UNITED STATES DEPARTMENT OF AGRICULTURE

NATIONAL ADVISORY COMMITTEE

ON MICROBIOLOGICAL CRITERIA FOR FOODS

(NACMCF)

PLENARY SESSION

Wednesday, September 28, 2005

The Committee met in the Omni Colonnade Hotel at 180 Aragon Avenue, Coral Gables, Florida, at 8:30 a.m., Dr. Richard A. Raymond, Chairperson, presiding.

Members Present:

RICHARD RAYMOND, Ph.D., Chairperson
ROBERT BRACKET, Ph.D., Vice-Chairperson
DR. GARY ADES, Member
DR. KATHRYN BOOR, Member
DR. SCOTT BROOKS, Member
DR. PEGGY COOK, Member
DR. DANIEL ENGELJOHN, Member
DR. TIMOTHY FREIER, Member
DR. LINDA HARRIS, Member
DR. WALT HILL, Member
DR. MICHAEL JAHNCKE, Member
DR. LEE-ANN JAYKUS, Member
MAJ ROBIN KING, Member
MS. BARBARA KOWALCYK, Member
DR. JOSEPH MADDEN, Member
DR. ALEJANDRO MAZZOTA, Member
DR. JIANGHONG MENG, Member
DR. DALE MORSE, Member
DR. DONALD SCHAFFNER, Member
MS. VIRGINIA SCOTT, Member
DR. JOHN SOFOS, Member
DR. STERLING THOMPSON, Member
DR. IRENE WESLEY, Member
DR. DONALD ZINK, Member

Attendance by Phone:

MS. EMILLE COLE (for Spencer Garrett)
DR. PATRICIA GRIFFIN, Member
DR. ANN MARIE MCNAMARA, Member
MS. ANGELA RUPLE, Member

Executive Committee Members Present:

DR. LEEANNE JACKSON, FDA Liaison
DR. DAVID GOLDMAN,FSIS Liaison
LTC. BRADFORD W. HILDABRAND, Defense Department Liaison
DR. ARTHUR LIANG, CDC Liaison
MS. GERRI RANSOM, Executive Secretariat
MS. KAREN THOMAS, Advisory Committee Specialist

FSIS STAFF:

DR. CELINE NADON
MS. NISHA OATMAN

FDA STAFF:

DR. MARY LOSIKOFF

OUTSIDE PARTICIPANT:

MR. MARK WORTH, Public Citizen

I-N-D-E-X

P R O C E E D I N G S

(8:30 a.m.)

DR. RAYMOND: Good morning everybody. For those of you who don't know me, and most of you do not, I have not met you yet, I am Dick Raymond. I am the new Under Secretary for Food Safety of USDA, and one thing I do believe in is starting meetings on time in respect for those who are able to get here on time.

I want to welcome you members and also our guests to this Plenary Session of the 2004-2006 National Advisory Committee on Microbiological Criteria for Foods.

This is my first NACMCF meeting, obviously, as the NACMCF Chair, but I don't feel foreign to the role that I will play with this Committee. I have served on many Advisory Committees, both State and National, and in fact, the day I got the call that the Senate had scheduled my confirmation hearing, I was in CDC serving on a National Advisory Committee for Pandemic Flu preparations. I have also served on the National Vaccine Advisory Committee for a couple years in my role as State Health Official.

I recognize the value that Advisory Committees bring to Federal Government and State Government, and I do thank you for the time you're going to spend helping us get through some very difficult issues. We will listen to your advice, obviously, and act appropriately.

The last six and a half years of my life I was serving as a Chief Medical Officer for the State of Nebraska, chaired many Advisory Committees for the Governor, then Governor Johanns, now Secretary Johanns. And I must have done a decent job during those Committees because he asked me to come to Washington and work with him and Chair this Committee and a few others. So I'm looking forward to the exchange today.

I know we've got a lot of work to do and I know we'll do it diligently and openly. Most of you probably know the guy to my right, Dr. Bob Brackett, a whole lot better than you know me. Now Bob's kind of been up and down the last week whether he's going to be with us or not, and I think he felt a little bit nervous about letting me chair the Committee without

him sitting at my right, since this is one of his passions. So I'm really, really glad that Bob was able to shake loose, at least for today, to work with us on this. I'm going to give part of the responsibilities of this meeting to him so I can sit back and watch and learn.

Before I go any further though, I do want to say that the USDA Food Safety Inspection Service, the Department of Health and Human Services, Food and Drug Administration and the Centers for Disease Control and Prevention, Department of Commerce, National Marine Fishery Service, and the Department of Defense Veterinary Service Activity are all seeing you as performing a valuable service to help us do our job. NACMCF is providing the scientific advice to our nation's food safety programs, which are several. And on behalf of those sponsoring agencies that I just listed, I would like to thank each of you for your hard work and for sharing your expertise and supporting the activities of this Committee, not just today, but on all subcommittee work that you also do.

The three newly formed NACMCF

Subcommittees that met this past July to begin work are the Subcommittee on the Analytical Utility of *Campylobacter* Methodologies, chaired by Dr. Dan Engeljohn, the Subcommittee on Consumer Guidelines for the Safe Cooking of Poultry Products, also chaired by Dr. Engeljohn, and the Subcommittee on Determination of Cooking Parameters for Safe Seafood for Consumers, chaired by Mr. Spencer Garrett.

Before I continue, I do want to mention that it's especially unfortunate that Spencer Garrett and also Angela Ruple are unable to be with us in person this week as they were directly affected by Hurricane Katrina at their home base in Mississippi. We are glad that they and their colleagues that serve NACMCF are safe and sound and getting back up to speed after the storm damage that they suffered and their institution suffered. I think Angela is going to be with us, if not already on the phone, and we're not sure about Spencer. We certainly wish them and all of our other colleagues along the coastal states well during the time of rebuilding, and we will miss our National Marine Fishery Services folks during this

week's meetings especially.

Filling for Spencer Garrett today as Subcommittee Chair is Dr. Lee-Ann Jaykus of the North Carolina State University. We are grateful to Dr. Jaykus for taking on this responsibility on such a short notice. Thank you, Lee-Ann for your willingness to take on the work for the Seafood Subcommittee this week. I think we probably are in good hands, at least that's what everybody tells me.

Now, this morning our Subcommittee Chairs will report their progress to us on each of the important food safety projects. As a matter of fact, the *Campylobacter* group intends to wrap up their work today, hopefully, and they have submitted their document to the Full Committee for consideration of adoption today. This *Campylobacter* methods project is very important to us at FSIS as it will provide us with NACMCF guidance for establishing a *Campylobacter* method for an upcoming broiler rinse baseline study.

We will also hear reports on the poultry cook and seafood cook discussions. Both these projects will greatly benefit consumers and our

Federal agencies with the most current information on safe cooking parameters for these products on related food safety issues.

Also at this morning's sessions, fortunately, Bob Brackett is here, and he will be introducing a concept for a new FDA work charge for NACMCF; that being the assessment of the food safety importance and public health significance of *Mycobacterium avium* subspecies *paratuberculosis*. That's a mouthful. So Bob, I'm glad you're here to introduce it; I don't have to.

Before we have Committee members introduce themselves so I can start putting names to faces, I'd like to turn the floor over to our Vice Chair, Dr. Bob Brackett.

DR. BRACKETT: Thank you, Dick.

First off, I would like to welcome on behalf of the Committee too, Dr. Raymond to this role as Chair, and I think that you will find it not only interesting, but actually quite rewarding to participate. And also, I'd like to welcome everyone to the Plenary Session this morning. I'd like to

thank the members for volunteering their time and the expertise and the support of the activities of this Committee. As you know, your participation and effort will allow us and the Committee here to move forward on a number of important public health protection and food safety initiatives. And so I do really look forward to what is often very insightful discussions.

At this time I would like to stop and allow you all to introduce yourselves. So we'll go around the tables. And make sure that you speak into the microphones since this is being recorded, state your name and your affiliation. And I'll guess we'll start with Tim Freier.

DR. FREIER: Hi. Tim Freier with Cargill.

DR. ZINK: Don Zink with FDA, Center for Food Safety and Applied Nutrition.

DR. THOMPSON: Sterling Thompson, The Hershey Company.

DR. COOK: I'm Peggy Cook with Safe Foods Corporation.

DR. ADES: Gary Ades, Independent Consultant.

DR. BOOR: Kathryn Boor, Cornell University.

DR. BROOKS: Scott Brooks with E & J Gallo.

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

DR. JAHNCKE: Michael Jahncke, Virginia Tech.

DR. SCHAFFNER: Don Schaffner, Rutgers University.

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

DR. HILL: Walt Hill, formerly FSIS, now a free agent.

(Laughter.)

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

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

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

Epidemiologist.

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

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

MS. SCOTT: I'm Jenny Scott with the Food Products Association.

DR. SOFOS: John Sofos with Colorado State University.

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

DR. MENG: Jianghong Meng, University of Maryland.

MAJOR KING: Robin King, Department of Defense.

DR. LIANG: Art Liang, CDC Food Safety Office.

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

DR. GOLDMAN: David Goldman with the Office of Public Health Science at FSIS.

DR. JACKSON: LeeAnne Jackson, FDA,

Center for Food Safety Applied Nutrition.

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

At this time could we phase over to the phone and have those folks who are hooked in by phone introduce themselves?

DR. McNAMARA: Ann Marie McNamara, Silliker.

DR. BRACKETT: Ann Marie, we didn't quite hear you and our court reporter isn't hearing that. Could you try speaking a little bit louder and we'll see if that is any better.

DR. McNAMARA: Ann Marie McNamara, Silliker.

DR. BRACKETT: It was Ann Marie McNamara from Silliker Labs. I'll just repeat it so that our reporter can hear it.

MS. RUPLE: Angela Ruple, NOAH Fisheries.

DR. GRIFFIN: Patricia Griffin, Centers for Disease Control.

DR. RAYMOND: Is John Kvenberg on the line?

(No response.)

DR. RAYMOND: Okay, I think that's all that we have for now. At this time I'd like to turn the floor back over to Gerri Ransom of our Executive Secretariat, who can provide you with some other additional information that you'll need.

MS. RANSOM: Okay. Good morning everyone and welcome again. I wanted to take care of one more introduction today. To my left we've got Dr. Celine Nadon who is a Food Safety Fellow at our office who is going to be helping us with our *Campylobacter*, and also with our seafood work in the next couple of days.

As always, if anyone needs any assistance, please don't hesitate to contact me or Karen Thomas if you should need anything. I also wanted to mention for any guests today who wish to make public comment, to please sign up outside with Sally. You are limited to ten minutes for each public comment, so please get on the list if you'd like to do that.

I also wanted to point out to our guests that we do have a table out front with NACMCF related documents. So feel free to pick up any materials that

you would like. Also, if you would like to distribute any materials, please see Sally about that.

Okay. Related to NACMCF business, I have a couple of things I wanted to mention. At this point, we're just about halfway through our 2004-2006 NACMCF term; time flies. This current Committee and Charter will run through September 23, 2006. And very shortly Karen and I will be initiating the long ream of paper work that we have to go through to renew the Committee. So we've got that in mind and we will be working on that.

I also wanted to mention that the week of March 20, 2006 is being looked at as our next week of meetings. I know a couple of you do have a conflict with this time, so we may be looking at another week in March or beyond. But please get in touch with Karen or I and let us know how this week in March looks for you, and other weeks in March as well.

On a minor note, I wanted to remind everybody, please look under Tab 3 in your notebook on the address list and let us know if there's any changes that need to be made to your contact

information.

And finally, most importantly, I wanted to mention to you, make sure that you're pretty prompt in getting Karen your information for reimbursement for travel, because we are at the close-out of our fiscal year so she's under the gun to get the travel information in to reimburse you. So please see her if you have any issues with that.

And also I wanted to say, we do apologize if you've had any trouble related to hurricane Katrina and getting reimbursed for the last trip, because that did cause us some problems.

I'm looking forward to working with you for the rest of this week, and so far we've had good meetings. At this time I'm going to turn the floor back over to Dr. Raymond.

DR. RAYMOND: Thanks, Gerri. And you'll note we're now fifteen minutes ahead of schedule. So now we're going to get into the work part of this Committee, and the first is going to be Analytical Utility of *Campylobacter* Methodologies, and we'll follow that with the Determination of Cooking

Parameters for Safe Seafood for Consumers, and follow that thirdly with the Consumer Guidelines for Safe Cooking of Poultry Products.

So now, with no further ado, I'll call upon Dr. Dan Engeljohn to lead our *Campylobacter* discussion. Dr. Engeljohn will explain the document and then Dr. Brackett will lead the discussion for adoption.

First, who just joined us on the phone?

MS. COLE: Emille Cole, National Marine Fisheries Service.

DR. RAYMOND: Thank you, Emille.

Is there anybody else that's joined us that we didn't hear?

(No response.)

DR. RAYMOND: I didn't think so.

Okay, Dan?

DR. ENGELJOHN: Thank you very much. I was honored to be the Subcommittee Chairperson for the *Campylobacter* work that we've done this past year. I had twelve members assigned to this Subcommittee. We had additional members of the Full Committee who

joined us in helping to address the questions that FSIS specifically asked the Committee to address.

If I could, I'll just walk through and give an overview of what we did and where we stand today, and then some housekeeping things, because we have a couple of changes to the document that were submitted to me earlier so that we could get them typed up, and we'll pass them around to the Subcommittee and Full Committee members so that you can review those written changes in advance.

And then I have two documents that were submitted that were asked for as part of the Subcommittee's work. We'll also identify what those documents are.

There were six questions that FSIS asked the Committee to address with regards to *Campylobacter*.

I'm sorry, Gerri, did you have a question?

MS. RANSOM: I just wanted to say the handouts are in the process of being copied and they're going to be emailed to the folks on the phone.

DR. ENGELJOHN: Thank you. And I have

them here, Gerri, if I can get some help in passing them around, that would be helpful, while I'm talking. Just do the overview. *Campylobacter* has been an issue that this Committee has dealt with over the years. In 1993 the Committee actually worked on the issue and published a journal article about *Campylobacter*. FSIS then came back to the Committee to ask questions twice in the past. In 1999 we were specifically asked to address *Campylobacter* and its ability to be used as a performance measure in addition to *Salmonella* in raw classes of meat and poultry.

At that time the Committee did work on the issue but did not come to conclusions, in that it believed it needed more information from the Agency before it could actually address the issue of establishing a performance standard for *Campylobacter*.

And then in 2002 FSIS presented information about a baseline that we had completed, but had concerns about the methodology. And so really, since 2002, FSIS has been specifically looking as to what methodology should be used in order to standardize that methodology and begin conducting a

formal baseline study that could be used to inform risk management.

Did someone just join us on the telephone?

DR. BRACKETT: Or did someone just leave us?

DR. ENGELJOHN: All right. With that, then I'm not going to read the six questions, because I think there is a need to go through the document. Dr. Raymond or Dr. Brackett, are you going to walk us through? Okay.

We'll go through the document, I believe paragraph by paragraph, or at least page by page for substantive changes. As I said, there will be three documents that are going to be handed around that contain some suggested changes with wording that the Committee does need to review.

And with that, I think I'll stop there and begin the process.

DR. BRACKETT: Okay, thank you, Dan. And again, did someone else join us on the phone? Right now I have Patty Griffin, Ann Marie McNamara, Angela Ruple and Emille Cole. Is there anyone else on the

phone?

(No response.)

DR. BRACKETT: The way that we have done these before, and I think we'll work this way too, as Dan said, we'll go through page by page. With each page we'll ask for any comments or questions about the document. When you do ask, the procedure we have used in the past is to take your table tent (card), bring it up like a flag, and state your name and affiliation for the reporter when you do ask your questions.

So I guess, first of all, we'll start actually on Page 2 to make sure there's nothing that anyone sees in this. That's just the Table of Contents. Actually getting into the text, Page 4, the Executive Summary.

Ann Marie McNamara?

DR. McNAMARA: (Inaudible.)

DR. BRACKETT: Ann Marie, could you hold on. We're going to put a microphone up to the speaker phone so that we can hear for the court reporter.

All right, sorry, could you start all over again, including name and affiliation?

DR. McNAMARA: Okay, I'll try again.

This is Ann Marie McNamara from Silliker. And I wanted clarification under the third bullet point in what was meant by the Committee. It says "FSIS must clearly state the objectives and potential use of the baseline data and determine data collection from a single carcass rinse for the analysis of *E. coli*, *Salmonella* and Campy data that would be beneficial for the evaluation of an indicator organism for the industry and agency."

And I am confused about what the benefit for the evaluation of an indicator organism is, because the only indicator organism there is *E.coli*. You're really looking at *Salmonella* and *Campylobacter* as pathogens.

DR. BRACKETT: Okay, Dan?

DR. ENGELJOHN: This is Engeljohn with FSIS.

On that particular issue, I think the Agency as well as looking at not just the pathogens that may serve as a means by which the Agency could look at progress with regards to sanitary dressing and

the level of exposure of pathogens on products, but we're also looking at process control. And presently the Agency is working on a project partnering with the Agricultural Research Service in which we're looking at nonpathogenic indicators of process control in the slot of operation.

And so we broadly stated indicators because we didn't want to limit ourselves to just pathogens.

DR. McNAMARA: Okay, thank you for that clarification.

DR. BRACKETT: Lee-Ann Jaykus?

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

Just a wording suggestion on the third paragraph, second -- actually third, fourth line from the bottom, "prevalence and numbers," since you're talking about enumerative data.

DR. BRACKETT: Prevalence and numbers of *Campylobacter* is what you're saying?

DR. JAYKUS: Correct.

DR. BRACKETT: Dan, did you have any

comments? Do you have any comments about that suggestion?

DR. ENGELJOHN: I'm sorry?

DR. BRACKETT: Do you have any comments about that?

DR. ENGELJOHN: Oh, no, it sounds great.

DR. BRACKETT: Okay, so we can include that.

And just to go back, Ann Marie, did Dan's explanation answer your question?

DR. McNAMARA: He did answer the question. I don't think it's very well stated, but I understand where he was going.

DR. ENGELJOHN: If I could, Ann Marie, Barbara Kowalcyk has actually offered some change later in the text with regards to this particular issue, I think. And so maybe with her new language, we can possibly adjust that particular bullet based on what she submitted.

DR. McNAMARA: That would be fine, Dan.

DR. BRACKETT: So we'll need to come back to this bullet then.

Any other questions or comments on Page 4?

(No response.)

DR. BRACKETT: Page 5?

(No response.)

DR. BRACKETT: Page 6?

MS. KOWALCYK: Barbara Kowalcyk.

I had a question on Page 5, second paragraph. Just for statistical purposes, in the last sentence it says, "In that report a broiler was defined as a young chicken of either sex usually under thirteen weeks of age, and FSIS has proposed to reduce that age requirement to under ten weeks."

For statistical purposes, I would hate to see the study to later have apple to orange comparisons, and I would recommend as a statistician that there be a clear-cut definition of what a broiler chicken is at the onset of the study.

DR. ENGELJOHN: This is Engeljohn. I'll offer an explanation to that.

This wording actually was taken directly from the previous report that the Committee worked on with regards to performance standards for broiler

carcasses. So we took the wording from that particular document. And it was really intended to provide some clarity to the Committee members as to what a broiler is.

In practice, what is considered a broiler by industry is consistent. But there is a regulatory definition that is not consistent with current practices.

So in reality, when we actually do conduct the baseline or we do refer to broilers in practice, that is a consistent application. It's just how we define it in the regulatory text that's different. And we're in the process of changing that in the regulation. It won't change in practice what birds are actually offered as broilers.

DR. BRACKETT: Page 6? No comments on Page 6.

Page 7? Lee-Ann Jaykus.

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

I'd like some clarification on the last sentence of the second paragraph to the bottom

regarding the surveillance research project.

DR. BRACKETT: This is on Page 7, second from the bottom paragraph, last sentence?

DR. JAYKUS: Correct.

DR. ENGELJOHN: This is Engeljohn. If I could, I'll attempt to answer this, and if any of my Committee members can provide any additional help, that would be great.

I would also point out that Dr. Patty Griffin from CDC has provided a change which you got this morning. And maybe that will also help answer. But the Agency did want to insure that, and the Committee wanted to insure that when we conduct this baseline study that we just don't focus on the two species that we believe to be of greatest public health concern, because there may in fact be others.

I think in our discussions by the Subcommittee, Dr. Irene Wesley actually identified some issues with regards to turkeys coming to slaughter and that possibly we should be concerned, or at least looking into, whatever species we might need to be looking at.

So I think the real issue was we should not just blindly go into a study and look at just the two that we know to be a problem, but to also try to get a sense for what other pathogens, related *Campylobacters* should be looked at.

DR. BRACKETT: Is there a comment on the phone? Background noise?

Dr. Hill?

DR. HILL: Walt Hill, unaffiliated.

In the second full paragraph on Page 7, the word thermophilic is used twice, and I'm not a classical microbiologist, but I think maybe thermo-tolerant is the more commonly accepted term there because *Campylobacter* really doesn't grow well above forty-five degrees.

DR. GRIFFIN: Could that comment be repeated for the people on the phone? This is Patricia Griffin.

DR. HILL: Sorry, no one's accused me of speaking more softly usually.

The word thermophilic is used twice in that paragraph, and I think the word thermotolerant is

more accurate there.

DR. BRACKETT: So your recommendation is to change reference to --

DR. HILL: Yes, the first line in that paragraph and in the third to last line, change thermophilic to thermotolerant.

DR. BRACKETT: Heads are shaking around the table that that's correct. Any opposition to that?

(No response.)

DR. BRACKETT: Okay, we'll do that.

Oh, Irene?

DR. WESLEY: I'm going to back up all the way to Page 4 and I'm going to use the idea that coming from the Midwest I'm an hour behind you folks on the east coast.

(Laughter.)

DR. WESLEY: I just wanted to look at Page 4, third bullet statement up from the bottom. The question I'm raising concerns the statement, "with modifications as indicated throughout the report."

I would like to know if someone could

insert, perhaps the Chair could insert, how modifications would be relayed to the Committee. Would it be relayed to you? Would it be relayed to the folks actually doing the work in the FSIS lab? But if there are modifications or developments that are made, what is the best avenue for making sure that these are sent to you? What is the channel for doing this?

DR. ENGELJOHN: If I could get some clarification, Irene. Which -- I'm not sure that I understand what changes. You mean in terms of if the methodology changes it would be changed in the lab?

DR. WESLEY: If there are modifications that are coming after this group has finished their work, what is the channel, if any, for getting further -- if there are further developments in the field? How do we get these to you?

DR. ENGELJOHN: With regards to laboratory methodology?

DR. WESLEY: Right, exactly.

DR. ENGELJOHN: I think, if I could, I would just opine that FSIS will assess what changes

could or should be made. Because this Committee has worked on this issue, at an upcoming meeting we'll likely just inform you of those changes. We haven't done that in the past, but I don't see that as being a problem. For those of you interested that participated on the Subcommittee, as the Chairperson I would feel comfortable just sending out information to you to let you know what changes we made and possibly get feedback from you.

DR. BRACKETT: And that was one question that Ann Marie McNamara mentioned before, that we are going to come back to later in the document, that particular bullet point. So before we move forward, should we ask if anybody from the west coast wants to go back to Page 1?

(Laughter.)

DR. BRACKETT: So we're on Page 7. Any other changes, aside from what was noted earlier?

(No response.)

DR. BRACKETT: Page 8? And I think this is the question that Patty Griffin had, is that not the one?

DR. ENGELJOHN: No, I think Patty's is on Question 4.

DR. BRACKETT: So we have Page 12. And this is the insert that you had handed out at the beginning, Dan, Question 2?

DR. ENGELJOHN: No. I have inserts that are going to affect Question 4 on Page 12, and inserts I handed out that -- oh, I'm sorry, I didn't have that sitting in front of me. Yes, and Barbara Kowalcyk is who submitted that question.

MS. KOWALCYK: On Page 8 though, before I get to that, on Page 8 in the last sentence of the second paragraph --

DR. BRACKETT: Barbara, could you speak a little louder?

MS. KOWALCYK: Barbara Kowalcyk.

On Page 8 in the second paragraph under Question 2 in the last sentence, "The Committee also recommended that FSIS be in consultation with other entities to correlate *Campylobacter* methodologies when possible."

Would it be possible to add an example or

scientific entities? It kind of was unclear to me what entities you were talking about.

DR. ENGELJOHN: Well, we could add information. I think as the Subcommittee dealt with this issue, we know that our European counterparts are in fact working on Campy methodology, as well as around the world, and then in particular in the states we have the ARS researchers, many of whom are working on different methodologies, and then there are research institutions dealing with that.

So if I could suggest a change then maybe to address that? The Committee also recommended that FSIS be in consultation with other entities, such as European, Government officials, and other research institutions. Would that address your issues?

MS. KOWALCYK: Yes.

DR. RAYMOND: Dan, may I -- Dick Raymond. May I suggest that when you say "would include," instead of saying European, why don't we say other national governments, or whatever the right language would be, instead of limiting it to European, other Federal agencies, and other private and state

institutions doing research, or something to that.

DR. ENGELJOHN: That's a good point.

DR. BRACKETT: Irene?

DR. WESLEY: Irene Wesley.

I have two documents that I shared with the Chair that I think are probably perhaps just left in the hands of the Chairperson. One of them is an Audit Committee on Food Analysis, and this is their April, 2005 protocol for detection and enumeration in foods.

The second document that I shared with Dr. Engeljohn is a draft of the technical specifications for an EU monitoring scheme for Campy in broiler chickens.

I bring this to the Committee because one, both of them use the guidelines of the Gooden laboratory protocols for detailing all of the conditions for analysis, and I think that that detail should also be incorporated in the protocol that's ultimately adopted by FSIS for their baseline.

I also bring them here because they're current and they do show the desire of this Committee

to look to the other side of the Atlantic Ocean for potential comparison of methods.

DR. ENGELJOHN: And I think with that, possibly we could add a footnote to reference these two documents. Irene had promised to bring the documents to the Committee for our review. And what I intend to do is, when we get this document done, and we'll be sending out a revised version to the Full Committee, in that document we will also include copies of this. So we'll scan them into a file and make sure everyone has a copy of it.

But I would note that they are in fact, and would be quite help to FSIS in the design of our program. So we will incorporate them.

DR. BRACKETT: And where would you propose to put the footnote on the document?

DR. ENGELJOHN: I think in that actual sentence where it says, "The Subcommittee also recommended that FSIS be in consultation with other entities, such as other national governments, Federal agencies, and private institutions," what we just added, and then add a footnote there with these two

documents.

DR. BRACKETT: Okay.

Walter?

DR. HILL: I'm Walt Hill.

I have a couple of comments on that large paragraph in the middle of the page about a third of the way down. And I also suggest in the future maybe we could number the lines to facilitate these kind of indications.

Is it true that the Committee would like to reference the creation of a performance standard at this point, talking about regulatory policies and risk assessments? Is it the intent of the Subcommittee and also the Full Committee then to have this data perhaps support some kind of performance standard? That's a question.

And also the word "in relation to indicator organisms," perhaps we really mean the utility of indicator organism?

DR. BRACKETT: Walter, where are you looking specifically?

DR. HILL: I'm right about in the middle

of that large paragraph on Page 8 where it starts, "The Committee also suggested that FSIS has considered *E.coli*, *Salmonella* and *Campylobacter* from the same carcasses rinse to obtain information in relation to an indicator organism."

I believe that the intent is to use *E.coli* as an indicator organism and that data would support the utility of that conclusion.

DR. BRACKETT: Dan?

DR. ENGELJOHN: That sounds very good. Thank you.

DR. BRACKETT: And that relates back to what Ann Marie mentioned.

DR. HILL: Yes. And then finally, right after that, we're talking about relative -- I'd like to make a comment about relative sensitivities of qualitative versus quantitative methods, especially when you're looking for indicator organisms.

FSIS got into a little bit of a difficulty with the previous study where they were looking at the utility of generic *E.coli* as an indicator of O157, and the methods they used had different sensitivities. So

you end up with a sample being negative for generic *E.coli*, but still having a positive enumeration for O157, which doesn't really make any microbiological sense.

So in any design of the study when you're looking to compare these organisms, presence, absence or quantification, you need to use the same method sensitivity in order to have those results meaningfully comparable.

DR. BRACKETT: How would you, or do you propose changing the language in that particular sentence or that paragraph?

DR. HILL: Well, I just think that maybe there could be a sentence inserted, that to make sure that these data and utility in terms of looking at the possibility of indicator organisms, that method sensitivity be addressed. Or you could spell it out in even more detail, that methods of equal sensitivity must be used.

DR. BRACKETT: Dan, did you have any suggestions or response to that?

DR. ENGELJOHN: I tried to write down

what Walt was saying, which I'm fine with adding that as guidance. So, let's see, I guess before the sentence that says "The Committee stated that FSIS," before that we'll add a new sentence that says, "To insure that data have utility for use of indicator organisms, methods sensitivity must be assessed to assure that they are of equal sensitivity to those used for the pathogens."

Is that what you're suggesting, Walt?

DR. HILL: Essentially, yes.

DR. ENGELJOHN: Okay. Clearly, I will need some help on editing that sentence.

DR. BRACKETT: If we could read that again, just for the people on the telephone.

DR. ENGELJOHN: It says, "To insure that data have utility for the use of indicator organisms, method sensitivity must be assessed to make sure that they are of equal sensitivity to those used for the pathogens."

DR. BRACKETT: Any other comments about that insertion?

DR. ENGELJOHN: I would add that if in

fact we find that we can word that better when we're editing the document, if we could have the license to just make those -- get the intent there, but make it more pretty and understandable, we will certainly work on that.

DR. BRACKETT: Walter, did you have anything more?

DR. HILL: Not on that page, no.

DR. BRACKETT: And Kathryn, I saw your flag was up. Did you have a comment?

DR. BOOR: Just to reiterate what Walt and Ann Marie said. I wanted clarification of the fact that *E.coli* and *Salmonella* were the indicator organisms in question for *Campylobacter*.

DR. BRACKETT: So this addresses your concern as well?

DR. BOOR: Yes.

DR. BRACKETT: Okay. Any other comments on Page 8? Joe Madden?

DR. MADDEN: Joe Madden, Neogen Corporation.

On the paragraph that begins,

"Specifically, the Committee suggested that FSIS consider," at the end of that it says, "inspected plants to ascertain if regulatory policies are successful."

Are we talking regulatory policies or intervention strategies here?

DR. ENGELJOHN: I'm sorry, Jim.

DR. BRACKETT: This would be the sentence above the one we just talked about.

DR. GRIFFIN: This is Patricia Griffin.

I can't hear at all, and also I think someone on the phone doesn't have their phone muted.

DR. BRACKETT: Yeah, that's a good point. People on the phone, unless you're speaking, if you could put your phones on mute that would be helpful.

MS. COLE: Well, you know, some of us are on cell phones here in hurricane land and we can't do that.

DR. BRACKETT: Sometimes you can mute cell phones with Star 6. I don't know if that's universal.

Joe, would you state this again for the

people on the phone and try to yell out in the microphone?

DR. MADDEN: Joe Madden, Neogen Corporation.

I'm questioning the second paragraph after Question 2. The second sentence begins, "Specifically, the Committee suggested that FSIS consider such things as" -- and going on.

What I am specifically questioning is, that "of products in the inspected plants to ascertain if regulatory policies are successful," do we mean regulatory policies there or intervention strategies, is the question I have?

DR. ENGELJOHN: And I think it's a good suggestion, Joe. Intervention strategies would be fine to modify that to.

DR. BRACKETT: So replace regulatory policies with intervention strategies.

Other comments or questions on Page 8?

Irene?

DR. WESLEY: On Page 8, the third paragraph down, around sentence number 4, and I concur

with Walt Hill that numbering the lines would really have been helpful, there's a phrase "multiple points along the poultry processing line."

Would it be appropriate for this Committee to state when the carcass will be sampled during processing?

DR. BRACKETT: Same paragraph, Dan, fourth line down.

DR. ENGELJOHN: I'm sorry, Irene. The wording you wanted to add was what?

DR. WESLEY: Just clarification to the Committee. Would it be appropriate for this Committee to specify at what point carcasses would be sampled?

DR. ENGELJOHN: The issue of multiple points along the processing line was intended to mean that we would pull samples other than as our current practice, which is to only pull a sample in one location, such as post-chill. The intention would be to pull samples similarly or modified from what we're doing in the ARS/FSIS study that's under way right now, in which we're pulling two samples, one at re-hang and one at post-chill. And this Committee has in

the past in the previous report on performance standards for broilers suggested that FSIS should in fact be taking samples at multiple points, so that you may take it at re-hang, post-chill, pre-grinding and on whole parts.

And so the Agency has not yet identified at which points it would pull those, but would in fact be looking at expanding it from just taking one sample per establishment.

So is it my understanding then "at multiple points" does not convey that?

DR. WESLEY: Multiple points is fine. The question is, somewhere in this document do you feel it's appropriate once perhaps the comparisons are completed by the ARS/FSIS group in Athens, to stipulate that these samples are going to be pulled at a point?

DR. ENGELJOHN: I'm not sure I know how to answer your question.

MS. RANSOM: Do we want to collect data to determine what points we should be sampling at?

DR. WESLEY: Perhaps that would be

appropriate. But I think if you want to lock this down and define it, that somewhere along the line you have to indicate at what point samples will be pulled, and as Gerri commented, if you want to say that the final point where carcasses will be sampled will be based on on-going studies, that's fine. But I would like to see clarification.

MS. KOWALCYK: This is Barbara Kowalcyk.

I had similar concerns throughout the document, and that's why -- I don't know if we want to jump ahead to the paragraphs that I wanted to insert, but I really feel that there should be some sort of sampling and data collection protocol developed that would outline that, so that you do not in the end have an apples to orange comparison, so that all -- you know, when you're conducting the study, that you do draw from the same points, you do sample in the same method from plant to plant, from instance to instance.

DR. ENGELJOHN: This is Engeljohn.

I would point out that before FSIS actually designs the baseline study and implements it, it will create a document that will fully describe the

precise points and the locations, the times, anything at all that needs to be captured would be put into a written document and then training to our FSIS employees in pulling those samples would occur. So there will be a very detailed document pulled. But the Committee itself was not -- the Subcommittee in particular, nor this Committee, was specifically asked to define for FSIS where those points would be. FSIS will, through a series of types of assessments, make that determination, document that, and the baseline then would remain consistent as we go through it.

DR. BRACKETT: And I might point out sort of with relation to this, for the Committee members to keep in mind that the purpose of this Committee is to look at the scientific basis of the questions here and that any kind of policy decision should not be recommended.

DR. GRIFFIN: This is Patricia Griffin.

Would one way around that be to say, "The Committee's understanding is that," and then just quote the previous speaker's very nice description of what FSIS would do?

MS. KOWALCYK: This is Barbara Kowalcyk again.

In my subsequent paragraphs that have been handed out, I do address that and specifically say that FSIS should develop a design and a sampling and data collection protocol and that that should be actually brought back before the Committee, because the statistical -- the sampling and data collection methods are very important statistical aspects of the data, which will really greatly affect the validity, the generalizability, and the interpretability of any results from these studies. And given that FSIS does have funding for continuous on-going baseline studies, this should be addressed very, you know, rapidly.

DR. ENGELJOHN: I would say if maybe we could look at what Barbara has rewritten, which would be on the next page when we get to that.

DR. BRACKETT: John had a comment about this page?

DR. SOFOS: John Sofos.

Similar language exists in the previous document, the broiler document, and I was on that

Subcommittee and I think the intent is that the place of sampling would be selected such that would allow comparison of the affects of interventions, as we say there, whether they work or not. And because the Subcommittee didn't know at that time exactly what interventions are used throughout the industry, they determined that FSIS would figure out exactly which points should be tested in a way that the interventions would be evaluated whether they work or not. And I think that's what the intent of this is also here.

DR. BRACKETT: So what I'm hearing is that it was the intent of the Subcommittee to keep it general with the understanding that more detailed documents would be forthcoming?

DR. SOFOS: Right.

DR. BRACKETT: Dan, any other comments?

Walter Hill?

DR. HILL: Yes. Walt Hill.

Is there the intention that the Agency would bring this protocol before the Committee, or would they just issue it as their intent and proceed

without further review?

DR. ENGELJOHN: The intent of the Agency at this time is to develop that protocol and test it once this document is adopted as a guidance document, and then begin the baseline studies as quickly as possible after the beginning of the year.

The Agency would in fact come back to this Committee either with the design and present it to them so that they have access to it, but as Barbara had mentioned as well, there will be on-going baselines for which the opportunity to come forward with the design of baselines in general would be something that the Agency may consider asking for a new charge from this Committee to look at.

So I think the issue would be to go ahead and get started with a baseline, but because we are going to be doing on-going baselines, at some point the Agency should come back to this Committee with an actual design of a baseline and ask for in-put specifically on that, since we've not had this Committee do that before, other than for the ground beef baseline. This Committee did look at that

protocol in terms of the design that we were going to do.

So we will be coming back possibly with a new charge at a later meeting on this particular issue.

DR. BRACKETT: Other comments Page 8?

(No response.)

DR. BRACKETT: Okay, we'll move forward to Page 9. The one comment we already have is with the handouts that were sent out, Question 2, one was a paragraph to be inserted at the last paragraph on Question 2.

Dan, did you want to respond about this?

DR. ENGELJOHN: And this is one all of you should have a copy of it. It's one that Barbara has put together. And it is intended to address the issue that because in fact the Agency is going to be doing on-going baseline studies, it would be on the recommendation of this Committee to bring back the design features of those programs. I think people do need a chance to read.

The first one, which says "Question 2

insert at the end of last paragraph."

DR. BRACKETT: Does everybody on the phone -- does everybody have access to this document?

UNKNOWN SPEAKER: No, we don't.

DR. BRACKETT: I will read this comment for you, but you should have it in print as well. I think it was e-mailed to them; is that right?

MS. RANSOM: Yeah, it should be in cyberspace somewhere, but we better read it.

MS. RUPLE: This is Angela. I did receive it.

DR. BRACKETT: I'll read it for those on the phone who have not heard it. The page says, "Question 2, insert following at the end of the last paragraph," and that's on Page 9.

"NACMCF is aware that FSIS has received funding for on-going baseline studies and that FSIS intends to begin a broiler baseline study in January, 2006. In any scientific study the sampling and data collection methods employed, as well as the study design parameters, are critical in assessing the validity, interpretability and generalizability of the

results. Therefore, in addition to addressing study parameters, it is important that NACMCF address statistical and data collection issues that should be considered in designing any future baseline studies. NACMCF recommends that the Agency come back with a charge to the Committee to broadly and continually review the statistical aspects as well as the data collection methodologies of any future baseline study designs."

And that paragraph would be inserted at the end of the other discussion for Question 2 on Page 8.

Any other questions? Kathryn?

DR. McNAMARA: This is Ann Marie. I have a question.

DR. BRACKETT: Okay.

DR. McNAMARA: Can you hear me?

Seeing as I don't have it in front of me, maybe Barbara can clarify this for me. It seems that the directive for paragraph states that in new and up-coming baselines they should be brought before the Committee for review, not necessary that this one has

to come back to us.

MS. KOWALCYK: Correct. Because this study, it's my understanding, would start in January, 2006, and there would not be sufficient time. But this would address some of the issues that have already been brought up this morning, insuring that the sampling and data collection methods are consistent and appropriate so that these results from this and other studies, I guess I should say future studies, would be generalizable to the entire population.

DR. McNAMARA: Thank you. I appreciate that comment and I concur.

DR. BRACKETT: Kathryn Boor.

DR. BOOR: Kathryn Boor.

Moving on now to the top paragraph on page 9 where there is in my opinion some conflicting information that's presented that's not entirely reconciled, and I think that some referencing would be appropriate in this paragraph so that we see who the principal investigator is whose data currently suggests that a back-up enrichment would not be

recommended, since that would only increase positive samples by one to two percent, whereas previous research had indicated that a back-up enrichment in conjunction with a larger rinse size would increase positives by eighteen percent.

I'd like to see that reconciled so that we know which research led to which decision and then how we've come to the conclusion that a back-up enrichment is not necessary.

DR. BRACKETT: Dan, did you want to address that?

DR. ENGELJOHN: I would respond by saying when we ask our research advisor, and we had four research advisors from the Agriculture Research Service, who work on *Campylobacter* methodology to come and make a presentation to this Subcommittee, and it was the work of one of those researchers that actually dealt with the issue of the one to two percent positives versus the FSIS data from previous work that we had done where there was a higher percent positives.

So we can find a way to make that more

specific.

DR. BRACKETT: Lee-Ann?

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

Just a second on sort of what Kathryn said. I think it needs to be clear that they're intending that -- that you guys are intending on using a 100 ml rinse, because there's not a real clear statement of that.

And second of all, in the first full paragraph, smack dab in the middle of Page 9, that paragraph talks about Campycefex media throughout, but at the second to the last line of that paragraph the document states modified Cefex agar. And I think that's confusing to a reader.

DR. BRACKETT: I'm going to take one step back here.

Is the previous statement by Kathryn, is that settled now? Are you comfortable with how that's going to be handled? Okay, so you're going to reference it?

DR. ENGELJOHN: I'm going to reference

one of our ARS researchers who provided that as a comment to the Subcommittee as a research advisor.

DR. BRACKETT: Okay. And then to Lee-Ann's question about whether it is in fact modified or if it is the original formulation.

DR. ENGELJOHN: I believe we are talking about modified where we are now, and so I'm not understanding what would help clarify that though, Lee-Ann.

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

The entire paragraph just talks about Campy Cefex and there's never any indication of a modification to that product or to that formulation. Okay, sorry. That's modified CCDA, not modified Cefex.

DR. BRACKETT: Jenny, you had a comment?

MS. SCOTT: Yes. I think that the modified Campy Cefex is the Oyarzabal medium and I think that that does need to be clarified.

DR. BRACKETT: Would you have a suggestion as to how to best clarify that?

MS. SCOTT: I think I'd have to go back to the Oyarzabal paper and determine how they described the media that they used, and then when referencing the Oyarzabal paper we can specifically refer to that medium and then fix the last sentence. The last sentence, I guess we can just call it modified Campy Cefex agar, and then when we mention the Oyarzabal paper, make some reference to the fact that he modified Campy Cefex.

DR. ENGELJOHN: If I understand it, if we could just add how the method was modified, that would answer your question?

DR. JAYKUS: Correct. Lee-Ann Jaykus.

Or else if you just did as Jenny said, reference to Oyarzabal method as a modified Campy Cefex. As it currently reads it's not clear.

DR. COOK: Dan?

DR. BRACKETT: Peggy?

DR. COOK: This is Peggy Cook.

I actually looked this paper up this morning for the very same reason. And if I remember right from the original meeting, the conversations

were centered around Campy Cefex, exactly how you stated, and then we went to the modified Campy Cefex upon doing the paper due to cost and the documentation in the paper of recovery of Campy is equal to the Campy Cefex. So it probably does need some clarification if it is in that paper.

DR. BRACKETT: So for the purpose of approving this document, how should the language be changed?

Jenny?

MS. SCOTT: In looking how this is written, could we in the last part of the sentence say, "The Committee ascertained that modified Cefex agar (Oyarzabal et al., 2005) would be a sensitive cost effective choice."

That takes you back to the Oyarzabal paper to find out the specific modification to the agar.

DR. BRACKETT: Everybody else okay with that? Irene?

DR. WESLEY: I had a question. Since the Athens group I would assume is modifying their Campy Cefex agar and Oyarzabal was merely citing that

modification, perhaps it's appropriate to go back to the source; namely, the Athens group, and ask them if they have a publication that details their current modified Campy Cefex agar protocol.

DR. BRACKETT: Joe?

DR. MADDEN: Joseph Madden from Neogen Corporation.

I have the Oyarzabal paper here and they refer back to the original publications where that medium is described. So I think if those references were added, that would take care of the issue we've got here.

DR. BRACKETT: Okay, good, thanks. Very good.

Any more of the questions on the paragraph that's going to be inserted at the end there?

(No response.)

DR. BRACKETT: Everybody's okay with that.

Any other questions or comments about anything on Page 9?

(No response.)

DR. BRACKETT: Very good. We'll move to Page 10. And again, in the handouts there is offered a replacement paragraph for the first paragraph under Question 3. Dan, did you want to address that?

DR. ENGELJOHN: I would add that this too was presented by Barbara, and would you like for me to read it as you did the last time?

DR. BRACKETT: Please.

DR. ENGELJOHN: And I would point out that -- at least Barbara has something to add. She believes that we could provide greater clarity to the paragraph that we had there.

And so what is being suggested, replacing the first paragraph then on Page 10, would be, "As discussed previously, sampling and data collection methods are critical in assessing the validity, interpretability and generalizability of the study results. Therefore, in determining the sampling and data collection methods used in the baseline studies, several statistical considerations should be addressed. Foremost, the study objective or objectives should be clearly stated, the population of

interest should be identified, and the sampling unit selected should be representative of that population. Sampling methods should also take into account other potential factors, such as seasonal and regional differences, as well as inter-flock and inter-plant correlation. In addition, there should be some statistical justification to the sample size selected for the study. The Committee recommends that FSIS consider the statistical power in selecting the number of plants, number of carcasses and frequency of sampling for the baseline study and FSIS should create a power calculation matrix to determine the optimal sample size. Further, samples should be randomly selected and the sampling and data collection methods should be consistent throughout the study. Specifically, FSIS should define how carcasses will be randomly chosen at establishments for rinsing and at what point or points in the process they will be selected. Handling factors such as rinse method; i.e., type of neutralizing diluent rinsate, shipping temperature conditions and microbial testing procedures, should be specified and consistent for all

samples throughout the study. To assure consistency in sample as well as data collection, it is recommended that a sample and data collection protocol is developed and those involved in carrying out the protocol are trained at a centralized location."

DR. BRACKETT: Any comments on the recommended insertion, replacement really? Barbara, did you have a comment?

MS. KOWALCYK: Just a general comment. I tried to -- in reading the document, I tried to -- several themes seemed to come up in particular. So I tried to really kind of capture that in one statistical -- in one paragraph that really got into some statistical issues that seemed to be cropping up throughout the paper.

Please forgive me. I don't really have a great microbiological background, so in the handling factor sentence I took a real stab at that. I don't know if I used the right terminology and would like help on that.

But the idea here is the way you -- I repeat this again -- the way you sample and collect

your data greatly impact the results of the study, and they need to really be outlined and addressed in all the baseline studies.

DR. BRACKETT: Don Zink?

DR. ZINK: I think she's made some good statistical recommendations. I think there has to be kind of a reality check, because in doing this, FSIS is going to run into issues with, you know, plant schedules, inspector duties, things like that. In other words, complete randomness is not always achievable in practice.

And so I think there has to be some caveat, or at least everybody has to know, whether we modify words in here, everybody has to know that this is the ideal we're striving for here. But in reality there may be limiting factors in how you can collect this data. So I think maybe just a phrase "insofar as practical" be included in here.

The other thing is about training at a centralized location. I think we really mean that they would have a common training program. These don't necessarily have to be a central location.

DR. BRACKETT: Barbara, do you want to respond to that?

MS. KOWALCYK: Yes. Barbara Kowalcyk

I agree. I guess in clinical research, which is what my background is in, there is only so much you can do and there are always protocol deviations that you need -- you know, you need to deal with at the end of the study. But it is a good idea to come up with some sort of protocol and, you know, look at the factors that will affect that protocol and it will be built into it.

But I just wanted to make it clear that there would be a protocol developed, an actual protocol, and that some randomness to the extent possible would be introduced. As I said, in clinical research frequently there is bias built right into it. You do the best you can. You really cannot ever get truly random.

DR. BRACKETT: Do we have any changes to the language, per se?

DR. ENGELJOHN: I would -- this is Engeljohn to address Don's issue and -- both issues,

actually.

About halfway down where the sentence begins, "Further, samples should be randomly selected," if we insert what Don said, which was "insofar as possible, samples should be," I think that will take care of that issue.

And then in the last line on the centralized location, since FSIS no longer does centralized training, I think if we just substituted "at a centralized location" with the words "with a common format," that would address those issues.

MS. RANSOM: Can I move us back to one area? Lee-Ann, you had mentioned the issue of the 100 versus 400 ml rinse. Were you going to say anything further on that?

DR. JAYKUS: Yes. Lee-Ann Jaykus.

Yeah, I was, because the acid sensitivity is entirely dependent upon the volume of rinsate. And it does state here that -- this is the second paragraph from the bottom, the second to the last sentence, "Researchers conducting the present ARS/FSIS Broiler Rinse Study determined a 100 ml volume of BPW

was sufficient." But I think we need a stronger statement, such as, "and this is what NACMCF recommends be consistently used," or something like that.

MS. RANSOM: I know we had a lot of in-house concerns about a comprehensive -- of the external as well as internal areas of the carcass, and looking at a 100 versus a 400 ml rinse. Now we don't have data, and there may be logistical concerns about even collecting that data. We did have some concern about the 100, because we typically use the 400.

DR. JAYKUS: This is Jaykus again.

And my point is, I think you have to be consistent with the volume you use. And I think that's an extremely important consideration for the baseline study.

DR. BRACKETT: What are the recommended changes to the document, if any?

DR. JAYKUS: Jaykus again.

If the Committee recommends 100 ml rinsate, then it needs to be clearly stated with perhaps something -- a statement to that effect at the

end of that sentence, "and the Committee recommends use of this volume of rinsate."

I think Gerri's point, however, is that -- is 100 milliliters even sufficient?

MS. RANSOM: Gerri Ransom.

What would be the basis of selection of 100 ml? I'm not sure that that has been validated against anything.

DR. BRACKETT: Irene, you've got a comment?

DR. WESLEY: Excellent point, again addressing that first paragraph. I'm going to assume that this study that's been conducted in the rinse pilot has thoroughly evaluated and has a statistical basis for coming up with 100 mls. 100 mls is not much, and I think we've already mentioned previously that there's going to be a variation in the size of the birds that are going to be sampled.

On Page 8 there's a reference to increased sensitivity if you go with 400 mls. I'm very reluctant to agree on 100 mls considering it's not much liquid, it's not much rinsate. This, I'm going

to assume, has been cited that there is statistical validation of the data, and I think before we go into determining or agreeing to 100 mls, that we -- that either a reference in a peer review journal be cited, if there's an in-house study, that that be statistically validated.

In following up on the volume, which I think 400 is probably more legit considering my experience with bird carcasses, I don't think 100 is going to do it. I think I'd like to back up to the statement, about halfway through, about Line 10, when there's a statement made about using buffered peptone water or sterile tap water; folks, a sterile tap water is going to cause Campy to become immobile. And when Campy is immobile it's pretty well dead. So again, if there is a reference in there that shows that sterile tap water is not going to compromise the validity or the viability, excuse me, of Campy, then hunky-dory. But I would really like to see that reference and have it validated.

There is a comment in the Nordic procedures that I shared with Dr. Engeljohn. In the

English translation there is a comment made about suspending Campy in water and the consequences of that, and the Nordic Committee does recommend some type of a nutrient or buffered broth.

DR. BRACKETT: Do we have any other response to that at all, first from anyone on the Committee?

Walter Hill and then Peggy.

DR. HILL: I think the key word here is validation, and I didn't see that enough throughout the document that we review.

The issue of a smaller rinse volume is to concentrate the cells of *Campylobacter* to improve the sensitivity. Unfortunately, you also concentrate inhibiting substances and interfering substances that may be present on the carcass. So the only answer to that is validation of the different rinse volumes, and there has to be a comparative study to show that you're not increasing one factor and then decreasing it by another one.

So the question is, you need science to answer it.

DR. BRACKETT: So what would be a recommendation to the document, if any? Dan?

DR. ENGELJOHN: Jenny actually has a change, and if she doesn't get it in her change, I also have a suggestion.

MS. SCOTT: My suggestion, given all the comments that were made about this, is that we insert a sentence that says "FSIS should determine the specific volume of rinsate to be used and provide a scientific basis for the volume selected."

DR. BRACKETT: And where would that be inserted?

MS. SCOTT: It could be inserted after the statement that said, "Researchers conducting the present ARS/FSIS broiler rinse study determined a 100 ml volume of BPW was sufficient."

DR. BRACKETT: The third full paragraph down?

MS. SCOTT: Yes.

DR. BRACKETT: On Page 10. Irene, you had another comment?

DR. WESLEY: Not only the volume of the

rinsate, but let's get away from distilled water. I can see someone looking at this and saying, "Oh, distilled water is just as good as buffered peptone water," and coming up with zip Campy's. That's one way to lower the level of Campy on carcasses since you used distilled water. So not only volume, but also describe the rinsate.

DR. BRACKETT: Dr. Raymond had a question.

DR. RAYMOND: In my naivete, my newness, I have a question that I think is a very serious question, however. This is the Scientific Advisory Committee to FSIS. I'm not sure as the Under Secretary I'm comfortable having the advice from the Scientific Advisory Committee saying we should develop a protocol. Because if we develop a protocol and we get zip Campy or whatever, then we are wide open to criticism again, and I'm calling upon you folks to advise us, not to tell us to go develop the best protocol. You should tell if it's 100 or 200 or 400, if it's peptone, if it's distilled water. That's what the Advisory Committee does do.

Now we take your advice and we can adjust it if we think we have a damn good reason to change it, but I guess I want to hear from -- the statement is here that ARS Committee, the researchers at Athens have decided 100 mls is satisfactory. I want to know how confident the Committee is. They put it in the report. I want to know -- I mean is the Committee confident enough on what they saw at Athens? I'm not say yeah or nay. It's in here. I want to know how confident that Committee is or do you need more time to do more research?

Dan, as Chair of the Committee, what was the feeling of the Committee on the 100 versus the 400?

DR. ENGELJOHN: Well, the issue on 100 versus 400 was that when we brought in the research advisors from ARS who were conducting the study and developing this methodology, presented what they had. We did not look at the data that ARS had used to establish the 100 ml. So that was not something as we as a Subcommittee looked at.

DR. McNAMARA: This is Ann Marie on the

phone. May I jump in?

DR. BRACKETT: Go ahead.

DR. McNAMARA: Ann Marie from Silliker.

When the Committee evaluated the different methods that were out there, like the modified MDCCA and the Campy line agar and the Norm Stern method, what we were doing was evaluating these methodologies based on the scientific literature and the fact that they had been used in multiple surveys. Therefore, it being used in multiple surveys, is also a way of validating methodologies.

So you know, we're kind of referencing -- we're jumping around to different points here saying this diluent can be used or that diluent can be used, but really in my estimation what we were looking at was the Norm Stern modified Campy Cefex media using all their parameters, which was 100 mls, using the modified media, using their diluent, and trying to assess whether that would be sufficient for FSIS to use in a baseline.

There was a lot of considerations that went into the choice of that particular method, but in

my estimation we were evaluating it based on the method that was used by ARS using their specific parameters and the fact that that methodology has been used repeatedly in surveys to give it validity.

DR. BRACKETT: Kathryn, you've been waiting.

DR. BOOR: Kathryn Boor.

Just to follow up on Ann Marie's point. I think that that makes an excellent point, which is that in this report we never come right out and say, "and this is the method." And I think that that's what she's saying. And I think we can make that point more strongly.

Actually, I have just a minor point in the third paragraph on that page, just to define BPW as buffered peptone water, the first time it's used.

DR. BRACKETT: Good point.

DR. ENGELJOHN: So if I could then, Celine, did you add what Lee-Ann Jaykus had suggested, which is "and NACMCF recommends use of this volume of rinsate"? Did that get added to the document?

DR. BRACKETT: The first question, does

the Committee agree that 100 mls is right? Walter?

DR. HILL: Well, in deference to the Under Secretary, I think that the questions being asked has no definitive scientific data to support the comparison between those two sampling volumes. And like any other good choice that scientists would make, they show me the data. And I think that we have to -- in lieu of not having that data available, it's directly applicable to answer the question; we have to recommend that that data be obtained.

DR. BRACKETT: So is that something you could put into the language here to address that?

DR. HILL: That there should be scientific justification for whichever volume in this case is chosen. There's a lot of variables that need to be examined.

DR. BRACKETT: Peggy:

DR. COOK: I was going to say in reference to what Walt is commenting on, if the terminology was changed that NACMCF recommends this volume of rinsate be validated, because we have not been able to look at data at this point.

DR. BRACKETT: Don?

DR. ZINK: At the outset of this, we all agree there were so many methods that have been examined, so many permutations of them, virtually none of which have ever been in a head to head comparison. I think we went into this, at least it was my understanding, that we were going to have to sort through a bunch of unlike information and unvalidated information and make a sort of an expert call, if you will, on what procedure FSIS should go forward with for a baseline.

It's a true statement that the question of 100 ml versus 400 ml, or for that matter 200 or 300, hasn't been rigorously validated. I think we have to step back and say, are we going to make a call here on a method for FSIS based on validated scientific studies? If that's the case, well, we better outline what needs to be done and give ourselves a year or more to do those studies. Or, are we going to make a best guess expert opinion call here as to what we should go forward with?

I felt fairly comfortable hearing the

researchers on their comfort level with 100 mls. But it has not been rigorously validated and I don't think that we can change that fact.

DR. BRACKETT: Would it be reasonable to suggest that in the language here that you put something to the effect that the methods be described and be resubmitted to the Committee to be accepted? Because it sounds like it's kind of up in the air as to what people are going to accept in the document here.

DR. ENGELJOHN: FSIS is in fact going to be conducting validations in and of itself in terms of its methodology. And so it will in fact establish why it's doing what it's doing and why it made the selection that it did. I do not think it would be prudent to say that that has to be prior approved before the Agency starts the study.

In this case, I think we have enough information to go forward. We've had a project under way for this past year in which we have used this particular methodology and are quite pleased with how it is in fact working out. But again, I think that we

are intending to do some validation between now and January when we begin the baseline, and then we certainly do and likely will come back to this Committee with the protocol that we had used. But I'm not looking to ask this Committee to prior approve that protocol.

DR. BRACKETT: Walter?

DR. HILL: Just one other comment. It was made in the document that it was observed that FSIS also samples for *Salmonella* on broiler carcasses and that is a 400 ml method. So if you won't accept the 100 ml method, you have to ask FSIS to rethink their sampling for *Salmonella* as well.

DR. ENGELJOHN: And those are the issues for which the Agency is in fact looking into. Is there enough to be able to do that kind of documentation, pull an additional sample? Those are the kind of things that we are in fact intending to do between now and the start-up of the survey in order to answer those questions. We have a need to be able to compare data from one year to another, recognizing that things change over time.

And so I think the Agency's intention is in fact to look at this issue and determine whether or not we have enough information to go forward, and then how that will effect what we do in comparison for future years.

DR. BRACKETT: So again, back to the language that's on the screen right now. We have actually two recommendations up there. One is to delete reference to distilled water. And I'm hearing that you want to leave that in, Dan?

DR. WESLEY: Do you have a reference on it?

DR. BRACKETT: Or provide a reference for it?

DR. ENGELJOHN: I don't have -- again, I would go back to the ARS researchers who provided us the in-put on the protocol that they used, and use that in terms of the documentation the Agency would rely upon.

DR. BRACKETT: Does that answer your concern with ARS reference? Irene?

DR. WESLEY: If you could somewhere

insert on the question of volume, which is going to be critical, either some kind of a document that you folks have reviewed statistically to show there's no difference between 100 and 400. I think that would also add credibility to the ultimate selection of a volume.

If you have studies that were done before the 100 ml was adopted, that would be appropriate as long as they've been statistically validated so that this baseline, if it goes forth with 100 or goes forth with 400, will not be criticized at the end because the volume of rinsate was not correct.

DR. BRACKETT: What's your pleasure, Dan?

DR. ENGELJOHN: Again, I think as the document is written now in terms of the method being used, FSIS should determine the specific volume of the rinsate to be used and provide scientific justification for that volume chosen.

And you're adding that we also need to deal with the issue of the distilled water as part of that. So we can modify the sentence to deal with both in terms of the method, the volume of rinsate and the

use of distilled water, as two things that we will specifically be providing justification for.

DR. BRACKETT: Could you just say volume and type of rinsate?

DR. ENGELJOHN: Yes.

DR. BRACKETT: Any other comments about what's up here? And I will read this for the sake of the people on the phone.

So right now the way it stands, what would be acceptable to the Committee is on the third paragraph, last sentence on Page 10, which would state, "Researchers conducting the present ARS/FSIS Broiler Rinse Study determined a 100 ml volume of BPW was sufficient, and NACMCF recommends that this volume of rinsate be validated. FSIS should determine the specific volume and type of the rinsate to be used and provide scientific justification for that volume chosen, including referencing studies and documents statistically validated that compares 100 mls versus 400 mls."

Yeah, this may need to be prettied up as you stated before too, but that's the -- that's the

essence and intent of this.

Irene?

DR. WESLEY: If we can go back to Page 10, the opening comment, "The choice of," may we insert the word "a choice of validated diluents"?

DR. BRACKETT: This is the second paragraph?

DR. WESLEY: This would be -- yeah, the second paragraph that begins, "The choice of." Just pop in "validated" in there.

DR. GRIFFIN: I have another comment on the third paragraph, the last sentence where it says, "Rinse buffers should be at four degrees before rinsing and rinsate should be put on ice as soon as possible."

I'm imagining a situation in a poultry plant and I don't know what "as soon as possible" means. I think it would be good to put some sort of a time requirement on that.

DR. BRACKETT: Okay, and that's Patty Griffin.

DR. ENGELJOHN: This is Engeljohn with

FSIS.

Within the protocol itself we direct the inspectors on how they pull these samples. And traditionally they are either in the operation with an ice container for which they're putting them on. But the protocol does in fact spell out how they should do this. We don't actually have a time specifically in which that has to be done, but we do in fact in the instructions for previous studies have in fact used ice containers that go on to the floor and you put the diluent into that.

MS. RANSOM: Gerri Ransom.

I've seen it written as "immediately place on ice."

DR. GRIFFIN: This is Patricia Griffin.

That would work, if what you're saying is they're there with something on ice and that's how it's done, then we can convey that. Otherwise, I could imagine that in, you know, ten percent of plants a sample is obtained and put on a counter some place and put on ice after lunch.

DR. ENGELJOHN: Then I would suggest we

make that modification to say "should be immediately placed on ice."

DR. BRACKETT: Okay.

DR. ENGELJOHN: If I could go back to the top of that paragraph. I'm not sure if we got it typed in as suggested. I think it was intended to say, "the choice of validated neutralized diluent" is what the suggested wording was.

DR. WESLEY: On Page 10.

DR. ENGELJOHN: So it should be "a choice of validated" --

DR. WESLEY: I'm looking at Page 10 on the hard copy and I don't see the same terminology up there.

DR. ENGELJOHN: It's because she typed in "a choice of validated." If you would just remove that and put between -- before the word "neutralized" put "validated." And I believe that addresses --

DR. WESLEY: Right. I just want to emphasize the spirit of validation in this. Because this document is going to have ultimately international -- you know, folks will see it all over

the place, and I think it's important that we use the word "validated" so that if someone else picks up this protocol, they know that someone else has taken the time for the comparisons.

DR. BRACKETT: Barbara?

MS. KOWALCYK: Barbara Kowalcyk.

I have a comment on the second paragraph, probably third sentence, where it says, "If samples are taken after a chemical treatment there is need to outline the specific agents and to record those intervention treatments on the sampling form."

Just to kind of reiterate even what Irene said, in the spirit of this, really, if the -- in designing the baseline studies and carrying them out, it is important that the Agency define the study objectives, both primary and secondary objectives, and if the objective is to assess the efficacy of interventions, that should be laid out. I guess I just don't like the terms "if the samples are taken after a chemical treatment." That kind of leaves it, you know, maybe they will be, maybe they won't be, we'll just see.

DR. ENGELJOHN: This is Engeljohn.

I would point out that in practice each establishment uses different methodologies for intervention treatments. There is no standardized method. And so the intent was to document what interventions are in place at the time that we pull the samples. So that is what that message conveys. It's not giving the plant the choice to do this. This is their practice. We pull a sample at a given point within that operation and we believe that there may be some impact on what treatments are in place in that plant. We want to capture what are the treatments.

MS. KOWALCYK: Barbara Kowalcyk again.

Just to make sure though that the Agency and the plants understand that that is a secondary objective of the study and the study would likely not be powered sufficiently to detect any differences or any effectiveness of interventions.

DR. ENGELJOHN: Yes. It is not the intention of the baseline study to actually determine the differences between interventions. It's to identify what interventions actually are used and may

impact the analysis.

MS. KOWALCYK: Okay. I just wanted to clarify that because I've seen lots of misuse of data from that type.

DR. BRACKETT: Walter?

DR. HILL: Walt Hill.

Don't the interventions have to be properly noted in order to determine which neutralizing protocol will be used when the sample is collected?

DR. ENGELJOHN: Yes. This is Engeljohn with FSIS.

The issue is that the Agency doesn't actually have a list of what all is used in the plants. And so there will be a period of time in which the Agency will need to make some decisions as to how we're going to have prior knowledge as to what's being used in plants so that we can insure that we're using the proper diluents and types of methodology in that plant. So there's going to be a need to have a process in place to address that without having that prior knowledge.

DR. BRACKETT: Okay. Irene?

DR. WESLEY: Just a question then. So you will be taking two samples from the plant if you're looking to evaluate the effectiveness of intervention strategies?

DR. ENGELJOHN: And we are not -- FSIS is not going to be evaluating the effectiveness of intervention strategies. We will be doing -- the intent really is to get a baseline, the national prevalence of these organisms in the process throughout the chain, not at this time to make a determination about the effectiveness of one intervention over another. That will likely not be the intention of this baseline study.

DR. BRACKETT: Barbara?

MS. KOWALCYK: Barbara Kowalcyk.

And I might recommend changing that sentence if samples are taken, because it certainly, when I read it, led me to believe that there was an objective, even if it was secondary, to determine the effectiveness of interventions.

DR. ENGELJOHN: Would changing the word

"if" to "when", would that address the issue?

MS. KOWALCYK: Yes.

DR. ENGELJOHN: Okay. If you could change the word "if" to "when". Thank you.

DR. BRACKETT: Walter?

DR. HILL: Dan, without trying to second guess the Agency to any degree, if such data is collected, won't there be a lot of interest or tendency or desire to at least see what's going on between these different samples to look what the effect of interventions might be, at least unofficially, if not officially?

DR. ENGELJOHN: Certainly. This is Engeljohn with FSIS.

There's a number of needs for data within the Agency to inform risk management. And the first is to find out what the national prevalence is of the organisms, the levels and what's there. There is also an intention to have on-going baselines, for which we may in fact design studies specifically to look at interventions to see if in fact we need to be pursuing one intervention over another in terms of

recommendations. But that would be a different type of study.

The intention here with this particular baseline is to find out what the national prevalence is in industry with the practices used today.

DR. BRACKETT: Barbara.

MS. KOWALCYK: Barbara Kowalcyk.

Just as long as I'm clear that the Agency -- I'm just concerned about misuse of data, and it is important that the Agency consider clarifying in the design of the baseline studies that there may be a secondary objective of looking at interventions that would be exploratory only in nature.

DR. BRACKETT: Dan, did you want to think about how to --

DR. ENGELJOHN: I don't know how to answer that, other than a protocol design will be explicit as to what our intention will be. If in fact at another time the Agency is going to be looking at intervention effectiveness, that would be a likely new study. I don't envision that it's going to be a part of this on-going baseline for this particular project.

DR. BRACKETT: But if I'm hearing Barbara right, you would like something inserted to make it clear that that is going to happen?

MS. KOWALCYK: Well, that they're going to collect the data. The Agency is going to collect data on interventions, okay. And what you don't want to have happen is that later on it is misinterpreted that you can use this data to come to a conclusion about interventions. So typically what you will do is, you will state something like we are collecting this data for exploratory purposes only, and is not intended -- it's intended to be used to develop a future study. It's just something that you can clarify so that someone down the road doesn't misuse the data.

DR. BRACKETT: Do you have a suggestion for how we could insert something in this?

MS. KOWALCYK: Let me work on that for a minute and come up with a sentence.

DR. McNAMARA: Could I make an interjection here that I think would clarify it? This is Ann Marie.

DR. BRACKETT: Yes, Ann Marie.

DR. McNAMARA: This is Ann Marie McNamara from Silliker.

I think everyone on the Committee would agree that if we wanted to do a specific baseline looking at interventions, especially by different chemical treatments, it would be a totally different design. And I think that all this paragraph was getting at is that there should be some attempt to take note of the chemical treatments being used and the correct diluent -- to insure the correct diluent is being used in the plant so that the neutralization of the chemical would occur for sample integrity purposes only.

I don't think that FSIS can use this data for any other reason except to insure that the chemicals are properly neutralized and that the sample was collected properly. I don't think that any scientist would then try to extrapolate the data collected to say that an intervention was appropriate or not, because it's a totally different design that needs to be used.

Does that help clarify it?

DR. GRIFFIN: Patricia Griffin. May I make a comment?

DR. BRACKETT: Patty?

DR. GRIFFIN: I think we're hearing both things, that this is not the reason that we're getting this information, and yet the information is going to be there, and it's hard to keep scientists back from looking at information while being aware of the circumstances under which it was collected. And I think the idea that was put forth that it could be used for hypothesis generation for another study is very good.

Our Agency is under a horrible budget crunch in the coming year. If your Agency faces the same problem, there may not be that future study for a long time and people may really want to look at data that's not great to get a sense of what might help. Industry might want to know. You know, what does the data show? What are our hypotheses about what might work or not, even though the data was collected in a not statistically wonderful way because the study

wasn't designed for that?

So I think that we can do both. And my suggestion is that on that sentence, in the middle of that paragraph, that begins, "If samples are taken after a chemical treatment," I would at the end of it say, you know, "on the sampling form using standardized language." Because if they're willing to just write it in in handwriting and one person calls it a chemical X treatment and another person calls it an X chemical treatment, nobody's ever going to be able to look at it. And I think there are certain treatments that tend to be used and they could be -- to the language used to report them.

DR. ENGELJOHN: And I think that is a helpful suggestion inserting the words "standardized language."

And then to get at the other issue, a new sentence following that, possibly, "Information related to chemical treatments is being collected to insure sample integrity, not to measure the effectiveness of the treatment, but may be used to assess future study design related to interventions."

Maybe if we added that, that would be much more clear?

DR. GRIFFIN: Could I make a suggestion? You last read "may be used for generating hypotheses," and then I forget the rest of your text.

DR. BRACKETT: The current text as Dan suggested is "Information related to chemical treatments is being collected to insure sample integrity."

Oh, Dan has more.

DR. ENGELJOHN: And then following that, "not to measure the effect of the treatments, and may be used for generating hypotheses in the design of future studies related to interventions."

I see some nods. I think we can work on that language to make it better.

DR. BRACKETT: Okay. Any other comments on the phone? Patty or Ann Marie?

DR. GRIFFIN: No, that's fine.

DR. McNAMARA: I'm fine.

DR. BRACKETT: Okay. So we're still on Page 10 with the additions that have been put on the

screen.

Are there any other questions or concerns about Page 10?

Irene?

DR. WESLEY: Irene Wesley.

Page 10, the second paragraph from the bottom that begins, "The Committee discussed micro-aerobic." It's a minor change. There you go, micro-aerobic and we're in good shape.

DR. ENGELJOHN: Page 11.

DR. BRACKETT: Oh, wrong page. Okay.

DR. WESLEY: Thank you. That's it.

DR. BRACKETT: Anything else on Page 10?

(No response.)

DR. BRACKETT: Okay, we'll move on to Page 11. Now Irene, your comment goes in there. Second paragraph on Page 11. First paragraph on Page 11.

Jenny?

MS. SCOTT: I would like some clarification on the statement that says, at the end of that paragraph that "FSIS should take into account

the adjudication issues around these methods."

I have no idea what that means.

DR. COOK: This is Peggy Cook.

I believe again from the Committee meeting that what that was referring to was that there are different ways of achieving the incubation condition and that those once again should be validated to determine what is the proper way to incubate samples upon collection and so forth.

MR. RANSOM: Gerri Ransom.

One concern was if you're using anything other than a tri-gas incubator, you have to have a concern about uniformity of the incubation conditions. So I don't know if that needs to be worked in.

DR. BRACKETT: Jenny, can you think of any other clearer language than "adjudication", or others on the Subcommittee?

MS. SCOTT: I think it comes back to validating the methods you're going to use to insure that they do what you're expecting them to do. I think maybe that we would say something that FSIS should validate the specific protocols for using gas

filled bags, and leave it at that, or the methodology for using gas filled bags.

DR. BRACKETT: Everybody seems okay with that.

Anything else on Page 11? Barbara?

MS. KOWALCYK: Forgive me, as I said before, I don't have a strong microbiological background. But my interpretation, and especially from all the conversation that's happened this morning, *Campylobacter* is very time sensitive. There's been a lot of discussion about incubation time or the need for incubation. What about culture time? I don't know if that's an issue or if that's already been addressed. How long the cultures would have to sit before they would --

DR. WESLEY: You mean samples or cultures?

MS. KOWALCYK: Well, the samples. How long once you -- forgive me. But once you've put them on the culture how long would they -- or on the plate, how long would they have to sit? I don't know if that's been addressed. I don't even know if that's

important. I'm just asking.

DR. BRACKETT: Dan, did you want to respond to that?

Peggy?

DR. COOK: This is Peggy Cook.

You're right. *Campylobacter* is sensitive to sample collection, you know, harvesting the sample back to the lab, incubation and so forth. And there is an incubation time for modified Campy Cefex in here. Right at the moment I'm not flipped over to it. Here it is. At 42 plus or minus one, for 48 hours, on Page 9.

DR. BRACKETT: Anything else on Page 11?

MS. RANSOM: Gerri Ransom.

The classic description for wet mount I believe needs adjustment. The cork screw motility, the spiral organism, type of language, multi-spiral forms and chains, the striking feature of the wet mount's not portrayed there.

DR. BRACKETT: Where is this?

MS. RANSOM: This is in the third paragraph, Page 11. It says "tumbling motility." The

cork screw motility, pairs of cells that resemble the gull's wing span, the classic view that you see in the wet mount that says you've got *Campylobacter*. That's not portrayed.

DR. BRACKETT: So are you suggesting --

MS. RANSOM: That some of that language be added.

DR. JAYKUS: Lee-Ann Jaykus.

Actually, I think that would be appropriate to put in the Appendix, because it does outline the methodology and there are some issues where you could actually provide that detail.

MS. RANSOM: Okay.

DR. JAYKUS: Perhaps instead of using "tumbling," you could say "*characteristic* motility."

DR. BRACKETT: Other comments? Barbara?

MS. KOWALCYK: Just a general comment, and I don't know if it's just me being -- sampling methods are used kind of interchangeably throughout the document, and especially since we started talking about statistical sampling methods versus sampling methods such as in the fourth paragraph where "The

Committee recommends that FSIS use consistent sampling methods," probably in the editing there should be some attempt to differentiate between the two, if at all possible.

DR. BRACKETT: So what I'm hearing you say is that --

MS. KOWALCYK: It's just a general comment.

DR. BRACKETT: -- difference should be made from the methods for statistical sampling versus the actual physical sampling?

MS. KOWALCYK: Yes. It gets rather confusing, because you keep reading about the sampling methods. They're actually talking about two different things, I think.

And then the last paragraph, "The significance of viable non-culturable differences." Is the Committee actually asking that the Agency seek out the advice of -- when it says "not determinable at present but research is needed," is the Committee actually asking that the Agency seek out advice on this? I wasn't really clear on that.

DR. BRACKETT: Dan, did you want to respond?

DR. ENGELJOHN: On the first issue, we will go through the document. I made a note that where we can say sample collection methods, we will, versus the statistical. So we'll try to make that more known.

On the issue of the research, this was something for which as we typically do in NACMCF reports is to identify research gaps so that it gives a heads-up to those in the research community that this is an area which would help inform us for the future. So this is something we weren't going to wait on. It actually should be done and we're just making that recommendation. When it's done and it informs us as to how we might need to modify things, then we'll take that into account.

DR. BRACKETT: Walter.

DR. HILL: Walt Hill.

With respect to the last sentence in Paragraph 3 on Page 11, "FSIS should address how many colonies per plate to perform a confirmatory test of a

wet mount." I'm not enough of a Campy bacteriologist to address this specifically, but it seems to me that the key you're asking is, what other things are likely to grow up on plates that could be mistaken for *Campylobacter* and how often does this occur. And I would guess that that could be perhaps flock specific or seasonally specific or geographically specific. It would be very difficult to know -- what kind of competitors and what frequency you would mistake them for *Campylobacter*. So it's not easy to pick a number to start with, but perhaps it might even be operator dependent, and maybe we should put some sort of cautionary detail in there about the difficulty of having a rigorous statistically validated procedure to accomplish this.

DR. BRACKETT: Dan, you want to comment?

DR. ENGELJOHN: I'm looking at you, Walt, for a suggestion of what you would like to add there.

DR. HILL: From past experience, I think the issue is training, and the more plates that the analyst can look at and get good feedback on, the more

familiar they'll become with what the limitations of the sampling or the colonial selection procedure might be. And I'm hesitant to put any specific recommendations because I don't know what competitors can pop up. And I assume that that would be quite dependent on the incubation temperature. The lower the temperature the faster everything will grow, and the more colonies you might have to search through in order to find those few illusive *Campylobacter*s. And I suppose you could have some kind of sampling requirement where you pick colonies until you're 95 percent sure that if *Campylobacter* was present in a frequency of less than ten percent, you would have at least one *Campylobacter* you pick. But then we're talking possibly hundreds of colonies per plate.

So I think the key is the Agency should look at analysts' training and make sure that the proficiency of each analyst is sufficient to handle these kinds of samples under varying conditions.

The answer is no.

DR. BRACKETT: So how do you want to handle the language in the document? What suggestions

do you have?

DR. HILL: I just think that we should stress analysts' training and proficiency testing.

DR. ENGELJOHN: If we added at the end of the sentence, "FSIS should address how many colonies per plate to perform a confirmatory test of a wet mount and the training of the laboratory technicians," would that get at your issue?

DR. HILL: Well, addressing a number of colonies to pick seems like we're asking them to say, "Okay, if you pick ten colonies you're going to be home free and that's all you need to do."

And what I'm saying is that you can't predict really that that will be sufficient and that you have to rely on analysts' expertise to make that judgment. And I know the statisticians' toes curl when those situations come about. But unless we have adequate data describing the relative occurrence of *Campylobacter* on these plates under all conceivable laboratory and sample collection and flock conditions, we can't give them a number.

DR. BRACKETT: Walt, your point is well

taken, but how do we change the document to reflect that?

DR. WESLEY: I concur with Walt Hill. I have been confused many times looking at Campy. I'd like to suggest a comment as follows: An estimated X percentage of Campy Line colonies are ultimately confirmed as *Campylobacter*. And the reference for that would be to go back to the initial papers that were describing Campy on Campy Cefex and have those folks look at their data and come up with a number.

DR. BRACKETT: Don Schaffner had a comment as well.

DR. SCHAFFNER: I'm not sure if this has already been addressed with Walt's suggestion at the end of that last sentence in black, but I was just going to suggest that FSIS should consider analyst training and proficiency in addressing how many colonies per plate to perform, blah, blah, blah.

DR. BRACKETT: Don Zink.

DR. ZINK: I just hate leaving things kind of up in the air and nebulous like this. Everything they've said is true. I mean we know this

is one of the dark corners of microbiology.

I think we should put a statement in there that reflects the fact that the experience and training of the analyst as well as the type of non-*Campylobacter* organisms in the sample will affect the -- they're certainly going to affect the results. I'm not sure exactly what word to use here. But they're going to affect the qualify of the data that we get, okay.

I think we ought to just go ahead and pick a number, okay. You're going to be doing large numbers of this. I think we ought to pick a number. And if I had to recommend one, I'd say pick at least five colonies, you know, typical colonies from the plate. It's good to have all that language in there about the training and the experience of the analyst, but you know, you're going to do this with what you've got, okay. After you go through some training program and everything else, you're still going to be left with people with varying degrees of experience, varying degrees of ability to eyeball these colonies, and you're going to be left with inevitably some

samples are going to come along that are going to be difficult. You're going to have non-*Campylobacter* organisms that may look similar to some and different than others. The quality of a person's eye differs.

I think we ought to just state a number and draw the line there and make a statement in there that these factors will be confounding factors that will affect the efficiency of recovery of the organism no matter where you draw the line.

DR. BRACKETT: Joe Madden.

DR. MADDEN: Joe Madden from Neogen Corporation.

I agree with Don. Generally in *Salmonella* or whatever, we have them pick three to five colonies of typical morphology on the media being used. So I agree, a number should be picked.

But I disagree with the use of the word in that last sentence, "confirmatory test." I've worked with *Campylobacter* for years, like Irene, and I've confused tumbling morphology before and it's turned out to be something other than *Campylobacter*. So I don't have a suggestion of what to say unless we say

something like semi-confirmatory or something like that. But later on we talk about PFGE and serotyping and all of that. I do not think tumbling motility can be used as a confirmatory test, is the bottom line.

DR. BRACKETT: Lee-Ann?

DR. JAYKUS: Lee-Ann Jaykus.

A couple things. I think we're getting caught up, and this same issue is again covered in the Appendix, and if you have a fairly detailed protocol in your Appendix, and I don't think it's very detailed in terms of this quote, "confirmatory", or how many colonies to pick. But I think that's an important consideration.

I would tend to recommend that we cover most of this information in the Appendix.

DR. BRACKETT: Barbara?

MS. KOWALCYK: I just wanted to make a comment on the training of the laboratory technicians. In my background, I have -- it is not uncommon that you have a study where you're looking at something that is somewhat qualitative in measure and the person measuring it has to make a judgment call. And usually

the way you try to deal with that is to do some sort of consistent training for all those involved in making the assessments, just to kind of acknowledge that that is an issue and that you did make some attempt to train the participants in the study on how to collect the data so that you're kind of all on an even footing, even recognizing though that that's probably not going to happen out in the field.

But I do recommend -- I like the idea of training the laboratory technicians because it does acknowledge that fact.

DR. BRACKETT: I'd like to bring this around and sort of finalize the language here.

So what we have up here is added after "wet mount", "and the training of the laboratory technicians."

And then we have another suggestion, "and estimated X percentage of colonies to confirm there's *Campylobacter* reference to determine X."

We've had suggestions for at least five typical colonies on the plate, which I hear Lee-Ann Jaykus is saying may be more details than we need in

this part of the document, to leave this to the Appendix. And the reference to FSIS should consider analyst training and proficiency.

So, what language is going to be our final language here?

MS. RANSOM: Gerri Ransom.

At one point we intended for our method to say "do a wet mount on every colony morphology that you see." There's actually a typo in the method that I have since discovered, but we wanted to try to hit every morphology.

DR. BRACKETT: Joe Madden suggested "semi-confirmatory" up there.

We need to have something we can agree on here for the language here.

Don?

DR. ZINK: How about we put a specific number in the Appendix part of it. I agree that details should go in the Appendix, or as Gerri suggested, it's perfectly fine with me if you look at each colony type on there.

I still favor putting a sentence in here

that NACMCF realizes that variation in analyst technique, even in spite of training, will result in some differences in recovery. Or you could leave that out. I don't feel really strongly about that because I think everybody knows that.

I don't want to leave it up to having FSIS to recommending that -- I don't think it's right for us to recommend that FSIS, if they give thought to this and come up with a number on their own, because -- I mean, for Christ sakes, they came to us for the method.

DR. BRACKETT: Subcommittee members, any other resolution? Irene?

DR. WESLEY: Okay. Right where your cursor is, let's take "and" and make that "an estimated." Right there, just -- all right. A period after recovery. New sentence, "An estimated," okay. And then after the parenthesis, period. And then "FSIS should consider analyst training and proficiency to achieve," and then come up with a percentage, or "should consider analyst training to achieve proficiency in identifying Campy."

DR. BRACKETT: Walter?

DR. HILL: I admire Don for trying to cut the Gordian knot by coming up with a number. But once again, I think we're being a little inconsistent, because we talked about 100 mls of sampling versus 400 ml, and I guess the rigorous way to do it would be, let science give us the answer. And we might ask the Agency to validate the number of colonies that they're testing to assure that whatever number they come up with will meet their purposes.

I don't think we can second guess the number of colonies they need to look at given the particular sample universe that they'll be looking at over the course of the multi-year study perhaps. So some pilot study in the laboratory might be the best way to come up with a ballpark estimate of the number, and then there would be some data that would support that.

DR. BRACKETT: So is that something we can put in there? Dan, did you have a comment?

DR. ENGELJOHN: I'm fine with adding the language Walt suggests about FSIS should validate the

number of colonies through a pilot lab study.

DR. GRIFFIN: Are we suggesting that FSIS validate the number of colonies before they begin the study in January? Because I worry that that's not achievable, and I wonder if it's something that they could do in the course of the study.

DR. BRACKETT: Don?

DR. ZINK: Well, I want to say this too. I mean, as scientists, it's perfectly correct for us to say, "Hey, every aspect of this should be validated."

But this becomes we're building a wall brick by brick, and I feel like we're almost at a point now where they've come to this Committee for advice and we've advised them to go back and validate every aspect of what methodology we want them to do. And that's fine with me, if we want to do that. It's not a terribly great answer for FSIS, and if that's the case they should probably plan on a year or more worth of research, looking at 100, 200, 300, 400 mls, five colonies, ten colonies, twenty colonies, means of assessing analyst proficiency. It could go on and on.

I think we just have to decide as a Committee how we're responding to this charge and are we responding in a practical usable way so that they can begin the study by January. Maybe we'll tell them they can't begin the study by January.

DR. GRIFFIN: I agree with those sentiments, that there are some things they can do and get in place before, but the study is also a great opportunity to have a lot of specimens from which we can learn more. And it could be that they could choose an adequate number of colonies to pick, but in doing that have a sub-set of laboratories do a study to try to figure out what's the ideal number for the future.

DR. McNAMARA: This is Ann Marie from Silliker.

I also wonder if -- I agree with Don. You know, you can go back and try to validate everything. I did not think that that was what the FSIS was asking us to do. I thought they were asking us to evaluate the different methodologies that have been used out there and make recommendations on which one

would be applicable.

So my concern is, does anyone around the table have the Campy Cefex publication and does it say in there in their methodology how many isolates are picked?

MS. RANSOM: This is Gerri Ransom.

There is a paper put out by those ARS researchers (Line) that does deal with number of colonies and number of non-Campys pulled off plates, et cetera. That is in the literature. I don't recall any conclusions from it, but they did look at that.

DR. MENG: Jianghong Meng from University of Maryland.

A few years ago we did some study on Campy from Mitchell Meat Products. We picked five colonies from each plate. Our experience is that five are sufficient for our purpose. So I think five colonies should be okay for the study.

But when you look at it, there are different species of Campy, so sometimes you feel that you may want to add a few more because you are looking at the temperature factor C.*jejuni* and C.*coli*.

So I think for the Committee to recommend at least five colonies.

DR. RAYMOND: You guys wore Brackett out. He left.

(Laughter.)

DR. RAYMOND: You're here to advise me, not me to advise you. But I want to go with Don's comment and it goes back to Don Zink's. And I would suggest that the Committee consider saying a minimum of five colonies. That gives us some flexibility and latitude as we get into this. But I don't want to waste a year -- I shouldn't say waste. I don't want to spend a year doing a study to figure out how to do a study, because this is too important to take another -- I want to walk out of here from this meeting with guidance.

Walt?

DR. HILL: I think we have to keep in mind that this is supposed to be a quantitative study, and when you beat around the bush and all you're doing is maybe looking for the first positive colony to call that sample positive, that's fine, if you're doing a

qualitative study. But that's not the intent of the Agency, as I recall. They're looking to enumerate. And that throws a whole additional level of complexity and rigor and resources that must be dedicated to collecting that information. And when you make those kinds of small sample recoveries from a larger population, your sampling error goes up.

And if we want to have this data with any meaningful precision, we have to take into account the fact that these small number of positive organisms may be difficult to enumerate, not just detect.

DR. RAYMOND: Irene?

DR. WESLEY: I have to congratulate my colleague for picking five Campy colonies and having five Campy colonies indeed confirmed. I guess in Iowa we're sort of hokey. I've not had that kind of batting average. So congratulations.

DR. JAYKUS: I don't know if this will help. Lee-Ann Jaykus.

I put this wording, and I actually stuck it in the Appendix because I think it makes more sense to go there. But something like this may be -- and I

think this might deal with -- "a total of X percent." I would tend to say ten percent. "A total of X percent of typical colonies on a countable plate representing each colony morphology should be picked for semi-confirmatory testing by cellular morphology and motility on a wet mount using phase contrast microscopy. Each isolate demonstrating typical Campy morphology and motility will be further confirmed and speciated by latex agglutination. If FSIS intends on isolating and identifying species other than *Campylobacter jejuni* and C.*coli*, more colonies should be picked and sub-characterized."

DR. RAYMOND: Bob, we're on Page 15 now, just for your information. We're going to have to probably get that typed up and pass it around. That's big enough that I think the Committee needs to take a look at that.

Irene, how do you feel about the ten percent? You're the one that threw out the X percent. I'm asking you.

DR. WESLEY: I think I want to congratulate Walt for bringing this back on target.

If one of the goals is enumeration, all right, then direct plating may not be giving us everything we want it to give us. And I'm going to say this in sort of a disjointed effort. I appreciate the urgency to get this going. I also appreciate what happens if you go into something with not all your horses lined up.

So if the point is validation, then that's going to toss us into a whole other ballpark of are the techniques we have for confirming Campy at this point okay for the study. And the question you're asking is, am I comfortable with ten percent?

I'm comfortable with any method that will give you the answer that you don't have to at the end of the year say, "Geez, I wish we had done this, this or this." And we come back to the point of validation.

DR. RAYMOND: Walt?

DR. HILL: Walt Hill.

I appreciate Lee-Ann's verbiage there, and I think it does a good job. However, how are we going to interpret the data? Is it for each plate that we find a positive? Are we going to call it essentially

a 4-tube MPN and not count colonies and look at a table for four different plates at that dilution? I think that that might be the end result. And maybe that's not so bad.

DR. McNAMARA: This is Ann Marie on the phone. May I jump in again?

DR. RAYMOND: Go ahead, Ann Marie.

DR. McNAMARA: Ann Marie from Silliker.

You know, I congratulate us for all trying to define this, and it may be indefinable. What Lee-Ann is suggesting is ten percent of the colonies, and a countable plate may be up to 300. So just say there's 300 colonies there, the analyst would be picking thirty colonies for confirmation by microscopy. And you know, from being in the laboratory and doing Campy analyses, they're going to be spending an enormous amount of time and it's not going to be practical on large scale analyses.

I think in hearing everything that's being discussed, I would go back to what Don is saying and go back to a minimum of five colonies, but also go back to the original papers that were done by Norm

Stern and see what he is advocating in the method that appears to be the one that's going to be used in these baselines based on the recommendations of the Committee. If it's already defined there as one of each morphological type or a number of colonies, then we need to use what's been established in the literature.

DR. RAYMOND: I'm going to make a suggestion at this point in time. We were scheduled for break a while back. We could probably spend the whole day on this. I'm going to suggest that we take a fifteen minute break and that we be back in the room here sharply at 11:00. We're going to get Lee-Ann's lengthy paragraph. We're going to type it up and put it on the board up here.

My suggestion that I have, trying to remember what Lee-Ann said, but it will give us something to work from. We need something to work from. We need a product. And it might be an Appendix. But we may adjust Lee-Ann's to say, "a minimum of five colonies, up to ten percent." That addresses the 300 colony issue. You don't have to do

thirty, you have to do five. If you've got ten colonies in there, you still got to do five. But up to ten percent; you could do additional, depending on what you want.

So Lee-Ann, if you'd get your comment up here, we'll get it on the board, take a fifteen minute break, come back, be prepared to move on.

DR. McNAMARA: Can I make one comment?

DR. RAYMOND: Say your name and affiliation.

DR. McNAMARA: I want to ask if Ann Marie could summarize her suggestion, which I liked, if she and Don could work on a proposed sentence that they like.

DR. RAYMOND: We're going to give them fifteen minutes to do that.

(Off the record.)

DR. BRACKETT: I think we'll get started. We had, as we mentioned, put up some language on the screen. But I wanted to make a couple of comments about the comments from this point forward.

We're way behind on this. And it's the

expectation of the Committee that the document has been thoroughly discussed and debated in the Subcommittee and that it's ready to be voted on. Now is not the time to make substantive changes to the recommendation of the Subcommittee.

If you make a comment, please provide a suggested correction. Although all the comments are true enough, the purpose here is to approve this document. Anything else related to this should be done separately.

So, I guess up on the screen are the comments that I think Lee-Ann Jaykus provided. Is that how you wanted them, Lee-Ann?

DR. JAYKUS: In quotes.

DR. BRACKETT: And for those of you on the phone who cannot see this, it says, "A total of ten percent of the typical colonies on a countable, parenthesis, or lowest dilutions, close paren, plate representing each colony morphology should be picked for semi-confirmatory testing by morphology and motility on a wet-mount using phase contrast microscopy. Each isolate demonstrating typical

Campylobacter morphology and motility will be further confirmed and speciated using latex agglutination. If FSIS intends on isolating and identifying species other than *Campylobacter*, *jejuni* and *C.coli*, more colonies should be picked and further characterized" close quotation. So that's what she has added.

And that would have been at the end of the third paragraph on Page 11.

Do we have any other comments about that? Jenny?

MS. SCOTT: I thought the thinking was that we would say a minimum of five and up to ten percent of the typical colonies would be selected.

DR. BRACKETT: That was Dr. Raymond's suggestion.

UNKNOWN SPEAKER: No, but Jenny's stating that.

MS. SCOTT: I would suggest that change.

DR. BRACKETT: That's fine. Don Zink?

DR. ZINK: I can live with just about anything that's definite. In looking over this at the break, the reason I thought just leaving it at the ten

percent, is that makes the math a whole lot easier when you're trying to calculate, as Walt has said, back some quantitative result from this. If you look at ten percent of the colonies, trying to get all colony types in there, and three of them turn out to be *Campylobacter*, well, then you can adjust the total plate count accordingly rather easily.

DR. BRACKETT: It is my understanding, Dan, that the bottom paragraph, "a total of X" is going to be deleted. So we'll take that off.

Don?

DR. ZINK: Why don't we put in a total of -- A minimum of five, up to ten percent, in parenthesis, whichever is greater"?

DR. BRACKETT: And that's in the new paragraph?

DR. GRIFFIN: This is Patricia Griffin, CDC.

I didn't think we wanted "whichever is greater" because it could end up requiring people to test thirty colonies.

DR. BRACKETT: That was a comment.

Lee-Ann Jaykus?

DR. JAYKUS: Lee-Ann Jaykus.

I defer to Irene on this. Our experience has been that very infrequently, certainly on a direct plating, that you have a plate that has 300 colonies. But if you did, you would really want to get that quantitative data. And I think the only way you're going to be able to do that is by picking ten percent of those colonies.

Now, with that said, I don't think that that's going to happen all that often.

DR. BRACKETT: So you're comfortable leaving this the way it is?

(No response.)

DR. BRACKETT: Okay. Well if that's the case, we will do that, and then upon voting take that into consideration.

So we're trying to finish up Page 11. Are there any other comments or questions on Page 11?

DR. GRIFFIN: Patricia Griffin, CDC.

The very last paragraph, I had trouble with the first sentence, figuring out what it meant

with the two words "significance." Would this different phrasing convey the same thing? "The possible importance of viable non-culturable strain is not known. This topic could be brought before the Committee," et cetera.

DR. BRACKETT: Okay, would you repeat that again slower for our -- "The possible importance" --

DR. GRIFFIN: "The possible importance of viable non-culturable strain is not known. This topic could be brought before the Committee", dah, dah, dah.

DR. BRACKETT: Okay. Everybody comfortable with that?

(No response.)

DR. BRACKETT: It appears so. Thank you, Patty.

All right. So that brings us to the conclusion of Page 11, finally.

Irene?

DR. WESLEY: Since this document is really focusing on carcass rinses, I'd like to recommend that we delete the paragraph for ground

product. It is inappropriate.

DR. BRACKETT: Dan?

DR. ENGELJOHN: It's not inappropriate since the Agency may chose to do ground product. We haven't defined yet which products we're actually going to test. And this Committee previously recommended that we should be sampling all products for which we regulate.

So I think it needs to stay.

DR. BRACKETT: Let's move on to Page 12.

First of all, anybody here in the room? Jenny?

MS. SCOTT: At the end of the second paragraph on Page 12 where it says, "In certain circumstances where PFGE is not appropriate, MLST has been used successfully,"

I'm wondering if "not appropriate" is the correct wording, whether that should say, "In certain circumstances where PFGE has not provided useful information, MLST has been used successfully." And maybe Patty could help with that.

DR. BRACKETT: Any comments, Patty

Griffin?

DR. GRIFFIN: I don't think I have any helpful comments on that. But there was a suggestion that I had, remember, when somehow the e-mail I sent you with my suggestions got lost in cyberspace, and then I was asked to give some sentences. And it appears in this e-mail that I was sent today that gives several suggestions. And that goes either on Page 11 or 12.

DR. BRACKETT: We have it here, Patty. I was going to get to it.

Kathryn?

DR. BOOR: Kathryn Boor.

I have two comments on that second paragraph on Page 12. The first one is a more global comment, which is that I don't believe that we ever really come to a conclusion with regard to which subtyping strategy we should apply or which we would recommend. I think we sort of hedge a little bit there with that last sentence about "if PFGE is not appropriate, MSLT has been used successfully." So where do we start and which way do we go?

The second thing is that the comment about "PFGE being more readily available" -- now this is the fourth line down in that paragraph. I certainly agree with that. But the part about "easier to perform", I think a matter of opinion. We did both in our lab head to head, and I think that each one has its pros and its cons, and I think it's probably fair to say it's more readily available, but I think the next few words are probably best left out.

DR. BRACKETT: Are you suggesting first of all delete "easier to perform"?

DR. BOOR: Yeah, I think that would do it.

DR. BRACKETT: You have some problem with that? Okay, and you're first -- what was your first comment, the MLST?

DR. BOOR: The first comment was more global, which was I don't believe that we ended up saying, so what do we recommend?

DR. BRACKETT: How would you recommend --

DR. BOOR: Well, I think the Subcommittee needs to say, "So we recommend PFGE with a follow-up

with MLST," if that's the way it needs to be.

DR. BRACKETT: Don?

DR. ZINK: Don Zink, FDA.

I think we should recommend both PFGE and MLST.

DR. McNAMARA: This is Ann Marie from Silliker.

I thought our conclusion was in the final paragraph on Page 12 that the Committee recommends further research on the methods and that we only obtain isolates from the baseline. I thought our conclusions in our discussions were we weren't going to recommend any particular subtyping method at this time.

DR. GRIFFIN: This is Griffin, CDC.

That's where the comment that I've inserted comes in, because I consider resistance testing as a method of subtyping.

DR. BRACKETT: Walter Hill?

DR. HILL: The first paragraph on the printed version on Page 12, to me it gives the impression that there's data that processing

establishments have on *Campylobacter* subtyping. And I suggest that we just delete the words "processing establishment", so that "recognize that *Campylobacter* isolate subtyping data could be used to link."

DR. BRACKETT: So your suggestion is "The Committee recognizes that *Campylobacter* isolate subtyping data"?

DR. HILL: Correct.

DR. BRACKETT: Okay. And we still have the open question about --

DR. GRIFFIN: This is Griffin, CDC.

I actually -- I think that "processing establishment" has a role in that sentence. It may be difficult to understand as it's written, but I think the idea was that the Committee recognizes that *Campylobacter* subtyping data from isolates obtained in processing establishment could be used, dah, dah, dah.

DR. HILL: Could we just substitute "FSIS *Campylobacter* data for processing establishment"?

DR. BRACKETT: That's fine. Barbara?

MS. KOWALCYK: Barbara Kowalcyk.

The one question that popped into my mind

when I read this is, it can be done, but is it done, and if it is not done, is the Committee recommending that it be done?

DR. BRACKETT: What is the "it"?

MS. KOWALCYK: Well, that the data can be linked to track human illness. Okay, is that currently done, and if it is not, is the Committee recommending that it be done to track human illness?

DR. BRACKETT: Ann?

DR. McNAMARA: This is Ann Marie from Silliker.

And I'm recommending that that whole paragraph just be omitted, because the baseline studies that we're asked to evaluate are not going to be able to provide this type of data linking establishments to epidemiological or veterinary data, et cetera. I think this was just a general introduction that someone put in there about what uses or value could data of subtyping nature have. But the conclusion of the Committee was that we were not going to recommend, in the final paragraph, we weren't going to recommend a method and we were going to suggest

that further research be done and we only collect isolates for further use to define that research.

DR. BRACKETT: Jenny, is that your comment?

MS. SCOTT: That was it exactly.

DR. BRACKETT: Okay. So the recommendation on the floor, just to delete that whole first paragraph.

DR. GRIFFIN: Griffin, CDC.

I was not involved in writing that first paragraph, but I think it's important and I would like it to stay in.

DR. BRACKETT: Barbara?

MS. KOWALCYK: This is Barbara Kowalcyk.

I mean, I'm hoping that ultimately the purpose of the study is to reduce human illness, and I think it's important that that stay in. But I would like clarification on -- I mean, it just kind of hangs out there, that it can be used and it begs the question of why, you know, what are we going to do with it and why don't we use it?

DR. BRACKETT: Dan, do you want to

comment on the intent?

DR. ENGELJOHN: Again, it was meant to be an introductory paragraph for how the data could be used in the future to explain the process. It didn't have any substantive content there to direct anything, other than this is what may be done with the data as we generate it. We react to data today that in fact is from CDC that may be linked to a plant.

So it was just meant to provide some clarification. I don't think it matters one way or another whether or not it's there, in this document.

DR. McNAMARA: This is Ann Marie from Silliker again. Maybe I can clarify my comment.

The part that bothers me is that you can't use the data that's coming out of the baseline survey that USDA is proposing to do, and try to link that up to epi data or vet data. That would be a totally different design study. And that's why I have objection in that first paragraph.

There's potential ways to use subtyping methodology, but you wouldn't want to take say the 1200 results that you get out of this nationwide

survey and then try to link it back to epidemiological data or vet data; that has to be collected off the farm, which is CDC. It's not appropriate for the baseline as stated.

DR. BRACKETT: Any other comments?

(No response.)

DR. BRACKETT: So what are the wishes of the Committee? Do we keep that paragraph or get rid of it? We need to vote on this.

Okay, all those on the Committee who are in favor of keeping the existing first paragraph on Page 12, if you could raise your hands so we could get a count. And then tell me on the phone too who wants to keep it.

DR. GRIFFIN: This is Griffin.

I want to keep it. And I agree with the sentiment expressed earlier, that what are we doing all this work for, and the whole purpose of this work is to figure out where these organisms are coming from, why there's so much contamination and to reduce it. And I think that putting -- this paragraph helps to put that into context and I think it's important.

DR. BRACKETT: I'll take that as a yes.

Anybody else on the phone want to keep it?

(No response.)

DR. BRACKETT: Those who would like to delete it, please raise your hands so we can count. Who's counting?

MS. RANSOM: I think we have seven wanting to keep and nine wanting to eliminate.

DR. BRACKETT: And those on the phone, I presume that those other than Patty would like to delete it; is that correct?

DR. McNAMARA: I would. This is Ann Marie.

MS. RUPLE: This is Angela. I would also like to delete it.

MS. RANSOM: Eleven to delete, seven to keep.

DR. BRACKETT: Delete.

Moving on. Now we get back to Patty Griffin had submitted another change, which is to have a paragraph, which will now replace the one we just deleted. And you should all have that. If you don't,

let me know; we'll make sure that you get that.

Does everybody on the phone have Patty's recommendation?

MS. RANSOM: This is Gerri Ransom. It's the page that starts out, "The Committee recognizes that processing establishment," and Patty's paragraph is the second one that's underlined, "because antibiotic resistance among *Campylobacter* species," that's the paragraph?

DR. BRACKETT: And it says Page 12 on the bottom of that.

DR. McNAMARA: I apologize. This is Ann Marie. I don't have it. Could you read it for me?

MS. RANSOM: "Because antibiotic resistance among *Campylobacter* species is a public health problem and there are inter-agency agreed upon protocols for resistance testing, the Committee recommends that a defined subset of isolates be tested so the results can be used in an analysis to help understand how resistant *Campylobacter* species enter a facility and move through production lines and whether some resistant strains are maintained in facilities."

DR. BRACKETT: Any comments on suggested inclusions?

DR. McNAMARA: It's Ann Marie again, from Silliker.

You know, again, it all depends on how you study -- how you establish the design of the study. And I agree with Patty, that those are uses for antibiotic resistance, but you're not going to be able to trace patterns through a plant unless you use multiple sites and use multiple collection of isolates from a plant. This is a nationwide survey in which you're taking one sample periodically over a year period, capturing seasonality, et cetera.

So I just -- I don't mind the paragraph as long as it's tailored in a way that doesn't suggest that the data from this study is going to accomplish those objectives.

DR. BRACKETT: Do you have a suggestion how to tailor it that way?

DR. McNAMARA: I'm really at a loss because I don't have the papers here and I'm not at the meeting. I'm trying to do my best. But I think

that you can say something about antibiotic resistance being a public health issue and perhaps a sub-set of the data might be tailored in such a way to, you know, be useful.

But to make claims about being able to trace it through a plant or to look at different things, that would require a much different design. And I think that's what happens when FSIS designs a study and then the industry or public health officials, et cetera, try to use that study for multiple purposes for which it wasn't designed. And that's all I'm getting at.

DR. RAYMOND: This is Dr. Raymond.

Ann Marie, it does say that the analysis will help understand. It doesn't say it will create an action or a solution or a province. It will help understand. I think it is important to help understand how these bacteria resistant species do enter a facility, move through the production lines, and by doing the testing at periodic points in production lines, I think it will help us understand.

DR. McNAMARA: If the study design is one

that has multiple points.

DR. RAYMOND: Right.

DR. McNAMARA: From what we've said in this document, we've only said FSIS should consider that.

DR. GRIFFIN: This is Griffin, CDC.

Ann Marie, thanks for your comment. I'd be comfortable softening the statement, replacing the word "understand" with the words "developed hypotheses about."

DR. RAYMOND: It does say "define sub-sets of isolates," Ann Marie. I know without having it in front of you it's difficult to have somebody read it once, but it is a defined set of subsets which would help us develop a hypothesis about.

DR. McNAMARA: Okay. I like that change. Thank you, Patty.

DR. GRIFFIN: And I would make that "develop hypotheses," plural, "about."

DR. RAYMOND: Jenny Scott?

MS. GRIFFIN: It's Griffin, CDC.

While I'm getting into grammar, at the

bottom of Page 11, the third sentence, "The Committee recognized that PFGE is more readily available and easier to perform." We took out that whole paragraph, didn't we?

DR. BRACKETT: Yep.

MS. SCOTT: All right. Never mind. You don't have to fix the grammar.

DR. BRACKETT: Jenny Scott.

MS. SCOTT: Jenny Scott.

I have a question. Maybe Patty can answer this. About how the antibiotic resistant testing, which I don't have any objection to, would determine whether strains are maintained in facilities? To me that seems to imply doing some environmental testing as well, and I don't think that that is part of the study.

DR. GRIFFIN: This is Griffin, CDC.

I'm comfortable taking that out. I think it's meant to be a general statement rather than suggesting specific hypotheses.

DR. ENGELJOHN: This is Engeljohn.

Just to clarify, in the Subcommittee

discussion, we did talk about the issue that there may in fact be environmental harborage contaminants within facilities. So the Agency hasn't ruled out that we may in fact be looking for future studies to look at the environment.

So I would like to just leave the language as it is, because I think we are going to be looking more at the environment in the future.

DR. BRACKETT: Do we have the final language on the screen here? Is this what we want to do?

(No response.)

DR. BRACKETT: For those of you on the phone, I will read what it says now. It says, "Because antibiotic resistance among *Campylobacter* species is a public health problem and there are inter-agency agreed upon protocols for resistance testing, the Committee recommends that a defined set of isolates be tested so that results can be used in analyses to help develop hypotheses about how resistant *Campylobacter* species enter a facility and move through production lines and whether some

resistant strains are maintained in the facilities."

Everybody okay with that?

DR. GRIFFIN: Griffin, CDC. Dan, the word analyses is plural, right?

DR. BRACKETT: Correct.

Anything else on Page 12?

DR. GRIFFIN: This is Griffin.

That grammar thing was not on a paragraph that was deleted. So on that same page that we're looking at, that add-in page, the next paragraph, the fifth line, "easier to perform than," it's spelled T-H-A-N.

DR. BRACKETT: Okay. Thank you.

Anything else?

(No response.)

DR. BRACKETT: Okay, move on to Page 13.

DR. ENGELJOHN: There was one suggested change that Barbara did submit on the page. On the conclusion, I believe she's asking to add a final paragraph, I believe. Is it a stand-alone paragraph, Barbara, your conclusion there "to insure validity, interpretability and generalizability of the study

results, the sampling and data collection methods should be evaluated and a method protocol should be developed"?

Is that a final sentence that you wanted to add?

MS. KOWALCYK: I should say the last sentence in the second paragraph, as opposed to the last paragraph.

In addition, I would like to recommend changing in the first sentence in that second paragraph, "In designing the upcoming *Campylobacter* enumeration from broiler rinse samples, baseline studies and any future baseline studies, FSIS must clearly state the objectives."

DR. BRACKETT: Any other questions or comments about 13?

(No response.)

DR. BRACKETT: The next sections are after the references. These I would hope would be more editorial than anything, that if you have suggestions, give them to Dan. If you think there are references that are missing, those also need to be

included in there.

DR. ENGELJOHN: There will be two that are added, at least, that were handed out this morning.

DR. GRIFFIN: This is Griffin, CDC.

I'm sorry, are we finished with Page 12? I had another comment.

DR. BRACKETT: Well, we were. We were on 13.

DR. GRIFFIN: I'm sorry. That's what I mean. Are we finished with 13?

DR. BRACKETT: Yes.

DR. GRIFFIN: Can I make another comment?

DR. BRACKETT: Go ahead.

DR. GRIFFIN: I had trouble understanding the next to the last sentence. "This method would be widely available to industry constituents and easily used with high volume sampling rather than previous MPN methods." And it just may be me. I had tried changing it in the edits that I sent you, that perhaps you didn't get. And maybe this is incorrect how I phrased it, but I said, "This method would be widely

available to industry constituents and easily used with prime numbers of samples that is impractical with MPN methods."

DR. BRACKETT: And where are you? Where was this supposed to be?

DR. GRIFFIN: The next to the last sentence on Page -- on the conclusion.

DR. BRACKETT: Okay.

MS. RANSOM: Could you repeat that for us, Patty, one more time? This is Gerri.

DR. GRIFFIN: "This method would be widely available to industry constituents and easily used with prime numbers of samples that is impractical with MPN methods."

DR. BRACKETT: That's what it says now. Did you have a change?

DR. GRIFFIN: No, I guess that is the change. I'm okay.

DR. BRACKETT: 13 is completed.

14, there will be two references added, and they are what, Dan?

DR. ENGELJOHN: These would be the

references that Irene provided this morning on the Nordic Committee on Food Analysis with their *Campylobacter* enumeration in foods and the draft technical specifications for an EU monitoring scheme for *Campylobacter* in broiler chickens. So we'll add those as references.

DR. BRACKETT: Okay. Jenny?

MS. SCOTT: Jenny Scott.

In addition, when going through the references, I found one reference in the text that was not cited here, and one cited reference that I didn't see appear in the text. So I'll be looking to fix that.

DR. BRACKETT: Appendix 1, Page 15.

MS. RANSOM: This is Gerri Ransom.

I think the word -- this is towards the end of the last paragraph in Appendix 1, the word "confirmed and characterized" are interchanged. It should be that the "organisms are characterized with wet mount," and then "confirmed with the serology." I think those two words are interchanged.

DR. BRACKETT: Any other comments on Page

15?

(No response.)

DR. BRACKETT: Okay, moving right along, Page 16.

DR. ENGELJOHN: I did want -- this is Dan Engeljohn.

I did want to add that Dr. Berrang from ARS also participated in the meeting. Although he wasn't an invited speaker, he did come offer in-put at the Subcommittee, and so I'd like to add his name to the list of research expert consultants that met with us.

UNKNOWN SPEAKER: And he paid his own way also.

DR. BRACKETT: Okay, we can add that. So that would be in Appendix 3, Page 16, Dr. Mark Berrang from ARS.

Okay, I think that's it. Did we address everything that we were supposed to?

DR. ENGELJOHN: There was one other hand-out that FSIS did provide, which is in terms of some of the validation that the Agency is in fact

undergoing now as we prepare to start up the baseline, we had a series of things that our laboratory is looking into to validate the methodology, and so we provided that just as an indication this is what we're going to do and then ask if the Committee had any suggestions or modifications to that. But we're intending to just go ahead and do these things based on the comments received today about the additional things to look into. We will in fact address those as well.

DR. BRACKETT: Our next order of business is actually to adopt this whole document, but it needs to be understood that once the changes and edits are all made this will be circulated to the entire Committee again to make sure that everything has been done.

At this time, what we need is a motion to adopt the document, including the suggestions discussed today.

DR. WESLEY: I so move.

DR. BRACKETT: Irene Wesley, move. Second?

DR. MADDEN: Second.

DR. BRACKETT: Joe Madden. Okay, so the motion has been made and seconded to adopt this document that we have been discussing, including suggestions discussed today. We'll circulate that to the Committee.

Any discussion about this?

(No response.)

DR. BRACKETT: All those in favor, aye?

(All responded with "aye".)

DR. BRACKETT: Any opposed?

(No response.)

DR. BRACKETT: Okay, we'll pass this document. So we're done with this part. Thanks, Bob. Thanks, Dan, for the report. And thanks to the Committee for the work. I really appreciate the fact that you were able to get this done quickly for us because it is such an important issue at FSIS to get this study moving along the way. So I appreciate the hard work you guys have put in as a Subcommittee to bring this to us today.

With that, we'll take a change of pace and

I'd ask Dr. Lee-Ann Jaykus to give a report on her Seafood Cook Subcommittee.

DR. JAYKUS: I'm actually representing Spencer Garrett who is the Chair of this Committee, but has been detained because of Hurricane Katrina issues.

We met during the last general meeting of NACMCF. We have not met since. At that time we were given seven questions in the charge. The Committee consisted of ten members. Eight of those members were there for the entire meeting and two of them kind of floated in and out, depending upon other requirements. And Mary Losikoff back here was also very, very helpful in our meeting.

We basically did on a very cursory level address all seven of the questions, which you should be able to refer to. But I'll go ahead and tell you them very quickly.

1) What pathogens and parasites are of concern in seafood purchased by consumers? 2) Do cooking methods differ in their ability to eliminate the identified organisms? 3) Do the cooking

requirements differ by type of seafood, e.g., fin fish, mollusk and shellfish or crustaceans? 4) What effect if any does the condition of the seafood have when purchased (raw, cooked, frozen) on the cooking treatment required? 5) Is there a single temperature that will insure food safety for seafood? 6) Are there consumer methods of preparing seafood that need to be addressed, or other consumer methods; for example, some consumers believe that the lime juice used in cerviche will, quote, "cook the product"? And, 7) Should consumer advice vary based on any susceptible at risk populations?

The Committee did spend a fair amount of time discussing how to define cooking. The NACMCF document on pasteurization was very helpful in that regard, and we will continue those deliberations today.

We also did provide some answers and some data to these various questions on one or more levels, given the confines of being at this location.

Kathryn Boor, Joe Madden, and myself worked pretty hard in trying to put a draft document

together in some form, and that was circulated to the Committee in August, I believe, late August. And Emille and Spencer have since worked on that document to a certain extent, and we do have a working document to go with.

I have two questions for clarification, Bob, if you can provide those. The first is that the Committee felt that we would prefer to address the questions in a slightly different order. Is there a problem with that?

DR. BRACKETT: I don't have any problem with that.

DR. JAYKUS: Okay. And the second question for clarification is that we were uncertain as to whether you wanted us to address some of the microbial toxins, such as *Staphylococcus aureus enterotoxin*, also toxins that might be associated with harmful algal blooms and histamine. The reason being is that, of course, many of those or most of those are quite heat resistant. So we would like clarification on that. That will help our deliberations.

DR. BRACKETT: It was originally meant

just to mean microbiological agents. The toxins we sort of understood, but those are each stable anyway.

DR. JAYKUS: So it's acceptable with you and FDA folks if we exclude those in our deliberations?

DR. BRACKETT: Right.

DR. JAYKUS: Thank you.

DR. RAYMOND: That's the end of the report?

DR. JAYKUS: That's it.

DR. RAYMOND: Thanks for the brevity.

Now, I'll ask Dr. Engeljohn to be equally brief.

(Laughter.)

DR. ENGELJOHN: And I will. I am proud to say the Committee that I Chaired for the safe cooking of poultry, we had twelve members. We met twice, once at the last meeting to put together a document to address the seven questions that were raised, and then we met Monday and Tuesday of this week.

We believe that we have finished our work

in terms of crafting responses to those seven questions. I might just point out that this is a timely issue for the Agency. There have been a couple of outbreaks related to poultry products, and in particular to poultry that was uncooked but appeared to be ready-to-eat to the consumer.

This Committee did come to some conclusions. One is that the minimum temperature for safety for cooked poultry for consumers to use would be 165. This is important for us to come with that conclusion, in that the Agency does have a number of temperatures that it provides to the consumer, ranging from 165, 170, 180, depending on which part of the bird you're looking at. And so we've come to one conclusion and then some guidance as to what should be done for consumer education in the future.

And then secondly, we do in fact have what we think is a very useful document that can be provided to the small businesses, in particular for how to validate cooking instructions, which is an important need for the Agency in that cooking instructions are not something that most manufacturers

have validated. So we've provided some frameworks for them to use in order to properly address that.

And then more importantly, the recommendations from the Committee ultimately will influence the Agency and Risk Management as to whether or not we would pursue a regulation change to require that any time uncooked poultry is used in a product that appears to be ready to eat, that that be actually identified on the principal display panel, which is something we don't require now, but actually probably was a major contributing cause for why the consumers undercooked this product using a microwave.

So we have met twice now on this document. We have a document that I believe is completed. The Subcommittee worked very hard this week. What we're going to do is redraft the document based on all the input from the Committee and send it out to the Full Committee with the hope that we would get any edits between now and the next Plenary Session, and then can adopt the report at the next meeting.

Thank you.

DR. RAYMOND: Thanks, Dan. By the way,

thanks for Chairing two of the Subcommittees. Now I know why I don't see you in the hallways very often back in D.C.

Bob, are you going to present now your new charge?

DR. BRACKETT: Yes. It's actually not a new charge. What I will be doing is, it's really a pre-charge. It's something that we were going to bring forward as sort of a heads-up of an issue that will be coming the next time. The specific questions will be provided in the next meeting. But it's for those of you who have been involved with, or even concerned about, *Mycobacterium avium* subspecies *paratuberculosis*, (MAP)s as we call it for short. It's a very complicated and a somewhat debatable food safety issue.

And so I'm going to just sort of give you background here. You will be getting the charge. We will be providing you with as much of the science background as we can.

Just as a way of background, for those of you who may not be familiar, MAP is associated with an

animal disease known as Johnes Disease, which is an infectious bacterial disease in ruminants. We do know that -- actually worldwide, but specifically in the United States, Johnes has been spreading slowly through the domestic livestock population, and it is considered to be endemic in many areas, many countries and many actual areas within the United States. And within the United States, the dairy cattle represent the largest population of MAP infected animals that would be of concern to us, and are therefore the most likely source of direct or indirect, indirect meaning perhaps by manure use on produce has been suggested.

And it does appear that the primary source of *Mycobacterium* is the infected cattle herd, especially dairy cattle with Johnes Disease, but we do realize that there are a number of other domestic and equally of concern, wild animals that are susceptible and may serve as environmental sources of contamination that could reinfect even domestic herds.

The organism is not just found with cattle or in effect in cattle. It has been isolated from the environment as well, both water, a variety of

foods, including milk and ground beef. So it is an issue that could affect both FDA and USDA-regulated products. And it is being heavily investigated as a pathogen of animals that at least has the potential of being naturally transmitted to humans, which is why it's a concern to us.

Some of the areas that we are going to consider with this are the foods that are most concerned with respect to this organism, what sort of processing parameters, regardless of what type of food it is, would insure the destruction of MAP, if it was assumed to be a human pathogen, which it's debatable now, if there are any sanitation practices that one could take to insure destruction or elimination of the organism from the food environment.

And really, an equally important part is to identify research that's needed to establish or eliminate MAP as a cause of human illness. There is research out there. But all of these pieces need to be put together in the context of foods. That's the last slide that I have there for this.

And so what you will see at the next

meeting is, we will be providing some very specific questions as we've done before for NACMCF to consider, and at that time we will also be providing you and asking for additional scientific evidence that might be available, and we'll also be probably engaging in some, and maybe looking for recommendations in the meantime, of outside experts that could be brought to bear since all of the expertise is not found in this room.

And that is all that I wanted to say today. I'd be happy to answer any questions. But more will be coming.

DR. WESLEY: What is your time frame for sending us our charge for addressing these questions, begin to address these questions, et cetera?

DR. BRACKETT: We'll actually be giving the charge at the next full NACMCF meeting. And so in the meantime we'll be developing the specific charges, statements, as well as some of the possible experts.

DR. RAYMOND: Thank you, sir.

We're at the point now where we'd like to ask if there's any public comment. We had no one

submit their name desiring to comment, but you're certainly welcome to do so at this time.

Sir? And would you step to the microphone because it's being recorded, and provide us with your name for the record, please.

MR. WORTH: My name is Mark Worth. I work with Public Citizen, which is a non-profit consumer organization based in Washington, D.C. with about 150,000 members.

I came late today. I apologize. Has the seafood portion been discussed yet?

DR. RAYMOND: Yes, it has, Mark. We'd be glad to have your input on it.

MR. WORTH: And there's more of that coming tomorrow, right, the seafood?

DR. RAYMOND: The Subcommittee will be working tomorrow. What we got today was an interim progress report from the Committee.

MR. WORTH: Okay, great.

DR. RAYMOND: Not a final report.

MS. RANSOM: This is Gerri Ransom. We're working this afternoon.

MR. WORTH: I know that this is an FDA issue. Are there any FDA people here today?

DR. RAYMOND: Dr. Brackett.

MR. WORTH: Oh, great. Hi.

DR. RAYMOND: And others.

MR. WORTH: We met before, recently. Again, I'm sorry I'm late. I got awful directions from Map Quest, so I recommend anybody using that to confirm that somehow.

We have filed extensive comments to the FDA along with another non-profit group in Washington called the Center for Food Safety, regarding the FDA's recent approval of the use of irradiation to eradicate *Vibrio* and other micro-organisms in oysters, clams, mollusks and so forth. It has been mentioned in the risk assessment for *Vibrio*, and I notice that it is in one of the documents here, it is in the document on seafood. I could literally go on far beyond the meager fifteen minutes of public comment allowed during this four day conference, but I just wanted to point out some of our main concerns.

Number one, the D-values that are

necessary to eradicate *Vibrio* in shellfish were based on documents, believe it or not, that do not address this issue specifically. It appears as though they were just pulled out of thin air.

Number two, the rule did not consider the effect of irradiation on the shells of the mollusks, and this might sound like a trivial matter, but actually submitted by the petitioner and mentioned in the rule was the fact that different thicknesses of the mollusks could affect the ability of the irradiation to kill the bacteria inside the animal, and it does not mention at all the potential that toxic chemicals could migrate from the shell into the meat.

This is an issue that's been lingering for years, that the Federal Register Notice rather irresponsibly dismissed, was the fact that chemicals called 2-ACBs (2 substituted alkylcyclobutanones) which have only been found to occur in irradiated food that contain fat, which is basically all foods, were not considered adequately in the rule. The FDA made no effort to identify the either potential or adequate

or actual content of 2-ACBs in mollusks. These chemicals have been associated with colon cancer development -- I'm sorry -- colon tumor development in rats and genetic damage in human cells. This is an issue that we brought up with Dr. Brackett in a meeting last year, I believe.

And finally, the rule completely ignored a study that was done in which irradiated clams were fed to lab animals and there were rather grievous reproductive problems and premature death of offspring.

Also, in the Federal Register filing there were personal attacks by name made upon me and a staff member at the Center for Food Safety in Washington. I don't know how often the FDA makes personal attacks against people by name in the Federal Register. I'm not necessarily embarrassed by this, but I think it's a unique situation, and now my name and the name of a staff member at the Center for Food Safety will be listed -- will be mentioned in the Federal Register in perpetuity, which I think was an inappropriate action by the Agency.

I guess my question is -- I have a reputation of having a long preamble and then asking the question. My question is, is given these problems, and these are just a few of many, and I know this is not the purview of the USDA, how big of a role does the Agency see irradiation as an intervention step for *Vibrio* and other bacteria that are perhaps less common but still problematic to mollusks?

Thank you.

DR. RAYMOND: Thanks, Mark. Any other public comments?

Then I'll declare this particular portion of this NACMCF meeting adjourned. We are right on schedule for lunch.

MR. WORTH: I'm sorry. I believe I asked a question and there are about fifty people in the room who might be able to answer it.

DR. RAYMOND: I think the Subcommittee on Safe Practices for Preparing Seafood will probably, you know, address that in their report.

MR. WORTH: Well, there's only one word in the report and this is the only public comment

period, and I think it would not be unreasonable to ask for an answer from somebody, even maybe from Dr. Brackett.

DR. RAYMOND: Mark, the report was not presented today. It was an interim. It was a progress report. They are going to reconvene at 1:00 this afternoon and you are welcome to sit in on that Subcommittee meeting and observe and listen and see if they answer that question, or if they're working toward your question.

I will give the USDA an opportunity if they do wish to respond, but if this is not the proper time to respond I'm not going to make them respond if that's part of the report that the Subcommittee is working on. It's a work in progress.

MR. WORTH: So how can you credibly -- how can you credibly state that the consumers, and I guess I'm the only consumer representative here.

DR. RAYMOND: I'm a consumer.

MR. WORTH: Well, it's nice that you have a seat at the table, because I don't.

How can the Agency credibly state that

consumers are stakeholders in this discussion when A, there's a fifteen minute comment period for a four day meeting, and B, that there's fifty people here that can't answer my question. It's a very simple question.

How big of a role does the Agency see or does the Agency foresee irradiation as an intervention step for seafood?

DR. RAYMOND: Mark, I'm going to go back to the comment you made --

MR. WORTH: On a scale of one to ten; is it a one; is it a five; is it a nine?

DR. RAYMOND: Mark, you made the comment consumers only get fifteen minutes out of a four-day meeting. I need to clarify that comment. This is the open public meeting from 8:30 to 12:00. It's not a four day meeting that we ask the public to comment necessarily. We have Subcommittee meetings. A lot of work is done by the Subcommittees to present the report.

Today what you heard and saw was a very lengthy discussion on the report that we were asked to

approve today on *Campylobacter*, you know, and that was a very public discussion, everybody in the room got to hear it, and we've asked for comment on that.

Now the point that you're making the comment on is a work in progress that is not done yet. That's why this Committee has been appointed by the President to give scientific advice, perhaps by the Secretary, perhaps I don't know who. This Committee is appointed to give scientific advice through due diligence and through due study and through due conversations and discussions to provide advice to the FDA, to FSIS, to the Department of Commerce, and other entities, so they can develop policies and guidelines that will protect the public safety.

MR. WORTH: Well, I tried to -- you know, I'm going to check my -- I'm checking my clock here. I don't mean to be sarcastic. But you know, I came here to raise scientific and technical issues, but now I'm talking about structural issues about how this meeting was put together, and frankly, I'm not interested in how the agenda was structured, who got to say what when, and I think that the reason that

nobody has answered my question is problematic.

Was there a decision made? Was there a vote taken by the group here not to answer questions raised by consumers, or are you making the decision by yourself? Did people get a memo saying if anybody asks a question from the microphone, not to answer it?

DR. RAYMOND: Mark, first of all, I invited you to attend the working group this afternoon. That's when they'll get down in the weeds and do an in-depth discussion on issues like the one you're raising. You're invited to attend that.

I also have asked Dr. Brackett if he would care to respond to that if the FDA has a position, and he's going to do that right now.

MR. WORTH: Okay, thank you.

DR. BRACKETT: First off, having to do with the public comment period, and if you haven't been to the NACMCF meetings, as Dr. Raymond just stated, this Committee is asked to give scientific information on specific, very specific issues that are addressed in the agenda. They are not to make policy recommendations what either Agency, whether it would

be USDA or FDA, would choose to do in the future.

With respect to what would be done here, there is a very specific charge with respect to seafoods and it is listed on the agenda, which is determination of cooking parameters for safe seafood for consumers. That is the only thing the Committee will be deliberating today with respect to seafood. And that is what we hope to get comments on. There are many, many other related food safety issues that could be brought up in a public comment. But this Committee is not going to address them.

DR. RAYMOND: Thank you, Dr. Brackett.

Now, any other public comments?

(No response.)

DR. RAYMOND: We may have reached the 12:00 hour, but we certainly will accept public comments if anybody has any.

Seeing none, then this meeting is adjourned. We'll take one hour for lunch and then the Subcommittee will reconvene.

(Whereupon, at 12:00 p.m. the meeting was adjourned.)