place to adjust for that?

And I ask that as a practical question that the agency needs to be ready to consider and perhaps even start working on it before even any methods are proposed.

And a similar question is the

difference between regulatory testing and baseline studies. one of the desires perhaps would be to have better, faster, cheaper, maybe not so specific or accurate methods for baseline studies so you could do more and collect more information. But if that's the case, how do you use those to develop performance standard regulations and use different methods than in the regulatory laboratories?

And the final issue is industry, perhaps not as big as FSIS, but for their own sake they like to use FSIS methods to keep themselves covered, and what is industry going to react to when they see some very high tech and perhaps expensive to implement methods that the agency is moving toward?

Not real scientific questions. Just sort of practical, regulatory applications.

Thank you.

DR. WITHEE: Thank you.

Dan, do you want to respond at all?

PARTICIPANT: I mean, to the first part of his question, which I think was, you know, consider the regulatory context for making any changes, and clearly we do consider that and need to consider that. I mean, our regulations are what they are, and they specify as you pointed out very particular ways and methods for arriving at various endpoints in terms of data, and if we make changes as is being suggested by this charge, then our policy has to move with it, yes.

Dan.

DR. ENGELJOHN: This is Engeljohn with FSIS.

And I agree that the policy ramifications are part and parcel to what we have to do here, but from the perspective of, I think, these charges that we're working with here in terms of the questions, I think it's a given that we will have to develop the policy

in concert with, and that will be a public process.

But from the perspective of where I am as a risk manager anyway, it becomes even more imperative that we're also attending to the issues of infectious dose and making sure that we're dealing with the issues of what constitutes a level for which there's adulteration versus evidence of processes being out of control.

As we get better, more specific, and refined information I think those questions become all the more important, but as a risk manager, I see them as separate things that will be done in concert with.

And so we really are looking at what is the best available information to find out what's there and what the relevance is of that information, and then from that, take that and develop appropriate strategies that will address that from a public health perspective.

So I think not that I can direct this Committee to do anything, but from the perspective of it is helpful to me as a risk manager anyway to know what information is there and then we deal with the other aspects of it probably in another charge later as we go through this process.

DR. GOLDMAN: Thanks, Dan.

Lee-Ann.

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

Thank you for bringing all of that stuff up, Dan, because I think what I'm going to say at least addresses some of that.

The first thing I want to say is that you guys need to be aware, and I think several people are, that there was a very recent FDA AOAC contract that looked into methods validation and verification. It's a huge document. I have been told it is available publicly. It came out about a month ago.

So we don't want to reinvent the wheel here, and probably in refining the charge that document should be looked at first.

The second thing is that I look at the scope and I think it really, really needs to be limited, and without telling you how it should be limited, my personal opinion, and I do a lot of work in this area in methods development, is that there are some key things that absolutely need to be considered.

One is pre-PCR or what I tend to call upstream sample processing prior to detection.

The second is this whole idea of the molecular target. Should it be DNA? Should it be RNA? Should it be a protein?

Particularly with respect to viability, we absolutely have to develop enumerative assays. That's critical for what Dan was just saying, and so that needs to be a major consideration.

I think we need to look at this point in time about what is practically like within the next five years going to be available. Nanotechnology is wonderful, but it is not going to be available in the next five years for applications to foods. So I think we can talk about those things as coming, but I don't think those are practical technologies for tomorrow.

DR. GOLDMAN: Barbara.

DR. KOWALCYK: Barbara Kowalcyk, Safe Tables Our Priority.

I just wanted to come back to something that Walt had brought up. That is the microbiological baseline surveys and the performance standards. I mean, it's my understanding that HACCP was built really on a statistical quality control, and the idea is you would be continually updating performance standards.

There has been some -- I know the National Academy of Sciences looked at the

derivation of the performance standards from the microbiological surveys. It would be helpful to know if that's something you're going to want the subcommittee working on this to be also considering the derivation of that.

DR. GOLDMAN: Thank you.

Walt.

DR. HILL: Well, since turn about is fair play, I'd like to make a charge to FSIS, and that is to pursue the area of developing regulations that will be, if possible, method independent, but certainly not as tied closely to methods as they are now, and also to, if possible, develop regulations that will be a little more broader in scope than one particular genus and serotype when we know we have other members that essentially have the same public health impackt as 0157 does.

I know that was done ten, 12 years ago for expediency, but it has caused a lot of problems during this past decade because we

were unable to take action on pathogens in food that need to have those things addressed.

So it's a little off topic, but I think that's only fair since you've given us a very broad topic as well.

DR. WITHEE: Actually that point about serotype versus genotype is super important, and I should have emphasized that more in that if you're really detecting the genetic risk within that sample, i.e., you are looking for shiga toxin producing genes and virulence factors, not for a particular cell surface antigen on the bacteria --

DR. HILL: We can have all of the excellent molecular techniques you want to have, but if we don't have the regulatory apparatus to take advantage of those results, it's of academic interest.

DR. GOLDMAN: All right. Are there any other comments or questions or clarifications needed for this?

I think from the agency point of

view we've gotten a lot of very helpful input into our effort to refine the charge.

I need to correct something, a word I used earlier. These two charges now that you've heard from FDA and FSIS will be refined based on any further comments and presented to the Committee at the next plenary session, not for acceptance, but just for work. So I wanted to clarify that.

(Laughter.)

DR. GOLDMAN: Spencer.

MR. GARRETT: I just need to make an announcement before we go to the public comment period.

DR. GOLDMAN: Okay. So I think I want to thank Jim Withee very much for coming out. You probably flew over Ames, Iowa on your way here from California.

(Laughter and applause.)

DR. GOLDMAN: And so I do appreciate your work and the work of your collaborators that you showed on your last

slide for presenting this and providing a stimulating presentation, and we'll keep working on it. So I appreciate that.

We are 15 minutes ahead on our agenda, but we're at a break. So I want to gauge the Committee members. It's up to you all if you want to take a short break or forge ahead.

Okay. We will move ahead then.

We have not been notified of anyone in the public that they are interested in making a comment, but before we move to the public comment, Spencer had an announcement. I'm sorry.

MR. GARRETT: Yes. It won't take long, but some of you know Dr. Al Rainosek very well. He's our statistician that's worked very diligently with this Committee and has shared some of the same concerns that you share, Barbara, but he was involved in a very serious car accident, oh, six weeks or so ago. A semi-trailer truck ran over his car, spent

a lot of time in the hospital. He's now in a rehabilitation center, and they do anticipate full recovery, but it's going to take some time.

So I just thought I'd bring that up to the Committee.

Thank you.

DR. GOLDMAN: Thank you, Spencer.

Are there any members of the public who wish to make a comment at this point?

(No response.)

DR. GOLDMAN: All right. Seeing none and hearing none, we will move to the final part of our agenda. As you heard at the beginning we are at the end of the work of this particular Committee, and we have four members of this Committee whose term has expired or who otherwise will not be members of the next Committee, two of whom are present with us, and we want to recognize the service of those two Committee members and publicly

thank them for their service to the Committee for these past two years and for some of them many years before that as well.

The two members who aren't here who are leaving are Patty Griffin from the CDC, who could not be here today because of the *E. coli* and spinach outbreak and her work on that. And then John Kvenberg from FDA (retired), another long term member of the Committee is not here with us, as well.

But we do want to recognize Larry Beuchat and Kathryn Boor for their service, and we'd like for you two to come up and be recognized for your service.

(Pause in proceedings.)

DR. GOLDMAN: I just would like to take a moment to read the letters, if I could. Larry and Kathryn and the others will have a letter signed by Dr. Raymond and Dr. Brackett, the Chair and Co-chair of NACMCF.

"We at the Departments of Agricultural and Health and Human Services,

with our colleagues at the Department of Defense and Department of Commerce, wish to thank you for providing your scientific expertise to further insure the health and welfare of American consumers. The subject matter expertise you brought to the National Advisory Committee on Microbiological Criteria for Foods allowed for lively scientific debates on a variety of topics. We value the contributions you made and appreciate the time and effort you provided to discuss challenging issues.

"On behalf of the sponsoring agencies, we would like to award you with this certificate of appreciation and thank you for being a member of the NACMCF and making it such a success. We have the utmost confidence that you will continue to make very important contributions toward the safety of the American food supply. We extend our best wishes and thank you for a job very well done."

(Applause.)

DR. GOLDMAN: We also have a very nice parting gift. It's a clock for those who can't see from the back there.

(Whereupon, at 11:11 a.m., the meeting was concluded.)