UNITED STATES DEPARTMENT OF AGRICULTURE

IN Re:

NATIONAL ADVISORY
COMMITTEE ON
MICROBIOLOGICAL CRITERIA
FOR FOODS

MEETING HELD ON FEBRUARY 13, 2004, 8:30 a.m.

Sheraton Buckhead Atlanta
3405 Lenox Road., N.E.
Atlanta, GA

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

(See proceedings.)

REPORTER: BOB ADDINGTON

CONTRACTOR (not present): R & S TYPING SERVICE

2-13-04 NACMCF Meeting Participants

Vice-Chair:	Dr. Robert Brackett
NACMCF Members:	Dr. Gary Ades
	Dr. David Acheson
	Mr. Dane Bernard
	Dr. Larry Beuchat
	Dr. Peggy Cook
	Dr. Catherine Donnelly
	Dr. Stephanie Doores
	Dr. Frances Downes
	Dr. Dan Engeljohn
	Mr. Spencer Garrett
	Dr. Patricia Griffin
	Dr. Lee-Ann Jaykus
	Dr. Robin King
	Dr. Mahipal Kunduru
	Dr. John Kvenberg
	Dr. Carol Maddox
	Dr. Roberta Morales
	Dr. Eli Perencevich
	Ms. Angela Ruple
	Dr. Skip Seward
	Dr. John Sofos
	Dr. Katie Swanson
	Dr. R. Bruce Tompkin
NACMCF Executive Committee:	Dr. Art Liang, CDC
	LTC.Erik Torring, VSA
FSIS Staff:	Ms. Gerri Ransom
	Ms. Karen Thomas
FDA Staff:	Mr. Don Kautter
	Mr. Brett Podoski
	Dr. Richard Whiting
NMFS Staff:	Ms. Emille Cole
	Ms. Barbara Comstock
Outside Participants:	Ms. Theresa Scheuring, Wayne Farms LLC

P R O C E E D I N G S

February 13, 2004, 8:30 a.m.

DR. BRACKETT: Welcome to today's plenary session of the 2002-2004 NACMCF Committee. I'm Bob Brackett. For those of you who don't know me, I'm the vice-chair for the Committee and Director of FDA's Center for Food Safety and Applied Nutrition.

Unfortunately, Merle Pierson will not be here today. And we knew that. He is busy and detained in Washington with some things that he has to do, and I know he sends his regrets. He does enjoy being here.

To continue, Dr. Pierson and I wanted to mention that our 2002/2004 Committee has been extremely busy as you all know better than I do. Particularly in assisting our food food safety agencies with a variety of actually quite complex issues that you are dealing with, scientific issues.

And the members of this Committee are providing an invaluable service to both USDA and FDA and the other participants, the Department of Defense (the Department of Commerce, CDC). All of these rely upon the deliberations that you accomplish when you come to these meetings and in between.

And so I want to commend the Committee on the hard

work that goes into these scientific discussions that we have and the important role that they play in helping to provide a good scientific foundation for the decisions that the regulatory agencies must make in terms of regulations and programs that are aimed at reducing foodborne illness and improving public health.

These reports that you provide here serve as a part of the basis for science-based decisions on behalf of the regulatory agencies in areas that not only have regulatory issues, but also in directing research that we need down the line. And that also is quite an important function.

So on behalf of the full Committee and the Federal agencies that sponsor NACMCF, I'd like to thank each of you for the continued service that you give to the Committee, and also for giving up your valuable time and for volunteering to support the Committee. We really appreciate it truly.

Your participation and effort is allowing all of the agencies to move forward on a number of different public health protection and food safety measures and at this time I'd like for all of you to be recognized. And so what I'd like to do is go around the table and have each of the Committee members introduce themselves and also state for the record their affiliation. And I guess we'll start over

with Dr. Beuchat.

DR. BEUCHAT: Larry Beuchat, University of Georgia.

DR. PERENCEVICH: Eli Perencevich, University of Maryland.

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

DR. DOWNES: Frances Downes, Michigan Department of Community Health.

DR. ENGELJOHN: Dan Englejohn with Food Safety Inspection Service.

DR. KING: Major Robin King, U. S. Army Veterinary Corps.

DR. MORALES: Roberta Morales RTI.

DR. KUNDURU: Mahipal Kunduru, Dole Fresh Vegetables.

DR. ADES: Gary Ades, independent.

DR. DOORES: Stephanie Doores, Penn State University.

DR. MADDOX: Carol Maddox, University of Illinois.

MS. RUPLE: Angela Ruple, NOAA Fisheries.

DR. SOFOS: John Sofos, Colorado States University.

DR. SEWARD: Skip Seward, The American Meat Institute.

DR. COOK: Peggy Cook, Tyson Foods.

DR. SWANSON: Katie Swanson, independent.

MR. GARRETT: Spencer Garrett, NOAA Fisheries.

DR. DONNELLY: Kathy Donnelly, University of Vermont.

DR. TOMPKIN: Bruce Tompkin, retired from ConAgra.

DR. ACHESON: David Acheson, FDA.

DR. KVENBERG: FDA.

MR. BERNARD: Dane Bernard, Keystone Foods.

LTC. TORRING: Erik Torring, DOD.

DR. LIANG: Art Liang, CDC.

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

MS. THOMAS: Karen Thomas, Food Safety Inspection Service.

DR. BRACKETT: Great. Thanks much. So moving on, I'm also pleased to report that all three of the active subcommittees that we have going on right now have made strong progress towards meeting their objectives this past week as well as during all 2003 meetings in June and August.

And the subcommittees include the Subcommittee on Microbiological Performance Standards for Broilers, which is chaired by Spencer Garrett; the Subcommittee for Criteria for Refrigerated Shelf-life Based on Safety, which is chaired by Don Zink; and finally the Subcommittee on Scientific Criteria for Redefining Pasteurization, which is chaired by John Kvenberg.

And so at this point, what I'd like to do is turn over the floor to Gerri Ransom, our Executive Secretariat who

can also provide you with some additional information that you will need. Gerri?

MS. RANSOM: Good morning. Congratulations on making it to the last day of your meeting. I know everybody has worked very very hard this week and we thank you for that. I wanted to mention that as always, if you need any assistance, please let myself or Karen Thomas know, and we'll help you out.

First I want to start out by pointing out to you that the minutes from our last two plenary sessions that took place in August of 2003, are under the green tab in your notebook. So if you'll go ahead and review those. Those are also out on the table and they are stapled together, so you can find both the August 20 and 22nd sessions reported on there.

Additionally, I'd like to point out to you and many of you have been working on this, under the yellow tab in your notebook we have blank calendars. Karen Thomas is working on scheduling our next plenary session and additional subcommittee meetings. So please fill those out for Karen and provide them to us before you leave or as soon as possible after you get back, because we would like to get additional meetings scheduled.

I also wanted to mention there's an address list under

the pink tab of your notebook. Please take a look at that and make sure your particulars are accurate and let us know if you've got any changes.

Also I wanted to mention for our members of the public we do have a public comment period today. So feel free to sign up out at our desk. You have - - we can give you up to ten minutes for comment and we welcome that. So please go ahead and do that.

And also, for our guests, I wanted to point out and I'm sure many of our guests have already found these outside on the table, there are documents available for you related to the NACMCF work.

And at this time I will turn the floor back over to Dr. Brackett.

DR. BRACKETT: Thank you, Gerri. At this point, I'd like to proceed with some of the issues that have been before us in some of our committees. And the first is the Performance Standards Committee. And this group has actually moved beyond the previous work with ground beef and actually has made some strides with new work on broilers.

And I believe Spencer Garrett has a document, and I think he's actually passed it out; to present to the full Committee today for consideration for adoption. And you'll

be hearing from him shortly. But also, he realized that this is the first time you've seen it, so you may need a minute or two to read it. Actually, we'll probably give you quite a bit longer than that.

This group is moving forward through various raw meat and poultry commodities and evaluating the existing performance standards for *Salmonella* and the Committee has actually worked to define the general principles and the mechanics and requirements for setting up performance standards that will serve as the underpinnings for future decisions that are made.

Future plans for this group are to also evaluate performance standards for turkey, beef carcasses, market hogs and ground products. And so the group is focusing on the unique and special considerations that are needed in developing and applying performance standards specific to these commodities.

Also, before I turn it over to Spencer, I cannot really move on without mentioning that Spencer and his group actually deserve a special pat on the back as we had double tasked them at our August 2003 meetings. During these meetings, this subcommittee was presented with an additional charge to review the Food Safety and Inspection Service Proposed Microbiological Baseline Study Protocols

for Raw Ground Beef Components.

The group was successful in completing a review of the Food Safety Inspection Service Raw Ground Component (Baseline protocols), and after the deliberations of the full Committee, a final document was adopted at the close of our August 2003 meetings.

The document, for the record, is entitled NACMCF Response to USDA FSIS Request for Guidance on Baseline Study Design and Evaluations for Raw Ground Beef Components. And you will find copies of this outside on the table.

FSIS is evaluating this document for incorporation of improvements into their baseline protocols and they've already made some changes based on this.

And at this time what I'd like to do is turn the floor over to Spencer Garrett who can provide some background on the document that he's handed out and perhaps any special instructions. Spencer?

MR. GARRETT: Thank you, Mr. Chairman. We have before us a document entitled Response to Questions posed by FSIS Regarding Performance Standards with particular Reference to Broilers (Young Chickens).

As you recall, we have been asked six questions relative to various classes of food commodities. And the

six questions are:

1) What constitutes scientific sufficiency to support the use of an indicator organism in lieu of a specific pathogen for measurement against a performance standard?

2) What constitutes scientifically appropriate methods for incorporating regional variations when developing performance standards? Also seasonal variations?

3) Quantitative standards appear to have more technical challenges associated with them than do qualitative standards. What special considerations need to be attended to in the development of quantitative baseline data? What special considerations need to be attended to in using quantitative baseline data for the development of quantitative performance standards?

4) What are key scientific considerations that need to be attended to when developing risk assessment for application to the development of performance standards? What are key scientific considerations that need to be attended to when using risk assessments in the development of performance standards?

5) How are these standards working and are they helping to ensure the safety of the nation's meat and poultry supply?

And 6) Are there more effective alternatives to these (*Salmonella*) performance standards, and if so what would they be?

Now, those are the six questions, but you see they have various facets, so they kind of go up geometrically. But the - - only a government bureaucrat would say that.

But, or a microbiologist. We've been working diligently on this. We made quite a bit of progress earlier before this meeting. We had submitted a draft where we were to all the Committee members. And then we've re-worked it since we've been here in our subcommittee.

And I realize that you haven't had time to read it, so what I'd like to do is take about 30 minutes and let everybody read the document, obviously. Or take whatever time you need to do that.

Secondly, I do want to point out, though that we thought we'd be very clever and that we could make this document one size to fit all so it would also include ground chicken. Well, after our deliberations and so forth, we frankly decided we couldn't do that. We just weren't clever enough.

And so if we do address ground chicken it will be a separate document but we're convinced it would be a much shorter document and it would be much more rapid. We just

couldn't incorporate it into this document.

So with your indulgence, Dr. Chairman, what I'd like to do is ask our colleagues to just quietly read this document for the next half hour or so. There have been changes made to what was sent to you. We started to do a red-line strike out or something to show you all the changes, but quite frankly it would look like a mafia offshore banking account, wiring diagram. It was just so confusing. So if we could just read it for the next 30 minutes or so, then we'll start our deliberations.

DR. BRACKETT: I think that's fine. My watch says fifteen minutes to nine, and so why don't we take until fifteen minutes after nine to allow you to review the document and we'll start up then.

MR. GARRETT: I'm confident that as you look through the document, that you saw that it was very similar to the ground beef document. Because in fact, many of the scientific considerations relative to the questions asked are very similar. They just needed tweaking relative to the particular commodity, being broilers.

So what I would like to do is go though the document page by page, as we've done in times past. As I've pointed out in other venues and forms, I'm what you might call an executive dinosaur. I don't do PowerPoint presentations.

Well, I do do PowerPoint presentations. But I would like for us to stay with the printed page here.

And as were going around and as Dr. Brackett was indicating, the accolades to our group, I, we need to give some special accolades to two of our staff members from our NOAA Fisheries Laboratory, Emille Cole on my left, and Barbara Comstock behind me. They're the people that really truly make all this happen for my participation.

And then of course our subcommittee members themselves. I'm just the leader of the band, you know. Score the tunes, waive the baton and try to get us through this stuff.

So what I would like to do is start with page one, the title page, and are there any changes?

DR. KVENBERG: Remove draft.

MR. GARRETT: Remove draft. Very well. We'll note Dr. Kvenberg's contribution. Page two? Page three? Page four? Page five? Page six? And if I'm going too fast, just slow me down.

Page seven? Let me take you back to page six. See, you thought this was going to be a walk in the park. Right? I just need to make a technical note, the last sentence on page six. The FAO risk assessment concluded that the existing dose response models for *Salmonella* were

inadequate to characterize the dose response relationship observed in outbreak data.

I'm not certain if the foot note number six, there, the World Health Organization reference, if that's the same reference or not. But we'll make it technically correct. The document does say that. We'll just make the correct technical notation. Now, back to page seven. Page eight? Page nine? Page ten?

DR. DONNELLY: I'm sorry, but a comment on page ten, at the very top, contribution of the meal components. Could we just clarify whether that's meal consumed by a chicken, or a meal consumed by a human that might include a chicken?

MR. GARRETT: I presume it's a dietary issue, is it not? So how would you like that to be reworded? Should it be meal serving components?

MR. BERNARD: The concept here is the things eaten along with the chicken. So it would be a human.

MR. GARRETT: So then how would you write that? Just the - -

DR. SWANSON: Other foods eaten.

MR. BERNARD: Other foods eaten - -

DR. SWANSON: With - -

MR. BERNARD: On the risk of - -

DR. SWANSON: Chicken - -

MR. BERNARD: Contracting *Salmonella*.

MR. GARRETT: So I just scribed it quickly, contribution of other foods eaten relative to the risk of salmonellosis. Does that pretty much get it?

DR. GRIFFIN: I have a question on page nine.

MR. GARRETT: Sure.

DR. GRIFFIN: In the fourth bullet, the examples begin with scalding, rather than earlier in the process. And I'd be interested in - - earlier in the process, with relation to end point. Prevalence - - of *Salmonella*.

MR. GARRETT: And how far earlier?

DR. GRIFFIN: Well, meat's on entry to the plant.

MR. GARRETT: Excuse me, Patty. When people are making comments, would you please state your name and your affiliation for the record, please?

DR. GRIFFIN: I'm Patricia Griffin with CDC.

MR. GARRETT: I mean, that's fine. I'm just looking for an answer. Would any other Committee member like to comment on that?

DR. ENGLEJOHN: This is Englejohn with FSIS. I'm sorry Patty; I didn't quite get the question that you had.

DR. GRIFFIN: So I think that when the chickens come into the plant, how the proportion of them that are

carrying *Salmonella* and the amount of *Salmonella* on them relates to the final product.

And here in this example, we give them a scalding. And I'm wondering if we should begin earlier.

MR. GARRETT: Patty, I think it may be, and we may want an additional one, but I think the intent here, as I read it, the data relate to specific process steps, strokes, interventions. So there would have to be a process step accompanied with an intervention at that step, e.g., scalding, defeathering, evisceration, and so forth.

I think that's the context in which the recommendation for gathering the data is being made.

DR. GRIFFIN: Might there not be intervention in the way they are slaughtered?

MR. GARRETT: I'm the fish guy. Although a poultry pathologist. Yes.

MR. BERNARD: Dane Bernard. I think Dr. Griffin's concern is addressed later in the document when we talk about various sources of variabilities, specifically effects of regionality, seasonality, we do talk about things that go on in the grow-out area and the condition of the birds coming into the facility.

In terms of this particular line item, really the only thing that happens in the plant before the scald is the

hanging of the birds. So this really captures what goes on in the facilities.

DR. GRIFFIN: Well, I felt better when I read that later part because I think it does address it. But I also think that earlier stages relate to the final number of *Salmonella*. And I'm concerned that it's not captured here.

DR. BRACKETT: This is Brackett from FDA. Patty, are you talking about on-farm sort of things?

DR. GRIFFIN: It could include that. But I was thinking more about entry to the slaughterhouse. So what happens before scalding? What are the steps just before scalding?

MR. BERNARD: The trucks are received, the birds are unloaded, and they're hung. And prior to the scaling, they're stunned and bled. So we could add stunning and bleeding.

DR. GRIFFIN: Well, the fact that you don't know how to intervene doesn't mean that it's not a step that's important in the final contamination.

MR. BERNARD: We can add it.

DR. GRIFFIN: And transport, as well.

DR. ENGLEJOHN: I just, I'm not real sure which bullet you're on.

DR. GRIFFIN: The fourth bullet on page nine.

DR. ENGLEJOHN: The second bullet on page nine then, identifies that we're looking for statistically valid data on the prevalence and cell numbers throughout the farm to table continuum, so I believe that that would be where it captures your issue. We may need to clarify it, if that's what you're asking, but I think that particular bullet gets at the issue, we need more information about the prevalence and cell numbers throughout the entire system, not just at the point we said.

DR. GRIFFIN: Then I don't see why bother listing scalding, defeathering, and evisceration, et cetera, if we're not listing some of those other steps that come before.

MR. GARRETT: Patty, it relates to the interventions and what the interventions do to the cell numbers at that step. That's why the steps and the interventions are combined. Because you're trying to determine what in fact the reduction is.

John Sofos, you have a question?

DR. SOFOS: I think it's implied in this, because it says data that relate specific process step/interventions, to changes in prevalence and cell numbers to know the changes implies that you know what you started with. So in

a way it's there.

DR. GRIFFIN: For me, it's not there, but maybe I just don't understand.

MR. GARRETT: Well, we can come back to it, but let's think about what's been said relative to collecting the data on the farm all the way back, and then these specific steps that relate to interventions that, relative to cell numbers. And then what we say further.

First, Dr. Beuchat and then Dane.

DR. BEUCHAT: I'm not a poultry person either, but Patty's point, if there's going to be some intervention to steps that might be put in place to enhance reductions of *Salmonella*, then a baseline just preceding scalding would seem to be important. That information.

MR. GARRETT: Dane?

MR. BERNARD: Thank you, Chairman. I would propose to accommodate this discussion that the following modification be made: That that bullet to be changed to read as follows: Data that relate each specific process step, strike interventions, strike e.g., scalding, defeathering, evisceration, washing, chilling, to changes in prevalence and/or cell number. By including certain steps we've inadvertently made it appear that these were the ones of concern, and I think that we can, with this modification,

may take care of the intervention.

DR. BEUCHAT: So that would include all steps then.

MR. BERNARD: Yes.

MR. GARRETT: Is that better Patty?

DR. GRIFFIN: I don't know. I guess it's better than excluding those earlier steps.

MR. GARRETT: Well, it has everything now, I think.

DR. GRIFFIN: Yeah (Positive response).

MR. GARRETT: Very well. So that would read then, the data that relate to each specific process step, to changes in prevalence and/or cell number.

Without exception?

Page ten? We talked about the other foods eaten relative to salmonellosis. Any more on page ten? Page 11? Page 12? Page 13?

DR. GRIFFIN: Yes, I have a question. Sort of on a similar line. On these bullets, I think pre-slaughter practices are covered very well on page 14. But they're not mentioned here as something that should be focused on.

MR. GARRETT: So you would like to have pre-slaughter practices before regionality?

DR. GRIFFIN: Maybe I just need to understand why it's not bulleted here.

MR. GARRETT: Would anyone like to explain that?

DR. ENGLEJOHN: I would say that the issues noted here are in particular things for which FSIS has control over in the design of its baselines. Since we only take control of the birds once they arrive at the facilities. The issue you raise about pre-slaughter practices are things for which the agency can be asked to find ways to obtain that kind of information. But it wouldn't be things that we would have knowledge of, other than it being voluntarily provided to us.

DR. GRIFFIN: Right. But when I read the questions posed to the Committee, the questions don't say only talk about things that FSIS could do.

DR. GARRETT: On the next page as you indicate, we cover pre-slaughter practices that may be presented for slaughter. So the only difficulties I'm having, should there be another phrase than pre-slaughter practices? I think that's what I'm trying to wrestle with.

DR. GRIFFIN: Right. I guess what I - -

MR. GARRETT: It should be on the farm practices, or the regional on farm practices for example, that may vary or differ.

DR. GRIFFIN: I think just somehow taking account, and it could just be a bullet that said pre-slaughter practices. But I guess when I read the document, and

again, I just read it fast now, I have the sense that it's a little bit focused towards things that FSIS could do, and yet I didn't see the charge written that way. And so I would prefer that the document be broad and include what any regulatory agency or anyone could do.

MR. GARRETT: The Chair would like a little help. Can someone help us to add another bullet? I'm just wondering if the word pre-slaughter is the correct word. It would seem to me that you're talking about variations of concern. It would seem to me at least, I know back in the '60's when I was actually in the industry, that there were in fact some regional difference in terms of on the farm practices. Of course, I went from the 2,000 house to the 70,000 house, too, during my brief career.

MR. BERNARD: Dr. Griffin is correct. The microbiological character of the birds coming in is affected by what happens before they get to the slaughterhouse. Those factors, many are chronicled on page 14.

My understanding, however, the charge is to make adjustments or to consider factors in making adjustments to the performance standard which necessarily is an FSIS administered standard. I'm not disagreeing at all. And I could certainly entertain adding a bullet here that

reflects what's already on the next page. But I too am a bit confused as to what the role of the Committee is relative to the charge. And my understanding of the charge is to look at possible adjustments in a performance standard administered by FSIS which means it starts at the back door of the plant.

However, that will be influenced by the nature of those birds coming in, which is influenced by what goes on in the grow-outs. No doubt about it.

DR. GARRETT: Yeah, (Positive response). I think just from my personal perspective as well, the questions are being given to us relative to possible adjustments. However, at the same time, they're asking very specific and detailed scientific questions. They go beyond just what an agency has the authority to do.

They're asking scientific questions what should be considered relative to a specific action. So I think that the question you raised is certainly appropriate, and I think we can deal with this issue. Just say on the farm practices, and put a bullet here, and then go on.

And then that is actually further than explained on the next page.

DR. GRIFFIN: Right. So on farm and transport, I would include. And I guess I do get the feeling reading

this document, that the push is towards things that could be addressed in an FSIS-regulated plant. But it seems to me that if the contamination is higher than we want at the end, the plant owners could talk to their suppliers and say that there are some critical steps before the animals enter the plant that could be adjusted. So that you have a cleaner animal entering the plant.

DR. ENGLEJOHN: In order to be consistent with the next page then, I would just suggest instead of on farm practices, we use pre-slaughter practices. It captures all of that.

MR. GARRETT: What I put is just on farm and transportation practices.

DR. ENGLEJOHN: And I suggest you just use pre-slaughter practices.

MR. GARRETT: Oh, pre-slaughter, pre-slaughter?

DR. GRIFFIN: I actually prefer the former because pre-slaughter - -

DR. ENGLEJOHN: Well, pre-slaughter on the next page includes the things that you're talking about. And otherwise, we probably should change that title on the next page.

DR. GRIFFIN: That's fine.

MR. GARRETT: So we'll just put pre-slaughter

practices and that's further detailed on page 14. 15? Stephanie?

DR. DOORES: Does the term probiotic under 1(c) mean to include things like antibiotic usage or competitive exclusion, or is, are those concepts warranted as a separate concept in here?

MR. GARRETT: Stephanie, were are you specifically? I'm lost.

DR. DOORES: I'm sorry. Page 14. Number 1(c).

MR. GARRETT: I would refer that to one of the subcommittee members.

DR. TOMPKIN: I think in this case probiotics are the use - - it's competitive exclusion. It is not, it does not include antibiotic usage.

DR. DOORES: Then, I guess my question would be then, should that be included in this list?

MR. GARRETT: That would be fine. Should antibiotics be included in the list?

DR. DOORES: I would suggest that it would be.

MR. GARRETT: That's fine.

DR. DOORES: Prophylactic use of antibiotics.

MR. GARRETT: I see. I realize that we're all erudite microbiologists, but realizing the people that may read this not understand what probiotics means, should we

put in parenthesis competitive exclusion? And then we'll add, antibiotics?

DR. DOORES: Do you want to use the term antibiotics, or prophylactic?

MR. GARRETT: Prophylactic antibiotics?

DR. DOORES: I think that would be preferable.

MR. GARRETT: So with the parenthetical phrase competitive exclusion after probiotics, and then we've added prophylactic antibiotics. Any more on page 15? 16?

DR. DOWNES: In the, under B, the second to last sentence to me indicates that if there are seasonal variations, or regional variations, that they would be acceptable and that broilers purchased in one area of the country, there would be a higher tolerance for a higher level of organisms than in another part of the country.

Then my follow-up question to that is, how does that achieve a food safety objective or a public health impact of this unless there's some additional intervention in those areas to inform the consumers that what they are purchasing are not the same as what they might purchase in another part of the country.

MR. GARRETT: Thank you. I didn't read it quite that way. I personally read it that this is merely explaining how one would tease out these different types and kinds of

variations through regression analysis, so forth and so on. And not that this is - - that we're advocating a standard for seasonal variation at all.

DR. DOWNES: Well, your last sentence says that the performance standard would be based on these differences - - based on these differences should be considered.

MR. GARRETT: Under B?

DR. DOWNES: Yes. The following sentence.

MR. GARRETT: Well, let's chat about that.

DR. DOWNES: I mean, I appreciate that it's a reality. But should, does that achieve what is intended with these performance standards? I would say that the Committee has gone way out on the line by making a statement in this. And I think the best thing to do would be to answer the question, which is, what are the seasonal variabilities, and then make no further recommendation as to - - maybe the performance standard is set at that regional or seasonal level that is of most concern.

MR. GARRETT: Any other comments? I would note that I would think it would be a regulatory impossibility just due to the impracticality of having seasonal performance standards, quite frankly, just from my regulatory history. But I'm again not disassociated with this food section. David?

DR. ACHESON: Would it be fixed if we just changed the should to could?

DR. DOORES: How does, still. I get back to the question of how does that achieve a food safety objective? You set different performance standards for different parts of the country. Why have a performance standard then? Because if it's supposed to be set to achieve a food safety objective, then if you have different ones across the country, you're no longer achieving that goal.

MR. GARRETT: Bruce?

DR. THOMPKIN: Could be reworded such that if significant regional or other differences are identified, then this could impact on a processor's ability to comply with a performance standard. That way, you're not taking a position one way or the other.

DR. DOORES: I would have no problem with that.

MR. GARRETT: Say that again?

DR. TOMPKIN: Well, the first phrase is the same right up through the comma. Then this could impact on a processor's ability to comply with the performance standard.

MR. GARRETT: If significant regional or other differences are identified, this could impact upon a processor's ability to comply with the performance

standards and that would take care of it.

DR. DOORES: And strike the last sentence?

MR. GARRETT: Yes.

DR. DOORES: Thank you.

MR. GARRETT: Strike the last sentence in the paragraph?

MS DOORES: That is the last sentence now.

MR. GARRETT: Maybe we'd better go to page 17. Page 18? Katie?

DR. SWANSON: There are several references to ground product here. I don't think that it hurts the reading of the document. But you had indicated that you were trying to separate it out. So I don't know if it needs to be changed.

MR. GARRETT: Thank you. As I recall, our subcommittee deliberations, we thought we'd leave these in. But correct me if I'm wrong, but I think we actually said for particular, we'd leave these in.

DR. SWANSON: On that same point, number four, why do you need the parenthetical comment for ground product?

MR. GARRETT: It was just that it seemed to have; this had the most relevance for ground product.

DR. GRIFFIN: But doesn't it have relevance for other products as well?

MR. GARRETT: Sure, sure. We'll get it out. Any more on page 17? Excuse me. I'm on page 18.

DR. DOWNES: On page 18. Again, number two, the first point on that page, quantitative data better - - I would suggest changing it to predict achieving public health outcomes.

MR. BERNARD: DR. Chairman? Could I have that again, please?

MR. GARRETT: Say again? Quantitative data better predict achieving public health outcomes?

DR. DOWNES: Correct.

MR. GARRETT: 19?

DR. KING: On the very last sentence on this page, in assessing the public health impact from *Salmonella* on broilers, cross contamination on surfaces, utensils, and ready-to-eat food should be considered. I wasn't really sure what the subcommittee was trying to get at with that sentence. Did they suggest taking samples from some of those areas, or products, or - - I wasn't sure how this tied in with this section.

MR. GARRETT: I think it related to and some of the subcommittee members correct me if I'm wrong. I think it was relating to, that when one does the assessments relative to the public health impact, you have to think

also the possible cross contamination possibilities as opposed to just the entrée item chicken itself.

DR. GRIFFIN: I have a question about how sampling is done.

MR. GARRETT: Well, let's get this one first. Put this one to sleep first.

DR. GRIFFIN: I'm sorry.

MR. GARRETT: Does another subcommittee member want to - - wasn't that the context in which that was inserted? Nobody seems to remember but me? Does that explain that to you, Robin, then? Now, we're ready, Pat.

DR. GRIFFIN: I just have a question about how sampling is done. Again, reading this for the first time, talking about how deep the sample is taken, et cetera. I just would, what I would imagine is that there would be a tool that would take say, five samples from the carcass, each at a certain number of millimeters depth. And that would get a certain weight of sample and that you would do maybe five samples and pool them. And maybe that's what's done, but it sounds a little bit as though different people do different things. And it's hard to know when you're analyzing a sample how many grams were initially taken, whether they were taken from one place on the carcass, or five different places. And I'm just wondering if I just

don't understand it, or if it is that variable.

MR. GARRETT: I'll refer that question to Dr. Engle.

DR. ENGLEJOHN: I assume you mean me. You shortened my name.

MR. GARRETT: I'll never get home.

DR. ENGLEJOHN: I think in part the discussion here relates to how FSIS conducts its sampling program for broilers. We actually take a rinse sample. So I think our discussion here was that there, in trying to determine how to take samples and a baseline that may include more than just the broiler itself.

There are other mechanisms that can be used. But when we do an actual baseline, there's only one procedure used, and it's our FSIS inspectors who actually do that. So it would be a very well defined uniform procedure that we would use, when we ultimately do a sampling.

If we were to do something more than just the broiler, such as suggestion here of looking at a weighted sample and so forth, then we would define that procedure, and it would be uniformly applied across the board.

MR. GARRETT: And I think also on page 21, when we get there, I'll point that out. That gives a little bit further explanation of standardization of sampling and so forth.

Any more on page 19? Page 20? Carol?

DR. MADDOX: On the type of establishment and production volume, it would probably be assumed that it would be included, but the number of birds processed in the lot, - - and it might want to be addressed specifically - -

DR. BRACKETT: Excuse me. Would you move the microphone closer to you?

MR. GARRETT: You have to - -

DR. MADDOX: I'm just concerned that the lot may be sized, might be a consideration that might be a consideration that should be specifically spelled out. I know I'm not real familiar with broilers, but when the hen studies were done, it seemed that we made significant improvements on-farm by reducing the number of birds that were infected. But once they're all processed simultaneously, then you dilute that out by processing many together that would inflate then the amount - -

MR. GARRETT: I think I may understand - - I may be wrong. I think in the broiler industry the lexicon production volume kind of means that. 21? And Pat, I want to go back to the second full paragraph; methods used for sample collections, shipment, laboratory analysis, should be standardized and validated so that the desired information can be consistently obtained through a

subsequent data analysis.

I think that brings in the concept of what you were saying.

DR. ENGLEJOHN: Excuse me. On page 21, since you went to that paragraph, in the third line at the end, the word much should be must.

MR. GARRETT: It's not much?

DR. ENGLEJOHN: Must.

MR. GARRETT: All righty. 22?

DR. DOORES: Before we get into that next section, there's a discussion in this section about the difficulties of providing quantitative data for *Salmonella*. And there's a discussion of the cumbersomeness, if there's such a word, of the MPN procedure. Is there a recognized procedure that you're going to be using for quantitative assessment? Is that to be developed? It doesn't warrant more specifics in here?

MR. GARRETT: I don't have the score to that tune. Any subcommittee member like to address that issue? What you're saying - -

DR. DOORES: I'm just saying that in general.

MR. GARRETT: It's just the overview. MPN's are encumbering, so are you thinking of something else later?

DR. SOFOS: On page 23, we state in the middle of the

page, the last sentence. In part it says the need is the development of cost effective quantitative methods for pathogens which are not as expensive as the MPN procedure.

DR. DOORES: Thank you, John.

MR. GARRETT: Thank you, John. 22? 23? 24? 23? John Kvenberg, 24?

DR. KVENBERG: I'm not sure any word changes are needed, but I'd like to discuss the findings on 24, recommendations on 25, and the way it relates back to page 10, which I had no problems with, in going to.

But just for my clarification, because I think there may be a core thing in here I'm trying to understand is that according to the FoodNet data, the way I read this thing, there was no observed difference between 1996 and 2002, in point three.

It says however, in the text at the bottom paragraph of the page, and I don't know if there's a cause and effect situation that based on FoodNet data, there was a 24 percent decrease or decline in campylobacteriosis between the same period, which indicated that poultry is of lesser significance. Then the recommendation of, on page 25 says, should work in collaboration with CDC to measure the impact of performance standards for broilers and salmonellosis and other relevant enteric diseases.

And that's reflected back on page ten, the term of other enteric diseases. I guess just for my benefit, and I don't want to slow your process down here. Is there some indication, this just kind of leaves me with - - these are facts. But the Committee's drawn no conclusion on a potential utilization or an effect of the performance standard here on other enteric diseases, specifically *Campylobacter*.

Can someone clarify - - this recommendation is that we should pursue it, although there's no findings to this point. Is that right?

MR. GARRETT: I think the issue is, and let me articulate what I think you just said. The issue is, that on the one hand while looking at the FoodNet data, the incidence of salmonellosis doesn't seem to be decreasing, it is decreasing dramatically relative to campylobacters. So it is having certainly a decided effect, is point one.

Point two, and I didn't quite get your - -

DR. KVENBERG: Point one, the paper that the Committee drew that conclusion, that there was a dramatic effect in the reduction of campylobacteriosis, attributable to the performance of management of *Salmonella*. Is that what - -

MR. GARRETT: Well, there's certainly a reduction.

DR. KVENBERG: Whether it's attributable is - -

MR. GARRETT: Yeah, (Positive response). Whether it's attributable is something else again.

DR. KVENBERG: And I guess my second point was, just to clarify it, is there's not a specific, it goes into general specific recommendations that performance standards for broilers on salmonellosis and other relevant diseases, it certainly seems like this is the hot lead relative to tracking down specific disease reduction using FoodNet data for campylobacters. Is that true? Is the Committee concluding that, or is this - -

MR. GARRETT: Well, we're certainly noting it.

DR. KVENBERG: Noting it. No recommendation then?

MR. GARRETT: No. We don't want to do away with FoodNet data, obviously, but you can, - - you can't over conclude or over extend what the data is telling you but I think it's dramatically - -

DR. KVENBERG: I won't take much more time, just then to get there. How do we connect the dots between the FoodNet data and cause and effect in performance standards? Because I think it's an important dot, dots to connect. We do that, we would do that through strains? Typing?

MR. GARRETT: Patty? I'm sure you can tell us.

DR. GRIFFIN: Yes. One comment I think you're getting at it, is recommendation number two, is that the

relationship between serotypes isolated from broilers and human clinical isolates. We know that there are certain serotypes types of *Salmonella* that are strongly associated with poultry and are less likely to be found in other animals.

And so as we're accumulating more years of data in FoodNet, we may be able to do an analysis in which we just look at poultry associated serotypes and look at the incidents of *Salmonella* over time. And see whether there's a difference. Because as the Committee knows, there are over 2500 serotypes of *Salmonella* widely distributed.

And so when we're looking at the weight of all *Salmonella* over time, we're just looking at a hodge podge due to many different food vehicles, and non-food vehicles.

DR. KVENBERG: Thank you for the clarification. And that being said, since recommendation number two speaks to serotypes, and specifically, as referring to *Salmonella*, I guess my question would be, is FoodNet going to be a benefit in measuring other enteric disease reductions attributable to the practice of the performance standard for *Salmonella* in broilers? Specifically, *Campylobacter*. Is that something worth pursuing?

DR. GRIFFIN: Well, every year we measure the incidents of *Campylobacter* in FoodNet sites and compare it

with previous years.

MR. GARRETT: Thank you. Dane, did you want to comment?

MR. BERNARD: I'm not sure that there was any modification that came out of - -

MR. GARRETT: No, there was not. There was just some discussion of how do these things connect.

MR. BERNARD: We did have - -

MR. GARRETT: And we're getting much closer to connecting the dots.

MR. BERNARD: We did have an extensive discussion on it, as obviously a temporal relationship between the performance standard on *Salmonella* and the decrease in campylobacteriosis. But absent data on *Campylobacter*, because of methodology difficulties, no baseline, et cetera.

It's difficult to say one for one, and that's, I think that's why we made a dot where we did.

MR. GARRETT: With that, page 25?

DR. MADDOX: Would there then be a recommendation - -

MR. GARRETT: Carol, you have to - -

DR. MADDOX: Sorry. Would there then be part of that recommendation number one to include *Campylobacter* as part of the parallel studies? As one of the other relevant

enteric diseases?

DR. SOFOS: I think we state somewhere that enteric pathogens should be considered as part of the studies.

DR. KVENBERG: I think that's on page ten.

DR. MADDOX: I just wonder if it would be worth specifying *Campylobacter*, since it would make that link with the FSIS and the CDC data.

DR. GRIFFIN: I would favor that, as I can't think of another pathogen that we're thinking of other than *Salmonella* and *Campylobacter*.

MR. GARRETT: Bruce?

DR. TOMPKIN: And on page 25, under recommendation, number one, we could simply change the latter part of the sentence to read, on salmonellosis and campylobacteriosis, to make it more specific. And that was the intent, how to connect the dots, and that's what we would hope FSIS and CDC could do, would be to get together and try to sort out how to generate the right data to allow us to measure the impact. So salmonellosis and campylobacteriosis.

MR. GARRETT: Without exception? Page 26? Dane?

MR. BERNARD: Just a thought. Does the Committee still have a charge on *Campylobacter*?

MR. GARRETT: Um hum. (Positive response.)

MR. BERNARD: I was just wondering if there's some way

to link, but I think - -

MR. GARRETT: I think I would just go on with this, and then when you get to that issue, deal with that issue. I mean, the important point is to get campylobacteriosis in here. And I can say it, I can't spell it.

DR. DOWNES: Before we leave page 25?

MR. GARRETT: Yes, Ma'am.

DR. DOWNES: Point number two, the relationship serotypes, did the subcommittee consider genotype, or specifically PFGE type as an additional source of important information?

MR. GARRETT: We really talked about serotypes. But, Dane?

MR. BERNARD: That may be a better question for Dr. Griffin, Dr. Liang, in terms of what they can track, or what data can be obtained and fed into a database and utilized, I guess.

Right now, I'm not sure that that kind of data is commonly available.

DR. GRIFFIN: The clinical isolates are, and it depends on the serotype how frequently they're added to the database. The part I don't know about is the FSIS side, and how regularly those genotypes are posted for comparison.

MR. GARRETT: Dr. John, I mean, Englejohn?

DR. ENGLEJOHN: I don't have a response to that. Gerri Ransom, can you maybe provide some input on that?

MS. RANSOM: I believe we are doing PFGE on all our *Salmonella* isolates. I don't think they're being, they could be being submitted to FoodNet as well. PulseNet. PulseNet. They are submitted to PulseNet.

MR. GARRETT: A way to perhaps maybe address this to get us through this, just say and possibly blank. And you know, so we don't lose the concept.

DR. ENGLEJOHN: Just another thought on that. Since it is a recommendation. I mean, it clearly, I'm not real sure at the moment if we are doing that yet, but in any case, you could certainly make a stronger recommendation with the agency to pursue that.

MR. GARRETT: Give me the correct wording, I mean, I, we fish people use different genotypes. So it's possibly blank, and then you're saying it's a PDDE's, or THDL's, or, talk to me. PFGE?

DR. DOWNS: Strongly urge both agencies to submit *Salmonella* PFGE, types to PulseNet for national comparison.

MR. GARRETT: Well, what I put down, we can come back to that if you'd like to go that strong. I just said the relationship between serotypes and possibly PFGE's isolated

from broilers. If you want to go stronger than that, you know, let's chat about it. What I'm trying to do is get the concept in there that it needs to be done, or at least it needs to be considered.

DR. DOWNES: The suggestion over here is just to put in genotype rather than genetic relationship.

MR. GARRETT: Just genotypes? So it says and possibly genotypes isolated from broilers. Any more on 25?

DR. MADDOX: Spencer, how does that read again?

MR. GARRETT: Say again?

DR. MADDOX: How does it read again?

MR. GARRETT: The relationship between serotypes and possibly genotypes isolated from broilers in human clinical isolates should be investigated. 26?

DR. GRIFFIN: I'm sorry. On 25. Do we have to modify that with the word possibly?

MR. GARRETT: So it would read serotypes and genotypes. 27? 26, folks. 27?

DR. MADDOX: Point three then, should we, also modify enteric pathogens to specify campylobacters?

MR. GARRETT: Carol, other than enteric pathogens I didn't get the rest of it.

DR. MADDOX: Modify it to specify campylobacters to be consistent with the recommendation.

MR. GARRETT: Well, here I think this is more general. This would include *Campylobacter*. I mean, there may be who knows out there.

DR. KVENBERG: I think just this point again for clarification. I don't want to mess with the text. But it seems to me that we have a much better shot at *Campylobacter* bacteria than we do with other enteric pathogens getting tied into this story. I mean, I would defer to CDC, Dr. Griffin and those folks.

But there seems to be at least some hope for, as I said earlier, to connect the dots on that pathogen side.

MR. GARRETT: Would you like to say such as *Campylobacter*, or - -

DR. KVENBERG: Yeah, (Positive response). I don't think it would hurt, if that's a solid lead, and it certainly seems encouraging, I don't know why you would, if the committee feels - - in doing that, why not?

DR. GRIFFIN: I was happy with the way this one read, being a little broader. Because it could include *innocua* and other organisms which we think are acquired from food and can cause opportunistic infections. But it does include *Campylobacter*, so I was happy with the broad language.

MR. GARRETT: Dr. Acheson?

DR. ACHESON: I wonder if you could sort of mix the two and specify *Salmonella*, *Campylobacter,* and other enteric pathogens. Would that work?

DR. GARRETT: Yeah, (Positive response). That would work. So cell numbers of *Salmonella*, *Campylobacter*, and other enteric pathogens? Page 27? Page 28?

Give yourselves a good hand. I think we have a document here.

And with that, Dr. Brackett, I'll turn the meeting back over to you. One thing, we'll go through this to make a technical edit for commas, splices and things of that nature, which we do with every document. Thank you.

DR. BRACKETT: Thank you. Good discussion. At this point, Spencer, I'd like to thank you for doing this. And I would like to know if we can have a motion to accept the document as it has been modified, subject to these editorial revisions.

DR. SWANSON: So moved.

DR. DONNELLY: Seconded.

DR. BRACKETT: State your names as well please?

DR. SWANSON: Swanson.

DR. DONNELLY: Donnelly.

DR. BRACKETT: Motion to accept the modified document has been seconded. Is there any discussion on this motion

at all? All on the Committee signify by saying Aye, if you agree with this.

Spencer, it is accepted. Since the discussion ran a little bit of time longer than we had anticipated in the schedule, what I think we'll do now is break for the fifteen minutes, and then start on the next subject immediately following the break. John Kvenberg?

DR. KVENBERG: Just, is this an appropriate time to check out for people who are staying?

DR. BRACKETT: If you didn't ask for an extension for your check out time, I did, and they were happy to do it till 1:00. But if you didn't do that, now would be a good time to do that, I think.

DR. KVENBERG: Thank you, Sir.

(OFF THE RECORD)

DR. BRACKETT: Just for the record, Gerri Ransom went back to double check exactly what they do with isolates, so she would like a couple of minutes to explain to everybody, so they know what their procedures are. Gerri?

MS. RANSOM: I just wanted to mention that as far as FSIS, our *Salmonella* isolates from ready-to-eat product, we do run PFGE on those and those are submitted to PulseNet. We are giving our *Salmonella* isolates on our raw products to ARS (Agricultural Research Service), and they are

running some PFGE on these isolates, although there are too many to run all of them.

So we are getting some PFGE data on our *Salmonella*, raw *Salmonella* - - isolates.

DR. BRACKETT: Thanks. Now I think we'll proceed with an update on the Criteria for Refrigerated Shelf-life Based on Safety. FDA referred this issue of defining criteria for refrigerated shelf-life based on safety to NACMCF in 2001. And this was also an action item in the 2001 *Listeria* Action Plan that was released by USDA and the Department of Health and Human Services in January of that year.

The action plan stated that "FDA and FSIS will seek advice from a scientific advisory committee on the scientific basis for establishing safety-based, use-by date labeling for refrigerated ready-to-eat foods." And Don Zink, who is the chair of the subcommittee was going to provide us with an update, Don had to leave as you know. So in his absence, we'll have Dane Bernard provide that update. Dane?

MR. BERNARD: Thank you, Dr. Brackett. It should be obvious to everybody I'm not Don Zink. I don't have a Texas accent, don't work for FDA, those are just a few of the top line differences.

I think this can best be described as a "work in

progress", and I had forgotten actually, that this charge was given to the Committee in 2001. How time flies when you're having such fun.

The title of the document, "Considerations for Establishing Safety-Based Date Labels", which we have coined the acronym SBDL's, safety-based date labels, for refrigerated ready-to-eat foods. Based on the output from the FDA USDA risk assessment on *Listeria monocytogenes*, and resulting listeriosis.

Aside from the impact of consumer's susceptibility, a key risk factor is the opportunity for LM to multiply to a level of public health concern. Therefore the risk management strategy, one of the risk management strategies being considered is the utility and establishment of safety-based date labeling.

As you have noted, Dr. Chairman, we have been asked to consider various aspects, and we have been given five questions to answer in that regard. I won't read those questions. They're obviously in the draft.

We do have a draft document. We have found this to be a very challenging and complex topic, but like other topics that this Committee has successfully addressed, we are anticipating that we will eventually wrestle this beast to the ground as well.

It is still, and I think the subcommittee's view, a rough draft, needing much more work. At this particular meeting, we've spent the better part of two days reviewing where we are and at the suggestion of one of our Committee members, and accepted by the subcommittee, on these two days, we actually started from the back of the document, since one always starts from the front and that receives most of the attention.

This time we actually started from the back and worked forward beginning with question five and moving through question three. So questions two and one, we really didn't address.

We also spent considerable time on the appendices attached to the document. And while I think in my personal view, considerable progress was made, it's difficult to see that progress coming to fruition at this point, but I'm sure it will. Don Zink complimented the subcommittee for it's time and efforts, but asked that at least one more meeting be set prior to the August date which we still hope for completion of a final document to present to the entire committee in August of actually 2004.

So the Secretary is now looking for dates for the subcommittee to meet between now and August to try and make significant progress. I think we all on the subcommittee

note that without some effort between now and even another meeting, that our chances of pulling this together by August are slim, but that's still the plan, Dr. Chairman, thank you.

MR. GARRETT: Thank you, Dane. Are there any questions for Dane before we move on at all? Thank you again, Dane.

And so that brings us to our last formal issue of the day, which is the scientific criteria for redefining pasteurization. As you may remember, FDA also referred this issue to NACMCF in response to the 2002 Farm Bill that contained language amending section 403-(h) of the Federal Food, Drug, and Cosmetic Act to include that a food is misbranded if it purports to be pasteurized, unless "such food has been subjected to a safe process or treatment that is prescribed as pasteurization or has been subjected to a safe process or treatment that destroys the most resistant microorganisms of public health significance that are likely to occur in the food."

The subcommittee addressing this issue is reviewing alternative treatments to traditional heat pasteurization as well as the issue of most resistant microorganisms of public health significance that are likely to occur within the food.

And so at this time, I'd like to ask the subcommittee chair, Dr. John Kvenberg to give us a status report on that issue. John?

DR. KVENBERG: Thank you, Chairman. We've thrown up (information) on the screen just to let you know where the status of how we're organizing our work. We do not yet have a rough draft of our document. However, we have many pieces to it that we plan to collate. And like the dating group that foresees the need for a working group meeting in the interim, our work group also is looking for the ability to get together.

Once we have put the pieces together, the outline I'm going to present to you this morning together. Perhaps May or sometime in that timeframe, the working group felt that would probably be the appropriate point.

Just to give you the overview of how we're organizing this, the, as the Chairman just pointed out, the basic statement is presenting the problem, we will just start off the paper with stating that and the questions that were asked.

We do spend a lot of time, and I'll review this morning the current state of affairs in our struggling with the definition of what pasteurization is. In addition to the Food and Drug Administration's requirement, the USDA

has asked us to consider for their purposes what pasteurization means relative to the commodities regulated by FSIS, and so we're dealing with trying to be inclusive on pasteurization and what it means.

You'll see under the processes and technologies, although these are just listed technologies, a lot of work has been done already by the working group members, either singly or in combination in teaming up with others. And we do have these papers. Our plans as to how to standardize the text of these papers so that they will be consistent in their format and come up with a table of relevant points as you see under Section (C) under there, for organization of each discussion paper, the technologies that are under consideration.

Next, if you can scroll down to four, we are proposing to look at end product performance standards. We're viewing this to begin with, part of the working group's consideration at this meeting, was to step back and - - but I failed to mention on the section above, is we added the section of traditional thermal processing.

It occurred to us that we had a discussion of all the new technologies. It would probably serve us well to have the traditional time/temperature relationship of pasteurization discussed as well.

And in that regard, here under four, several of us have agreed to get together and consider the history of pasteurization requirements as they apply to fluid milk, liquid egg products, and crab meats, and juice. Juice, we'll point out was a recommendation that came forth in a previous NACMCF document. But these are all examples of how the term pasteurization in the traditional time/temperature situation have developed.

Secondly, in the formation, we take note of the activities of the other working groups within NACMCF under the idea of establishing appropriate language that we have coined, and I'm not sure it will end up at this point, but food safety objective type considerations on the considered performance standard that we're charged with looking at.

It's also been pointed out to us on point number five, that process is only as good as you operate it. And so that although some of the technologies that have been put forward have got great promise. The actual delivery system on how you validate and verify, terms familiar to us from NACMCF, need to be considered. So we're going to be reviewing that.

Also, we are challenged with these new technologies of the organisms of concern behaving differently when we have these kind of lethality treatments put to them. So the

whole idea of how you develop the appropriate target, and looking at surrogates and others will be a challenge for us, as well as recommending knowledge gaps and research needs.

I think they will be very specific in this document, and the obvious ones, research needs is how do you measure what organism to come up with for a performance standard.

In that regard, we considered the concept of what we've coined the black box equation. And we've got examples. Now that we have listed out basically what performance of products are currently regulated, and I guess we should throw refrigerated pasteurized crab meat into this mix, because it's one we're going to be considering, into the log reductions that are to be achieved by the processes that have been sort of bench marked as the end result of what the process should achieve. And we have various other concerns and items that we're going to be dealing with in the paper as well.

I would next draw your attention to - - our current definition, I guess is at the bottom there. I'll just keep going after the first two working - - do you have the current definition? There. This is our current working definition of pasteurization, and stay tuned. It is subject to change. We've had some lengthy discussions up

to this point trying to come up with a concise statement of what we're dealing with when we're now stepping out of the traditional consideration of what pasteurization means.

I think it's a very deep question, and the full Committee will, I think, take note and we need to be very careful in how we define this.

And in our discussions this week, these are the questions that we have currently put on relative to the significance of the definition and the working document that we're putting forward.

So I guess that would typify that we're kind of into, some deep and broad ranging thinking in our discussion points of exactly what it is. We mean to be clear on what pasteurization means and how you achieve it.

That Chairman, is basically where we're at. I can't project that we would have a completed document by August. At this particular point in time, it will be largely dependent on how much progress we make in the interim. What we will do is come up with specific technology documents that have been put together so far, standardize them, send them back to the individuals, then meet in the working group and put the other segments together and we'll have a, I think a clearer picture of what state the document will be in by the next full Committee meeting.

DR. BRACKETT: Thank you, Dr. Kvenberg. Does anybody have any questions before we move on?

That concludes the working business of the subcommittees and reports.

And at this time, we're going to move into our public comment portion of the program. And as of right now, we have one commenter. And so I would ask the person to come to the microphone, state name and affiliation. And I guess the rules are that we will have ten minutes per comment.

MS. SCHEURING: Theresa Scheuring, with Wayne Farms, LLC, based out of Oakwood, Georgia.

I work for them as their Corporate Laboratory and Regulatory Affairs Manager. And I appreciate being here today. I just had a couple of comments, and one question, actually, regarding the draft for the broiler document that was reviewed.

The first comment was on page 14, number 2(a). My comment, there is plant sanitation. You have an example of, and I'm not sure if this is the only thing that you would be looking at for type and number of NR's (FSIS Non-compliance Reports), but that is not - - from an industry perspective, that is not always indicative of actual plant sanitation.

Because number and type of NR's will vary from

district to district. So I would like to ask that we may redefine, or add additional criteria to determine true plant sanitation.

And the next comment was on page 15, 3(a), and this is more of a question. Chilling procedures, will you be monitoring chiller types, pH levels, water pH levels and chlorine levels? Or is, you know, I'm not sure what chilling procedures all includes there.

And from an industry perspective, going through the process, I think that would be important to the study.

And my last question and comment, on page 21, second paragraph, middle of the paragraph, laboratories that are involved in the testing of samples must be appropriately accredited for these analyses. My question is, for clarification, are we referring to the FSIS 17025 standard, or are we using a different standard there? And that's all I have. Thank you.

DR. BRACKETT: Thank you for your comments. Would anyone like to respond at this time to her questions? Spencer Garrett?

DR. GARRETT: Thank you, Dr. Chairman. I just might point out, and I certainly appreciate your comments, and your comments have been noted for the record, and I'm quite confident that the USDA and FSIS will consider those

comments in addition to the report that we have issues.

The first comment relative to the NR's, I think you should understand that what we're trying to do is merely indicate that we're answering question three, what constitutes scientifically appropriate methods for considering variations that may be due to regionality, seasonality, and so forth and so on.

From the tenor of your comment there, as well as some of the other comments, I thought I heard a regulatory chapeau if you would, being concerned about possible regulation. But the point simply is, in this consideration for this particular body, we're merely looking specifically as scientists answering the questions. So your comments will be very valid as being part of the record as this whole thing goes forward to the USDA. Thank you.

DR. BRACKETT: Dane Bernard?

MR. BERNARD: Thank you. I shared Theresa's concern over NR's, as you recall, as we wrote the report. I think there is a general conception publicly, that NR's are in some way correlated with microbiological performance. I think those of us who live with this day in and day out in different plants have a different view, and I think having this here will clarify one way or the other whether that's true or not, and I think that's where we netted out on

that.

And we were particular and descript about lab accreditation to leave it to the Agency to make that decision since it would be oftentimes agency laboratories that would be developing the data that's asked for in the report.

DR. BRACKETT: Thank you Dane. Any other questions? I would ask if there's anyone else that wishes to make a public comment at this time.

Seeing that the public comment period is closed, Spencer, did you have a --

MR. GARRETT: Yeah, (Positive response). I just wanted to make one other comment. I don't think that I thanked our subcommittee members enough, for really putting up, one, with me. I mean I you know, I said the flogging will continue until morale improves. But it's just a wonderful bunch of people to work for and work with.

We certainly appreciate everything everybody's done.

DR. BRACKETT: Thank you, Spencer. I'd like to second that. I really would like to thank all the members of the Committee, and especially the subcommittee chairs who do a lot of this in addition to their day jobs.

They do a lot of hard work that really answers important questions, considering the issues that we've

discussed this morning.

I'd also like to thank all of you for coming to Atlanta. Those of you who are from Atlanta, I'm sure appreciate this. But this is a different venue from our normal area in Washington, D. C., and it does require some of us to travel a little bit further.

The fact that we have industry and consumer guests at this meeting, it's also an indication of the importance of the work of this Committee. And so it is appreciated, and your participation.

So before we adjourn, Gerri Ransom has one more comment to make.

MS. RANSOM: Karen is beginning to analyze the calendars that you've been turning in, and we do, as people have been mentioning, we are targeting a meeting in August. And thus far, it's looking like the week of August 16th in Washington D. C., is going to be our next full Committee meeting.

And as we've mentioned, there's probably going to be a couple of subcommittee meetings prior to August. But please get your calendars in, but that is what we're looking at, at this point, the week of August 16th, for Washington, D. C.

And again, thank you for all your hard work this week.

DR. BRACKETT: Thank you, Gerri. And with that, the meeting is adjourned. Have a safe trip home.

(Whereupon, the hearing closed at 11:05 a.m.)