UNITED STATES OF AMERICA
DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

NATIONAL ADVISORY COMMITTEE

on

MICROBIOLOGICAL CRITERIA FOR FOODS

Omni Shoreham Hotel
2500 Calvert Street, NW
Washington, D.C.

Wednesday
January 23, 2002

The above captioned meeting convened at 9:00 a.m.

Chairperson:

Kaye Wachsmuth
Deputy Administrator, USDA-FSIS,OPHS
Washington, DC

Executive Committee:

Vice-Chair:

Janice Oliver
Deputy Director
FDA,CFSAN
College Park, MD

Centers for Disease Control Liaison:

Arthur P. Liang, MD, MPH
Director, Food Safety Initiative Activity
CDC, Atlanta, GA

FDA Liaison:

LeeAnne Jackson, Ph.D
Health Science Policy Advisor
FDA,CFSAN
College Park, MD

Commerce Department Liaison:

E. Spencer Garrett
Laboratory Director
National Seafood Inspection Laboratory
National Marine Fisheries Service
Pascagoula, MS

Defense Department Liaison:

LTC Robert Webb
Chief, Food Safety & Public Health
Department of Defense, Veterinary Service Activity
Falls Church, VA

Executive Secretariat:

Brenda Halbrook
USDA, FSIS, OPHS
Washington, DC

Advisory Committee Specialist:

Karen Thomas
USDA, FSIS, OPHS
Washington, DC

Committee Members present at the 1/23/02 meeting (*designate was not present):

Dr. David Acheson
University of Maryland
Department of Epidemiology & Preventive Medicine
Baltimore, MD

*Mr. Dane Bernard
Food Safety and Quality Assurance
Keystone Foods LLC
West Conshohocken, PA

Dr. Larry Beuchat
University of Georgia
Center for Food Safety & Quality Enhancement
Griffin, GA

Dr. Robert Buchanan
U.S. Department of Health & Human Services
FDA/CFSAN
College Park

Dr. Catherine Donnelly
University of Vermont
Department of Nutrition & Food Science
Burlington, VT

Dr. Stephanie Doores
Pennsylvania State University
Department of Food Science
University Park, PA

Dr. Frances Downes
Michigan Department of Community Health
Lansing, MI

Dr. Daniel Engeljohn
United States Department of Agriculture
Food Safety and Inspection Service
Washington, DC

*Dr. Jeff Farrar
California Department of Health Services
Sacramento, CA

Mr. Spencer Garrett
(Emille Cole, Assistant)
U.S. Department of Commerce
National Marine Fisheries Service
Pascagoula, MS

Dr. Tsegaye Habtemariam
Tuskegee University
School of Veterinary Medicine
Tuskegee,AL

Dr. Michael Jahncke
Virginia Polytechnic Institute and State University
Hampton, VA

Dr. Mahipal Kunduru
Dole Fresh Vegetables, Inc.
Salinas, CA

Dr. John Kvenberg
U.S. Department of Health & Human Services
Food & Drug Administration
Washington, D.C.

Dr. Anna Lammerding
Laboratory Centre for Foodborne Zoonoses
Health Canada
Guelph, Ontario
Canada

Dr. John Luchansky
United States Department of Agriculture
Agricultural Research Service
Wyndmoor, PA

Dr. Carol Maddox
University of Illinois
College of Veterinary Medicine
Urbana, IL

*Dr. Roberta Morales
Research Triangle Institute
Durham, NC

Dr. Marguerite Neill
Memorial Hospital of Rhode Island
Infectious Disease Division
Pawtucket, RI

*Dr. Alison O'Brien
Uniformed Services University of the Health Sciences
Bethesda, MD

Dr. Angela Ruple
U.S. Department of Commerce
National Seafood Inspection Laboratory
Pascagoula, MS

Dr. Skip Seward
American Meat Institute
Arlington, VA

Dr. William Sperber
Cargill, Inc.
Wayzata, MN

Dr. Balasubramanian Swaminathan
U.S. Department of Health & Human Services
Centers for Disease Control & Prevention
Atlanta, GA

Dr. Katherine Swanson
The Pillsbury Company
St. Paul, MN

Dr. David Theno
Jack in the Box, Inc.
San Diego, CA

Dr. Robert Tompkin
ConAgra Refrigerated Foods
Downers Grove, IL

Others present:

Dr. Elsa Murano
Under Secretary for Food Safety

Dr. John Hogan
Acting Deputy Under Secretary for Food Safety

Audience participants:

Caroline Smith-DeWaal
Director of Food Safety
Center of Science in the Public Interest

Carol Tucker Foreman
Consumer Federation

P R O C E E D I N G S

9:00 a.m.

DR. WACHSMUTH: Good morning. Everyone can hear? I am very pleased to see everybody this morning, and I'd like to take a few minutes just to review what we'll be doing during the course of this week. We'll be covering quite a bit of territory, and I thought I'd give you a little bit of a roadmap. You have the agenda, and our primary topic will be the Salmonella performance standards. That subcommittee is chaired by Spencer Garrett who will be making most of the presentation. The standards are an important and a hotly debated issue these days.

As you recall from our meeting in May, Congress mandated that this Committee consider Salmonella performance standards, and Spencer's subcommittee began to do that last summer, and has met through the fall. Now, they're working hard to bring their conclusions to view before the full Committee, and they'll resume their deliberations this afternoon, once you've had a chance for some input.

Since the issue is so critical to the way the Agency protects the food supply, both the Under Secretary and I urge each of you to participate in the

discussion to the fullest extent. The more robust and thorough our discussions, the better the products will be, so don’t be shy. We have what we think is a very balanced Committee in terms of perspectives that you bring to the table, so we'd like to hear from you.

Of course, the performance standards aren't the only thing you'll be dealing with. We'd also like to address blade tenderization and E. coli O157:H7 ? that subcommittee is chaired by John Kvenberg, and John will give us a report on his committee's conclusions tomorrow morning.

Following that presentation and discussion, then Dan Engeljohn, who chaired the subcommittee on hot holding temperatures will report on that subcommittee's charge and recommendations to the FDA.

And the last, but not the least, subcommittee report will come from Mike Jahncke on CODEX, and this is a discussion paper on proposed draft guidelines for the validation of food hygiene control measures.

And in addition, Bob Buchanan will act as a chair of a subcommittee investigating criteria for refrigerated shelf life, based on safety. And he'll introduce this issue to the Committee and lay out the charge. This is an issue that's shared by both FSIS

and USDA, and we're looking forward to the outcome of that subcommittee's work and discussions.

So that's an overview of what we'll be doing for the remainder of the week, but now, before we get to work, I'd like to introduce our first speaker, Dr. Elsa Murano, Under Secretary for Food Safety. Dr. Murano was sworn in as Under Secretary on October 2, 2001. She has an extensive background in the field of food safety, as both a manager and as an educator.

Most recently, before coming to USDA, Dr. Murano spent six years with Texas A&M University at College Station, where she served as the Director of the University's Center for Food Safety within the Institute of Food Science and Engineering. During this time, she also served on the University's Department of Animal Science Research Advisory Committee, and the Food Safety Response Team of the Texas Agriculture Extension Service. She also served as the chair of the Food Safety State Initiative Committee of the Texas Agriculture Experiment station.

In 2000, she was appointed Professor in the Department of Animal Science. Dr. Murano has served on the National Advisory Committee on Meat and Poultry Inspection prior to being appointed as Under Secretary.

So she's well aware of our two advisory committees and the way they interact to merge the science with the policy.

And there are many other accomplishments and honors in Dr. Murano's portfolio, but I'll stop now and at this time, I'll give you Dr. Murano.

DR. MURANO: Thank you, Dr. Wachsmuth. I have to tell you, I like this podium. Usually I have a problem with podiums, so this one's okay.

DR. WACHSMUTH: Me too.

DR. MURANO: Good morning everybody and welcome to Washington. I'd like to certainly welcome you on behalf of Secretary Veneman, and on behalf of the Department of Agriculture in general, and on behalf of FSIS. We're very, very glad you could join us for this very important meeting. I haven't had the opportunity to work directly with this Committee before, as I have with others, but I know many of you individually. I respect you as colleagues and fellow-scientists, and I am confident that your opinions reflect the objectivity that is so critical to the scientific process.

As most of you know, I have spent most of my career as a researcher in food safety, and these

experiences have shown me the importance of sound scientific studies and how they should influence policy. In fact, you may say that this is the reason I decided to join USDA and accept President Bush's nomination to serve as Under Secretary for Food Safety.

So expert advice from this Committee, as well as from the National Advisory Committee for Meat and Poultry Inspection, is crucial, in my opinion, in enabling policy makers like me to establish science-based policies. In past years you've provided input on issues such as microbiological testing of fresh produce by the Agricultural Marketing Service, the Listeria monocytogenes risk assessment by FSIS and FDA, and on Vibrio parahaemolyticus by FDA.

But today we turn to you again and ask you for your input on other important food safety issues. Before you get to work, I do want to talk a few minutes specifically about performance standards, one of the issues you have been asked to address. I believe it has emerged as one of the most important topics of the last few years.

Well, science tells us that performance standards are needed. They serve as a measure of the success of food safety programs. And for FSIS,

performance standards are an important verification tool within the HACCP environment. However, it is not enough to set just any performance standard, we should recognize that the wrong standard can mislead us into believing that systems that are designed to control hazards are working, when maybe they are not. So we must set performance standards that are reliable and that are accurate, in terms of reflecting when control of hazards has been lost.

As you may know, the recent court decision on supreme beef has sparked a public debate on performance standards. While the court decision addressed only the enforcement of those standards in grinding operations, the debate has widened to the role of performance standards and food safety regulatory programs in general.

So the work of this Committee has taken an even greater importance in answering some of the tough questions that have emerged. Your charge was to answer four specific questions, as well as to address some additional issues regarding the usefulness of performance standards in predicting food safety.

Well, I know you have been working very diligently on this effort. I'd like to thank you in

advance for all the hard work and all the time that all of you have invested in this effort. As Kaye and I indicated to you in our letter to the Committee, which I hope some of you got. I realize there's been a problem with the mail in the last few months, since September 11th, but the documents that you are going to produce on performance standards will be extremely helpful to the National Academies of Science, who are undertaking a broader study of this issue at the request of Congress.

So any decisions we ultimately make regarding performance standards will have a far reaching effect on how we protect our nation's food supply. Your expert opinion, as well as that of the National Academies of Science, will be instrumental in helping us make those decisions.

So, in short, I look forward to hearing your input on the performance standard issue, but I'd also like to thank the Committee for the work you've put in on the other issues on the agenda. These are also important to our mission, and I look forward to hearing your report on these as well. So thank you all for your deep commitment, and for the contribution that each of you makes towards enhancing food safety.

Now, before I turn the microphone over, I have a more pleasurable task, perhaps, and that is of presenting a gift to Dr. Kaye Wachsmuth who you may have heard, is retiring very soon, and this is in recognition of her leadership and accomplishments as chair of this advisory committee. I've had the pleasure of working with Kaye for just a few months, since coming to Washington, but during that time I've had the opportunity, certainly, to see just how valuable she has been to the scientific efforts behind FSIS. I think FSIS has been very fortunate to have Kaye Wachsmuth leading the charge at the Office of Public Health and Science, and it's my pleasure to share this day with her.

I think this is her ? well, I know it is her last chairing of this Committee, so I was just asking her how many Committee meetings has she chaired, and she couldn't remember. It's been such a wonderful thing that she’s lost track, I believe, so maybe you can help her out. I know she's getting older, that's why she's retiring, so you may actually prod her memory.

But without further ado, I'd like to certainly let you know that during these six years that

she's been at FSIS, she's led this Committee, in my opinion, and from the comments of others, with great professionalism, integrity and dedication. So Kaye, if you'd like to come up here, we'd like to offer you a gift.

If you can help me to congratulate Kaye by ?

(Applause)

DR. MURANO: So on behalf of all of us, we're going to give you this beautiful tote so that you can tote all your memories in there.

DR. WACHSMUTH: Thank you so much. This is lovely. It's elegant. But no books. Thank you so much. And my memory is failing me.

(Applause)

DR. WACHSMUTH: Okay, now we can go on. I'm not going to take up your time with lots of words, but I do appreciate it, thank you.

And now I'm going to turn the chair over to the co-chair, Janice Oliver from FDA.

DR. OLIVER: Thank you very much. Good morning everybody. It's really a pleasure to be here with you once again, and I too would like to welcome Under Secretary Dr. Murano, all our Committee members and other guests for the first plenary session of 2002

of NACMCF. I've been looking forward to this meeting with, I would say, mixed feelings and mixed sentiments for quite some time. On the one hand, I was looking toward renewing our acquaintances as a Committee, listening to the recommendations from the subcommittees that have been meeting, as Kaye said, since we were last together, and beginning a lot of new initiatives.

And more importantly, I wanted to thank you for all the time that you all have taken and are taking to support our agencies. I've always been grateful for your willingness to assist us, but when I think of the events of last September, I'm even more grateful and more thankful, and it's really remarkable. It's really taking a lot more time for all of you, especially with the traveling that you're doing and so I wanted to say that we really appreciate it.

And as you know, your recommendations are being used by several federal agencies, and I'm certain that no one would believe that at times some of us disagree between the agencies. But you know, there's one thing we always agree on and that is the need for your assistance, your advice and your guidance.

But as I said a few minutes ago, I really have approached this meeting with mixed feelings. The

difficulty I have with this particular meeting is that it'll be the last time that I'll be sharing the chair of the Committee with Dr. Wachsmuth, and as we all know, and Dr. Murano has said, Kaye's going to be retiring in a couple of weeks, and like all of you, I will miss her greatly.

I've worked with Kaye for a long time now in different capacities. Kaye came to FDA from the Center for Disease Control, and introduced us all into a much better working relationship with CDC, and a much better understanding at the Center for Food Safety, of epidemiology and its needs and its role in public health.

She also was always gracious. She was always gracious to everyone, always gracious in chairing a meeting, and this meeting, and had what I saw was a great respect for people and was well respected by everybody in the Center whom she managed and everyone missed her, and still do, and still remembers her.

She's also given me, and given the Center, and given all of you of her great knowledge in public health, in epidemiology, and in microbiology, and we've all benefited from it. Kaye and I have had a lot of talks. We both had little dogs, not great big dogs,

and we both always have been comparing notes and it seems our dogs were always going to the vets for many similar things, so we always compared notes on our dogs.

But Kaye has always taken, for me, all the time that I needed and really gave me a lot of time and advice, personally, and was there for me then and always with FDA too, and I've appreciated that on a personal note.

But with her retirement, and with that in mind, I would like to take the opportunity to present to Kaye the Center Director's Special Citation from the Center for Food Safety and Applied Nutrition. Joe Levitt would have liked to have been here himself, but he is unable to be here, and I'll read the citation. It says,

"In gratitude for her service as the Chair of the National Advisory Committee on Microbiological Criteria for Foods, particularly her stewardship in obtaining the Committee’s recommendation on the safety of fresh juice, sprouts and produce, all of which have enhanced FDA's public health protection program."

(Applause)

DR. WACHSMUTH: I did not expect any of this.

Thank you so much. I can't tell you how much I've enjoyed my time at FDA, and at USDA, and I think we've all made great strides in the past six years. I'm glad to have been a part of it. Thank you both.

(Applause)

DR. OLIVER: Kaye did not know this. She wanted to ? we usually see each other's remarks before, and I sent the remarks, but I said please eliminate the last half of my talk, so they did. But even though Kaye will be vacating us as chair, I hope that she'll allow us to call on her in the future for her expertise and I know she'll share it willingly. But, as Dr. Wachsmuth said earlier, we have a great deal to do and accomplish in a relatively short period of time, so I'll turn the program back to Kaye. Thank you. But how about giving Kaye one more round of applause?

(Applause)

DR. WACHSMUTH: Now I turn into an ogre. I have a few more things. What I'd like to do first is to go around the room, and have each of you introduce yourself, your affiliation, and any other information that you think would be of interest to the Committee so that they understand, maybe, why each of you is here, what you bring to the table. And I will start with

Peggy and go around.

DR. NEILL: Dr. Peggy Neill from the Brown University Medical School, Public Health and Infectious Disease Specialist.

DR. SWAMINATHAN: Bala Swaminathan from Centers for Disease Control and Prevention, Foodborne and Diarrheal Diseases Branch.

DR. KUNDURU: Mahipal Kunduru, with Dole Fresh Vegetables, microbiologist by training.

DR. LUCHANSKY: Good morning, I'm John Luchansky with USDA-ARS up in Philadelphia, the Microbial Food Safety Research Unit.

DR. HABTEMARIAM: Good morning. Tsegaye Habtemariam, from Tuskegee University, epidemiology risk analysis.

DR. SEWARD: Skip Seward, formerly with MacDonald's, now with the American Meat Institute.

DR. RUPLE: Angela Ruple, lead microbiologist for the National Marine Fisheries Service, Pascagoula, Mississippi.

DR. ENGELJOHN: Dan Engeljohn, Food Safety and Inspection Service, and I'm Director of Regulations on the policy side of the Agency.

DR. ACHESON: Dave Acheson from the University

of Maryland, and my background is clinical infectious diseases, microbial pathogenesis and epidemiology of food borne diseases.

DR. DOWNES: Frances Pouch Downes. I'm the Director of the State Public Health Laboratory in Michigan.

MR. GARRETT: I'm Spencer Garrett with the National Marine Fisheries Service. I direct the National Seafood Inspection Laboratory, which is a large food safety testing laboratory. I also serve as our Agency's principal public health spokesperson, and I'm the chairperson of the subcommittee for microbiological performance standards.

MS. COLE: I'm Emille Cole, National Marine Fisheries Service.

DR. SPERBER: I'm Will Sperber, Chief Microbiologist for Cargill.

DR. KVENBERG: I'm John Kvenberg. I'm the Deputy Director of the Office of Food Programs within the Center for Food Safety Applied Nutrition, Food and Drug Administration.

DR. THENO: I'm David Theno with Jack in the Box Restaurants. I'm a grill cook that moonlights as the food safety guy.

DR. BEUCHAT: Larry Beuchat, Center for Food Safety, University of Georgia.

DR. TOMPKIN: Bruce Tompkin, Vice President of Product Safety for ConAgra Refrigerated Prepared Foods.

DR. DOORES: I'm Stephanie Doores, food microbiologist in the Department of Food Science at Penn State University.

DR. SWANSON: Katie Swanson, Director of Microbiology and Food Safety for General Mills Company.

DR. HOGAN: I am John Hogan. I am the soon-to-be-departing and acting Deputy Under Secretary for Food Safety, former Chief Counsel for the House Agriculture Committee.

DR. MADDOX: Carol Maddox from the University of Illinois, College of Veterinary Medicine. I direct the Clinical and Diagnostic Microbiology Section.

DR. JAHNCKE: Michael Jahncke. I'm the Director of the Virginia Tech Seafood Center.

DR. BUCHANAN: Bob Buchanan, FDA, Center for Food Safety and Applied Nutrition, where I'm the Senior Science Advisor and Director of the Office of Science.

DR. LAMMERDING: Anna Lammerding. I'm head of Microbial Food Safety Risk Assessment, Population Public Health Branch of Health Canada.

DR. WEBB: I'm Bob Webb. I'm representing the Department of Defense, Veterinary Service Activity.

DR. LIANG: Art Liang, Centers for Disease Control and Prevention, food safety office and former Hawaii state epidemiologist.

DR. JACKASON: LeeAnne Jackson, Health Science Policy Advisor for FDA, CFSAN, and I also serve as the liaison to the Executive Committee for NACMCF.

DR. OLIVER: Janice Oliver, Deputy Director, FDA, Center for Food Safety and Applied Nutrition.

DR. WACHSMUTH: Okay, I'm going to skip over the next two people and have one more slidng announcement, but a very important one. We now have a permanent exec sec. Our Executive Secretariat, Brenda Halbrook was selected recently, and I think she's already doing an outstanding job. We've had many compliments from the room et cetera, so I think Brenda can take a bow. And she also has a few housekeeping notes.

MS. HALBROOK: Good morning. I just want to make sure that you're all aware of the documents we placed at your seats this morning. You all should have the two ... documents on this, the background information and charge to FDA, and the other is the

subcommittee report, and we also put out the document that the subcommittee for performance standards worked on last night, as well as the slides that Spencer Garrett will be speaking from this morning.

We also put in your packets that were mailed to you, your calendars ? it's very important that we get those back. I'd like to collect them from you some time between now and Friday. You can give them to me or to Karen Thomas so that we can plan future meetings and subcommittee meetings with you.

We also put at your seats a little packet of restaurants. It's a very small list. There are many, many more restaurants in the vicinity than what you see there, but those restaurants can accommodate a larger group if some of you would like to get together in the evening for dinner.

And finally, there have been some changes in the travel procedures within the Agency, and I'm going to turn the mike over to Karen Thomas, our Advisory Committee Specialist, who thankfully is back now from maternity leave, and she will explain to you some of the new procedures we have to follow.

MS. THOMAS: Good morning. First of all, I can only accept original travel vouchers now. I can no

longer accept a faxed copy. I still accept a faxed copy of your expense sheet and receipts ahead of time to speed up the process with reimbursement, but I will be mailing you an original voucher to sign. It'll be Federal Expressed to you, and also to speed up, if you can, Federal Express it back to me.

Reimbursements won't take long for me to input, once you send me your information. It should only take 1 day to input and since it's going to be processed directly to NFC, it should only take seven to 10 business days, and you will receive a check in the mail. The check is going to be in the mail. I'm sorry for all the delays since I've been gone. I'm working very hard to get everybody reimbursed. Some of your checks should be there when you get home.

DR. WACHSMUTH: Okay, thank you. And the last thing before I turn this over to Spencer, is I would follow the usual procedure. If anyone has a comment, who would like to make a comment, please raise your tent card and whoever is chairing at that moment will recognize the card. That way we can keep the discussion a little orderly, make sure everyone who has something to say has an opportunity to say it, and it also helps our audio technical group recognize the

microphone that's being used and they'll raise the volume, so you can be heard. And then if you'll address your comments to the Chair, that way we'll prevent any fights among the members. And I think on that note, I'll turn this over to Spencer and let him lead us through the subcommittee's report, and I think you have some comments as well. Spencer.

MR. GARRETT: Thank you very kindly, Kaye. Can everyone hear me okay? Good. What my job is this morning, and I certainly welcome everybody here to Washington, even though I'm located in Pascagoula, Mississippi. But my job as subcommittee chairman is to report on where we are in our deliberations relative to the Microbiological Performance Standards. And in that light, you should have two reference documents before you.

As you know, in your booklet there was a mail out of the draft report ? that's not the document from which I'm going to be speaking. The reason being is that the subcommittee met all day yesterday and partly into the night to revise that document, and so you should have a redline strikeout document entitled "Chairman's interim progress report, NACMCF Microbiological Performance Standards." That's the

first document, with a December ? excuse me ? January 23 date.

Secondly, you should have a hard copy of some slides that have yet to be made, and I'll be speaking from this hard copy. And realizing that we have a lot of material to go through, and notwithstanding Kaye's animation, what I would really like to do if I could, and with your indulgence, if you would let me go through these hard copy slides and you withhold the questions until I will get through them, but just please write down any questions you have on the hard copy slide, then we'll go back through them and answer ? we'll have plenty of time to answer any questions.

It will then be our intent to take any comments if you'd write them down, again, on the hard copy slides, and provide them at the conclusion of this morning's proceedings. Then the Committee will meet this afternoon and readdress those questions with a few towards bringing, again, a revised document forward Friday morning ? or excuse me, tomorrow afternoon.

Now you can see why Emille sits on my left.

The point that I'd like to make, or at least try to make if I could, is that there is a voluminous amount of material. We'll certainly take all comments

and we will have a process to work through those comments.

So, with that understanding, however, if there's just something that you have to say and you can't ? just don't agree with, or you want to throw a shoe ? please don't throw the water pitcher at me ? then please just raise your card and flag, and Kaye will recognize you and so forth. Let's see how that works. I'm going to be speaking from these ? this document that has our ... logo on it. It's the only publicity we give these things.

So starting on page two, as Elsa indicated this morning -- and I will be probably going through this rapidly in some portions that are intuitive ? USDA is seeking guidance on the scientific ? what the scientific decision points might be in revising the Salmonella performance standards, to make them more reflective of current Salmonella prevalence in all ground product classes.

Also, however, they're reviewing ? they're seeking review and guidance on how the current performance standards are working, whether they're helping to insure safety of the nation's meat and poultry supply, and whether there's a more effective

alternative to the current performance standards, and if that should be the case, what are those alternatives. And you would find that on page one of your redline strikeout report.

In addition to that, though, FDA also ? excuse me ? USDA has also provided four specific questions to us to address as a Committee. The first is, elaborating scientific sufficiency in use of indicator organisms in lieu of specific pathogens for performance standard measurement. Appropriate scientific measurement methods for incorporating regional and seasonal variations and other factors. Special considerations when developing baseline data and using that data to support performance standards. And what are the key scientific considerations for applying risk assessments in developing performance standards. And again, all of that is found on page one of your interim report.

The subcommittee, as indicated, has been meeting both face to face and intermittently through phone conversations, and has reviewed a great deal of data which I will give -- information and publications and presentations ? which I'll get into in a moment. But I think I should point out and indicate right at

the very beginning that we have come to a conclusion, and that subcommittee conclusion is that we agree that performance standards are a valuable and useful tool for defining an expected level of control at one or more steps in the process.

Now, in terms of the way we approached our review of the questions that were presented to us, as I indicated, we reviewed numerous reports. We received presentations from subject matter experts, if you would, in different areas, and all of those activities in terms of the scientific reports, the policy reports, the expert elicitations that we've received, you can find in Appendix 1 to again, this interim strikeout report before you. It's really not my intention to go in there. The reference materials are for your perusal.

As we began to engage in the deliberations, it became apparent to us ? and I'm on page six of the slides ? what I'll call the slides ? it became apparent to us that the questions weren't really in the right order to begin to address the deliberations, or at least to facilitate the addressing of those deliberations, and they needed moderate tweaking.

So, with concurrence of the Agency

representatives on the Committee, and others, the subcommittee kind of tweaked them and reordered them. So now, as opposed to what was originally sent us, the first question is, What are the key scientific considerations and applications in the use of risk assessment in the development of performance standards? And you'll find that ? you'll find what I'm addressing on page four of your redline strikeout report.

Secondly, what's the scientifically appropriate methods for considering variations that may be due to regional, seasonal, and other factors when developing performance standards?

Three, what constitutes scientifically appropriate methods for considering variations that may be due to regionality, seasonality, or other factors when developing performance standards?

And four, what are special considerations in development and use of baseline data for performance standards?

In terms of where we are, we have prepared draft answers, in terms of general principles and guidelines ? and I'm on page seven of my slides. To prepare these draft answers for full Committee consideration to questions one, two, and four. We've

only given a partial response, however, to question three, because it's incomplete because we've been going through a ? a detailed data analysis and that is an ongoing activity of the subcommittee, and the regional and seasonal and other factor variations that we're looking at are literally thousands and thousands and thousands of data points that are being summarized for us by FSIS and our expert, Dr. Al Rainosek. So this brings me ? so we're not quite complete with that question.

This brings me to page eight of my slide presentation, and it brings me to page five, I believe, of our interim report.

In terms of question one, and specifically, question one again asked, what are the key scientific considerations that need to be attended to in developing risk assessment for application in the development of performance standards? What are the key scientific considerations that need to be attended to when risk assessments in the development of performance ? when using risk assessments in the development of performance standards?

And we have, and in my slides I'm merely trying to encapsulate the principal recommendations

that the subcommittee is making. There is certainly more foundation text, if you would, in the report. But in answering question one, there are several considerations that need to addressed, or at least resolved. That is, the provision of sufficient information to complete an exposure assessment and hazard characterization to conduct a risk assessment is necessary. So there are certain information and data needs, obviously.

Risk assessment should be conducted in accordance with the CODEX principles and guidelines, for the conduct of microbiological risk assessment. Thirdly, actual numbers of Salmonella present in a ground product need to be determined, or at least estimated, and the subcommittee has provided for an estimation protocol, including sample size requirements on page five of the redline strikeout document.

Further, on page nine of my slides, when you deal with question one, it's also necessary to identify information needed to complete a exposure assessment, which includes many factors that -?and these factors influence both the frequency and levels of Salmonella contamination between the time period of ground beef manufacture on the one hand, and consumption on the

other. Factors considered may be ? they're listed on slide nine: frequency of consumption, serving sizes, methods and degree of cooking, different kinetic models in terms of inactivation and growth, temperature storage, and so forth.

Further, on page ten of my slides, risk assessment for different commodity ground products should be initiated individually because if that were to be done it simplifies the risk assessment models and some of the needed data probably already exists in various USDA collection programs.

It was pointed out to the subcommittee, or the subcommittee gleaned, that frankly, USDA as an agency, collects a great volume of data, and the data is collected through different programs while they're complementary and not necessarily duplicative, nevertheless, there needs to be some way of merging these databases for better use, if you would, of the information that would be contained in those databases ? among, between the various data collection models.

Exposure assessments must be done in a transparent manner, so obviously people can follow the assessment process and not only exposure assessment, but risk assessment, so risk analysis for that matter,

must be done in a transparent manner. And for those that -- that are so inclined, I would urge you to look at the definition of transparency in the CODEX general principles and guidelines for microbiological risk assessment. That definition is being currently ? attempted to be currently used around the world, and it is quite specific as to its requirements.

Risk assessment should be designed to allow effective use of techniques, such as the conduct of sensitivity analysis on a relative uncertainty. All of this information or foundation wording is found on page six of the interim report.

Risk assessment should be written in a manner that allows risk managers and stake holders to understand key factors that contribute to risk, that influence decisions in accepting one performance standard over another.

Risk assessments often require that assumptions be made regarding uncertainties associated with factors that influence conformance with microbiological performance standards and the relationship between the standard itself and the public health estimate contained within the assessment. Such examples are level of pathogen present, pathogenicity,

the microorganism, amount of food consumption assumptions, ... and chemical characteristics of the food, and the extent to which the food was processed.

Understanding the distribution of aggregate uncertainty of probability throughout the risk assessment is a desired feature, however, it is not always feasible. We do recommend, however, that single value worst case estimates should be avoided, particularly when more than one factor contributes to the overall performance. So the point simply is, when you don't know everything, you necessarily do not have to default to the worst case scenario assumptions.

On page 12 there are certain data needs. Question one dealing with risk assessment, and they fall within the areas of quantitative Salmonella data in meat and poultry, the need for USDA to establish an epidemiological data collection system that relates Salmonella ? or salmonellosis, rather, to different commodity groups; defining relationships between hazard and reduction health and risk; industry data indicating what worked to reduce Salmonella, and then making that data and that information available across the entire spectrum of the industry so that other people can take advantage of those intervention strategies; a specific

USDA management activity to merge databases for performance standard development ?- and that goes back to the earlier issue that I talked about, collecting just volumes of data programmatically for specific type programs that could be enhanced by programmatic sharing of that data. Proof of reduction of Salmonella resistance as well as some reduction of some other pathogens; and codifying all data for public release for program improvement purposes.

In terms of question two, on page 13 of my slides, question two deals with what constitutes the scientific sufficiency to support the use of indicator organisms in lieu of a specific pathogen? And so in addressing question two, we came very quickly to two conclusions. One is we need some definitions, primarily for our benefit, that is what is an indicator organism? How is that defined?

So an indicator organism indicates a state or a condition. An index organism, on the other hand, is one where the levels or frequency of one microorganism reflect the level or frequency of another organism of concern. In other words, there's actually a mathematical relationship, if you would, between the two.

Also in addressing question two, it became apparent very quickly that question two, as we began to deliberate this question, that actually encompasses three different -? not differing, but different -? conceptual elements which need to be considered separately in order to adequately review all aspects of the scientific sufficiency.

So, we go on to question two, A, B and C. A, relates to the use of an indicator organism in lieu of a specific pathogen, and you'll find our foundation documents on page eight in the report, foundation wording, and I'm on page 15 of the slides. Use of an indicator organism in lieu of more specifics -- more specific pathogen, that is being done and the subcommittee understands the rationale stated, both for the pathogen reduction as a final rule, and the Philadelphia report, which is commonly called the Philadelphia report. It doesn't ... by the way. E. coli -? got to lighten this up a little bit -? E. coli can be used as a direct measure of control of fecal contamination of slaughter, however, it must be understood that E. coli in ground beef may not be a direct measure for the concentration of fecal contamination of carcasses immediately after storage,

due to storage conditions throughout the distribution chain.

On page 16, there are certain attributes that support the use of the -? the natural occurrence support the use of indicator organisms in lieu of the specific pathogen ?- relevant species, carcasses, primals and trimmings, and ground products derived therefrom. The number five, and we're located on page 16 -? or slide 16 of the -? of my slides and page eight of our report. These five deal with similar survival and growth characteristics, shared common sources for both in the animal gastro-intestinal tracts, direct relationship between stated conditions that contribute to the presence of enteric pathogens and indicator organisms, high frequency of detection when contamination of fecal origin exists, and finally, practical isolation, detection and/or enumeration efforts.

Another aspect of question two relates to using an indicator organism or class of data for measuring against the performance standard. On page 17 those are listed, and they appear on page nine of our interim report. And those relate to current microbiological performance standards for all meat and

poultry are based on the presence or absence of Salmonella to measure, if you would, a level of processed control. The standards are based on an estimated Salmonella prevalence for a commodity. E. coli and Salmonella are intended to measure control of the stated condition that would lead to the presence of enteric pathogens, and it is thought that we need to analyze the data to determine if there's a relationship between the frequency level of E. coli and APC, or other combinations of indicators for alternative approaches. And there's much more wording in developing these things on page nine of our report.

Also, we've drawn out the regression analysis as one of several tools that can be used to determine processed controls for relationships.

The final part of question two concerns use of one pathogen as one measurement of performance for another pathogen. Attributes of the pathogen contributing to the science of efficiency of using one pathogen to indicate the presence of another, include: similar survival and growth characteristics, shared common source for both pathogens, qualitative or quantitative relationships of one pathogen related to the other pathogens ?- pathogen or pathogens, and

control measures for one pathogen being effective for the second pathogen or pathogens.

So our data needs, again, as might well be expected for question two. And those are outlined on page 19 of these slides. These include data to demonstrate that the indicator microorganism relates to the state or condition of the associated commodity pathogen. Data demonstrating indicator microorganism reductions lead to reductions in pathogens in commercial operations and food borne illnesses. Data analysis to determine whether population-based relationships can be estimated between classes of microorganisms and target microorganisms. Relationships -- frequency relationships or concentration relationships between the two pathogens for all species ? ... primals, and trimmings in ground products. Data including the ... of time that the reductions in one pathogen will lead to reductions in the other pathogen in commercial operations.

Which brings us to question three, and I'm now on page 20 of the slides. Page 11 of our interim report. What constitutes scientifically appropriate measures for considering the variations that may be due to regionality, seasonality, and/or other factors when

developing performance standards. These -? these issues, obviously, represent variables. And understanding variability for the conduct of risk assessment is certainly desirable. Effort needs to be put in to determining what the sources of variation are, and understanding, if you would, the public health relevance of the sources of variation.

Question three also needs to be broken into two parts because one deals with methods for the acquisition of data, and the other deals with the evaluation of that data. So we will get into A and B.

So A is scientifically appropriate methods for the acquisition of data to consider variations due to regionality, seasonality, and other factors in developing performance standards. It's -? in terms of acquiring data, the subcommittee felt that it would really facilitate the data acquisition process and probably the paradigm by which decisions can be made relative to one, how to analyze the data, and two, perhaps premise public policy decision making after that analysis.

And what the Committee is recommending is that when you think about going after data from the appropriate products, you might want to take a look at

the meat and poultry production modules themselves so you can then gather data and determine the factors that may influence the microbiological status of animals presented for the slaughter, the slaughter practices themselves, the interventions that reduce contamination, and the handling and holding of raw meat and poultry. And you find a much better explanation of this on pages 12 and 13 of the interim report.

And I would point out to you that on pages 12 and 13 of the interim report, on page 12 you'll see there is A through I factors that may influence microbiological status of animals presented for slaughter, quite a few. The same is true for slaughter of ..., same is true on page 13 for interventions that reduce contamination, A through D, and for the handling and holding of all meat and poultry, dealing with rapid chilling, temperature control, contamination probabilities or possibilities, and so forth. And there are others. This is not meant to be an inclusive list.

On page 22 it struck the Committee that if you're going to design a new study ? or someone is going to design a new study, after you look at these modules, you really need d) to think about

contamination relationships, or perhaps interrelationships. And I'm on slide 22 -? and first there is the internal/external relevance -? and people are gee, what do you mean by that? What I really mean by that, or what the subcommittee really means by that is, you know, what is the contamination on the external part of the hide ?- you know, the carcass, the animal -? the hide, whatever -? got to remember I'm the fish ... and shrimp ain't a big deal -? and then also, the gastrointestinal. So, what are those relationships?

The assessment subsequent to slaughter -? and also, it's very helpful if you can discriminate between controllable and non-controllable factors affecting the frequency and concentration to help identify means to reduce contamination clear across the food chain in those production models earlier that we talked about.

Moving on to page 23 -? secondly, after you've figured out how you're going to get the data or acquire the data, how are you going to analyze the data? And that's what we call 3B. And as you're doing this data evaluation, some of the things ?- and we didn't try to put everything in that you need to do -? but some of the things you need to determine -? and this is also found on page 13 of our interim report -?

is to see if you can assign variation to some cause. What is the variation? Is it just normal variation, or is the variation in your data relative to some cause?

Determine if the size of the caused variation can be reduced through control measures, through either intervention technology, best practices, or what have you. If the cause is uncontrollable, however, then one needs to consider if the variation is significant in terms of public health consequences. And all that's on page 13 of the report, I hope. Yes, I see it is.

I'm on page 24. Question three also has data needs. One is comparison of the current year 2001 FSIS industry raw ground beef data. Compare baseline data to recent performance standard test results. Determine the effects of association of specific raw materials with individual and multiple regions, select supplier sets and multiple supplier sets and imports. In other words, if you're just looking at raw materials coming in, have more than just a primitive understanding of what the possible confounders may be -? or not confounders, rather, but what the possible bias -? and I use the bias in the true sense of the word -? it can be a positive bias - what that data represents, because there's many people out there that have numerous

control programs relative to acquiring raw materials, so they don't have the down stream qualities.

As I indicated, we're not through with that question. We are looking at more data, and I'll say more about it in just a moment.

Question four dealt with indicating the quantitative standards appear to have more technical challenges associated with them than do qualitative challenges. And what special considerations need to be attended to in the development of qualitative baseline data, and what special considerations need to be attended to in using quantitative data -? baseline data for the development of quantitative performance characteristics? Say that fast five times.

Well, again we thought we needed some definitions here to make certain that everybody that may read our report is on the same page. So a quantitative variable is defined as a variable that can be measured numerically -? and they are, of course, called a quantitative variable. Something like colony forming units per gram, for example.

A qualitative variable, on the other hand, is a variable that cannot assume a numerical value, but can be classed in two or more non-numeric categories,

such as a presence or absence.

So with that understanding, we determined that the rationale for development of quantitative numerical variable baseline data certainly helps in defining the magnitude of a specific organism in a specific product for public health risk estimation due to possible exposure. So therefore, that type of data certainly enhances assessment of risk. Likewise, data acquired from various points along the production line provide more specific information in many instances, than does end product testing. Quantitative data also allows determinations of changes or trends -? and changes of trends for particular organisms. And finally, quantitative data certainly facilitates development of performance standards.

Another aspect of question four, on page 27 of my slides -? got to remember, I'm a poor man from Mississippi -? we can’t afford projectors. I use paper. We really want you to write down, if you would, on these -? on these papers. Special considerations and technical challenges for quantitative basis -? well, there’s one, two, three, four, five, six, seven -? six, seven -? but one of the points we want to make out is there's not too much difference, if you would,

between the special considerations -? really need to think about, when you're dealing with qualitative issues or quantitative issues -? baseline data issues -? most of them pretty much are very similar.

However, there are two that have specific relevance for quantitative data as opposed to qualitative data considerations. And those two are starred -? the methods for sample collection, including matching samples -? meaning matching a specific carcass downline to the specific ground product, whatever the end product may be; the shipment of samples, laboratory analysis, including laboratory accreditation. And then special techniques for both detection and quantification of whatever it is you're interested in.

On page 28 of our slides, scientific considerations when considering use of baseline data to establish performance standards. Well, again, you need to know the relationships between the performance standards and possible public health consequences. You need to identify confounding factors, whatever they may be, to the extent that you can. Oftentimes you may not be able to index all confounding factors. Need to adopt proper performance standards and steps in the process from where the samples were collected to

establish the performance standard. You need to anticipate expected rates of non-conformance. You need to generate quantitative data to develop quantitative performance standards, and when you do that, that will impact testing by both the government and industry, and obviously, test methods must be standardized.

Page 29, in terms of the application of quantitative or even qualitative performance standards, which is found on page 16 of the redline report. Performance standards, once supported by appropriate sampling plans and control limits, must discriminate between conforming and non-conforming levels of performance. That's what they're all about.

Quantitative performance standards may be appropriate to achieve certain public health goals, whereby reducing the concentration of a pathogen is sufficient to control the risk, without eliminating the pathogen itself. Quantitative and qualitative performance standards may be used when verifying the ability to either control or reduce a pathogen? pathogen’s level of concern. Qualitative presence or absence tests are defined ? it should be understood that the qualitative presence or absence tests are defined by some lower limit of sensitive method, i.e.,

negative in 25 grams.

So, in summary, I again want to reiterate on the subcommittee's behalf, that having gone through this, we believe that performance standards are a valuable and useful tool for defining an expected level of control at one or more steps in a process.

We concentrated on the appropriate text to provide general principles and guidance for considering the four questions presented to us by FSIS. Appendix 1 indicates the numerous formal documents we reviewed in reaching our guidance, recommendations. Obviously, as members of the subcommittee, we individually bring professional experience -- experiences, which also bear on the matter and subject.

The question dealing with seasonal and regional variations on the development of performance standards is still under review, and will be further addressed in the session by the subcommittee. When that's completed, our guidance will be forwarded to the full Committee for consideration. Reviewing guidance on how the current performance standards are working, whether they're helping to insure the safety of the nation's meat and poultry supply, and whether there are more effective alternatives to performance standards,

and if so what would the alternatives be still has to be addressed.

Following the completion of these questions, the subcommittee will address the data issues associated with regional and seasonal and other factors in ground chicken and turkey. In this latter part, it is not anticipated that those deliberations addressing those latter commodities will be as lengthy since the same general principles and guidance protection should virtually be the same.

And with that introduction, I'm more than willing now to open it up for discussion, going back to the first slide if you want to go through these in order. I'm in your hands.

DR. WACHSMUTH: Okay, I guess one place we might start is just to ask if any other members of the subcommittee have something they'd like to add to the chairman's report. Okay. One thing Dr. Murano noticed in ? and it'll help the discussion, the four questions that were rearranged and reworded by the subcommittee - ? they may not be correct on the slide. They don't seem to be quite the same as what's in the text on page four.

MR. GARRETT: Yes, that is -? you have to

understand on the slides I'm merely trying to shorten and encapsulate them so I can abbreviate -? but by and large, it's what's in the interim report.

DR. WACHSMUTH: I was just trying to stop anyone from writing that over on their slides.

MR. GARRETT: Okay, I’m being pointed out that there's typo on slide 13.

DR. WACHSMUTH: Okay, meanwhile, Bruce Tompkin, you have a question?

DR. TOMPKIN: I think it might be worth noting that the slides that Spencer's been going through are just to facilitate discussion and introduce everyone to the text, but as a full Committee, we all must agree with the written words. That's what's going to be communicated to the Agency, or actually all the agencies, so be certain that you're agreeing with this written text.

DR. WACHSMUTH: That's a good point, Bruce. Okay, Spencer, I'll let you lead us through this. I don't know if you want to go through the document at this point or stay more general or stick to the slides, it's up to you.

MR. GARRETT: What I would like to do if it's possible is to hear from perhaps some members of the

Committee that are not members of the subcommittee in terms of how do you feel in terms of the depth, breadth, scope of what we've done to date, or at least so far, and realizing that we -? that this is a redline strikeout document. You were provided the earlier document, but this again is a different document, because we did have the privilege of meeting yesterday. If you have any particular concerns. It would be our intent to try to finalize this document -? this redline strikeout -? Friday, so I would like to be apprised on any comments you might have or how you would like to best proceed -? if you would like to take a 15 minute break, for example, to read the thing or would you like to -? what would you like to do? It would be my intent -? I would think that we might be able to finish this document by Friday. Yes.

DR. DONNELLY: Cathy Donnelly, University of Vermont. Just a point of clarification. In the slides that you presented, I don't know if the Committee talked at all about stress adaptation, but I think, especially where you're talking about indicator organisms or substituting one pathogen for another, and especially like on page 13 of the report, some of the pretreatments that the carcasses undergo -? did you at

all address the need for consideration of stress adaptation and recovery methods to maybe get after potentially non-culturable organisms?

MR. GARRETT: I think that -? again, going to page 13, I think that we did discuss stress, we did discuss non-culturable, for example, and came to the conclusion that primarily -? let me deal with stress first -? that we dealt with it in terms of an intervention as opposed to a special consideration, though we do recognize that depending on what level of sensitivity you set in the performance standards, then you have to deal with it.

Secondly, in terms of the nonculturables, we, as many other people you know, from a performance standard, if you can't culture them, you're going to have a performance standard premised on what you can culture. You have to do what's been done for many, many years and that's simply to -? they're not applicable in performance standard paradigm. Bill? And any other Committee member, now who would like to add on, please weigh in. Bill.

DR. SPERBER: I'm Bill Sperber with Cargill. Kind of a general, philosophical question regarding the approach of the subcommittee to this challenge.

I'm wondering if you approached this with a mindset of kind of a zero budgeting process, where you had a blank slate to consider all possible options for performance standards, or do you think the subcommittee -? or do you feel the charge to the subcommittee was biased in favor of selecting a particular pathogen, or Salmonella as the performance standard criterion? The reason I asked is that in going through the slides, I think the first mention of any specifics was on about page eight where you mentioned getting information about Salmonella, which led me to think that maybe somehow the Committee was prejudging the situation in favor of Salmonella.

Then on slide 11 you mentioned pathogen performance standards, and it wasn't until a little later in your review that you get into the topic of indicator organisms. I wonder if the subcommittee is open to the possibility that a single indicator criterion could, in fact, serve the public health interest in minimizing and eliminating pathogens in these particular raw products.

MR. GARRETT: Let me respond to that and then any other subcommittee member that may wish to add additional remarks, feel free. But to answer your

first question, no, our paradigm addressing this was not from the zero based budgeting point, or necessarily a cost point, although we did consider cost and had some debate, quite frankly, whether there was more cost associated with qualitative performance standards such as -- or quantitative performance standards, and what the cost of running MPNs are and so forth. We did discuss that. But, no, what we tried to do was indicate to give general principles and guidance, and if we're going to have performance standards relative to the four questions which were asked, what should be the scientific and application considerations.

Secondly, in regards to your question about are we fixated on Salmonella, the answer is certainly no. The only reason that we talked about Salmonella and so forth is because we were presented, in our background materials, with a ruling, and USDA did indicate that the -- the premise upon which they use Salmonella in the HACCP rule -- we reviewed that. We did review the report, and so what we are in fact doing is using Salmonella to test the assay and example of one performance standard.

What we're doing, is we're indicating that you can have numerous types and forms of performance

standards, but if you're going to have them, then these are the considerations -- scientific, technical and application -- that you need to consider. And we do talk about that, you'll see, in the report. Bob.

DR. BUCHANAN: Thank you. Having heard the last two comments, and knowing the details of what's in the report, I think that we ought to go back to Spencer's suggestion that we take some time and allow the people who were not on the subcommittee involved with the details of the document, an opportunity to read it over, because both of the two questions that arose are discussed at great length in the document itself. And so it might be helpful, particularly considering that we do need to get useful information by this afternoon if we're going to go back into deliberation and finalizing this document, that we take the time as a full Committee to review it and identify the areas where there are deficiencies or things that have been left out, et cetera.

MR. GARRETT: I would certainly agree with that. The report -- I won't say is a quick read, but it's an easy read because ... and so why don't we take, say, about 15 -- 15 to 20 minutes?

DR. WACHSMUTH: I may be a slow reader. I

think more like a half an hour.

MR. GARRETT: Half an hour? Okay.

DR. WACHSMUTH: And it's time for our scheduled break, almost on the dot, so unless anyone has another burning comment, we will break for a half an hour and will resume with discussion of the document. Okay? Good.

DR. NEILL: I was just going to say since we're deferring question three further until the subcommittee is able to obtain the data subsequent to this meeting, then maybe people could triage and focus the attention on the sections of the report that deal with the other questions.

DR. WACHSMUTH: Okay, good suggestion. Question three will be deferred, so if you concentrate on one, two, and four, we may be able to have something to send to the Agency by the end of the day Friday. Okay, thanks.

(Whereupon, a 30 minute recess off the record was taken.)

MR. GARRETT: Yes, Madame Chairman, before you proceed -- I'm not quite certain how you would like to proceed, but I would suggest is that we have an opportunity to ... the document, which is the redline

strikeout document from our deliberations. Are there any comments which those -- I presume the face page and then -- there is notation too to the document, by the way. People notice that?

PARTICIPANT: Uh-huh.

MR. GARRETT: Just goes to show you that we're not a zero defect program, but I would think perhaps the easiest way to proceed, Madam Chair, might be to go just relative to the questions themselves, because the first two pages of the document, quite frankly, are background information and material being moved to the appendix, but it's factual material.

Question one, then, begins on page five and goes through page seven. Would there be any questions on that? Seeing none, then, I will go to question two --

DR. WACHSMUTH: One thought, Spencer. When the subcommittee decided to reorder the questions and change them slightly to better approach them, you might give the Committee a sense of why this was question number one. Is it first step? Is it -- you know, the most important? That would help me.

MR. GARRETT: Yes, I think -- and if I'm incorrect any subcommittee member certainly can correct

me -- but I think in looking at the issues that were prescribed -- and many of us are microbiologists that have been around engineering -- it was felt that to address the issues, what you might really want to think about is indicate, if you're dealing with public health consequences, obviously there's several ways to deal with those, including risk evaluation, risk assessments, assessment of risk -- which are three different things. Let's start there and work backwards in terms of if you were going to be evaluating risk, or assessing risk, what would you need? And so I think that's why we put that question up first. And it facilitated, then, the discussions. Moving -- any other questions?

DR. SWAMINATHAN: I have a comment -- this is Bala Swaminathan from CDC. Not being a risk assessment group, I find the last three or four lines on page six quite unintelligible. Is there a simpler way for the Committee to phrase it so that the common non-risk assessor could understand what you're saying? I'm specifically referring to, "Ideally, the distribution of aggregate uncertainty would be estimated probabilistically so that the overall uncertainty of the risk estimate and the expected

public health gain is achieved as a result of implementing or changing a performance standard can be estimated."

MR. GARRETT: Let me respond --

DR. SWAMINATHAN: Can you replace that?

MR. GARRETT: You'll be happy to know that while I may be a groupie, I'm not necessarily a risk assessment groupie either, but I think what that's trying to really say is that there is a lot of uncertainty in life and there's certainly a lot of uncertainty when you do risk assessments, and it's very helpful if you can determine, if you would, what the total -- totality of uncertainty is in the risk assessment process, which is a very formal process which goes through a number of very formal steps -- try to get the totality of that uncertainty, or at least try to estimate it. But we do have some, not only risk assessment groupies in our group, we've got some sure enough risk assessors, and if anybody would -- I think that was my understanding. Bob.

DR. BUCHANAN: Swami, we hear you and we'll put that into plain language.

DR. SWAMINATHAN: Thank you. I have one more comment on page seven, if I may? I'm referring to the

second bullet of data needs, "The Agency should establish a mechanism to obtain epidemiologic data to determine the portion of salmonellosis in the US population attributed to the commodity group for which performance standards have been established."

Has the subcommittee discussed ways of doing this, and is the subcommittee able to provide some guidelines to the Agency as to how they would go about establishing such a mechanism? Do you specifically attribute cases of salmonellosis to certain commodity groups? Would this be done strictly on the basis of epidemiologic data or are you, as a subcommittee, thinking of source tracking methods and such? Or a combination of epidemiologic and microbiologic methods?

MR. GARRETT: If I may, Swami, let me just say as one subcommittee member -- and try to remember, I'm a fish out of water here -- I'm a seafood guy -- but I was somewhat surprised myself that that mechanism didn't really exist because in past years, we've provided funds to CDC to kind of do that for us. But regardless of that, we didn't really go into any -- any active discussion on how that mechanism could be formulated, whether it's passive surveillance, active surveillance, epi studies, reading newspapers,

whatever. It's -- so if that would be a recommendation, we can certainly deal with that, or if not, hold that over, because that will also -- remember in question three dealing with data, we're holding that question open because we are looking at a lot of data, and we can add that to the data list, if that would be helpful to those data considerations. But I would prefer subcommittee members to respond as well, if they so choose.

DR. WACHSMUTH: You have a question to your left -- to your right, sorry. Dr. Habtermariam.

DR. HABTERMARIAM: Thank you. Mr. Chairman, a couple of comments and a question. Both epidemiologic and risk assessment. I want to say that I was very impressed with several points that have been made on pages five, six, and seven. You know, quite well thought out in many ways. Just to point a couple of things. For example, the key issue in my book of risk assessment is that as opposed to say, chemical or toxicological risk assessment, we're dealing with that ... phenomena. These organisms change over time and therefore this issue of the growth connected minus recognition of values -- this is very important, and I appreciate the point that is being made.

On page seven, as an example, on the top of that page, the point about using single value as worst case estimate and not doing that is very important. Instead of that, which ends up being problematic looking at families of distributions makes a lot of sense, and that is also recognized, and I appreciate that point.

And also, on that same page, the question was asked earlier, Salmonella was selected as a target organism because we looked at the prevalence of Salmonella, it is much more significant compared to any other agent. And I think if we could have actually a good model and a good assessment done on this other prototype, it's actual impact on public health could be quite significant, and I'm sure economists would appreciate that point. Again, that is very well done.

I wanted to indicate ... although the prevalence of Salmonella is very important, I think we also need to recognize that incidence -- we forget risk assessment what is critical is ... incident, the dynamic picture over time as opposed to the -- that one static picture of prevalence, and looking at that and the rate of spread of this organism, and its transmission pathways are a critically dangerous

assessment -- and that does not seem to be addressed and maybe could be done very easily.

The question that I wanted to ask was, a point is made on page six -- in the middle of page six about when you referred to risk assessment team to -- on page six, "specific data must be determined by risk assessment team." Would the subcommittee eventually recommend that the risk assessment of Salmonella be done at some point?

MR. GARRETT: Your question, if I understand, is would the subcommittee recommend that at some point a risk assessment be done. Quite frankly, we haven't -- we haven't -- we certainly hit around that issue. I don't know that we addressed it head on. We can take that back to the subcommittee. We are meeting this afternoon and just lay it on the table and see what happens.

But your comments, again, relative to the -- depending upon whether you're a risk assessment or non-risk assessor, some of the imponderables, if you would, dealing with kinetics and so forth, certainly do need modeling so that you can deal with them in some sort of risk assessment -- we think also are well taken. All I can say is I'll be more than willing, as the

chairperson, to take that back to the subcommittee and lay it on the table. Okay?

DR. WACHSMUTH: This may also be something -- if -- everything doesn't have to go through the subcommittee. I mean if the Committee thinks that it's a good idea, or a bad idea to do a risk assessment, you can talk about that right now. I'm assuming that Dr. Habtermariam thinks it's a good idea, but I don't know that. In this -- you don't have to funnel everything through the subcommittee. You can have a discussion here. Spencer can pick that up and take it back, but you could have those statements, because we -- those reports should be a report of the full Committee.

DR. HABTERMARIAM: Could I add just one more -- one point? I agree with Dr. Wachsmuth -- because they made some excellent points. Again, for example, the issue of merging databases. There's so much data at USDA and FDA and several places as well as academic institutions, and the point is very well made, to have access to these data which we have very strongly believed in, in order to really have transparent risk assessment, transparent and accessible data so that these could be validated and be actually challenged and be used not only here, but in fact, internationally. I

think that point is very well made.

And it seems to me that Salmonella could -- because of its significance ... to be an excellent prototype to really do a good, well designed and well developed risk assessment, with the ultimate point of -- to the end point being the public health impact as opposed to just Salmonella say -- you know, presence or absence in the processing. Ultimately, the end point has to be it's impact on human health and therefore, the involvement of CDC in that process as an example.

MR. GARRETT: Kaye, probably you can't see, Bob Buchanan has his flag up.

DR. WACHSMUTH: Okay, I was turning it over to you, to chair, Spencer, but I think I'll take it back.

DR. BUCHANAN: Two comments in regard to the question that was addressed to the subcommittee, and again reflecting my own personal bias, but I think I can also partially speak for the subcommittee. One, I think that the subcommittee felt that if you're going to relate a performance standard to some measure of public health, at some point there needs to be some assessment of risk done. Whether it's a formal risk assessment of a quantitative nature, or whether it's

something less than that, I don't think that we took a position on that other than the fact that there was an assessment of risk that was needed.

However, in responding more directly to your question, I would refer you back to the question for which the subcommittee was charged to formulate an answer, and this was specifically, "If a risk assessment was going to be done in order to develop a performance standard, what should be considered in that risk assessment?" So I don't think it's a question of whether it should or shouldn't be done, or whether we recommended that one is done or one isn't done, we were responding specifically to the question that was posed to us, and responded to it. Again, that's articulated in the document itself.

DR. WACHSMUTH: Robert.

DR. TOMPKIN: Bruce Tompkin. With respect to the question raised by Swami, at this point in time, or at least up until this time, we're at least not aware that CDC has been asked to generate data. That could be used in the risk assessment, and to evaluate the impact of the performance standards on a national goal. And we are, in this one statement, essentially encouraging that CDC be asked to do that. Just how CDC

would develop the data with the -- between the agencies and CDC, but we feel that the epidemiologic data are so important to the whole performance standard concept, because it should be based on a public health goal -- they should be.

DR. WACHSMUTH: Bob.

DR. BUCHANAN: Just a comment to impartially ourselves. Having looked over this section again for another time, and with the perspective of a night's rest, I think what is not real clear here in terms of the discussion is whether we're talking -- there is an assumption here that we're using Salmonella, and it might be good to indicate that this was as an example. This might be the information if Salmonella was being used as a performance standard. There does seem to be a jump fairly quickly from a general discussion to a very specific one, when in fact we were attempting to use it as an example of the types of data that might be needed.

MR. GARRETT: We can certainly write some transitional phrasing to handle that concern. I think several of us actually have that concern.

DR. WACHSMUTH: Okay, that might be helpful, and also the fact that you know, you're specifically

answering the question, because I think others might ask the same question that Dr. Habtermariam asked.

The other thing -- I have a question for the Committee -- under merging data. I know that the Committee asked for, and I hope received, all of the data that we could possibly pull together, including some from agencies outside of FSIS. And my perception of what was happening, which is just coming in and out of the subcommittee to listen, was that those data sets were all different enough that they could not be merged, and perhaps I had the wrong impression, but if the advice is that we merge data sets, the subcommittee might need to be a little more specific to help the agency.

MR. GARRETT: Thank you, Madam Chairman. I think that's not quite correct. There were disparate data sets that we have looked at, and understanding the data was collected specifically to answer different questions by the different -- whether it might be ARS or APHIS or FSIS. But I think the point simply is, there is a great deal of data existing within the agency, they could be eclectically cherry picked to answer specific questions, is one issue.

Second issue is the -- and I think what we're

truly recommending here -- is that FSIS put together a team, depending upon what questions you want answered internally, to take a look at some of -- and my agency has the same type issue dealing with fishery management issues. But secondly, also, in terms of the data -- and we're not done with the data -- let me explain that -- but even the data that FSIS collects itself, such as the set A data that through your performance standard -- a rural collection of data -- that data, those can also be used, we feel, but we really haven't gone through that issue. We're still looking at the different data sets.

And I do want to compliment, and I'll publicly compliment Dan Engeljohn and the entire staff -- every piece of data that we've asked for has been provided by your agency. Some of it -- I guess we'll be a little more careful of what we ask for -- but nonetheless, all of it is there, and we will be getting around to it. And we've made some preliminary analysis of the data already.

If anybody else would like to join in -- I'd kind of like to get to question two. Question two -- if this is on question one?

DR. TOMPKIN: I think there was another subject that we

kicked around, and that was whether the Agency should consider analyzing some of the samples that are collected for regulatory purposes, such as -- there is a program whereby samples of ground beef are collected and analyzed for E. coli O157:H7 and that's it. And yet, because the samples -- all that energy has been placed into collecting acceptable samples, and those could also be analyzed, for example, for Salmonella or other pathogens so that these relationships could be developed if they do exist. That was another thought that was discussed. And it's a question as to whether that's clearly stated in the text.

MR. GARRETT: I think probably it's not. We can certainly -- I'm certain that Bruce can clear that up for us and write some transitional words.

DR. WACHSMUTH: just as a point of clarification. I think for four or five years, the Agency looked at generic E. coli quantitatively in those 157 samples to see if there were correlations. It appears that the method for 157 is so much more sensitive that you could have 157 present and no E. coli, which sounds impossible, but it occurred. That those data -- and they're here, but they weren't considered very helpful. You're right, those are

exactly the kinds of things that your recommendations would be helpful to the Agency and how to treat those things.

MR. GARRETT: Moving on to question two. Remember we broke this into three parts. And the foundation wording begins on page eight of the report and concludes on page 11 of the report. Oh, I'm sorry.

DR. DOORES: I'm Stephanie Doores. You prefaced this section by providing the definitions for indicator organism and index organism. In just the cursory reading that we could do in the half hour, it appears that most of your discussion focuses on indicator organism versus index organism. And my question to you -- are you using those terms loosely in here, or is there a situation where you might choose an indicator organism that then becomes an index organism? Or could it be vice versa? Or is it even a possibility that you might have an indicator organism and an index organism for the same types of products?

MR. GARRETT: Two points. One, we hope we're not using them loosely, although I can assure you that we may have made an error, but I don't think so. The second point is that I think in answer to your question, it's all the above -- the three possibilities

do exist. However, Dr. Buchanan or others who are much more closer to this in these commodities. If we're talking seafood I can comment appropriately, but I think there are possibilities, or such scenarios that you could use all three. Anybody want to add to that? Bob?

DR. BUCHANAN: I think we kept the possibility of being able to develop an index organism open in the discussion, however, the degree of correlation that we've had historically for potential index organisms has been poor at best, and in order to keep these two separate and talk about a practical approach to performance standard using a surrogate, I think we did purposely concentrate on an indicator organism. There is a great tendency to slip back into referring to a correlation between one organism and another, versus one organism to a state or condition that is in some way associated to another. Certainly we would be appreciative if you go back and look at the language, because you're correct, in almost all instances we are referring to an indicator organism, not an index.

MR. GARRETT: There's one -- I can't see that far down. Yes, Balasubramanian.

DR. SWAMINATHAN: On page nine, the last sentence, I think the subcommittee needs to come up with a little more specific recommendation here. "The subcommittee suggests that the data be analyzed to determine if, for example, there is a relationship between frequency or level of E. coli and aerobic ... counter combinations of easily measured indicators and the likelihood of the occurrence of Salmonella within specific population of samples." I think it might be useful to the Agency if we came up with what is acceptable relationship -- define how strong that relationship needs to be in order for that indicator organism or group of organisms to -- to act -- to be acceptable surrogates for the pathogen.

Continuing on the last sentence, "It is suggested that regression analysis be used as one tool to determine if such relationships exist." Is that statement really necessary? Because one could use a multitude of complex statistical methods, why single out regression analysis?

MR. GARRETT: In answer to your first question, the -- we heard a presentation and also reviewed a paper which indicates that there are, in fact, may be some sort of relationship between -- such

as APCs and so forth. So all we're merely indicating is the Agency should take that into account and see if there could be, as an alternative, because that's one of the questions we were asked, if we're going to have alternative indicators what should they be? Well, in order to determine what they should be, there should be a study to determine what they should be.

Secondly, in terms of the issue of the mathematical relationship requirement between the indicator and the presence of a pathogen, could be a scientific decision. It could also be a management decision premised upon what the Agency feels like the acceptable level of protection would be.

Thirdly, in terms -- I agree on statistical -- there are many -- regression analysis and many sophisticated statistical techniques -- that sentence, to me at least, doesn't need to stay.

Have I answered that to your satisfaction? And any other Committee member, on this particular question, if you'd like to weigh in, this would be the time on this question before I move to the next c... question. Bob?

DR. BUCHANAN: Again, this is an instance where we need to be careful to distinguish between

indicator and an index organism, and this is one of those areas probably that needs to be tightened. If we're attempting to establish the quantitative relationship between one organism and another, we're now into the realm of the definition of an index organism. However, we can establish relationships between organisms that are appropriate for an indicator that, taking to account a relationship in terms of either source or attribute, that do not have to be quantitative in their nature.

The classic example would be the relationship between Salmonella and E. coli. Salmonella is an enteric pathogen. It is typically associated, in the case of meat slaughter and meat operations, with a fecal source of -- a fecal contamination source. Likewise, E. coli has long been recognized as a organism that is an indicator of fecal contamination.

Now, if you have a relationship there that is qualitative, it becomes very difficult, particularly when you're down at the low levels that these organisms occur in meat products, to establish a quantitative relationship. And so I -- it's very unlikely that you would be able to establish a index organism type relationship, but you could correlate it to fecal

contamination, a condition or state.

Now, if your primary source of Salmonella in these products was not fecal contamination, that is, it is not associated with the same source as E. coli, then you would question whether or not this is appropriate. And again, it goes back to the establishment of the -- let's see if I can come up with the right page in the report -- starting on the bottom of page eight and going on to the top of page nine -- "The key to establishing this relationship is the fulfillment of these five criteria." If these five criteria are not met, then the likelihood that one organism would be a good indicator of another is not fulfilled and you wouldn't go that far.

So, I would suggest that the section of the -- that you indicated on the bottom of page nine -- this may need to be expanded to indicate that this is not necessarily the quantitative relationship. There needs to be some kind of relationship between the two organisms that fulfill those five criteria.

DR. WACHSMUTH: Spencer.

DR. MADDOX: Yes, Carol Maddox. I had a comment regarding that -- was recently addressed also. The idea of an indicator -- we may not -- because of

the time frame and everything that these documents take to generate -- limit our discussion to an organism. An indicator, a successful indicator, might be evidence of an organism as revealed by something like quantitative PCR, thinking of the future usefulness of this document five, ten years down the road.

The other, more specific comment, in item (c) it refers to a pathogen being used as an indicator, and we may find, once we examine this, that actual better indicators are not pathogens, they might be something like enterococcus or some normal flora that represents fecal contamination in a better sense than limiting our discussion to a pathogen. I guess some of the data that we examined so far has indicated that some of these pathogens have absolutely inverse relationships and be confounding. I think we need to think maybe in terms of a little bit broader interpretation of indicator.

MR. GARRETT: Thank you. In terms of the first, you're indicating that the presence of an organism as opposed to perhaps, a viable cell, through PCR very well may be either now or in the future an indicator.

DR. WACHSMUTH: Spencer, can I go off for one

moment?

MR. GARRETT: I just want to make sure I get this down. And then secondly, though, I think while we're talking about one pathogen for another because that's one of the questions that was asked us. But I certainly agree that we should be thinking global and while we're trying to answer very specific questions, as we craft this general principle and guidelines, as I like to call these, we should be thinking that time is going to march on, so we thought we'd get as much bang for our buck as we can. Peggy? Was that Peggy I heard down there? Who is that, Kaye?

DR. WACHSMUTH: I was. Sorry, a technicality, but an important technicality. We do have scheduled at 11:45 time for public comments. I would like to delay that to continue this discussion until 12:15 and then have public comments. Is that alright with the one person who signed up? Okay, then let's proceed. Sorry to interrupt. Go ahead.

MR. GARRETT: Anybody --

DR. WACHSMUTH: John Luchansky had his --

MR. GARRETT: Okay, John. I'm sorry -- I don't want to say I can't see through Dan because he's a pretty intelligent person --

DR. LUCHANSKY: I just wanted to follow up on Carol's comment. It was some thing I was also to point out on page nine. Sometimes when you give examples -- and we're talking about Salmonella and E. coli, you overlook some other examples that might not be included, and I was just wondering, because I wasn't on the subcommittee, what the thoughts of the Committee were about alternative indicators. So in that paragraph labeled "B", the fourth point from the bottom, "Organisms or classes of organisms" -- I wonder if there were discussions, if we could maybe hear a little bit more about other indicators and what kind of discussions took place about some very general language there about classes of organisms. That would be helpful to me. Or maybe there wasn't.

MR. GARRETT: In actuality, I think there was not much time spent on looking at other classes. This one is just by way of an example. Again, this is not considered the sole possible combination of indicators. There may be, but if other Committee members would like to comment. I mean I can give you several examples other than E. coli as an indicator, for example. Yes.

DR. ACHESON: Yes, could I just try to

respond to that a little bit. We did discuss other issues -- enterobacteriaceae, going beyond E. coli a little bit. There was even some discussion in a sort of sub-subcommittee that we had when we were trying to address this of anaerobes -- maybe taking a genetic approach at anaerobes. That raises other questions in terms of DNA versus RNA, you know, are the organisms alive or dead -- just raises another bunch of questions. But that was discussed, and I think just for the sake of clarity we stuck to the better recognized example, but certainly that needs to be pushed further in terms of what's best.

DR. LUCHANSKY: Maybe just to foreshadow a little bit other alternatives will be considered -- put in some verbiage -- a sentence or two about --like the one you just said, or enterococci or something other than that would be helpful and I would encourage that research should be done ...

DR. BUCHANAN: If I might, again, I refer you to the end of page eight and the beginning, the top of page nine, and while the term is the use of an indicator organism, I think we're open to alternatives to the direct detection of the viable cell. However, I think this needs also to be couched in what are you

using the performance standards for. And so there needs to be a scientific approach relating the condition you're trying to control to the tool that you use to control it, or the indicator in question. So I would say a number of these different components or toxins or genetic approaches are valuable, as long as you, in some way, correlate it to the state or condition you're trying to measure. I would have some concern, for example, in a product where there may be remediation or any microbial treatments to using some of the techniques that cannot adequately distinguish between live and dead cells. You're going to wind up with a situation that gives you a false indication. You have the same problem in a number of entities with any one indicator. Each has its strengths and weaknesses -- again, it focuses on the identification of, I think, the five generic characteristics that have to be fulfilled in order to have one test organism, whatever, be correlated to an attribute that you're trying to measure.

So I think there was an attempt to keep it as generic as possible.

MR. GARRETT: Bruce.

DR. TOMPKIN: Some things may not be crystal

clear in terms of how this is reading. We had one foot the box that said we're writing a principles document that would apply to a variety of pathogens, or, let's say, microorganisms that the agencies may be interested in using as performance standards. So it's not specific to just FSIS.

On the other hand, we did have a charge to deal with Salmonella as a performance standard in ground products, and so we're trying to do both things. And so in some cases we're very broad in what we said, and other cases we're more specific, and it's getting that right balance where we may have had some problems, so if you see something that needs to be modified, let us know, because we want to make this as useful as possible, not just for the near term, but for the longer term. And these indicators may not even be microbial, they could be a chemical analysis of some sort. So we didn't even throw that part in here.

MR. GARRETT: Katie.

DR. SWANSON: Well, I'm not on the subcommittee, but I did sit in on the meeting yesterday just to find out where they were coming from and found they had spent considerable time looking at the principles of how one determines performance standards

and trying to address the specifics of the questions that were asked. But hearing the discussion that has occurred around the table and the confusion related to is it specific or not, probably the subcommittee needs to look very focused on dividing those two pieces out. These are the general principles that you need to apply as an example for the specific task under question. Here are some issues to be concerned. But spend some time looking at that format. Because if this group doesn't get the gist of that, then when it goes out to a broader audience, we won't be able to discuss these things around the table.

MR. GARRETT: David.

DR. ACHESON: Just to respond to that. I think that once the subcommittee broadens into some of these broader questions --

DR. SWANSON: We'll get there.

DR. ACHESON: -- my sense is that that will get taken care of.

MR. GARRETT: I was just thinking, in terms of the formatting and the mechanics, I don't necessarily think we need to reformat it, I think if we take some of these transitional statements --

DR. SWANSON: Exactly.

MR. GARRETT: -- and also put some bridge ... I like to talk about the bridge -- some bridge statements, if you would, I think that would probably correct that difficulty.

Any more questions on two? Swami?

DR. SWAMINATHAN: On page ten, under, I believe it's 2C, "One pathogen can be used as an indicator et cetera --

MR. GARRETT: You'll have to speak up just a little, Swami, sorry.

DR. SWAMINATHAN: Under question 2C, "One pathogen can be used as an indicator of the conditions affecting another" et cetera, looking at the bottom half of that page under "development and analysis of such data to determine through application of regression analysis" -- there we go again -- "or other appropriate methods whether population based relationships can be estimated between classes of microorganisms and the target microorganism should be conducted" -- I'm not sure I understand what you're saying here and how it relates to the question 2C. Could someone clarify this please?

MR. GARRETT: Bob?

DR. TOMPKIN: Well, this is the one I wanted

out. I'm sorry, I'm with --

MR. GARRETT: I'll tell you what this was -- what I would suggest that we do, I had difficulty understanding it too, although frankly, I think I probably do. I don't know if Dr. Rainosek -- anyways, this actually was put in by Dane Bernard and I understand he'll be here, but I understand we can certainly get this clarified, get that clarified, but also, Skip, I think, may be able to help clarify it for us.

DR. SEWARD: Well, it was just my recollection that the discussion surrounding the class of microorganism was taken into account, as I recall, the use of, for example, APC, and that if you had a state or condition that allowed fecal contamination to be present on meat and poultry, chances are that a general class of microorganisms associated with that type of state or condition would be elevated. And it was an opportunity to capture that, that that would allow d, a class of microorganisms to reflect the state or condition that could also then be an indication of the presence of the organism of concern. And I think that's what he was targeting in trying to get at when he raised this and tried to communicate that as to how

you would establish that relationship, what kind of evidence would be necessary in order to demonstrate that.

MR. GARRETT: Is that kind of like the same concept that -- in soil samples for anaerobes you ought to see a lot more spore formers, for example, for different classes of possible pathogens? If you think about that conceptually. I hate to use that particular example, given the time we're in, but -- Bob?

DR. BUCHANAN: Again, I'd like to reflect back on the degree of information that we need to collect in order to make decisions about the adequacy of any particular indicator test. I don't necessarily feel that we have to go to extreme lengths to develop a statistical or regression analysis, or detailed analytical correlation between the presence of one organism or another, particularly when you're in a situation where you're working with a commodity where there have been intervention steps associated with the product.

So, for example, if you've demonstrated through the use of one indicator organism that you get a reduction to a certain performance level, based on say, E. coli, and you know based on the characteristics

comparing E. coli to Campylobacter that you're going to get at least an equal reduction in the organism of concern, I don't think you have to go to a great length to show that you have two survivor curves and they're correlated and the slopes are such and such, et cetera. There is some qualitative data that can be acquired upon which you can make some reasonably informed decisions, and so I think we need to be able to capture not only this emphasis on quantitative data, there needs to be some qualitative decision making when appropriate. We're certainly not going to develop a single indicator and then have a requirement to go out or need to go out and establish for every other enteric pathogen that Salmonella or E. coli or whatever organism indicator you pick is the following mathematical relationship. I don't think that's necessary.

MR. GARRETT: Are there any other comments?

DR. HABTERMARIAM: I have one.

MR. GARRETT: Sure.

DR. HABTERMARIAM: Just wanted to follow what Swami raised. The second time about regression was at issue, but to just make this point. Methodology. It's possible that regression might work, and in fact might

not work. There might be scientific evidence that says that this has been tried. But I was also intrigued as to why that is picked out, especially bothered ... linearity. I'm glad you're not saying linear regression, but regression in general. But if there is scientific evidence, it would really be very useful to actually take that scientific evidence here, maybe in the list of references, but some of these strong statements need to be supported by scientific evidence where that has been available, if that is the case.

MR. GARRETT: Which --

DR. HABTERMARIAM: On top of page ten, and this same question about specifically raising regression analysis.

MR. GARRETT: Well, I thought we would get the regression analysis out of there. We got it out of there before, just say statistical methods or such.

DR. HABTERMARIAM: Same on top of page ten too?

MR. GARRETT: Yes. Yes, we had already agreed, I thought, to get that out. I thought, you know, if we're going to talk statistics, let's just say appropriate statistical methods and make sure you get an appropriate statistician. Any more? I think what

I'd like to do is just to go ahead and take these comments back. We are meeting this afternoon and we'll address them one by one so we can come back on Friday, okay? I would suggest quite frankly that in the interest of time that we skip question three because quite frankly, we're not finished with it yet. The reason being that we still have the data needs, and move into question four, which appears on page 14, and then if we have time for the general text, don't get me wrong, we would like guidance on 13, but time -- so I think it would be helpful to us if we moved to page 14, rationale for development of quantitative numerical -- where are we -- there we are -- quantitative standards ... more technical challenges associated than do qualitative standards and so forth -- and that actually goes from page 14 of the report through page 17. Any comments? Seeing none, I take this without exception. So then that brings us about -- of course my watch is always three minutes fast, but we're fairly close,I think, Madam Chair, to the public comment period.

DR. WACHSMUTH: Spencer --

MR. GARRETT: I'm sorry. Larry, I'm sorry, I didn't see you.

DR. BEUCHAT: Larry Beuchat. Could I ask for

a clarification on question three?

MR. GARRETT: Sure.

DR. BEUCHAT: Since you will be discussing it this afternoon. You mentioned that we need to be thinking globally, and in your slide you did use the word import --

MR. GARRETT: Larry, could I -- if you don't mind, would you indicate the page number?

DR. BEUCHAT: This is on page 11, question three. Does regionality -- can one -- does that imply outside the borders of the US? Isn't it international regionality that we're to be addressing?

MR. GARRETT: I think in -- that's a very interesting question to a fish guy since we import fish from 165 countries and export to 172. But I think in the context of what we're addressing here in this context, we're talking about regionality within the United States, relative to a United States performance standard. So regionality -- the same would be for seasonality and other factors. And in addressing this issue, other than laying down some general text that you see here, we are analyzing quite a bit of data from disparate data bases, from APHIS, from AMS, from FSIS -- actually from industry supplied data. So the answer

to your question is no, it's domestic we're talking about.

DR. BEUCHAT: Thank you.

MR. GARRETT: But as we're laying down these general principles I have to think about fish as well. Madam Chair, I think that concludes -- we'll certainly take these comments back, work diligently and come back Friday to see if we can pass these issues before the full Committee.

DR. WACHSMUTH: Okay, and the subcommittee will meet this afternoon as will the subcommittee on blade tenderization. And let's see, John Kvenberg will chair the blade tenderization. Dr. Murano just pointed out to me that this Committee does report tomorrow at two o'clock. We'll have some discussions, so there is another opportunity at wait a minute -- when was it -- 3:30, sorry, 3:30.

MR. GARRETT: Madam Chairman, it will be at 3:30 that we come back and plan our recession. Tomorrow afternoon.

DR. WACHSMUTH: I will say then we can get an update on what you've done and sort of a status report, if anyone has burning issues, they'll still have a little bit of time. But we can talk about that this

afternoon.

Okay, we do have on the schedule, time for public comments, and we have one person who signed up. Caroline.

MS. SMITH-DEWAAL: Can everyone hear me? I thank you very much, Madam Chairwoman for letting me have a few minutes, and I also appreciate the fact that you are having public comment at a number of times during the Committee's deliberations which allow us to weigh in at the discussion. I think that's a good practice. I'm Caroline Smith-DeWaal. I'm Director of Food Safety for the Center of Science in the Public Interest, and I've attended both some of the subcommittee meetings on this issue as well as this morning's discussion.

I truly appreciate the deliberative process the subcommittee is going through, and I think I benefit greatly by their chairman, but also by the powerful team that they have on this issue. And I appreciate the fact that they're trying to strike up general principles to cover a number of different commodities. But I think they fall a little short because we're really not working from a blank slate. With the recent court decision in Supreme Beef, there was an increased urgency for this Committee to guide

the Agency on actions with respect to the Salmonella performance standards. And you had some questions, I noticed, Spencer, on page two, on the background where the Agency specifically asked for guidance. But the document itself doesn't contain those questions, nor does it contain answers to them.

What is your plan for getting answers to those questions?

MR. GARRETT: Thank you Caroline, perhaps in going through the document and ending at question four on this, led you and perhaps others that we're not finished, that we do intend to answer those questions. We intend to answer the questions that were provided to us in the letter from the Under Secretary and Kaye Wachsmuth as well, specifically addressing those issues, and I think that we indicate that we do have a priority -- indicated on page 17 of the document -- indicating the priority manner in which we're going to complete our deliberations, and those questions are included.

MS. SMITH-DEWAAL: And I appreciate that you're deep in the forest, but -- and you're looking at all the trees, but I think the Committee really needs to keep its eye on the whole picture here and the fact that there is a

very critical and urgent issue related to the Salmonella performance standards and that applicability with respect to ground beef and potentially other ground product.

MR. GARRETT: Yes, just let me say that's the next priority after we finish these three questions today, d we address the questions, d the data, then the rest of the comments.

MS. SMITH-DEWAAL: And will that come up before the end of the week?

MR. GARRETT: Will that come up in terms of what?

MS. SMITH-DEWAAL: Discussion of the full Committee.

MR. GARRETT: Probably not.

MS. SMITH-DEWAAL: Okay. I just want to give the Committee some thinking points with respect to that. I think the Salmonella performance standard has demonstrated significant reduction in Salmonella in meat and poultry products following the implementation of the pathogen reduction HACCP final rule.

Clearly the Agency could design a performance standard differently, but the question is, that the Committee really needs to answer, is could they do it better? You're looking at issues about qualitative

versus quantitative standards, regional and seasonal variations, risk assessment versus baseline -- these are all differences. You could do it differently. But what -- would they offer and what kind of public health improvement would these offer? Especially when considering delay of doing a formal risk assessment, or cost of doing qualitative -- excuse me, quantitative versus qualitative testing. I mean these things -- perhaps the Committee doesn't deal with them, but delay and cost are things the consumers pay for. And the taxpayers pay for. And so those become very critical elements.

So, can you do it -- we know you can do it differently. Can you do it better considering issues of timing, and cost?

The performance standard must do more than demonstrate control, and I really do appreciate the subcommittee's conclusion on slide four, that it is -- the performance standards are a valuable tool, and I think that is a good solid statement. Except it doesn't include the word "public health" in it. And we would like to see performance standards that demonstrate process control, but that also accomplish a visible public health objective, like reduction in

Salmonella in meat and poultry products. That's a visible public health accomplishment that we can -- we can show consumers, and the government can demonstrate.

The risk assessment process is clearly the gold standard, but how long is it really going to take? I've been working and attending meetings for the risk assessment for E. coli 0157H7 in ground beef for -- I'm trying to remember, is it five years? Is it six years? I can't even remember it's been so long. And we are just at the stage of getting a risk assessment which we have significant concerns with. It's now being reviewed by the National Academy of Sciences. So we're not even close to having a final risk assessment after five to six years.

Consumers can't really afford these lengthy delays. I mean there are urgent needs for performance standards not only for Salmonella in meat and poultry products, but for Listeria in ready to eat products, for Campylobacter in poultry, and for E. coli 0157:H7 on beef carcasses, as well as performance standards in seafood, produce and other areas. So can we really afford a ten to 20 year process of risk assessment and the incredibly comprehensive process outlined in this document? You may think it's easy, but we know from

watching these risk assessments, it's taking much too long, as I am as well.

Let me just wrap up. We think that the Committee should recommend the use of baseline data during the time period that any risk assessments are being conducted. So if you plan to do risk assessments at all, don't leave the risk managers without a tool. You should encourage the risk managers, or in fact endorse the risk managers using baseline data to set performance standards, and then during that time period the risk assessment could progress. It's going to take five to six years anyway, so let's not leave consumers without protection during that time.

And just to conclude, we really think that the Salmonella performance standard has been successful, and the use of baseline data could clearly now be upgraded and modernized, based on data that the Agency currently has, but that the Committee should encourage and recommend the Agency to proceed with using existing baseline data to modernize these standards. Thank you.

MR. GARRETT: If I can -- Caroline, those are stimulating remarks. We'll certainly take each and every one of them under consideration, and particularly

the last comment that you made.

DR. WACHSMUTH: Thank you. We have another.

DR. FORMAN: I'm not on the list. May I make a comment?

DR. WACHSMUTH: Fine, it's open.

MS.TUCKER FOREMAN: Carol Tucker Foreman from Consumer Federation. I want to associate myself with Caroline's remarks, particularly those about the urgency of this Committee moving forward to some conclusions and leaving the government the ability to act in the interim using the existing baseline data is terribly important during this time. Most of us eat three times a day. If you want us to continue to eat meat, ground beef particularly, there has to be some assurance to the public that that symbol on meat and poultry products that says USDA inspected and approved has some meaning. And that meaning has to be one that's related to public health and to the level of public health to be desired and achieved.

I appreciate very much the process that you're going through here with regard to determining the scientific basis for making some of these decisions. I think it will add enormously to the strength of the decisions that USDA makes, as long as

the bottom line is that this is a public health program and that those standards have to be ones that will assure us a reasonable level of public health protection.

In that regard, in the end, the Department will have to make risk management decisions, after they get all your data, they will have to make risk management. They will have to decide how much of this is the responsibility of the producer and processor, how much is the responsibility of those who consume the products. It might be useful if, in answering the questions, and I would say particularly question three, that you make your recommendations to the Department and list some of the alternatives that they might address in terms of making risk management decisions. If you determine that seasonality and regionality are in fact variables, whose responsibility is it to control those factors? I can't control them as a consumer. Is it -- should we have a standard that says that those people who live in parts of the country, or during those parts of the year when there's a particular problem with meeting the seasonality/ regionality standards, is it then the obligation of the processor to take additional steps in order to meet a

public health goal?

I would urge that generally you would think about what the risk management decisions are that arise from your recommendations, and particularly with regard to question three. Thank you.

MR. GARRETT: Carol, thank you, as chairman of the subcommittee for those comments.

DR. WACHSMUTH: Any other comments from anyone in the public or of the Committee? John.

DR. KVENBERG: Thank you Madam Chair. Just a question of process for this afternoon, since we've run a half hour late, we beseech our subcommittee members to meet at 1:30. We have a lot of ground to cover, especially on the blade tenderize group. I'm sure that the other group does too.

DR. WACHSMUTH: Same for you, Spencer? 1:30?

MR. GARRETT: Okay.

DR. WACHSMUTH: Okay, let's take a lunch break.

(Whereupon, at 12:30 p.m., the meeting in the above captioned matter was adjourned, to be reconvened in subcommittee meetings this afternoon at 1:30 p.m.)