UNITED STATES DEPARTMENT OF AGRICULTURE

NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS

In the Matter of:

FULL COMMITTEE MEETING

Pages: 1 through 182

Place: Chicago, Illinois

Date: May 28, 1999

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BEFORE THE

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George IV Room
Ambassador West Hotel
1300 N. State Parkway
Chicago, Illinois
Friday,
May 28, 1999

The above-entitled matter came on for meeting, pursuant to notice, at 8:00 a.m.

BEFORE: KAYE WACHSMUTH
Chair

P R O C E E D I N G S

MS. WACHSMUTH: This is a slightly delayed welcome to Chicago, and a very sincere thank you for your commitment to food safety and to working with this committee.

I think we are in a very enviable position in the food safety community of seeing some progress, some progress in pathogen reduction in foods: *Salmonella*, *Listeria*, over the years, and correlated reduction we hope in some foodborne illnesses. There's even a slight indication in FoodNet data that we may be seeing that for *Salmonella* and *Campylobacter*.

But I think everyone here is very well aware of the other side of the coin, that we have much more to do and it may be even more difficult than what we've had to do before. We had a wake-up call with the *Listeria* outbreak. *Campylobacter* continues to be number one in the third year of FoodNet incidence accumulation of data. And we have some very challenging food vehicles available to us, like sprouts, so I think it's pretty obvious that we're going to continue to need the advice and the scientific expertise that this committee brings.

Now, the committee's been relatively stable since our meeting in February, but we've had some significant

changes in the sponsoring agencies, and I just want to run through some of that with you. Number one, Dr. Morris Potter is now officially with FDA and is the co-chair today of the meeting, and we do have a new member from CDC, Dr. Arthur Liang. We welcome you. This is Art's first meeting. He's been with the steering committee and has participated in some of the planning for the meeting.

Dr. Richard Ellis, who was the executive secretary, is happily going for a one-year assignment to the Food Agriculture Organization in Rome, where he'll be working with JECFA and other food safety expert groups. We've also lost another member of FSIS and the committee, and that's Dr. Ann Marie McNamara. Ann Marie has joined the Sara Lee Corporation as Vice President of Food Safety and Technology, and will begin there -- or did begin there on the 24th of this month. She joined FSIS and the committee in 1992 and made some very valuable contributions, so we wish her well and continued success in her new position.

And stepping in for Ann Marie, into the fray, is Dr. Daniel Engeljohn, who is the Director of Regulations Development and Analysis Division at FSIS. He is from what we call the policy side of the group, but he's also a very good food scientist. And I think those of you on the Meat and Poultry Subcommittee were able to experience his

leadership and hard work over the past few days, and he'll be with us on an interim basis at least. But welcome, Dan. And I've saved some of the best news for last, that is, we have a new executive secretary and a very able support staff for this meeting. And Dr. Karen Hulebak to your left is the first Chief Scientist for Food Safety and Inspection Service, and she's in the office of Public Health and Science. Until she came with us, Karen was the director of the policy research staff at FDA in the commissioner's office, and as such, she was the primary author of the first document for the Food Safety Initiative. So she's very aware of most of the issues that we'll be discussing -- are discussing now.

And Karen comes with a very strong background in risk-assessment and public health and is already making some invaluable contributions both at the agency and I think you'll agree to the working of the committee.

So I'd like to turn it over to Karen for a few minutes.

MS. HULEBAK: Thank you, Kaye, for those very, very kind words. Really, all I have to say is thank you to this committee for serving over the last couple of days as, I think, the hardest working most thoughtful, dedicated committee I have ever worked with, and I've worked with a

lot of committees. So congratulations to all of you. That's the first priority

The second priority is to thank team of people who worked with me to make this committee work. First I'd like to mention Mary Harris, who is immediately behind John Kobayashi at this moment. Thanks, Mary, very much. Working with Mary, working very hard, is also Shavonne Morris, who's been sitting out at the registration table -- I'm sure virtually all of you've talked with her at one point or another during the meeting -- Brenda Halbrook and Jacque Knight.

These folks have worked long and hard and have been really dedicated, and I hope you felt they served you well. But I certainly thank them a great deal.

Again, to follow up on an announcement that Mary made yesterday, we really want to help the committee make your travel reimbursements run smoothly, and I think Mary is planning to meet with anyone who wants help filling out travel vouchers today between noon and 3:00. So please come out to the desk and seek whatever help you need.

I'm delighted to be working with this committee. I don't know for how long I will be working with the committee because Kaye has many plans for me in the Office of Public Health and Science. But I've loved it so far and

I'll enjoy it as long as I can. So thank you very much.

MS. WACHSMUTH: Thank you.

Now, I think we'll go around the room quickly, because we do have quite a bit to get through today. First would be co-chair, like to say a few words?

MR. POTTER: Sure. Always shy and reticent -- I'd like to add my own and FDA's welcome and thanks to the committee. The committee has tackled a number of very difficult issues that are very important for FDA, and we value the input of the committee a great deal. So thanks a bunch, look forward to a good meeting today.

MS. WACHSMUTH: Let's just go around. If you could do your name and affiliations.

MS. JACKSON: Lee Anne Jackson, FDA, Center for Food Safety and Applied Nutrition.

MR. RUSSELL: Leon Russell, Texas A&M University.

MS. NEILL: Peggy Neill, Brown University School of Medicine.

MR. GROVES: Mike Groves, LSU School of Veterinary Medicine.

MR. LONG: Earl Long, CDC.

MR. OSTERHOLM: Mike Osterholm, Infection Control Advisory Network.

MR. ROBACH: Mike Robach, Continental Grain.

MR. ACHESON: David Acheson, New England Medical Center Tufts University.

MS. DOORES: Stephanie Doores, Penn State University.

MS. DONNELLY: Catherine Donnelly, University of Vermont.

MR. TOMPKIN: Bruce Tompkin, ConAgra.

MR. DOYLE: Mike Doyle, University of Georgia.

MR. BERNARD: Dane Bernard, National Food Processors Association.

MR. SEWARD: Skip Seward, McDonald's Corporation.

MS. HARDIN: Margaret Hardin, National Pork Producers Council.

MR. EKLUND: Mel Eklund, Mel Eklund and Associates.

MS. O'BRIEN: Allison O'Brien, Uniform Services, University of the Health Sciences, Bethesda, Maryland.

MR. FARRAR: Jeff Farrar, California Department of Health.

MR. KVENBERG: John Kvenberg, Food and Drug Administration.

MR. ANDERS: Jim Anders, North Dakota Health Department.

MR. KOBAYASHI: John Kobayashi, Washington State

Health Department.

MR. SVEUM: Bill Sveum, Campbell's Soup Company.

MS. SWANSON: Katie Swanson, the Pillsbury Company.

MS. RUPLE: Angela Ruple, National Marine Fisheries Service.

MS. NAGLE: Nancy Nagle, Nagle Resources.

MR. BUCHANAN: Bob Buchanan, Food and Drug Administration.

MR. JAHNCKE: Mike Jahncke, Virginia Tech.

MR. LIANG: Art Liang, CDC.

MR. SEVERIN: Scott Severin, Department of Defense.

MS. WACHSMUTH: Okay. I notice that the left-hand side of the table didn't learn to unhook these mikes. You may have to do that during the discussion. We don't have too many down either side.

Okay. The first thing that we need to do is adopt the minutes from the last meeting. And what I'd like to suggest is if anyone has small editorial comments -- I know there is at least one -- that if you could just give those to Shavonne Morris outside at the break, we'll make sure that we make those amendments.

Now, if there's anything substantive or any

corrections anyone has, or a motion to adopt.

MS. SWANSON: Move to approve the minutes.

MS. WACHSMUTH: Okay. If there are no objections -- now, what I'd like to do is turn the mike over to Dr. Potter to begin work on our first task, which is to approve the sprout document.

MR. POTTER: As I said before, FDA counts heavily on the committee to answer difficult questions, and a good example of that is the sprout document that the Produce Subcommittee of the National Advisory Committee has worked so hard on.

During our last meeting, the penultimate drop was discussed in great detail, and the Produce Subcommittee has now responded to those comments and is presenting its final -- I'd like to ask Bob Buchanan, the chairman of the Produce Subcommittee, to lead us through the highlights of those changes so that we can expeditiously move forward.

MR. BUCHANAN: Thank you, Morrie.

Just to give you a little history on this document, to remind you where we've been on it, for some of the new members that have only had to deal with it for a short amount of time, as part of the original produce document that the committee put out about a year ago, there was a section on sprouts, identifying it as a special

problem. Approximately two years ago, FDA having seen the original draft of the produce document that was approved from this committee, they had put in a request that we do an expanded evaluation of sprouts, particularly since the activity in the sprout area was changing rapidly.

The committee, working over approximately the last two years, the produce working group, has gone through the scientific literature on sprouts and developed the following white paper. Originally, it was going to be called a mini white paper, but anything that's bigger than a half inch, I don't consider mini anymore. So there is a rather detailed evaluation.

The Produce Working Group and other members of the committee have also had extensive investigations, including field trips, and we've learned a great deal about the sprouts and sprout industry. And I would like to thank, before we go any further, all the hard work on the part of the working group and the people that were involved in it, particularly some of our technical advisors, Larry Beuchat from the University of Georgia and Michelle Smith from FDA.

We did do an in-depth evaluation of the document at the last meeting. There were a series of changes that were recommended, particularly in the areas of the findings and the recommendations that came out of it. The document

has been circulated to all of you for your review. What we would like to do today is to do a final review of this document and finalize it at this meeting.

We are -- if you have changes or recommendations of an editorial nature, we would prefer that these just be provided directly to the secretariat or to Michelle Smith, and we will deal with those individually, hoping that the committee will accept our ability to work with that document in that way. What we would like to do is take over a limited time today to concentrate on any issues of substance that need to be discussed and finalized before we finalize the document.

So with that, I'll turn it back over to the chair, and we would be happy to have any discussion and go at it.

MR. POTTER: Why don't we try to go through this for your substantive comments, section by section. The document itself is behind Tab 5. I think -- well, there is an executive summary and an introduction. Do we have general comments on the document as a whole or on the introduction?

(No response.)

MR. POTTER: Okay. Seeing none, why don't we go then to the sprout-associated outbreaks? That section

starts on page 6 and runs to 15, ending with the summary perspectives gained from outbreak investigations.

Jeff?

MR. FARRAR: Thanks, Morrie. The first couple of comments are not substantive but I was asked to raise them in committee. A couple will be -- at page 9, under the Montevideo and Meleagridis outbreak, the first line says over 500 culture-confirmed cases. That should be changed to approximately. I think the number was 495. The bottom line on page 9, item number 1, says use of chicken manure to fertilize the fields before planting. Before planting should be stricken. The manure was used throughout the life of the alfalfa crop.

And then following that, on page 10, items 4 and 5 should be combined into one item to state, presence of livestock next to the alfalfa field.

MR. POTTER: Could you repeat that last statement, Jeff?

MR. FARRAR: Sure. On page 10, at the top, items 4 and 5 should be combined into a single item 4 that says, presence of livestock next to the alfalfa field.

MR. POTTER: Okay. Thank you, Jeff. Other comments?

MR. FARRAR: Yes. On page 12, under the

Salmonella Mbandaka outbreak, the number of California cases should be changed to 20 from 7, therefore the total should reflect 75 cases.

MR. POTTER: Okay.

MR. FARRAR: About four lines down, the sentence that starts with, a single lot of seed, that sentence should be modified to insert, grown in southern California.

MR. POTTER: So it's the single lot of seed that was grown in California?

MR. FARRAR: Correct.

Immediately preceding that sentence, Morrie, this needs confirmation with Bill Keene in Oregon, but I'm virtually certain that's the case, that this single Washington sprouting facility was not disinfecting the seeds, or disinfection of the seeds could not be confirmed at that facility. But that needs confirmation from Bill Keene.

MS. SWANSON: Isn't that covered in table 3? Table 3 identifies different sprouters and whether or not they were -- which is way the heck in the back -- whether or not they were using chlorination.

MR. POTTER: That's in page 60?

MR. BUCHANAN: That's fine. If it's reflected in the table, perhaps it doesn't need to be included in the

text. But it is a very important point that we're learning more and more about.

MS. SWANSON: I have a comment related to that. It's related to the same topic. The table on page 60 does identify which sprouters were chlorinating and which were not, but it doesn't identify which sprouters were associated with cases. And I think that if an extra column were added, that would tie the whole thing together.

MR. POTTER: I think on the table on page 60, all of these sprouters were associated with Mbandaka.

MS. SWANSON: No. That's why I think it'd be useful to add an extra column. And the title of the table may be misleading then.

MR. POTTER: Okay. Bob, did you pick up on the -- okay. We'll change the title of the table and add that column.

MS. SWANSON: Okay. Sorry, Jeff.

MR. FARRAR: Thank you, Katie.

Further down in that same paragraph, on the Mbandaka outbreak, there's a sentence that says two of the California sprout producers used a 20,000 ppm calcium hypochlorite seed treatment -- seed pre-soak. On further investigation, we need to modify that sentence to say, two of the California sprout producers used calcium hypochlorite

seed treatment ranging from 2,000 to 20,000 ppm before germination of the seeds.

We actually went back to those facilities, had them recreate the seed disinfection treatment. We measured the volumes and at least one of those was using something less than 20,000.

MR. POTTER: Will that require the table to be altered as well, Jeff?

MR. FARRAR: Likely, yes. I don't have the table in front of me.

MR. POTTER: Okay.

MR. BUCHANAN: Jeff, does that also indicate that we need to combine the sentence -- combine this sentence with the one next to it?

MR. FARRAR: No. What I was thinking of, Bob, was using the next sentence to say the third California was apparently not using a chlorine treatment for seeds. And we'll have to make this consistent with the table.

MR. BUCHANAN: Okay.

MR. FARRAR: The last line then, Morrie, would say only the facilities that did not pre-treat seeds were linked to the *Salmonella* Mbandaka infections.

MR. POTTER: Okay. Thank you, Jeff. Is that the extent of your comments?

MR. FARRAR: Yes.

MR. POTTER: Okay. Other comments on that section?

(No response.)

MR. POTTER: Okay. If we can then turn to page 16, if we start the microbial ecology section, and I think that runs to page 34. To page 24. So comments on pages 16-24 -- Katie?

MS. SWANSON: On page 22, at the first line, this is talking about *Listeria monocytogenes* and the potential for it to grow on sprouted seeds during refrigeration. This is true, but it can also grow on other produce so sprouts are really no different.

I would recommend adding, at the current time, there's no information that it could not grow on sprouted seeds and other vegetables during refrigeration, to point out that it's a similar situation.

MR. POTTER: How does the subcommittee respond? This is a document about sprouts. Do you --

MS. SWANSON: Yes. I only bring it up because earlier in this section it says that sprouts present a unique situation because of the growing phase of the sprouts allows for proliferation of the organisms. So this paper was only supposed to address those specific issues that are

related to the unique part of this amplification step.

I think it is entirely likely that *Listeria* could grow during the sprouting process, but once it goes into refrigeration the extra growth that could occur is no different than other produce. And so -- but we can't ignore the organist. It --

MR. POTTER: Okay. Bob?

MR. BUCHANAN: Katie, I don't quite understand, because the first part of that sentence specifically states, "It can grow on a wide range of foods of plant and animal origin at low temperatures, and there is no reason at the current time to assume that it could not grow on sprouted seeds during refrigerated storage."

Am I not --

MS. SWANSON: Okay.

MR. BUCHANAN: Doesn't that capture the thought that it will grow on a variety of foods?

MS. SWANSON: Yes.

MR. POTTER: It is an important point you bring up, but does the first part of the sentence take care of that concern?

MS. SWANSON: I think this group understands that. I'm just wondering about the broad communications. This is going to be read by a number of other people that

might not be able to take that subtlety, and adding this does clarify it. So I leave it up to the determination of the committee.

The same thing occurs for the *Yersinia enterocolitica*, because the last line says the same thing, it can grow in the refrigerator. Well, it could also grow during sprouting, and that's really the issue that is unique to sprouts. So I'll leave it up to the discretion of the committee whether that clarifies or isn't needed.

MR. POTTER: Okay. Peg?

MS. NEILL: I think Katie's point is quite pertinent, and I would point out for the full committee that part of the effort in the redraft was to focus this paper on, it's the amplification step, stupid. And that this was really the main thrust to try to bring out again, over and over, why sprouts are different, why they're not just like other produce.

So I would offer -- Katie and I will wordsmith something that tries to tie it back, because this wording sort of says it but not, I think, as hard enough as it should.

MR. POTTER: I appreciate that offer from Peggy Neill and Katie Swanson to structure an additional phrase there. I think that will be a useful introduction.

Other comments on this section?

(No response.)

MR. POTTER: Okay. Then let's move to page 24, current industry practices, and unless Bob corrects me again I will assume that that ends on page 34.

Comments on current practices?

(No response.)

MR. POTTER: Okay. Let's go then to page 34 through 49, prevention and intervention strategies for pathogens on seeds and sprouted seeds. This document was well-discussed during the last meeting, and I think that the draft we have in front of us reflects that discussion, so there shouldn't really be a lot left to chew on here, providing Dane continues to behave.

Okay. The findings and recommendations, starting on page 50 through 57, and the text in front of the tables.

Kate?

MS. SWANSON: Recommendation 4c indicates -- and that's on page 54 at the top of the page -- indicates the testing should be used when less than 5 log reduction is achieved. Recommendation 5c uses the term, requires testing, so I think we should have a discussion about consistency, whether we should recommend requiring or just recommend testing when the 5 log reduction is not achieved.

MR. POTTER: Okay. Let me read recommendations 4 and 5 and 4c and 5c, so that we can -- we're all starting from the same place.

Recommendation 4 is that seeds should be treated with one or preferably more than one treatment that has been shown to reduce the level of pathogenic bacteria on seeds. 4c amplifies that to say, "Based on currently available data on quantitation of pathogens and seeds and achievable reductions, seeds should undergo a combination of treatment strategies that will achieve a 5-log reduction in the levels of *Salmonella* species and enterohemorrhagic *Escherichia coli* 0157. This recommendation should be reevaluated as additional data become available. Intervention strategies that deliver less than a 5 log reduction should be coupled with microbiological testing of sprouts or spent irrigation water."

Recommendation 5, "The microbiological safety of sprout production could be enhanced by" -- and then part c is, "Require the use of validated microbiological assays to test sprouts or their irrigation water prior to harvest for pathogenic bacteria (see recommendation 4c)."

Okay. Dr. Buchanan, would you like to explain how that was drafted?

MR. BUCHANAN: Yes. That was based on the

discussions that we had at the last meeting, where it was felt that if you could not achieve a certain degree of inactivation in your prior treatments, that it would be not only advisable but it should be required to test the seeds prior to having them -- or test the sprouts prior to having them released.

There was discussion on what degree of treatment would be needed before you would recommend requiring microbiological sampling prior to release. It was generally agreed that a 5d would be appropriate for pre-germination seed treatments. What we tried to do is capture and link these two so that the two recommendations should be complimentary. They should not be separate. So it would read better -- probably recommendation 4c would be required to be modified, then that would be appropriate.

MR. POTTER: Could you offer that modification so that the group could pass judgement on it?

MR. BUCHANAN: I would suggest that the word in 4c, coupled, just be replaced by required.

MR. POTTER: Comments? David?

MR. BUCHANAN: Yes. We're going to have to reword it. Intervention strategies that -- for intervention strategies that deliver less than a 5 log reduction, microbiological testing of sprouts or spent irrigation water

should be required for intervention strategies that deliver less than a 5 log reduction.

MR. POTTER: David?

MR. ACHESON: Just a point of clarification. On page 16, when we're talking about the microbiological load on seeds, there were a couple of studies where there were 9 times 10 to the fifth, and another one with 3 times 10 to the seventh. Is a 5 log reduction going to be adequate?

MR. BUCHANAN: These are treatments of the seeds prior to germination, so it would be -- and the best data we have now on pathogens is -- the worst case we've seen to date is the *Salmonella* Mbandaka case that had -- and, Jeff, you're going to have to correct me -- I think it's two viable *Salmonella* per 100 grams of seed is the highest level we've ever identified in an outbreak.

Jeff, can you --

MR. FARRAR: Sure. That's true. We called yesterday back to the lab. We just finished the results on the Mbandaka implicated seed. There are two methods of analyzing the seed. One was a dry shredding technique of the seed. The other was an aseptic sprouting in the laboratory and then testing the sprouts. Both yielded similar quantitative results in the range of 2 CFU per hundred grams of seed. The maximum 95 percent confidence

limit included six, so a maximum of six was as high as we were able to detect.

The unusual thing about this lot of seeds was that we were able to isolate a pathogen from virtually every lot of seeds that we tested, so it appeared to be a very uniform level of contamination.

MR. POTTER: Does that take care of it, David?

MR. ACHESON: Yes.

MR. POTTER: Bob?

MR. BUCHANAN: Yes. I was going to say, the point is, is while there may be higher levels of just general bacteria on these seeds, these levels of pathogens that we've been able to find reported in the literature have been consistently extremely low.

MR. ACHESON: Would it be possible to state that in here?

MR. BUCHANAN: I believe it's stated in several places within the body.

MR. ACHESON: Okay.

MR. POTTER: Okay. Other comments on this section?

(No response.)

MR. POTTER: Okay. Table starting on page 58 -- we've already agreed that we would make some modifications

to the table 3 on page 60 to reflect the new information that Jeff presented.

Comments on the figure on page 61 and 62? Nancy?

MS. NAGLE: On page 62, on that flow chart, we have that place there where it goes from draining to cooling, and I don't think that that's done in every facility and I don't know how we want to talk about that in sprout production. I don't they are always necessarily cooled before they are packaged.

MR. POTTER: Okay. How does the text read --

MS. NAGLE: In the --

MR. POTTER: -- for that reference? Bob, do you recall?

Michelle? With the committee's permission, Michelle Smith will address that.

MS. SMITH: In the text that refers to those figures, there's a statement that says these figures represent the general flow process. It's not followed at all establishments for a number of different reasons. So this is an example of common practice but not everyone uses it.

MS. NAGLE: Okay. Maybe could we just put a footnote on the -- take that and put it as a small footnote on the table, so that it's not assumed that this is the

flow. We could just take it out of the text --

MR. POTTER: Perhaps both figure 1 and figure 2 could in their titles say, generally used seed production process in sprout production process, words to that effect.

MS. NAGLE: Yes.

MR. POTTER: Bruce?

MR. TOMPKIN: Typical.

MR. POTTER: Okay. Is that acceptable -- those changes acceptable to the committee? Okay.

If we could move then to the appendices. Jeff?

MR. FARRAR: Comment on appendix 3, if no one has anything before then.

MR. POTTER: We'll go to appendix 3 if you'll tell us what page it is.

MR. FARRAR: Page 90. Sorry.

MR. POTTER: Go ahead.

MR. FARRAR: The second sentence should be modified to reflect the new findings from the Mbandaka investigation. I propose that sentence be modified to state, quantitative analyses performed on seeds associated with illness attributed to sprout production found pathogens ranging from less than 1 per 100 grams to 6 per hundred grams on seed.

MR. POTTER: Okay. So that sentence will be

slightly modified to read quantitative analyses performed on seeds associated with illness attributed to sprout consumption found pathogens ranging from less than 1 to 6 per hundred grams of seed. Is that correct, Jeff?

MR. FARRAR: Yes.

MR. POTTER: Okay. Is that acceptable?

(No response.)

MR. POTTER: Okay. Other amendments to the appendices. Katie?

MS. SWANSON: No.

MR. POTTER: No? Okay. Had this been an auction, you would have just bought something.

Okay. Well, where we are then is, we've passed through the document. We have one modification that still needs to be crafted that will probably be five words or less from Peggy and Katie. Does the committee feel comfortable with approving the document as amended here with those additional changes yet to be made?

MS. WACHSMUTH: Okay. Are there any objections?

(No response.)

MS. WACHSMUTH: It's passed. That was very good work.

MR. POTTER: The final document will be published in the International Journal of Food Microbiology.

MS. WACHSMUTH: Okay. We just -- I'm wanting to pop the champagne bottle over here. What we'll do now though is take advantage of the time and move to some new documents that the committee has not seen before. This was some work that was done on Wednesday in the Meat and Poultry Subcommittee, and we'll have Dan Engeljohn lead us through it.

But before I turn this over to Dan, we have two different documents that we're reviewing: one the committee's been working on for been working on -- the subcommittee -- and that's advice on identification of hazards for very small meat and poultry plants. The other document is *Campylobacter* -- reviewing potential standard for that pathogen, and that was referred to this committee by another advisory committee for FSIS, and that is the Meat and Poultry Inspection Advisory Committee.

And we do have some members here today. Margaret Hardin has served on that committee. Were you present at the meeting where this -- okay. Well, possibly we could have some help from the audience if we have some folks here from that committee. But I'll turn it over to Dan, who will take us through those two document.

MR. ENGELJOHN: Good morning. Thank you for the opportunity.

I'm going to start with the *Campylobacter* performance standard issue, and I believe all of you should have gotten a summary of what the committee dealt with on this issue. And then when we complete that, then I'd like to move on to the hazard identification guide. I have a few overheads that I'll just run you through first.

The charge actually for dealing with the *Campylobacter* performance standard came from the National Advisory Committee for Meat and Poultry Inspection Subcommittee. And their specific request was that the National Advisory Committee for Microbiological Criteria for Food evaluate and recommend back to the Meat and Poultry Inspection Subcommittee the options for defining *Campylobacter* performance standards, for example, quantitative versus qualitative, and alternatives to a *Campylobacter* performance standard that accomplish the same public health objective.

That is the specific charge that came forward, and then I in my new capacity took the liberty of trying to break this out into maybe three specific issues that we could deal with the kind of tease this apart within the subcommittee. And what we saw to be the three issues that would address the charge from the Meat and Poultry Inspection Subcommittee were what is the relationship

between *Salmonella* and *Campylobacter*; what are the technical microbiological impediments to setting a *Campylobacter* performance standard; and should FSIS have a *Campylobacter* performance standard, or is there an alternative that would achieve the goal of prevention or reduction of a foodborne illness caused by *Campylobacter*? So I believe those three issues got us to the same charge that the Meal and Poultry Inspection Subcommittee presented to us.

You have a more complete summary of the findings and the recommendations and conclusions of the Meat and Poultry Subcommittee. I'm going to just generally state them here and then certainly entertain fuller discussion from the full committee on the specifics. But in terms of the conclusions, what is the relationship between *Salmonella* and *Campylobacter*? It was the subcommittee's finding and recommendation and conclusion that the relationship of intervention treatments is not known at this time, so it's a general statement of what we found.

With regard to what are the technical microbiological impediments to setting a *Campylobacter* performance standard, some of the issues were that the agriculture research service methodology for quantitating *Campylobacter* is not yet ready. My understanding is that it will be soon, but it's not yet ready at this time. And the

current methodology is expensive and I would assume to be rather difficult to perform. And then as well, there is an incomplete data base of the association of the organism with poultry.

Should FSIS have a *Campylobacter* performance standard, or is there an alternative that would achieve the goal of prevention or reduction of foodborne illness caused by *Campylobacter*? It's premature for FSIS to adopt such a standard, and an alternative indicator organism may accomplish the objective of reducing foodborne illness but we were unable to identify what that alternative would be.

Those are the conclusions on that issue. Now, they're certainly was a great deal of debate and discussion. We had a presentation by Geri Ransom from the agency who made a presentation to the National Advisory Committee for Meat and Poultry Inspection on the findings that FSIS has obtained regarding *Campylobacter* in federal establishments. And you will see in the summary paper that we put forward that there are a variety of issues in that *Campylobacter* is in fact recognized as the leading cause of foodborne illness in the United States at this time.

We have a lot of questions about how that organism associates with *Salmonella*, and the reason that that concern was raised is the fact that FSIS has a

performance standard regulation for *Salmonella* as well as a generic *E. coli* standard on the slaughter floor that are indicators of hygienic practices and the process of slaughtering and presentation of those birds in the federal establishment.

So we have issues that are indicating we certainly have a problem. The subcommittee recognized the seriousness of foodborne illness related to *Campylobacter*, but I think it's the conclusions of the subcommittee that we don't have enough information at this time to move forward with establishing what that performance standard should be, if there should be one, how it should be designed or what would accomplish the same goals. So that in general is the summaries of the subcommittee.

MS. WACHSMUTH: Thank you, Dan. There was also a paper -- a report from the subcommittee that did amplify some of their findings and recommendations. I'm assuming that all the committee members have a copy of that at this time.

What I'd like to do is open the floor for committee members to discuss the sort of conclusions or any points in the document which outlines in more detail the findings, the recommendations, and the conclusions. I think in the recommendations of note -- Mike, you may want to look

at -- one of the recommendations is that irradiation should be considered for raw meat and poultry products, especially those intended for high-risk populations.

Bruce?

MR. TOMPKIN: I have a comment on the handout, the document. It's very brief. The first bullet under findings states that the *Campylobacter* is the most frequently occurring foodborne pathogen, and that's a debatable issue.

I think what we really meant to say is *Campylobacter* is the most frequent cause of foodborne illness in the Unites States.

MS. SWANSON: Just a question on that.

MS. WACHSMUTH: Kate.

MS. SWANSON: I know FoodNet is looking for diarrheal disease. I'm guessing the *Campylobacter* probably exceeds that for *Staph aureus*, but *Staph* seems to have dropped off the radar screen as causing foodborne illness because of -- so is that an accurate statement?

MS. WACHSMUTH: It's an accurate statement if you qualify it with --

MR. OSTERHOLM: Actually, it's not an accurate statement. The data now clearly show that Norwalk [indiscernible] viruses are far in excess of any others,

even -- because now we can detect them. What is true is that it's the most commonly recognized bacterial cause of foodborne illness, and that's what we need to stated.

MS. WACHSMUTH: Did the FoodNet report cite the normals --

MR. OSTERHOLM: Well, there's only been limited sites that have been doing it. We're the only state right now routinely doing it. And right now, we're counting about a third, because you know, if you add *Salmonella*, *Campylobacter*, *E. coli*, and *Listeria* combined, you account for less than 2 percent of the episodes of diarrhea in the community, and which *Campylobacter* is about almost 40 percent of that 2 percent.

If you look though, Norwalk virus right now is well accounting for confirmed cases about a third of all the diarrhea completely, so 30 percent or 15 times what the other pathogens combined is associated with. Grant you that it's a much less serious illness as some of these other ones, but I think that it's -- we need to always clarify that relative -- to recognize bacterial pathogens.

MS. WACHSMUTH: Right. We could qualify it by bacterial or limiting it to FoodNet or Art Liang may have a suggestion?

MR. LIANG: Any of those except -- well, from our

point of view, we say the majority of these cases are of unknown -- to be perfectly sure -- recognizing that the FoodNet sights are selected, hopefully representative sample, but --

MS. WACHSMUTH: Well, we could alter that and say the most frequent cause of bacterial foodborne illness as detected in foodborne surveillance system.

Bob?

MR. BUCHANAN: I don't think that you've yet addressed Bruce's question. Bruce's question was does FoodNet differentiate diarrheal diseases from diarrheal diseases that are caused by foods? Have I got what your question was, Bruce?

MR. TOMPKIN: I was happy with the changed.

MS. WACHSMUTH: I think you've opened another issue, Bob.

MR. OSTERHOLM: I think what you were asking, Bruce, is a key one, is the most frequently most occurring pathogen, which is -- that's not the right terminology. Is it the illness, because pathogens could be all over the place and not cause an illness and so I think that Bruce is right on target with that. It just -- you add the bacterial in your finding.

MS. WACHSMUTH: I think we've got the fix on that

one. Any other -- Mike, you had your --

MR. DOYLE: Well, I just would come back to the recommendations issue, and I welcome the inclusion of the issue of irradiation, obviously. I guess I'm a little confused by what is a high-risk population, because I don't know of a high-risk population for *Campylobacter* in the sense that clinical illnesses, particularly in the advent of the issue of antibiotic resistance issues is severe, whether in many cases you're talking about high-risk or not.

I don't know how you would differentiate that, so I would recommend taking high-risk out of that.

MS. WACHSMUTH: I'll turn that back to -- do subcommittee members have any comments on that?

VOICE: Where is that?

MS. WACHSMUTH: This is the second page under recommendations. It's the fifth bullet.

MR. KVENBERG: I think the intent of the bullet -- Dan can speak to it -- was that if you know the target of the food being something like a nursing home or something else -- this question goes to the destination of the food, not the -- the commonly understood risk populations for any kind of bacterial disease are, at least at the high end of the age population, are those that are immune compromised or someone who is in a weakened

condition.

I think the point of the bullet was for the recommendation that irradiation should be considered for those foods identified to go to specific traditional high-risk. I may be wrong, but I would think that nursing homes or people in hospital situations where they have immune compromised situations or little kids in day care centers -- if the foods are going to those sites, I think that was the intent of the recommendation.

MR. OSTERHOLM: Well, I understand that, John. I still don't think it's appropriate. The point is, if you can prevent foodborne disease wherever it goes -- I'll tell you, there isn't a lot of chicken consumed in long-term care typically, depending on the ability of the individuals to eat chicken. It's more gummed foods.

The point being here is why just recommend it for a certain subsegment? If we think it's good enough for them, why isn't it good enough to prevent illness across the entire spectrum of people who get *Campylobacter* infections? I would argue today there are a lot of very healthy young adults who are acquiring a particular antibiotic resistant strains of these illnesses that are very serious and potentially life-threatening. I don't understand the logic of just saying only for high-risk.

Grant you that there's more potential mortality there or there's more potential serious morbidity, but there's serious morbidity in people who aren't typically considered high-risk.

MR. KVENBERG: I guess the only thing that I'm questioning is you're objecting to the words high-risk or especially with an emphasis on those populations?

MR. OSTERHOLM: I'm objecting to that whole last clause. I would just end it irradiation should be considered for raw meat and poultry products, period.

MS. WACHSMUTH: Okay. We have that proposal. But before we go forward, Morrie Potter?

MR. POTTER: Okay. Thank you, Mr. Chairlady.

First a statement from the folks who are tracking this meeting, and that is the conversation's been bouncing back and forth across the table and people haven't been identifying themselves each time. It's going to potentially make for misattribution in the transcript. So please, each time you feel compelled to speak, admit to who you are.

The other thing is, for this specific paper, Mike makes a point that this is about *Campylobacter* and while a general statement on meat and poultry safety may belong someplace, if that doesn't particularly pertain to *Campylobacter* and the disease it causes in specific

populations at risk, the subcommittee may want to rethink how these things are set.

MS. WACHSMUTH: Thank you, Dr. Potter.

Okay. I think we have a proposal to eliminate the last part of that sentence, which says, "Intended for high-risk populations. Is there an objection to eliminating that?

MR. KVENBERG: This is John Kvenberg for the Food and Drug Administration. Yes, I have a problem with totally ignoring the idea that this population is not at increased risk and it wouldn't be a good idea for an additional intervention, if it can't go across the board to at least emphasize somewhere that this is a step that can be taken to protect certain populations.

I think if we just totally strike it, it just basically -- there's no interim step, because I don't think tomorrow you can begin irradiation on all foods. Striking it doesn't --

MS. WACHSMUTH: Okay. Any other? Mike Robach?

MR. ROBACH: Mike Robach, Continental Grain. I would also be against striking it completely. It is an inclusive statement with special emphasis on a certain high-risk population, so we're not excluding any class of product. We're just trying to put additional emphasis where

we think there should be additional focus, and it could be the first step towards irradiating these types of products.

MS. WACHSMUTH: Art Liang?

MR. LIANG: I propose -- what if we insert high-risk for severe illness?

MR. POTTER: Mike Osterholm?

MR. OSTERHOLM: Well, first of all, I think that you have to be very careful because there really aren't good data to show that *Campylobacter* is a more serious illness in high-risk populations, and we've looked at that extensively. And in fact, interestingly enough, the overall incidence is actually lower than we see in adults -- older adults and young children than we actually would expect to see with the other *Salmonella*, et cetera. So I mean, if you want to make that intuitive assumption, that's fine, but the data aren't there to support that, number one.

Number two is that there are efforts undergoing right now to irradiate poultry for a broad spectrum of population use out there, and this will begin in the Midwest this summer. I would actually see this statement as actually hurting our effort, because now it's saying, Well, you really don't need to worry about that other population. Just get it to high-risk. And I think you could easily have that interpretation, and that has come up in the past.

So I come back to the issue that I don't agree with John, that this would only make it as an interim issue to get it to that population.

I can tell you, as someone who has worked a lot in tracing where *Campylobacter* related product goes, primarily poultry, to actually irradiating at selected locations like nursing homes, et cetera, to get it to day care centers is a virtual impossibility in the way the product is distributed today. If you want to sell it off the shelf, that's fine and then say nursing home people ought to come buy it here or day care come buy it here, but that's also counter-intuitive because that suggests that people who -- other part of those should get it.
So I still find this very troublesome, and in the real practical world out there the bottom line is get it out there for everybody, which is beginning to happen, and will happen a lot I think in the next 12 months.

MS. WACHSMUTH: Any other comments? John?

MR. KOBAYASHI: I favor leaving out the reference to high-risk. There have been many attempts in public health to identify high-risk populations such as high-risk for Hepatitis B, Hepatitis A, and our experience has been that it just doesn't work, because who perceives themselves to be in the high-risk population is subject to great

interpretation.

However, if the decision of this committee is to include this phrase, I would urge that clarification be made on what people are referring to as high-risk, because I hear different definitions, even within this committee as to what people are considering as high-risk.

MS. WACHSMUTH: Bob?

MR. BUCHANAN: Bob Buchanan, FDA. And while this seems to be a shift in the current discussion, it's not really. Not having benefit from being in these discussions on this issue, what I do have to say is reading this document over, you seem to have wandered far afield from the question that you were being asked.

I'm hearing a very general discussion about poultry safety. I don't see a very targeted discussion about performance standards and their effectiveness and how they're related to the question that was brought to you. So I'm --

MS. WACHSMUTH: Do you want to put the charge up again? I think what we're addressing here is the second part of that charge -- the second part of that sentence. I think the committee concluded that a performance standard for *Campylobacter* was not appropriate at this time, given the available data, and that although an alternative

organism standard might be acceptable, they could not identify one. And this is an attempt to identify alternative measures to accomplish the same public health objective.

MR. BUCHANAN: Well, except in the discussions that are taking place here, if you're irradiating the poultry and eliminating *Campylobacter*, you now have a performance standard of zero. So it's not separate from here.

You have a de facto performance standard based on if you're dealing with a technological alternative.

MS. WACHSMUTH: Okay. I think we need to hear from some members of that subcommittee. Are there any volunteers?

MR. ENGELJOHN: This is Dan Engeljohn. They certainly were vocal on Wednesday.

But we -- as far as the subcommittee goes, the effort was first of all to present the issue of the *Campylobacter* performance standard, and I do believe the focus was lead directly down the line of what we have existing, which at the moment FSIS does have a current performance standard for *Salmonella* on the slaughter floor. So I do believe that we looked primarily at an intervention or a strategy or an objective that could occur in the

slaughtering of the birds, and we did not have a discussion on post-slaughter activity. I don't believe that we had much of a discussion whatsoever on those issues of what to do once you moved beyond the slaughter floor to a ready-to-cook poultry product and then interventions that could be in place there. We focused primarily on the farm and slaughter activity.

So if I could just characterize that as to what the committee focused on, it certainly looked only at that aspect of it.

MS. WACHSMUTH: Okay. Well, this is now before the whole committee. So, John Kvenberg?

MR. KVENBERG: Well, I was an observer to that committee, and I think maybe the effects on this one would be basically, as Bob Buchanan put out, that maybe we could re-craft a recommendation on irradiation to state that it would -- I don't know if you can go as far as saying a performance standard, but it would basically eliminate the problem for all populations. That would get to your point, and we wouldn't have a discussion one way or the other. It's just saying that irradiation would be effective.

And then if you drop the risk group on the point of -- that Dr. Buchanan made, was that you basically are eliminating risk, that would be affixed to it.

MS. WACHSMUTH: Okay. Mike?

MR. OSTERHOLM: Mike Osterholm. I think one of the issues that I would urge the group to consider is that far too often we try to put *Campylobacter* and *Salmonella* into the same categories, and I think that that's an error.

First of all, remember, we hardly have any evidence of big community-wide outbreaks of *Campylobacter* infection in this country. We don't see it. It's a very different epidemiology than we see with *Salmonella*. On the other hand, we do know from our poultry work and the molecular fingerprinting that we've done now from poultry, where we continue to see 50 to 80 percent of birds that we take off the grocery store shelf are contaminated with *Campylobacter*. Imagine if ground beef had 80 percent of it contaminated with *Salmonella*? We'd be talking a very different ball game.

The point being is that this is a very substantial issue that continues to get -- really not addressed in the sense that to get the kinds of performance standards you're talking about, take something from 80 percent to 50 percent down to zero, there's really only one or two technologies that are going to allow you to do that. You know, you can improve things in the slaughtering area.

The second thing is I think most people, again, need to come back to the fact that why are we handling this the way we are, even at the consumer level? Remember that the vast majority of people don't get *Campylobacter* from chicken. The vast majority of people get *Campylobacter* infections from other food items served from that same kitchen where the chicken was processed. And when you get carcass liquor from a chicken in your kitchen, you've got a very dynamic situation with a hell of a lot of *Campylobacter* all over the place, and you're really trying to deal with that, which is very different than other slaughter products, et cetera, whether it red meat, other forms of white meat, et cetera.

And so that I even think as you look at performance standards, you know, even getting this down from 50 or 80 down to very small numbers is still a problem in the sense of how do we know the epidemiology of *Campylobacter* actually works versus the epidemiology of *Salmonella*, where you're talking about, you know, regrowth, mediums, et cetera. That's a very different situation. So I don't see how you can -- I just urge this mindset of taking *Campylobacter* and *Salmonella* down the same path is actually a problem, and I see that through this document that was appeared to be a somewhat frequent reference to the two of them back and

forth. And they're very different.

MS. WACHSMUTH: For those of you who did miss the presentation and the discussions in the subcommittee, I did observe that. And the reason that appears is that the charge from the other advisory committee was compared to the existing standard. And that's why you see that side by side. I don't think the committee was implying that they were a lot alike.

Peggy Neill?

MS. NEILL: I was just going to make a comment and then perhaps suggest a fix.

Throughout deliberations of this committee in previous meetings and this one, I think all of us when we've been given a charge have often, to the point that Bob made, accidentally begun to peek over the fence at the next step from whatever the charge is that was given to us, and we all did this a little bit in the risk assessments, and then kept trying to pull back to say risk assessment has got to be transparent and needs to be kept completely separate from risk management.

I think I'm seeing something psychologically similar here. And what I would suggest is, picking up the point that John made, we can often identify a population at high-risk for either a disease or a sequelae on an

epidemiologic basis, but we are unable to identify such a subgroup in the grocery store, in the clinic, or in the basically the real world. And therein has come to be a troublesome stumbling block for initiating effective public health interventions. Hepatitis A vaccine is a good example.

Now, having made all those editorial comments in trying to philosophically bring it back on track, I'm wondering if what we would do that captures the meaning of what we're after but remains scientifically correct here would be to indicate irradiation considered for raw meat and poultry products, period, which takes into account Mike's point, including the latter one with cross-contamination, et cetera, that could follow -- that hints at the benefit to be derived is that patient populations at highest risk for disease or sequelae would likely derive the most immediate and greatest benefit.

That still may not work, but it's trying to separate out some of the issues that we've been discussing.

MS. WACHSMUTH: Could you read it again?

MS. NEILL: Populations considered to be at highest risk for either disease or sequelae would likely derive the most immediate and greatest benefit. Because otherwise, I think you're going to have to get into a

paragraph that explains a lot of the points that have been brought up.

MS. WACHSMUTH: Bob?

MS. NEILL: Before we introduce anything new, any reaction to this suggestion?

MR. BUCHANAN: This is a reaction to that. An alternative approach to relate it more back to the original question that was being asked would be a sentence that basically would say, the use of irradiation or other technologies that can assure the elimination of *Campylobacter* would obviate the need for a performance standard.

MS. WACHSMUTH: Mike?

MR. OSTERHOLM: Just as part of the slippery slope situation I think that Peggy's just introduced, I don't know if you realize this, Peggy, but that would actually speak totally counter to what John said, because actually the most serious sequelae association of *Campylobacter* infection is Guillain-Barré syndrome. The highest peak incidence for Guillain-Barré syndrome associated with *Campylobacter* infection is between the years of 18 and 35 years of age, and otherwise in previously healthy individuals, in terms of what we see associated with *Campylobacter* infection.

So what John was meaning was nursing home patients, day care, et cetera -- the most serious sequelae, as you just stated. I think that's why I'm using that as an example of the slipper slope issues of why it's so darn confusing and why, if you really want to do that, you're just ultimately still going to get back to the issue of a general population phenomena.

MS. WACHSMUTH: Yes. We've got the two issue. Now, Peggy did introduce a new one that sometimes you can't identify these so -- is it -- your reaction, Peg, to Bob's proposal?

MS. NEILL: I just would speak to the point that my language was meant to bring out the point in a way that Mike just made, because a person who delved into the literature and saw that the highest risk for Guillain-Barré was in this group would then begin to realize it's a broad base and ergo, some -- I think that sounds correct. Bob's point speaks to the charge and speaks to the science.

MS. WACHSMUTH: Allison?

MS. O'BRIEN: Allison O'Brien. I can't sit here any longer, as a member of this subcommittee -- we spent no time, zero time on irradiation. It has become the dominant discussion point here.

We did speak to the charge we had. We spent a

lot of time discussing what we now by having a *Salmonella* performance standard. We wanted to know how has that affected *Campylobacter* levels at various step and processing. And we couldn't answer that from the data we had.

So to -- in recognition of the fact that *Campylobacter* is such an important bacterial pathogen in foodborne illness and that it's clearly related to chicken drippings, which we did understand -- we did understand that and cross-contamination -- we wanted to put a statement in to that point. And however we craft that statement, it was the secondary issue, honestly, in what our charge was.

MS. WACHSMUTH: Okay, John.

MR. KVENBERG: This is just to the point that Peggy made, and you said it very rapidly when you went through the first -- you inserted the word raw, one of Dr. Osterholm's major points, which is the true one, was discussed in committee, which was cross-contamination. So I'm just trying to be helpful to get the language through here. It's not clear under irradiation to be considered for inclusion in processing, the point would be the raw aspect and the attributes of irradiation.

So that would be the quick fix, and if you can't -- if it is counterproductive to continue this

discussion, maybe it could just be ended, to focus on the point of the performance standard being able to be met, and the focus would be on raw as well as processed. That was not clear. And you did state that, I think. You said raw.

Thank you.

MS. WACHSMUTH: Mike Doyle?

MR. DOYLE: I want to follow up on what Dr. O'Brien said. If you refer to the handout that Dan had prepared relative to *Campylobacter* performance standards, under the conclusions, I think the four points that are indicated address what Bob's concerns are, and that is, there's an incomplete data set. We don't have a complete full year of testing for what the presence of *Campylobacter* would be in poultry that has been processed under the current programs.

We don't have available -- the industry doesn't have available the ARS method, which is now believed to be the best method for quantifying *Campylobacter*, but ARS has yet to release that. It'll be another month before that's available, and that's important to the overall concept of developing a performance standard. And we still don't have well-identified intervention strategies for *Campylobacter* on farm and at slaughter, so with this lack of information, it's not possible at this point to identify performance

standards.

MS. WACHSMUTH: Okay. I'd like to go back to Bob Buchanan's statement. If you'd like to read that to see how the committee reacts to that in place of the current bullet concerning irradiation before we leave that.

MR. BUCHANAN: Let's see if I can reconstruct it. Use of irradiation or other technologies that can assure the elimination of *Campylobacter* would obviate the need for a performance standard.

MR. TOMPKIN: And you might add, at time of slaughter. That's really what we're talking about.

MS. WACHSMUTH: Okay. Before we get all over the place on this, any reactions to this statement? Katie?

MS. SWANSON: That would assume that all the poultry would be irradiated and wouldn't have -- there wouldn't be choice out on the marketplace. And I know that's a policy issue and not a science issue, but there's a capacity thing of whether or not you can do it, so you'd still need some kind of a performance standard for those products that wouldn't go through that intervention strategy.

It doesn't eliminate the need.

MR. BUCHANAN: I really hadn't thought in that -- I was thinking more in the terms of or, not and. Okay? You

pick one or the other.

MS. SWANSON: Right. But so you'd still need a performance standard, or -- if one is needed.

MS. WACHSMUTH: Mike Robach?

MR. ROBACH: Could I suggest that maybe we go back to the origin of all of this and, since this has become a debate on irradiation and that certainly wasn't the intent, I'm happy to say irradiation should be considered for raw meat and poultry products, period, and let's be done with it.

MS. WACHSMUTH: Okay. Unless there is strenuous objection, we will go with that sentence. Very good.

Bob?

MR. BUCHANAN: Just a general reflection on the document, and again, I wasn't in the discussions that took place. There seems to be a general equivalence in terms of the word chicken and the word poultry. Did you mean chicken or did you mean poultry, and if so, you may want to be consistent about which you select.

MS. WACHSMUTH: Dan?

MR. ENGELJOHN: On that particular issue, the information provided -- the more current information that we have related to chicken as opposed to poultry as a class of bird, which would include turkeys and guineas and a number

of other types -- and so we have chicken as the category of poultry for which we have the data. So from an FSIS standpoint, that's what we were focusing on.

So in general, we have poultry as a regulated species, that we have specifics for chicken, and so I think we were looking at young chicken as the issue put to us as a subcommittee for discussion.

MS. WACHSMUTH: As just a little more background, we had looked at young chicken or broilers -- I think we used this synonymously -- in terms of baseline data and the *Salmonella* performance standard. And we've been encouraged that the *Salmonella* levels now in chicken, young chickens, are 10 percent versus the baseline, which was 20 percent pre-HACCP, if you will.

And we were looking at what available data we have for *Campylobacter*, which is inconclusive at this point. We have some, but it doesn't include summer months and things like that.

MR. OSTERHOLM: Just for information, for the committee's consideration, we have continued to be checking both chicken and turkey, which is still not completely inclusive of all poultry, but I think Bob's point is a very important one, about the issue of poultry. And while we find what you find, Kaye, in terms of decreases in

Salmonella, we have not seen concurrent decreases in *Campylobacter* in off-shelf purchase product right now, and we are looking at it seasonally also.

And so we're, based on our previous seasonality testing, we're right where it is. The only thing that seems to be changing is we just continue to see the proportion of the *Campylobacter* resistance for acrenolins [phonetic] increasing. That's the only part that we see changing.

MS. WACHSMUTH: Dan?

MR. ENGELJOHN: Yes. I did want to let the full committee know that we did have a varied discussion on performance standards in general, and just the fact of what they should be and the direction the agency's going and so forth. And so there was, again, a very narrow focus of a performance standard at time of slaughter, and virtually -- we had no discussion in the post-process part of that.

From an agency standpoint, speaking for FSIS, we clearly are going in the direction of performance standards replacing all regulations, so there is certainly room for performance standards on the processed products, and we have established some on ready-to-eat products, not on the raw ones yet. But that is certainly something I think we should be thinking about for the future.

MS. WACHSMUTH: Jim?

MR. ANDERS: Jim Anders. I just have a question. John and I are sitting here with apparently two different versions of this May 26 paper. Which one is the latest?

MS. WACHSMUTH: That's very difficult to say from here. Maybe --

MR. ANDERS: For instance, on the statement of irradiation, he has different wording in his than I have in mine.

MS. WACHSMUTH: Maybe we should read them through --

MR. ENGELJOHN: To be perfectly honest, I don't know which -- I can tell you by just looking at them which one is the version you should be looking at. On the first page, under findings, on the sixth bullet where it says, there are incomplete data, the sixth bullet should be, there are incomplete data. And then it follows with three indentations with little -- they look like arrows.

I know that's a distinction between the two versions.

MS. WACHSMUTH: Dr. Kvenberg has yesterday's?

MR. ENGELJOHN: It should have been attached to your copy. Okay? I apologize. I didn't note that the date at the top was different. It should have had a different --

MS. WACHSMUTH: Mike?

MR. ROBACH: I just wanted to speak also to the different classes of poultry, and we have to be careful -- the data that we do have can be a little confounding. The 1994 and '95 nationwide broiler baseline study showed that 88.2 percent of broilers, which are young chickens, were positive for *Campylobacter*.

What's listed in the findings as the '98 and '99 chicken monitoring program for *Campylobacter*, showing 78.8 percent for positive, are not only young chickens. Included are other classes of chicken, which include breeders and spent hens, et cetera. The data that's not in there that we also looked at, which is the 1999 young chicken baseline study, which just started in January -- we have four months of data -- indicated that there were 67.7 percent of the broilers positive for *Campylobacter*.

So we've got some conflicting data. We've got different bases that we need to be careful that we separate out so that we're comparing apples to apples. And the reason that we felt we were not ready to have a discussion about a performance standard per se, is we have incomplete data that we're looking at right now. We don't have a valid comparison.

MS. WACHSMUTH: Okay. Katie?

MS. SWANSON: I wasn't on the subcommittee, but I

did sit in in the deliberations in the morning, and I'm curious about the fact that the quantification hasn't been brought up here at full committee, where, yes, the prevalence of Campy might not have gone down from one year to the next, but the level that would be in the product may have gone down.

Mike, you'll identify with mosquitos in Minnesota. Every lake has mosquitos. It's 100 percent prevalence, but some have more than others. And with *Campylobacter*, it might be that lower levels -- the levels are actually dropping but that's why we need those quantitative methods to be able to see if that's providing an intervention that will contribute to a reduction in exposure of people.

MS. WACHSMUTH: Michael Robach?

MR. ROBACH: Yes. I agree, Katie. We did discuss that. I think it's important to recognize that you have to have an accurate and reliable method that's available to everyone so we're all using the same methodology as we're doing our analysis. And again, there, we don't have a complete data set and we also have to recognize that the '94 and '95 baseline study was conducted with the MPN method and all the quantitative work to date has been conducted with the MPN method.

So once the ARS method is out there, we'll have something that we can begin to use and really establish where we're at in terms of quantifying *Campylobacter* throughout the process.

MS. WACHSMUTH: Okay.

MR. OSTERHOLM: In listening to this discussion and the discussions we've had in previous meetings, it's becoming increasingly difficult as an epidemiologist that's out there continuing to watch as many cases and instances of *Campylobacter* increase in our state for the last several years, and to continue to see that tied back so strongly to a single product, and epidemiologically, we can do it, and with the fingerprint mechanisms we have today -- so we can take the *Campylobacter* bugs out of the chicken and we can take the *Campylobacter* bugs -- in chicken and turkey I must say, because we see it both out of humans, and the match up is so complete.

I find it so ironic that we sit here and talk about how many angles can dance on the head of a pin. The bottom line is, we've got a hell of a problem in chicken. We know it's causing disease in humans. We've got a technology that can deal with it. And we seem reluctant to say that, in a way that I think is with the certainty -- now, performance standards be what they might be.

But the point is, is that whether you take it from 80 percent to 50 percent or to 30 percent or to 20 percent, we've got a hell of a problem. And to the average American consumer, I think if they heard this discussion I think they would be very frustrated with us because we're not saying what we really need to say, is the poultry industry in this country has to deal with this issue and they have to deal with it soon because they have the technology to deal with it. And the point being is there's a lot of unnecessary illnesses out there, and with the antibiotic resistance overlap now, that has made it even a much more severe problem than we even had five to seven years ago.

And I don't understand this reluctance. I realize the reality of doing business. I realize the difficulty of bringing poultry on-line, but until groups like this begin to stand up and take those kinds of positions and stands, we're going to be out there just continuing to count cases. And I will tell you right now, if we can irradiate 50 to 70 percent of the poultry in this country, we will see a 50 to 70 percent drop in the number of cases of *Campylobacter* overnight, which we will not see for *E. coli*, which we will not see for *Salmonella* because of all the other confounding food products that are involved

with those. But we will see it for this particular one.

And that frustrates us as we continue just to keep watching the *Campylobacter* numbers increasing out there.

MS. WACHSMUTH: Okay. Have we addressed that? Does the committee feel that they've addressed that by the recommendation which now says, irradiation should be considered for raw meat and poultry products, period?

(A chorus of ayes.)

MS. WACHSMUTH: Okay. I think what we've done is clarify a lot and recap some of the discussions, but as best as I can tell from the comments and from the chair, this report is accurate.

Dan?

MR. ENGELJOHN: I would like to make one comment. We didn't discuss as a subcommittee as to how this gets transferred back, in terms of a statement back to the other committee that made the charge, and I don't know the technicalities of how we do that. Do we need to make a motion to do something to that effect, or do they just get a copy of the findings, recommendations, and conclusions?

MS. WACHSMUTH: This will be reported back -- this report will be handed to the executive secretary for the Meat and Poultry Inspection Committee. And also, Dr.

Hulebak will be attending that meeting as the representative from this committee, and can also relay some of the discussions that have occurred in this full committee meeting. We had no plans to create another document.

Okay. If there are no objections to that approach, that's what we'll do. And this will be appended as the report to the minutes of this meeting.

MR. ROBACH: If this is the report that's going back to the inspection committee, I'd just like to make a couple of comments related to findings, specifically, the fourth bullet, which reads, "Preliminary FSIS data, based on a small number of samples, suggested the prevalence of *Campylobacter* in chicken has not decreased substantially since the 1997 implementation of regulations addressing *Salmonella* performance standards for large plants."

That bullet, in conjunction with the one below, I think could easily be combined into one statement, and since we are discussion preliminary data, I don't really want to have it carry a lot of weight, but I would like to take out the 1998, 1999 chicken monitoring program, which as I indicated earlier, covers all classes of chickens and is not a reasonable comparison to the broiler baseline study. And instead, insert the preliminary 1999 baseline study for broilers, which indicated that 67.7 percent of chicken were

positive for *Campylobacter*.

I think that's a more accurate representation, comparing apples to apples, understanding -- understanding -- that it is all preliminary information.

MS. WACHSMUTH: Bob?

MR. BUCHANAN: Just a word on protocol, having been around this committee a long time. The appropriate protocol as outlined in our charter is that reports from this committee should go back to the appropriate secretary that had it, and that secretary then will communicate it through the appropriate agency back to the requestor.

MS. WACHSMUTH: This -- we share the secretary for these committees, and that is the [indiscernible]. Thank you.

Any discussion of the proposal from microbody? Mike Doyle?

MR. DOYLE: I agree with Mike's comment. If indeed we include that bullet, we should compare apples with apples and provide broiler data consistently.

MS. WACHSMUTH: Okay. If there are no objections, we'll change the chicken data to the broiler data for the second part of that bullet.

MR. ENGELJOHN: Could we get Mike to tell us what that statement was that he read? Is that the statement

we're adding?

MS. WACHSMUTH: It's from the table that Geri Ransom presented at the meeting.

Okay. I think we'll move on now, turn it back to Dan. And, Dan, could you lead us through the procedure in the whole document on the guide and just as a word to that subcommittee, which is a fairly new subcommittee on Meat and Poultry. They inherited this project from almost a totally different committee who had the opportunity to visit some of the small establishments and to see some of their needs and situations. This group did not.

We will try to have some field trips in the future. The best that we could do before this meeting was the video that was sent to the full committee, which is a training video used by our educators or inspectors at Texas A&M. And I meant to send a letter of warning with the tape, but it got out before I had a chance.

Okay, Dan?

MR. ENGELJOHN: Yes. Thank you. I have a few overheads I'll just put up here to sort of concisely state where we're at on this issue, and then certainly walk you through the paper. I don't have overheads on the paper itself.

But to summarize, this subcommittee, the Meat and

Poultry Subcommittee, were asked by the steering committee some time ago to make the assignment, and FSIS followed that up with a very strong desire statement that this type of document was needed for the very small plant operators. And again, the very small plant operators will be coming under HACCP implementation in January of the year 2000.

With that in mind, our regulatory requirements require them to begin the process of developing their HACCP plans six months in advance of the implementation date, so they will begin the process of developing their HACCP plans this summer, in July. And so the basic points of what needed to be done was that this document needed to be non-technical. It needed to be written for the very small plant operator to be able to take this as a hazard identification guide and use it in the development of their HACCP plan. The agency did not have intention of developing such a specific guide.

And then again, to make it clear, this is a guidance document. It is not intended to be a scientifically referenced or presented paper, but was to be used as a guidance document to identify microbial hazards in meat and poultry. And that it was to address the FSIS regulatory requirements that would be in place. So this puts this document into a very unique situation of having to

specifically address regulatory requirements.

In general, the subcommittee, over the time that they had this project, I'm sure spent a great deal of time dealing with the format of what it needed to be. But the subcommittee, in previous meetings, came up with an agreement that there should be a very simple introduction, very basic introduction. There should be a table or a combination of tables that identify organisms that were reasonably likely to cause foodborne illness. And again, this is wording similar to what's in the FSIS regulation in their hazard analysis. They need to deal with those organisms or those situations where there's a reasonable likelihood of a hazard.

That there should be a very simple and basic justification on why the organism was selected or why it was identified as being something to be addressed. And then it would be helpful, in all likelihood, to have some type of an appendix that could provide additional information such as specifics about disease and conditions for growth, onset of symptoms and so forth, as well as some information about resources for where they could go to get additional information. So that is the format that was agreed to by the subcommittee.

And finally, just to put up here where this

situation is at this moment is that the draft document has been made available to the full committee as well as the subcommittee members themselves. They reviewed one draft this week and then the draft that you all have now is what was from the deliberations on Wednesday. And that it's important note that this document needs to be made available to the very small plant operators shortly, as soon as possible. But in essence within the next couple of months, they are going to have to begin the process of developing their plan and have it ready for implementation in January of 2000. So that's sort of where we're at at the moment.

Walking through this document then, we have an introduction that sort of sets the stage. And I'm looking at this and I see it has the May 26 date on it as well, and so the committee members should have picked up a packet this morning that has the latest version, because there has been substantial changes from the previous version. But this background section basically lays the framework that this is a guide. It's non-technical and it's going to specifically address substantive FSIS regulations related to the nine categories of products that have to be dealt with in terms of the HACCP plan.

So should I just ask for questions on that section?

MS. WACHSMUTH: Sure.

MR. ENGELJOHN: Okay. I would like to point out to the full committee that coming into this project late myself, there were assignments given and individuals were charged with putting together pieces and over time, this document was put together. But on the Wednesday morning start up of this project, I did not believe that we would be able to have a document to present to this full committee that could be acted upon. And I have to tell you that the committee was eager to work.

I had eleven of 12 committee members there as well as some of the observers who participated, and they wanted to work and they wanted to get this done, and I'm just so pleased that they took the assignments that they were given in terms of each -- there were groups that developed each of these sections. They made modifications. I tried to incorporate their changes yesterday so that we could get this done in an reasonable amount of time. And so I do think that as a subcommittee working on this, there was extraordinary effort put out on Wednesday to get this done.

So, with that in mind, if there are specific questions that I can answer -- I have the list of people involved on each of those little groups that put in some additional detail as to how this was designed.

MS. WACHSMUTH: Do you want to lead it, Dan, instead of -- so we won't get too many people involved? If you don't mind calling on people from there?

MR. ENGELJOHN: Okay. Bruce?

MR. TOMPKIN: I have another suggestion.

MR. ENGELJOHN: Yes, Bruce, what is your suggestion?

MR. TOMPKIN: I have another suggestion. This is actually, what, the second version that we've seen at this point, and some of us even on the subcommittee have additional modifications to it. If we walk through it, this is going to be very painful and time consuming.

I could say that all of us on the subcommittee had comments on the drafts. Dan did an excellent job of coordinating all those inputs, and I can attest that this document is definitely an improvement. And it's going in the right direction, but it's still is not quite there, and it needs an additional shot.

Now, I think it would be better if we were to add -- or just give him our comments and let him do it again. It leaves the committee in an unusual situation of having to pass or approve an incomplete document, but I don't know other --

MS. WACHSMUTH: We do have some discussion on

this, and I'll let Dan tell you some of the conclusions we reached and see how the committee reacts to that.

MR. ENGELJOHN: Some of the considerations -- I think we did begin the deliberations on the Wednesday morning within the subcommittee as to how we could get this document done, because it was my belief on Wednesday morning when I walked into this that we would not have anything like what we have today. I had no hope that we would be this far. And so I had thought of plans for how we could get us where we needed to go and get this document to the small plant operators -- very small plant operators within the next couple of months.

And so with that in mind, now that we've put together this draft -- and obviously, there needs to be more consideration given to the specifics and the details -- some consideration was given to the fact that we could possibly have some type of an interim acceptance of it or provide the full committee two weeks to review it and get their substantive comments back to me, as the acting chair of the subcommittee.

And then at that point, I would get copies of all the comments that had come in and possibly combined them, but also send you all the comments from the full committee, get that to you, and then convene a teleconference with the

subcommittee members, schedule that time as well as make that teleconference open to the public so that the observers, the public, could listen in as to what the discussions are, as well as the full committee. And then if the subcommittee, in review of the substantive comments that would come in from the full committee, believe that we had and were able to address all the comments from the full committee, that a decision could be made that the document could be finalized and then presented to -- in essence, be made available to FSIS, which brought up the issue of distribution and how it gets out to this very small plant operators.

And from the concern from FSIS, we will be putting out updated documents for the very small plant operators, and we have that packet that is at print now. And I'm assuming we'll be ready for distribution within the next few weeks. And so this document certainly would not likely be ready to be distributed with that packet, but through other means, we could -- the agency could make it available.

But the concern that FSIS would have is that it addresses specific regulatory requirements, and for that reason, there is a need to be sure that it meets -- I don't want to say the standards of the agency because that

certainly would be a big debate here, but at least meet the substantive needs of the regulatory requirements and therefore, there may need to be some editing of the document. And because this is not the scientific document that you normally would put out and publish, I needed to be sure there was a means set up in which this committee would be comfortable with changes. And a suggestion was made that possibly the subcommittee could review the suggested changes that the agency would have and then incorporate them as any other comment.

So that sort of lays the framework that possibly this full committee could get back their substantive comments to me within the next two weeks. I'll convene a teleconference with the subcommittee as well as anyone from the public and the full committee that would want to listen in and provide input, and then make a decision on that point of how we can finalize it and in fact have it available to the public, to the very small plant operators, within this summer period, which would be very timely for them.

MS. HULEBAK: This is Karen Hulebak, exec sec for this committee. Dan's proposal for how we might move the documents along for this subcommittee actually foreshadows some comments I'd like to make and some discussion I'd like to have with the committee later on today's agenda, matters

that I would like to help the committee move forward into a more streamlined mode of operation, use electronic distribution of documents as much as possible, and still maintain our need to reach out to the public and make all of our documents available to the public.

So consider this proposal from Dan as a means of getting the work done quickly, efficiently, involving the subcommittee substantively as it needs to, involving the full committee for its review and approval, and still keeping documents available to the public and opportunity to hear from the public from the committee.

MS. WACHSMUTH: Yes, Cathy?

MS. DONNELLY: Cathy Donnelly, University of Vermont. I really appreciate Dan's comments about framework, because I think when you're dealing with the really small plants it's so critical, and as non-technical as we all think this document is, any of you that have worked with plants that have five or fewer employees, their eyes are just going to glaze over with this document. So I think when we're dealing with this audience we really need to think about some proactive additional strategies that are going to make this document meaningful, and I'm wondering if any consideration has been given to the role of the FSIS field people or work with cooperative extension, because I

think that only when you put this in that framework is this going to have any meaning.

MS. WACHSMUTH: Yes to both of those questions in terms of disseminating the information, and I think that's what Dan was alluding to when he said there would probably be some editing and some explanatory material that the agency would want to add to this.

Okay. Mike and then John. Mike Robach?

MR. ROBACH: I agree with the comment about this being still too technical. I am not terribly comfortable with this committee turning this over to FSIS for making it a less technical document, having read directives and other correspondence that come out of Washington down to the field. They tend to confuse the issue rather than clarify it. So I would suggest that there may be another alternative for us to make this user-friendly.

MS. WACHSMUTH: So noted.

MR. OSTERHOLM: And I would echo just what Mike just said. But I also think that there is a certain mindset this document has to address, which is one that is often missed.

If you survey the average consumer today -- and we've actually done this, to look at this -- there's a belief that the smaller the plant, the closer it is to home.

With the more known face, the safer the product is. And in fact, we have quite good data that says just the opposite, that if you look at *E. coli*, which we've looked at very carefully in Minnesota, clearly the small plant represents a much higher risk for *E. coli* 157:H7 than does the much larger plants.

And I think that that's an important point to get across, that there is an urgency, grant you, that because what we call the attributable risk is much smaller, because they just have a much smaller share of the market, but within that small share of the market the risk is much higher for some of these issues and the data are coming forward on that. So I think that this document also has to help share why therein very important in this, and this is not just government picking on the little guy, that this is truly an area where there needs to be real effort made and some real concern. And this also demystifies a little bit that just because you're a big operator means you're bad, because in fact I wish we could basically duplicate in these smaller plants what we're seeing in the larger plants in terms of activities.

MS. WACHSMUTH: John Kvenberg.

MR. KVENBERG: This is John Kvenberg. I was an observer but I did participate in this working group, and I

just want to say everybody did try mightily to simplify the document for the small operator, and there's work still to be done.

My point is very specific toward the review, if it's going to be expedited and gotten out. And the group, when it considered recommendations relative to the tables that are in this document were having a difficult time when it came to the fully cooked or almost fully cooked prepared meal documents. We brought it up several times. I don't know what the fix is, but when you make combination meals, you introduce new opportunities for pathogens outside of the box.

So in review of this process, please note the tables are noted -- the pathogens that are considered are coming from beef, lamb, pork, and poultry and that's solely what this is. It doesn't include other things such when you have combination meals that may confound the factors. I don't know what the fix is on this for small business, but you need to be aware in the review of it.

Thank you.

MS. WACHSMUTH: Okay. Katie?

MS. SWANSON: My comment is very closely related to John's. I was there early and asked what percentage of the small businesses might make something other than a

traditional meat product, but some kind of a formulated product that had meat as a component. The answer to that question was about half of them, and that half has not been addressed in this document. Those types of products are really more like a food service or a restaurant-type situation than they are a processing situation in many cases.

And to Mike's point, they may do a lot of batching where they would cook up a pile of meat one day, try to cool it off but not get there because it's in such a large quantity, and then the next day fill it in to pasta or something like that. It's a huge potential risk that's been totally overlooked in this document, and won't be serving the needs for those people that have a very, very difficult thing that they're looking for, probably more complex than anything else that's here.

A lot of the hazard identification for the slaughter and just basic meat -- you can take a specific course on a specific type of animal to figure out how to do it. But these others are highly complex and so I'm not comfortable saying, Yes, go ahead and see if you can try it. It needs a lot more work in that area.

MS. WACHSMUTH: Okay. Mel?

MR. EKLUND: This is Mel Eklund from Seattle.

I was previously on the committee, and I spent two days with the state veterinarian in the State of Washington going through processing plants. And I'll agree with the comments made before, that some of these people are terrified where to even start on this.

With the seafood HACCP plans, we do have examples of work sheets, flow diagrams, and also HACCP plans, and I don't know whether this is going to be included in some of your other handouts to them, but I think some of these things for examples would be very helpful to these people to even know where to start. And I would strongly recommend something along this line to help these small plants, because they are in desperate need.

MS. WACHSMUTH: Dan can address that.

MR. ENGELJOHN: There are two issues I do want to speak to.

First of all, the nine categories listed and the fact that these very small plant operators have to come under HACCP would have to deal with any product regulated by FSIS. So we would include those products that have spices, extenders, binders, vegetables, fish, exotic species mixed in with them, anything that FSIS would regulate comes under the purview of this hazard guide in terms of what it needs to address. So clearly it is much broader than what the

specifics are here.

And then the second issue -- I need to emphasize very strongly that FSIS does not intend to make this an FSIS document. It will be an advisory committee document, and the only edits that I was suggesting FSIS would likely make would be if there's a regulatory requirement that was improperly cited or left out that should have been cited. It wasn't to make this is any way an FSIS document. So I just -- if that helps in your understanding, it is to be an advisory committee document, not an FSIS document.

MS. WACHSMUTH: Hold just a second. I think Art Liang had -- we have a list of folks here as their hands came up.

MR. BUCHANAN: Is this is going to be an advisory committee document instead of reviewing the document that FSIS is going to put out for their people, I have a real problem with that, and I think we need to have some substantive discussions about this document and who is it intended for, whether we have the right technical people to develop an educational document of this nature. And I have some real concerns -- and this is far as I'm concerned the first I have heard that this was to be an advisory committee document.

MS. WACHSMUTH: Anyone else here with historical

memory? Margaret?

MS. HARDIN: I've been the historian for three days now. Mike Robach and I are probably the two original members of this group that have been going on with this for almost two years now.

We have tried and tried and retried and reformulated and redesigned what the charge was for this document: how thorough do we want to be? What is our level of expertise to handle this project? That's always been a concern. And it has been told that it's supposed to be a hazard identification guide. End of discussion.

We've talked about model HACCP plans. We've talked about flow charts. We've talked about hazard analysis. We've talked about everything. It's supposed to be hazard identification. We're supposed to get it as basic as we can. We talked about after we finished with it having a group of extension agents look at it, because they are the ones who are most near and dear to the small plants. They're the ones who work with them on a daily basis, although some of us do teach HACCP to this level of group.

But we also realize that there would be some question as to, does this meet the requirements of a national advisory committee document? So we're kind of caught between a rock and hard place. If you have any

suggestions, that would be appreciated. We tried to include some references, but the references were for the benefit of the small plant in order to get more information, more than literature citings to reference anything we said in the document itself.

So I guess that's probably the most details I want to go into on history. If you want any more, check our minutes from our meeting.

MS. WACHSMUTH: Right. I do remember at the last meeting when Ann Marie proposed to the full committee that the document be in very simply terms so that it could be understood. My interpretation from her presentation was that this document would go to the small producer -- to the people who would be using it. Now, whether we're qualified as a committee to actually come up with that kind of document, that may be debatable. But I do think that was the intention, that a document be created by this committee that could be handed to the small producer.

Now, we can go back to the agency and get clarification, since this has been in progress now pre-dating most of us on the committee or the subcommittee.

Art?

MR. LIANG: Yes. Art Liang, CDC. I think this committee probably is the right one to identify the issues

and the messages, and there's no question. But I think there's also the question that, depending on the target audience, this committee may have no standing on that issue.

So I think that's going to be a part of the clarification we need is, is this a document that's going to be put in the hands of the extension service, or is this a document that's actually going to be handed to the small plant owner and employees?

MS. HARDIN: Probably both. Use the extension service as a method for distributing it.

MR. LIANG: Well, from a --

MS. HARDIN: It's not supposed to be a teaching document. It's supposed to be a document that they can take hands on and start using. Does that answer --

MR. LIANG: Well, no. It's really an issue of sort of -- in communications, you have to first identify your target audience even though it ultimately be for the benefit of the plant. If you're actually thinking of this as something that is going to be used primarily by a teacher, for example, then it would be -- the document would look very differently than it would be -- if it's for somebody that's actually going to teach the teacher or given directly to the plant. So --

MS. HARDIN: It's intended to give directly to

the plant, but if you've worked with any of the small plants, I'll bet they will still call up their extension agent and say, What do I do now?

MS. WACHSMUTH: And that was Margaret Hardin again. Dane, then Cathy.

MR. BERNARD: Thank you. Dane Bernard. Also having been one of the people who was associated with this back in the early days, the original concept was -- the hazard identification is the most difficult part of putting together a HACCP plan. How do you make it easier for small processors? The model that we started looking at was the hazards and controls guide, which was developed in the seafood industry.

The big difference and the problem that you run into almost immediately when you consider what to do and how to follow that pattern is that the hazards and controls guide for seafood is very specific for products. And we're not dealing with the breadth of products we're dealing with here. To, I think, follow what is in the HACCP -- the pathogen reduction in HACCP rule, you instantly default to the nine categories. The problem with that is that puts you at about 40,000 feet, and you need something that's down on the deck for the small processors.

So we have a document that reflects some very

good work, but may be essentially useless for most people who look at a product and say, How do I apply this document to my product? And keep in mind the hazard and controls guide for seafood also has within it controls. This does not. This just says, Here is a hazard to consider.

Once you get into, as Katie Swanson said, looking at what small processors in fact produce, we're coming into a population of plants who have the most unusual set of products that the agency has to regulate. There are several ethnic products, highly formulated products, and none of those will be addressed by a 40,000 foot document.

So it's a daunting task. All I'm laying out is some of the problems that we've debated in the past that we still haven't come up with a good solution for. Also, if it is to be a national advisory committee document, it probably needs substantially more work. Really, the only way to do hazard identification is, as this committee's basic HACCP document says, look at the flow chart. Look at the ingredients that are coming in and do your hazard analysis.

So I don't know -- we're more than willing to provide the agency with our best effort at satisfying the needs, but I'm not sure that we can in the time frame asked for, produce something that will really be of benefit to the small processors.

MS. WACHSMUTH: Morrie has a question to Dane's point, then Jim's had his hand up for quite a while, and then Cathy.

MR. POTTER: Dane, did you just suggest that you would feel most comfortable if this document were the committee's advice to FSIS rather than a document that would go directly to very small plants?

MR. BERNARD: I hadn't thought about it in terms of making any specific recommendation. I'm just trying to lay out some of the problems that were encountered as we got to the point where we are. Your suggestion might be appropriate, though, Morrie.

MS. WACHSMUTH: Jim?

MR. ANDERS: Jim Anders. I agree that it's difficult to make a simple document, and I think that the committee should not release any document unless they're adequately okay with what's in there.

But I think in the process of having a simply document, we've got to be careful that we don't give mislead, and I think -- I'm looking at Table 1, for instance, the second paragraph could very well be misleading, going along with what Mike Osterholm says. There have been reports that in certain types of groups of cattle, that up to 30 and 40 percent of them are carriers of

E. coli.

This says, "A small percentage of cattle and some sheep carry *Escherichia coli* 0157:H7 in the intestinal tract at the time of slaughter." That, I think, could be misleading to the small -- particularly the small plant operator and to the public, for that matter, that all plants -- that might be close to true in the bigger plants, but I'm not so sure that's necessarily true in the smaller plants.

MS. WACHSMUTH: That's a very good point. If Mike Osterholm were here, he would probably reiterate that in the *E. coli* 157:H7 case control study, one of the associations was with the local slaughter, which -- I don't know if that's indicative of what is coming in on the cattle, but there certainly is -- the majority of the surveys have been done with the young, uniformly-healthy animals, which would -- major production within the industry.

MR. ANDERS: Well, I agree. The possibility here is that we mislead even the smaller operator in the process of trying to give them a simple document. And I'm not sure we want to do that.

MS. WACHSMUTH: It's a good point. Cathy?

MS. DONNELLY: I think, for me, the real issue

that I'm troubled by is this document and the assumption that there's a level of technical expertise that exists in these small plants. And sometimes it's there but the majority of the time it's not. And so there's going to have to be some intermediate step so that there's almost the translator that works with this specific target audience that really doesn't have the necessary technical expertise.

And I'd feel comfortable with Morrie's suggestion of this be a document with some additional work that then is handed to FSIS to then implement.

MS. WACHSMUTH: Okay. Unless there are any objections -- sorry, Dan, but this may be a document we may want to work on further to put it in the form that the committee is happy with as a committee document and submit that to FSIS to use the information in an FSIS format.

MR. ENGELJOHN: Again, the agency is putting out a new set of documents specifically aimed at the very small plant operator which has a very, very basic section on hazard identification. And I think the agency looked to the future in the sense that this document that this advisory committee would put forward could ultimately replace the agency's document, if it was developed to that point.

Again, the agency is putting out documentation. It has a series of strategies in place with extension and

with videos and numerous means of getting information to the very small plant operator. So we do have a strategy for getting information there, it's just this is the one critical piece that we don't have substantive information on, for which this committee was hopefully going to be able to provide. And I think that it's appropriate that what is presented to the agency as advice to ultimately be put into the hands of getting it out to where it needs to go can in fact be done.

I'm just -- my concern was taking this committee's document and messing with it, because I don't want that to be the issue. Are we taking something that wasn't intended to be -- so if it's clear as to what the agency can do with the document when it's presented, then I think that's the exact thing that needs to be done.

MS. WACHSMUTH: So I think, in that respect, we can go back to the agency and get some specific clarification.

MR. ENGELJOHN: But in terms of going back to the agency to get clarification for what?

MS. WACHSMUTH: What do you want?

MR. ENGELJOHN: What the agency needed was a hazard identification guide for the very small plant operator, and that would cover every product that those --

in essence, the products that those very small plant operators would have to address under FSIS regulations. So that is what the agency needs.

MS. WACHSMUTH: Yes. I think my suggestion, in terms of clarification was, if the information is going to be used instead of the document, we could give the committee some assurance the integrity of the information -- how it would be presented.

Mike?

MR. ROBACH: Mike Robach.

We still have a fundamental problem because it is indeed a daunting task, and as this committee put together a generic document on HACCP that was of benefit to large producers who had the technical expertise to take that generic information and translate it into a plant-specific process, specific HACCP plan -- and I think what we're hearing today is we know small operators don't have that. And our charge was trying to put something together in a generic fashion that could be used as a basis to start the hazard analysis, and that is give some idea of where do you start with hazard identification?

Given the complexity and the multitude of products and processes that are out there in the very small plants, it would take this committee probably the next 25

years to get through all the different operations and processes and products to do a job that we would be comfortable with.

MS. WACHSMUTH: You're suggesting --

MR. ROBACH: I'm not suggesting that at all. And -- well, I might suggest that since this is my last term, so -- but, no. I wouldn't wish that on anyone.

I think that we do need some clarification back from the agency on what the expectations are because clearly, I think they have evolved and changed and we've gone back and forth a couple of different times, and I think we're as confused as every.

MS. WACHSMUTH: Katie?

MS. SWANSON: A thought occurred to me -- if this is going to be information that would support other information that the agency has already prepared, it might be useful to see what that information is and determine the gaps that exist and then enhance it, rather than working in a vacuum and trying to guess how this is going to dovetail into other things.

Another thing to consider is, as I mentioned before, some of these products are very similar to restaurant-grocery store type applications. Is there something that exists through the food code efforts that we

might be able to latch onto to educate these people, because again, that's another audience that is not highly technical. I don't know. I haven't reviewed that extensively, so I don't know if that's going nowhere or could be useful.

MS. WACHSMUTH: Okay. That's a good suggestion.

I think what -- we'd have to go back in terms of a charge to this committee. We did not find a written specific charge. I believe this came as a very broad charge from the administrator, from Tom Billy, to say, could the microbe committee please help us with some guidance so that small producers could identify potential hazards. And I believe that it's -- this kind of discussion is what it's going to take for us to arrive at what we need. It did not come to us in a charge more specific than then.

Bob?

MR. BUCHANAN: I would like to make somewhat of a -- and I'm not going to try to sidestep the issue here, but what is being asked of this committee right now is to provide specific information that will be associated with the implementation of a regulation. This goes beyond just simple scientific advice, and I think it would be very appropriate that at some stage in this that we send this over to our sister advisory committee, who actually in many ways has the charge for dealing with this type of issue.

We're here primarily to provide the scientific advice. When you're talking about --

MS. WACHSMUTH: That's the advice this committee has asked for. This is not going into a regulation or directive. It's guidance material.

MR. BUCHANAN: I guess I'm interpreting what Dan is saying about how this is going to be used as something very different. It appears to be, at least to me sitting here, that this will be used for the implementation of the regulation.

MS. WACHSMUTH: This is asking scientific advice, food safety advice, from a scientific committee for guidance for small producers. It coincides -- it will prepare them for things that are going on in a regulatory way, but it is not a direct part of that process.

Dan, do you want to comment?

MR. ENGELJOHN: Again, the issue is the agency does not have a hazard identification in terms of organisms for these very small plant operators to identify in their HACCP plans. We do not have that. We have no documents that would have that in it. And the agency did not intend to put that together itself, in that the HACCP plan was to be developed by industry as opposed to the agency.

And so that was -- I think that's the reason why

getting guidance on what organisms should be of concern for the nine categories of HACCP plans that would have to be dealt with. That's just really how basic it is.

MR. BUCHANAN: Can I then ask, are you not getting a response from the industry in putting these guides together, and that's why you've come to the advisory committee?

MR. ENGELJOHN: I'm sorry, Bob. I don't understand the question.

MR. BUCHANAN: You -- in your explanation a moment ago, you said you had anticipated that the trade organizations, the industry itself would have developed and put together advice to their members in terms of the hazard identification et cetera.

MR. ENGELJOHN: Oh, okay.

MR. BUCHANAN: Is the industry not providing this guidance, that you had to come back to the advisory committee?

MR. ENGELJOHN: To answer that in a roundabout way, the issue with the agency is that implementation of HACCP is an industry responsibility. The agency has a very special desire and need to provide guidance to very small plant operators. We do that through a series of all the regulations that we're dealing with in that the federal

government as a whole has a need to provide small business operators with guidance.

We have put together a series of documents and we have put together a document that contains a very brief section on hazard identification, but the agency chose not to go into specifics on how and what that hazard identification guide should have in it, and look to this advisory committee, which would have expertise to be able to provide that general guidance. So that's the reason why we weren't looking to trade organizations specifically to do this.

We were looking for a government effort to provide and make information available to small plants.

MS. WACHSMUTH: Okay. Dane and then Mike, and then we're going to wrap this up.

MR. BERNARD: Thank you. Dane Bernard.

I think that if this document were framed as advice to the agency rather than a national advisory committee stand-alone document, it might help ease what we do with it and where we go from here. I think the major gap left is some qualifiers that would make it clear that those formulated products are going to require attention beyond anything that this group can attend to in a short amount of time.

And what you've got is a document that lists all the potential hazards reasonably likely to present some illness in a category of products, which means then the discrimination is applied at the processor level to cut back on that level to what is important in their operation. And I think with some qualifiers, we can move ahead with a document in fairly short order that is advice to the agency that the agency can then do with what they wish.

I would not feel comfortable personally with a stand-alone national advisory committee document in the time frame I think that we have to perfect something.

MS. WACHSMUTH: Okay. Are there any major objections to this suggestion?

(No response.)

MS. WACHSMUTH: Okay. What we'll do is during the break --

MR. BUCHANAN: I would like to endorse it.

MS. WACHSMUTH: Thank you, Dr. Buchanan.

During the break, we'll get together and try to come up with a process and get back to you before lunch time, hopefully. So let's take a break now for 15 minutes, or a little more than 15, and reconvene at 10:45.

(Whereupon, a short recess was taken.)

MS. WACHSMUTH: Okay. Let's get started. Okay.

We're missing the leader for our next topic, so -- he's coming?

Meanwhile, to summarize what we hope is an acceptable process for the guidance material, we heard the committee, that it seems more appropriate to be giving advice to the agency, so that's what we'll do. And we'd still like for you to take the document that you have to get any of your comments, specifics or in terms of approach, to Dan within the next two weeks. Dan will convene the teleconference.

The subcommittee can hammer out for us the best words that will describe exactly what we're doing so it won't be misinterpreted; some guidance in how to apply it, what the limitations are. It doesn't include every product under the sun. And I think we'll go from there.

Dan?

MR. ENGELJOHN: June 11. How about by June 11? Give them a date.

MS. WACHSMUTH: Okay. June 11 is your drop-dead.

Okay. We move into our next topic, and that is qualified through verification. This was a charge and a document that came from the department through the Undersecretary for Food Safety to this committee to evaluate some scientific issues.

I'm going to turn it over to John Kvenberg and John, I think the charge -- and make sure we all know exactly what your ad hoc group was doing. This is not a new subcommittee. This was just a -- as we did with *Listeria* at the last meeting, when there is an issue that needs to be addressed in an emergent or one-time sense, then we try to get a group together with the most knowledge we think to apply to that.

John?

MR. KVENBERG: Thank you. I draw the committee's attention to two documents, one you received before the meeting, which was the Department of Agriculture AMS document, background and charge and questions that were asked of the national advisory committee. And the second document, which is the output of the committee has been circulated, and I hope everyone has that. I don't have overheads to go through this document. The document we put together is called the report on the QTV working group dated May 27. There's only one document on that.

The original charge, since you asked me to start there -- I'll read it to you -- was a succinct statement and a bunch of questions that followed. The statement was the "Qualified Through Verification Working Group of the National Advisory Committee on Microbiological Criteria for

Foods is charged with providing scientific evaluations and recommendations to ensure that the QTV program utilizes scientific base procedures to ensure food safety." And then it goes into the specific questions.

On the front end of the discussion that we had in the working group is that we were unable to actually meet the full letter of the charge as it was worded. And what we basically developed was a statement that the United States Department of Agriculture's AMS -- and its background of how it developed the voluntary fee for service program using HACCP principles and techniques for the fresh cut produce industry was asking questions of us after an evaluation of its program was presented.

One of the things the committee did make mention of is that we would go through observations. We did this on the front end of the document, and I'd like to review those because they basically are some of the criteria that we used in responding to the questions that were asked of us.

First, the NACMCF had previously published, and we used as a reference document the "Microbiological Safety Evaluations and Recommendations on Fresh Produce." We found that document, reproduced it, and used it to refer to. This was a previous existing document that the committee had produced. Specific information about groups or package type

processed commodities and distribution of products is needed to conduct a valid hazard analysis. That was a central them of our consideration in that it's very difficult to make generalized comments back to the questions when you have to consider the specific operation that's under a program such as QTV.

In order to conduct its process, you have to have a thorough understanding of the flow of the product and how it's processed in the plant in order to address the issues that were raised.

The next fact that we had considered before wading into the questions that we were asked is if the presence of coliforms is basically, in the consideration of the working group, has been ruled out as an appropriate indicator of fecal contamination because of the natural microflora background that you're going to be finding in products of plant origin. We considered that the prevalence of pathogens in produce and the considerations of the questions were asked is definitely a different profile when it's provided by raw meat and poultry products.

This goes to a consideration of something like a performance standard or a marketing criteria in it's usefulness because you don't have the same starting point specifically with total plate counts, and to detect

pathogens in these products on the raw incoming load is impractical. That was a consideration that we had.

The effective control at the source of materials basically was another major factor that we felt needed to be emphasized on this document, in that basically, other than gross contamination from products of unknown origin, a real key to providing safe food products is sourcing of materials and having an understanding of the incoming load is not contaminated because the load of pathogens is low. So that was the background consideration for the document itself.

In considering the questions that were posed, what we did in the document was in bold print reproduce the question as it was asked and provided the working group's response for the committee to the issues that were presented. We emphasized under the first point relative to statistical sampling plans -- I think the main point to emphasize is that as the committee has said many times, microbiological testing to verify process controls is not the way this ought to be designed, that it would be useful to establish baseline information and to conduct a hazard analysis.

On the second point, on the major brush of the questions that were asked relative to testing methods and procedures, we found that breaking this into several

parts -- and you can go through the issue -- it goes to a table that was presented on page 3, emphasizing the types of tests that may be applied, that can be used in assessment in a processing plant. And the recommendations were quite specific relative to the types of applications that can be observed.

ATP was looked at as a potential for use for assessing the effectiveness of cleaning and sanitation, specifically of food contact surfaces where you could get a contamination of product when sanitation broke down. We went to a lot of emphasis in our new broader idea relative to cut produce is that an appropriate indicator of how your process control is working would be the total plate count numbers. And this would have to be specific and information would have to be gathered on the profile and the type of product the QTV was looking at and making their assessment of, with an eye toward -- as the Hippocratic oath, do no harm, that the numbers should remain low or be reduced by the process.

It was the advice of those in the processing business that basically in order to effect a reduction of microbial load in incoming product, could only be affected to about 1 log reduction on average with current technology. We did not consider new technologies.

There was questions asked in the charge on the effectiveness and the appropriate use of *E. coli*. And basically, the working group focused in on the answer on *E. coli* as being an appropriate indicator to view supplier qualifications when the history of that supplier was unknown, in other words, when you don't have a vertical integration or confidence or want to audit incoming materials, *E. coli* may be an appropriate indicator for supplier qualification for products coming in, relative to indicators of pathogens within the plant and samples that could be taken. Target organisms that were identified for environmental monitoring were *Listeria* and *Salmonella* species.

Other than that, we have given specific remarks. There was a dialogue between the working group and the people that came in and made the presentation from AMS. It's my sense that they were quite satisfied with the response and felt the guidance as was provided was useful and adequate, so I guess it would be appropriate to ask the committee if the working group's recommendations are on target with the full committee.

MS. WACHSMUTH: Okay. Let's open this for discussion by any member or if any member of the subcommittee would like to add something --

MR. KVENBERG: Could I propose maybe we do it by -- there are only five things we could go through.

MS. WACHSMUTH: Yes. Would you read us through that, John?

MR. KVENBERG: Would you like to do it that way?

MS. WACHSMUTH: Sure. Go ahead. That's good.

MR. KVENBERG: Okay. Then if that's the way we'll proceed, if you'll note that the first question that has been reiterated in the document, what are the appropriate statistical sampling plans for product collection, with appropriate confidence limits -- that was the way the question was asked. And we responded as you note.

Any comments on section one?

(No response.)

MR. KVENBERG: Hearing none, section two dealt with microbial testing methods and procedures for assessing the microbiological conditions of the facility and the product throughout the process, and we gave a short response to the general statement and then several sections under section 2. We responded to A, B, and C.

Comments?

(No response.)

MR. KVENBERG: Question 3 in the general sense

dealt with the utilization of *E. coli* as an appropriate verifying organism to be used, and we had to subset this into several questions, but it went into generally the asking about *E. coli* as to its appropriateness. And as I said in my previous remarks, the working group focused primarily on total plate count as it went into an effective monitoring for process control, along with recommending the compendium of methods for microbiological examination from foods. That is, I think everyone knows, I think it's APHA document.

I'll give everyone a moment to review it.

MR. BUCHANAN: John?

MR. KVENBERG: Yes?

MR. BUCHANAN: Can I ask the rationale for selecting *Salmonella* as an organism for environmental testing?

MR. KVENBERG: Sure. *Listeria* was definitely, in my memory, the initial and primary environmental monitoring in a processing plant that could occur. The rationale for including *Salmonella* is that it could be, in certain circumstances, from field to factory, a potential in specific harborages or hiding places, I think, like *Listeria*. I think the primary focus was *Listeria*.

I could throw it open to the working group. I

don't feel strongly, but Katie Swanson or Nancy Nagle may have a comment.

MS. SWANSON: It was generally felt that *Listeria* was the primary organism for environmental monitoring, but there are some commodities such as melon that have been associated with a significant number of *Salmonella* outbreaks. So if you've got somebody that's dealing with a lot of that, you'd want to make sure that they didn't have a harborage area in that particular location.

So this list was not intended to say you have to do all of these in all situations, but you do need to do your hazard analysis.

MR. KVENBERG: Nancy, do you have anything to add to that? Yes. That was what I was trying to say relative to harborage and specific product. We kept reemphasizing the fact that the product and the process has to be evaluated on its individual merits, and *Salmonella* is just put in there, Bob, as a potential utilization for specific commodity niches, if appropriate.

MR. BUCHANAN: Can I recommend that that rationale in some way be included in the report you will be providing AMS? I have some concerns that it will magically get carved in stone that *Salmonella* is an appropriate organism for environmental testing when in fact what you

really are saying is that you should do an appropriate hazard analysis first.

MR. KVENBERG: We did state that in the document. This is the document that I believe is intended for transmittal to AMS for its use, so the fix ought to be here.

MS. SWANSON: May I recommend that under the application for *Salmonella*, we could say environmental monitoring (specific to commodity) or something like that?

MR. KVENBERG: In the table?

MS. SWANSON: Yes.

MR. KVENBERG: I guess that would --

MS. SWANSON: Either that or we could put a sentence leading into the table that says these may not apply in certain situations?

MR. KVENBERG: If I could draw the committee and specifically Dr. Buchanan's attention to question 2, subset b. Maybe the fix would be in the language in the document, where it says for environmental monitoring, *Listeria* and *Salmonella* species may be appropriate -- additional language -- it would be useful is we could just pass on this document to get the specific crafting of the revision right now.

I think it would fit there. If we have an assertion, it would be appropriate to do it now. For

environmental monitoring, *Listeria* species may be appropriate. And I think whatever thought you have or caveat that *Salmonella* would not be for general use, we should probably craft a statement right there after that sentence.

MR. BUCHANAN: I concur. And I think what you need to insert in that is a statement that refers back to the original development of the HACCP plan or specifically associated with the commodity.

MS. WACHSMUTH: John, you have several --

MR. KVENBERG: Okay.

MS. WACHSMUTH: I'll chair it from here if you'd like.

MR. KVENBERG: Yes. Please.

MS. WACHSMUTH: Peggy?

MS. NEILL: I'm wondering if the better fix, because of the intent of Katie's comment, would be to put the entire line of the *Salmonella* and then the environmental monitoring -- direct the entire thing into a footnote.

MR. KVENBERG: I'm sorry. We can't hear you.

MS. NEILL: I'm sorry. Peggy Neill.

I'm wondering if, in terms of picking up Katie's point, in terms of the intent and knowing how people frequently use tables, which is that they just glance

quickly at the table -- take the entire line, *Salmonella* species under organism/test, and then the meaning under application of it -- take the entire line and make it a footnote, organism, asterisk a or something like that, and just bring it down further, organism choice depending on commodity may include *Salmonella* species, et cetera.

MS. WACHSMUTH: Nancy's had her hand up for a while. No? Okay.

Mike?

MR. OSTERHOLM: I guess I'd come back to Bob's question. Having been involved in a number of these outbreaks on the produce-melon side, I've never found -- or our group has never found environmental testing of any of the produce, even in the face of the *Salmonella* outbreak, helpful. And that it's so sporadic, it's so much a function of what may be very well a non-probability sample kind of contamination that I question why *Salmonella*'s in there, because we've just not found it, even in the face of a known outbreak, to be reliable for identification, and that includes melons.

We've worked up several big melon outbreaks.

MR. KVENBERG: Madame Chair, maybe I could propose on fix and see how the committee feels, would be what would happen if we just struck it and didn't say

Salmonella at all, because I think, at least as far as how process control and operations within the environment *Listeria*'s appear to be useful in most applications. I don't know if that would be appropriate and make it go away?

MS. WACHSMUTH: Okay. That's the proposal to --

MR. KVENBERG: That's one possible fix, is just eliminate it.

MS. WACHSMUTH: The proposal is before the committee to drop reference to *Salmonella* under the environmental testing. Are there any objections from the subcommittee or any committee members?

Bruce?

MR. TOMPKIN: That would justify to produce, is that what we're -- this is just specifically to produce?

MR. KVENBERG: Yes. Produce under the QTV. Under the definition of the program of AMS. That's it.

MS. WACHSMUTH: Okay. Go ahead.

MR. KVENBERG: I'm done. Thank you, Madame Chairman.

I guess that takes us -- well, the question was asked on two and we had actually gone -- I guess we're on three. Are there any additional comments on -- questions about the generic organism and the proposal basically to focus on total plate count?

MS. SWANSON: Katie Swanson. If we strike it from the table, we also need to strike it from page 2.

MR. KVENBERG: Thank you. Yes. I had done that on my copy. Under b on page 2, where it says, "For environmental monitoring" strike and *Salmonella* in the text. And then you would strike it in the table.

MR. DOYLE: Mike Doyle. They also ask in the chart what sensitivity level must these test methods meet. And I think that, going back to the total plate count, it's nice when you say it fast they ought to do this, but what levels ought they to be looking for is what their bottom line question is.

MR. KVENBERG: We --

MR. DOYLE: Let me finish, John.

MR. KVENBERG: I'm sorry.

MR. DOYLE: I think what we need to do is have some baseline data to relate to, or they need that information before recommendations can be made. And I think that's what we ought to be recommending, and they need to go out and get those data.

MR. KVENBERG: If I can respond at this point, I think -- we debated long and hard what was meant by the statement of the level of sensitivity, and maybe there's another audit, but we did clearly state that it would be

useful to develop baseline data. The other approach or information we took was just to defer to -- it was less than ten. I'm trying to find it. It was *E. coli* only.

We talked about that on *E. coli*. We didn't talk about it on total plate count.

Do you have a recommendation for where we might say this, because we do it here. Where would we put it?

MR. DOYLE: It says, for monitoring the efficacy of cleaning and sanitation, plate counts or ATP may be appropriate, but I think it's important for the agency at that point to obtain the data that's natural -- normally occurring out there.

MR. KVENBERG: May I ask the question, where are you at in the document?

MR. DOYLE: Oh, I'm sorry. Page 2, the same section. Section 2b, third from the last line. That's where you refer to total plate counts and ATP.

MS. WACHSMUTH: So you're suggesting and insertion that this should be based on data gathered through a baseline study?

MR. DOYLE: Exactly.

MS. WACHSMUTH: Can we just -- Lee Anne Jackson is just pointing out to me that that is stated in 1, the answer to 1, second sentence.

MR. KVENBERG: The second sentence in 1 does say that, but it doesn't harm to say it again under 2 if you'd like, and reemphasize on this specific point that we're talking about developing baseline data to go to the sensitivity question. I guess that's where you want to do it.

It was difficult because the sensitivity question came up, I think, in the original request for document, was 2c, which we didn't respond to you may note. It said refer to 3a. Perhaps we could do it under that, what sensitivity level -- how about under c?

MS. SWANSON: John, if I may?

MR. KVENBERG: Yes.

MS. SWANSON: We had lots of discussion about this in the committee. We had the people who originally asked the question there and they said, Never mind, because every -- you have to look at every specific commodity to determine what the baseline level was. It had to be done on a case by case basis. They asked the question originally thinking they were going to be doing in-house sampling -- or internal sampling in addition to what was going to go on in the operation, and since we didn't recommend that they take additional samples, they didn't need the answer to that question anymore.

MR. KVENBERG: The document is not being modified then?

MS. SWANSON: Right.

MS. WACHSMUTH: Is that correct, AMS guys? I'm slightly confused at this point. Does this address your concern, if you refer to the answer to 1 in this discussion?

MR. DOYLE: I think it's an incomplete answer if we don't include that information.

MR. KVENBERG: Madame Chair, may I try again?

I think maybe the fix would be, if you look at the document and your specific question goes to what is the -- sensitivity level must be tested for the method. That's on page 3 of the document, where it says, question deleted. Refer to 3a1. That's where we could revise this and put in a statement relative to developing baseline information on total plate counts.

Would that satisfy the issue there?

MR. DOYLE: Yes.

MS. WACHSMUTH: Okay. We've got a fix. Bob?

MR. BUCHANAN: Just as a general comment on the establishment of microbiological criteria, which is what you're doing here, is one --

VOICES: No, no. We're being very careful not to do that.

MR. BUCHANAN: Okay. General principles of microbiological testing -- one, you need to establish, for whatever organism you recommend, a required method and the required sensitivity of that method. Now, in most of the methods that you have, somewhere in the document you have indicated the method by a reference. We need to ensure that all of the methods -- all of the tests so indicated have an appropriate citation for the method to be used. Someone should review those citations to make sure that there is a sensitivity associated with that test.

Number two, if in any way you're making a recommendation for a system based on some kind of baseline, then somewhere in here you need to indicate what is the level above that baseline, i.e., how many standard deviations will you allow before such time as you're no longer considered in compliance? If you have a baseline of 10,000 per gram, how many before you go above that, before you actually are considered in a defect situation?

So there's some general stuff here, but if you're going to make some decisions based on this microbiological data, you're going to have to be more explicit about what is the criteria upon which that decision will be based.

MS. WACHSMUTH: Dane?

MR. BERNARD: Thank you. Not having sat through

most of this -- but my understanding of the question was a much simpler request. I mean, Bob is right. If we're talking about setting criteria, then you kick in a whole cascade of things that were simply, from what I gathered, beyond the scope of the question. And while Mike is correct on his intervention, I think we're getting into a very deep hole and you're going to expand this document well beyond what was intended, I think.

If we're going to talk about setting criteria, are we talking about setting criteria cross industry or are we talking about setting criteria in facilities? All of these things have to be considered. And then you start talking about individual commodities processed in each facility, and then you set your numbers. But that was not my understanding of the intent here, so I think the suggestion originally -- I think we ought to go back to the original language and just leave it where it was.

MS. WACHSMUTH: Okay. John?

MR. KVENBERG: Yes. I have to wade in behind Dane Bernard's comments as, yes. It was the consideration of the working group not to set a criteria as a standard which would be applied by AMS at all. The message from the advisory group was basically, assess the process. And I think Dr. Buchanan probably hit on something we may be able

to use, the sensitivity of the method and a standard deviation beyond that method where action should be warranted that indicates the process is out of control.

I don't know how many standard deviations -- if two standard deviations above the count is the point you take the turn. I would defer, if they're going to go that way -- what that number would be.

MS. WACHSMUTH: Bob and then Katie.

MR. BUCHANAN: Dane, I appreciate that the questions were relatively simple as they came forward to us. But I think the committee would be doing less than its job when we make a recommendation that we also ought to also provide them with the implications of the answer we've provided them. And the implications are, if you're going to do this approach, there is a degree of sophistication that underlies these decisions that may not have been captured in the answer.

MS. WACHSMUTH: Katie?

MS. SWANSON: Unfortunately, the full committee didn't have the benefit of having a review of the QTV program, and I think that that might help to put some of this into context.

AMS is going to fresh-cut, ready-to-eat produce processors who asked them to come in and verify their food

safety system. These processors are doing on-going testing at some particular level. They can process anything under the sun. There is seasonality involved so counts can go up, counts can go down. And the question was related to, is there a standard set of tests that you can recommend that would apply across the board to all fresh-cut processors in all situations?

There was no intent to try to standardize a methodology. We had discussions about, Well, do you have to use the ban method because it's FDA regulated? And the answer was, They can use anything they darn well please because these are internal tests that they're doing to check on their own quality control function. So there was no desire to say, Gee, what's the magic count that's acceptable in lettuce? It was more, what are some techniques that these individuals can use to establish their own problems -- to determine if they have process control, if the intervention strategies are working, and those kinds of things.

So we're really -- if we try to develop criteria that would be applicable here, we're going beyond the scope of the original question, and they're nodding in the back, saying yes, we don't want to know that kind of information. We've answered the questions for them.

MS. WACHSMUTH: Okay. Dane's been up for a while.

MR. BERNARD: Thank you. If I -- could I request that the Chair review the charge to the committee for this particular endeavor? In direct answer to Bob's last intervention about this committee not doing its full effort to answer a question, I think that we need to focus in on what the question is. If we're going to go beyond the scope or the charge given to this committee and go into whether this whole program is an appropriate program and the scientific validity of the entire program, it's going to take a considerable effort beyond what we've already done.

We were not asked to do that. I think there are considerable questions as to the appropriateness of the program. If we're going to go beyond the charge, then it opens up a whole new line of inquiry that we need to pursue.

MS. WACHSMUTH: Okay. Jim, do you want to make a quick comment, then I'll have John --

MR. ANDERS: Yes. I just want to comment quickly on the -- AMS was there all the time. We spent about the first three hours trying to get across from them or get the information from them as to what they actually wanted. And because we had some concern about the term sensitivity here, we decided it's not what they wanted. Or they told us

that's not what they wanted.

In other words, we said, did they want a test that had to be 86 percent sensitive, or did that -- that's not what they wanted. And so we determined that the word sensitivity was not that -- yes. I think the whole committee probably doesn't have the information, like Katie said, that we had, where three of the people from AMS sat there and gave us that information, and we literally asked those. It took us three hours to decide even what it was they wanted.

MS. WACHSMUTH: I'd like to let John --

MR. KVENBERG: Well, let me go back to -- at this point in consideration, we did indeed spend a considerable amount of time trying to focus on this particular issue. And in my chair of this thing what I did was draw on the corporate qualities -- experience of the industry people because I viewed this charge as not being -- this is not a regulatory program. The basic charge, the underlying fact of what I understood the charge to be was that qualified through verification is verifying the program as put forth by the industry.

So what I did was ask the people who had corporate experience on quality and auditing what would be an appropriate measure to determine that your process was

under control? And the three people that had corporate experience on how you go about this were Bill Sveum, Nancy Nagle, and Katie Swanson. And the specific charge I asked them was basically to determine that your process was under control, you need to develop a trend analysis on the basis of something. And so we struck on the total plate count as an internal control to be conducted by the firm.

That's how this all developed. And I don't know about getting into standardization of methodologies for the program. I think that we refer to all these methodologies in the sensitivities as they are listed, and the full reference of this I think ought to be the APHA compendium on microbiological examination of foods. That's solely what we relied on relative to adequacy of methods.

I don't know if that's helpful, but that's where we are in the document on this question on 3. And I left it with, I thought -- I'm going back to where I thought we were in review of the document, which was Mike Doyle's point of, what are we going to do with a number, and I had something that I had put forward, that perhaps we could work with small letter c under 2c for a fix to the sensitivity level question, and then it all fell off the track.

So I would like to go back to that question with Dr. Buchanan's intervention and see if we can deal with the

issue we've been kicking around here under that point, if I'm wrong. Thank you.

MS. WACHSMUTH: I think that does take us back to point. But Nancy and Bob both have hands up. Nancy?

MS. NAGLE: I think we do need to go back. We did have the people from AMS who asked the questions were there, and I think that's really key because if we look at answering some of these questions with some of the things that Mike has brought up, we are setting de facto standards for these products based on no facts, based on no information. And I think that's a real key problem that the subcommittee had, or the working group had was that how can we set standards and pull these numbers out of the air with -- and say, if you have a plate count of 10,000, it's good. If you have 100,000 it's bad. We don't have any information on which to base that.

We know there's a lot of variation among different types of products and we spent a lot of time in the beginning of our discussion just even defining fresh-cut produce. It's not simple. It's much more complicated. We heard what we said about meat this morning. Well, this is even way more complicated because we're talking about roots, leaves, fruit, stems, all different types of plants, all different types of products, and they all have different

native microflora. They're all different.

And I think we can't just set a uniform standard. What's good on a strawberry may be totally inappropriate on a piece of lettuce or a melon.

MS. WACHSMUTH: So does this go back to the point of saying that this has to be based on baseline studies specific to the commodity?

MS. NAGLE: Well, but it also means that why would we be setting standards de facto in response to a question from AMS on a program that we're not even reviewing the whole program? I think that would be kind of a back door way of sneaking in de facto product standards or micro-standards without all of the other types of regulatory hearing and all that kind of stuff. I think this is kind of a sneaky way to do it and I don't think it's what we really intended or what we want to do.

MS. WACHSMUTH: What -- can you give a specific suggestion for modifying or not modifying the document that would address that?

MS. NAGLE: Well, I think, to go back to that question of the sensitivity, AMS withdrew that question. They withdrew the question. They said, Strike c, and that's what we did.

MS. WACHSMUTH: Okay.

MS. NAGLE: So that's why we didn't answer.

MS. WACHSMUTH: Wait a minute. Bill's been trying to speak.

MR. SVEUM: Bill Sveum. Let's make this very simple. Let's ask our customer to repeat what they asked us to do, the two guys from AMS, Eric and Randy. Did we meet what you asked us to do and is this sufficient?

MR. FORMAN: We recognize that in some areas of inquiry there may not be complete knowledge and a perfectly sound answer. An intellectually valid answer could be, more information is needed to provide that answer. But to the extent that information is available, we found you were completely responsive.

MS. WACHSMUTH: Bob Buchanan and then Katie.

MR. BUCHANAN: I'd like to go back to some of my earlier comments and re-state them.

My -- whether or not this program is warranted is not under -- I'm not addressing those kind of comments at all. What I am addressing is that if microbiological testing is going to be used as a means of verifying a HACCP program, once you have selected the organisms or classes of tests that you're going to be using, you must revert back to question 1 and there must be a statistical sampling plan established.

You have to have the performance curves for that plan. You need to be able to establish the range of normal variability associated with those, and you have to provide some kind of scientific rationale for making decisions. I will refer you to the meat and poultry HACCP documents that did a lot of work in laying out the types of statistics that are required for using a microbiological test for verification of a HACCP plan. There is a whole subset of statistics built around that use of microbiological testing.

I did not -- and when I said that we wouldn't be doing our job if we provide these as pertinent examples of how you use microbiological testing for HACCP verification, we also should provide them with the background information on the statistical requirements for using that tool effectively.

MS. WACHSMUTH: Either I misread or first paragraph and answer to 1 does not say that's what you're trying to do. It says, "Routine microbiological testing is done to verify process controls and is not sufficient to assure product safety." Studies require the numbers and types of samples is dependent on complexity and so on.

MR. BUCHANAN: For establishing process control is verification of a HACCP plan. And there are statistics that are used specifically for doing that type of testing.

MS. WACHSMUTH: John Kvenberg?

MR. KVENBERG: I'm trying to propose a fix so that we can go through the document. Would it be useful to refer to the work of the advisory committee on what was done in the meat and poultry documents that we had finished and reference them in this document? Would that work if we were going to address it under 1? Would that be appropriate? I mean, I don't even -- we have not considered those documents in the working group, but if there's previous guidance that was put forth --

MS. WACHSMUTH: What documents are you --

MR. KVENBERG: -- on how you do the statistical verification, I'm proposing that we could reference the NACMCF report on that for meat and poultry for guidance.

MR. BUCHANAN: John, there was no NACMCF report on that. This is the preamble to the meat and poultry HACCP regulation.

MR. KVENBERG: Okay. It's a federal document?

MR. BUCHANAN: Federal document.

MR. KVENBERG: Well --

MS. WACHSMUTH: Bruce?

MR. TOMPKIN: Bob is very correct, if you're going to create a regulation. But this is not a regulation. This is a process control system and how to assess it, and

anyone who is in that business would do what Bob is suggesting in their own establishment. But I think what is being proposed is beyond the scope of this particular document, and I'm quite comfortable with the idea of the question being deleted.

MS. WACHSMUTH: Okay. Katie?

MS. SWANSON: To reiterate Bruce's point, if we just strike c out of number 2, it's done because the AMS asked us to delete the question. So if they asked us to delete the question, we can just strike it off this piece of paper.

MS. WACHSMUTH: Okay. We are striking 2c.

MR. KVENBERG: Those are the facts as we had them. They were quite comfortable with deleting --

MS. WACHSMUTH: Okay.

MR. KVENBERG: That takes us I believe to any further comments that -- in 3. And I think we may have reverted back to 2. We fully covered 3 to everyone's satisfaction?

The previous discussion we just had kind of clarified how the working group gravitated to process control on total plate counts, and I don't see any other comments on 3.

MR. BUCHANAN: John, I guess I would like to go

back -- I'm sorry to do this, but in light of the conversation we just had, I would like to go back to question number 1, which is a question concerning what are the appropriate statistical sampling plans? The answer is -- to paraphrase the answer in the paragraph, is that you -- acceptance criteria are not appropriate for this type of sampling plan.

I concur totally, but there are appropriate sampling plans for using microbiological testing for process control verification that are not recommended to AMS that they should be aware of and that we should be providing them appropriate references so that they can be aware of the types of statistics that should be used with this type of program.

MS. WACHSMUTH: John?

MR. KVENBERG: That's what I tried to do earlier --and we didn't get there -- was to refer back to question 1. And I understand from your clarification one of the sources that may be drawn on to refer AMS too would be the Food Safety Inspection Service preamble or regulation that they have on-house on process control variations. Are there others?

MR. BUCHANAN: There is a whole subsection of statistics called process control statistics that would be

appropriate. It's used commonly in quality assurance programs from everything from making widgets on up to producing food.

MR. KVENBERG: Well, if I could, Madame Chair, could we fix this by then referencing appropriate references on statistical samples to refer AMS to under question 1, with the help of Dr. Buchanan?

MS. WACHSMUTH: Right. We could add one sentence that cites --

MR. KVENBERG: We can get a citation.

MS. WACHSMUTH: Okay.

MR. KVENBERG: And if we trust us to do that after -- we'll get the appropriate referencing under what --

MS. WACHSMUTH: Sounds good.

MR. SEWARD: On a separate note, in the section 3 -- excuse me. Skip Seward. When you reference the compendium as a source for the methods, that's not, I guess, meant to be exclusive of others? It's a suggestion of what might be appropriate. Is that right? That's the way I read it.

MR. KVENBERG: That is correct as we wrote it. And I'd be open to suggestion for some language to say additional sources may be appropriate. It wasn't meant to be an official required endorsement of that, but that's what

commonly is referred to, specifically when we're talking about the generalized methods that everyone uses as generally recognized. Total plate counts are -- you go to that document as a source.

MR. SEWARD: Would you like to have an intervention in there to say or other appropriate references? Or just change it to, are recommended, if it's a recommendation or are appropriate as other methods as well? I'm just thinking of the many methods which are available to do total plate count testing in addition to those that might be listed in the compendium, that might serve equally as well to do that.

I don't know if you want to put it in as an AOAC or approved methods or other methods which have been validated. It's a relatively small point. I just -- that if someone was to go into a plant and say, Well, is this method that you're using in the compendium? And they say, Well, no, it's not, but it's serving its purpose, how would that be dealt with. So I'm just looking for --

MR. KVENBERG: Can I respond just directly? Because I think -- the thought would be that AMS ultimately is going to have to make the call of what it wants to do. We can only give them guidance on this document. There was some desire in the discussion of the working group -- and

AMS was integral in this discussion -- to look for some uniformity in the approach.

But at the end of the day, we can only -- we could strike any reference at all -- this is simply guidance. We can either delete the reference or modify it. I don't see a problem.

MS. WACHSMUTH: Bruce and then Peggy.

MR. TOMPKIN: I think it's a good reference, but it could just say compendium methods and so on, for example, contains a description.

MS. WACHSMUTH: Okay. Peggy?

MS. NEILL: I'd like to ask whether the intent of including this citation will be spelled out in the document, in this intervention?

MR. KVENBERG: If I could, if I understand the question was directed at Dr. Buchanan, but it's a working group question I think. Is that correct?

I think in collaboration and my understanding of what we were going to do, Dr. Buchanan and I were going to reference appropriate referred methods for AMS for their consideration and leave it there. Is that -- is my understanding correct? Is that what we agreed to do and just basically identify the source for guidance? Am I incorrect in that?

MR. BUCHANAN: I was anticipating that there would be a short sentence to say there are statistics appropriate to the verification of microbiological testing within a food system. Here is appropriate citations where that information can be found.

MS. WACHSMUTH: Yes.

MR. KVENBERG: That's my understanding.

MS. WACHSMUTH: Is there a problem, Peggy?

MR. KVENBERG: We could probably craft the language before lunch, I would hope. We could see it, if you want to look at it before it goes out. It's clear to me.

MS. WACHSMUTH: Peggy, do you have a problem?

(No response.)

MS. WACHSMUTH: Okay. Do you want to finish up the document?

MR. KVENBERG: Sure. Are there any comments on intervention techniques question 4?

MR. BUCHANAN: John, an alternative wording to Bruce's suggestion could be simply that you provide this as an example and just say, Or other validated microbiological methods.

MR. KVENBERG: I think we have nods around the room. That's okay. That was on the APHA reference.

MR. BUCHANAN: Right.

MR. KVENBERG: Any other comments on 4?

(No response.)

MR. KVENBERG: Hearing none, any -- and 5 was rather brisk. Any comments on 5?

(No response.)

MR. KVENBERG: Madame Chair, hearing no additional comments, we will provide additional language on relative reference -- pertinent references on methods for utilization on referring to appropriate references for sampling -- statistical sampling to this document.

MS. WACHSMUTH: Okay. I think that takes us through the document. Bob and then Jeff.

MR. BUCHANAN: John, just one question. Was the -- during the discussions of your working group, was the primary focus on bacterial pathogens?

MR. KVENBERG: Yes. And the lack thereof, relative to human disease.

MR. BUCHANAN: Okay.

MR. KVENBERG: It focused on how do you measure for the pathogen in the product when it is so frequently encountered? And so the intervention strategies and the leap of faith that was made was that through process control and sanitation monitoring, you have the ability to reduce

the risk of multiplication steps of the pathogen and through selective sourcing, we tried to be clear in the document as well, that the raw materials is important in an incoming load.

Bearing in mind one of the pieces of information that came to light in the working group was people in the industry said, You're only going to affect a risk-reduction factor of 1 log across the board. That was the sense of the group. So that's --

MR. BUCHANAN: I was wondering if there was any discussion on what would be the appropriate test if your hazard analysis identified either protozoan or viral pathogens?

MR. KVENBERG: That was discussed in the working group and it's not on the document. There was some discussion about making inclusiveness of statements such as cyclosporin or *Cryptosporidium* in the document in certain instances. We discussed it briefly of how that would fit in the table and we couldn't work it in.

Perhaps some language that specifically guides them towards directed pathogens and specific situations to include parasites would a be useful addition to the document? I don't know where. Can we look at that. Just --

MS. WACHSMUTH: Just a second. We're getting a little bit ad hoc.

Katie?

MS. SWANSON: Katie Swanson. Isn't that addressed in the discussion of the hazard analysis has to be done to identify the hazards of concern and then the appropriate interventions would be addressed? I thought we had it covered somewhere in there.

MS. WACHSMUTH: Okay. Let's not recover the territory that the working group did if we don't have to.

Okay. Jeff?

MR. FARRAR: I'd just like to reinforce one statement on the first page and perhaps suggest a slight modification. That being basically the middle sentence that says, this response does not serve as an endorsement of the QTV program.

There was considerable debate and discussion among committee members about the appropriateness of the program, as Dane mentioned earlier. However, we recognize that was not our charge. However, the reason for the statement was to hopefully ensure that this body, in any shape form or fashion, would not be construed as endorsing this program over other programs. I'm just not sure the statement goes far enough.

I'd like the group to consider including a secondary statement along with that to state that this -- I'll suggest some alternative wording here.

The review of the technical questions from the QTV program should not be interpreted or used by USDA as an endorsement of the QTV program by this national advisory committee. This includes any reference to the review and marketing materials or in seeking OMB approval of the program.

MS. WACHSMUTH: Okay. Any comments for or against? Dane?

MR. BERNARD: I would support that.

MS. WACHSMUTH: Okay. Are there any objections?

(No response.)

MS. WACHSMUTH: Okay. If you could provide that in writing to John.

MR. KVENBERG: Just so I understand though. So that's a direct insertion in total that I've received that we put in --

MS. WACHSMUTH: In place of --

MR. KVENBERG: -- in place of? Okay. We have a new language for that one line. Thank you.

MS. WACHSMUTH: Okay. Bob?

MR. BUCHANAN: I guess I have a little

trepidation about the final phrase in regard to OMB. OMB will ask for what kind of technical evaluations of any program that comes before it has received. Stating that this has been reviewed by the advisory committee is certainly an appropriate response, if you have. Saying that it was endorsed by the committee is something else. But to say that it had been reviewed is appropriate.

MS. WACHSMUTH: Jeff, do you want to reply to Bob's comment?

MR. FARRAR: Yes.

MS. WACHSMUTH: And then Nancy as well.

MR. FARRAR: The QTV program provided a series of five very specific technical questions from within their overall program. We did not have an opportunity to review the overall program. I think if we had been presented with that charge, which would have taken considerably longer, there would have been some very strong reactions to the program about the content and direction.

So that's what I'm hoping to present is any misinterpretation that this group has reviewed the QTV program. We have not reviewed the QTV program.

MS. WACHSMUTH: Nancy?

MS. NAGLE: Yes. I too wanted to reiterate that. We did not discuss the program overall. We answered very

specific questions. We only answered those questions. We discussed no other part of the program, and I agree. We would have had a much different discussion if we had been reviewing the whole program.

MS. WACHSMUTH: Yes. I don't think that's the issue. I think the issue is the reference to OMB, if that's appropriate.

MS. NAGLE: Well, but I think the issue that we have is that if it -- Bob says, if OMB asks them, do they have technical review of their program and they say, yes, that's inappropriate. We answered five questions. We did not technically review their program. That's two different things.

We answered five questions that they asked us. We did not review the program. So that's where I think --

MS. WACHSMUTH: Okay. Then I think it stands. Unless there's any objection, we'll let the sentence stand as Jeff suggested. It is what this committee wants.

Peggy?

MS. NEILL: I wonder, to the extent that -- is it also implied -- when everybody's looking at things quickly -- we've all been calling it the QTV working group and the QTV this, and you think it's the program when in actuality it's just the technical questions from the

program. So somehow even just retitling this might strike the right note of clarity.

MS. WACHSMUTH: Report from -- a technical review of? I don't know. Any suggestions?

Bob?

MR. BUCHANAN: Just as a point of clarification, the subcommittee that reviewed this was a reconstitution of the HACCP subcommittee. It was not an ad hoc committee. It was not a -- et cetera. It was -- this was a HACCP question. It was put before the reconstituted HACCP working group which was never disbanded. It's always been kept active.

MS. WACHSMUTH: This is a new group though. I don't think that's -- no? Sorry. The steering committee doesn't agree.

Jeff?

MR. FARRAR: Peggy, I shared your concerns that even a statement worded this way may not fully divorce the national advisory committee from the QTV program. I'm somewhat lost though in how else to phrase that or what else to do to prevent that from happening.

The specific first part of the statement says, the review of technical questions from the QTV program. We can say the review of five technical questions, to add a

little further specificity. I'm concerned about the long-term association as well.

MS. WACHSMUTH: I believe that there is concurrence on the statement. I think that Peggy was further saying that perhaps the title should reflect the committee's work as a review rather than the title of the program.

MS. NEILL: As a response.

MS. WACHSMUTH: As a --

MR. KVENBERG: May I ask a question of clarification from the Chair?

MS. WACHSMUTH: Dr. Kvenberg?

MR. KVENBERG: Thank you. I'm just trying to stay up to draft the document, and I want to get through with it.

So we are going to retitle the statement of -- instead of the report of the QTV working group, which seems to be -- that would be stricken anyway, because it will be a NACMCF report when it goes out. It won't have this title. We would use a new title for this thing to say this would be the NACMCF review of technical questions from the QTV program. Would that provide clarity on the header of the document?

MS. NEILL: I think so, in the context of just

comments.

MR. KVENBERG: We'll just take the first part of the sentence that was provided in this language and title it, the review of technical questions received from AMS on the QTV program.

MS. WACHSMUTH: Okay.

MR. KVENBERG: Thank you.

MS. WACHSMUTH: All right. I think we're there.

Okay. Before we break for lunch, one other piece of information because I know some of you are leaving. We did look at the calendars and we have a date for the next meeting. And that will be September 21 to 24, and it will be in Washington. Through 24 -- it will be four days. We looked, and the vast majority of people can make that.

Okay. We'll take a break now and we'll reassemble at one o'clock.

(Whereupon, at 12:00 noon, the meeting was recessed, to reconvene at 1:00 p.m., this same day, Friday, May 28, 1999.)

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A F T E R N O O N S E S S I O N

(1:00 p.m.)

MS. WACHSMUTH: Okay. One thing that is not on the written agenda that is always a part of these meetings is a time for public comment at the very end, and we will have that. We have had no requests. That's one reason why it wasn't put on this agenda that you have. But we will take the time, and if anyone from the public has something to say, there will be someone here to here them, I promise.

Okay. We now have -- next is report from the risk assessment subcommittee. There were two sessions. And Michael Jahncke chaired those. Do you want to --

MR. JAHNCKE: Thank you, Madame Chair.

What I'm going to do is -- as Kaye indicated, we had two days worth of presentations, and I do have some notes that I put together last night, and Cathy De Roever has the file copies. I'm going to give sort of a Reader's Digest version of the two days' presentations.

We were scheduled for an hour but keeping in mind -- and the reason for this -- and also keeping in mind that an excellent summary of what was presented both on Wednesday and Thursday in the Federal Register notice that was included in the packet is excellent, plus the document of both of the status of the risk assessments and that

information -- both of those are in there, and those are basically good overviews of what was presented.

The first day we had the working group -- the working group on risk assessment came and made their presentation on *Vibrio parahaemolyticus*. They have developed a document entitled, "Risk Assessment on the Public Health Impacts of *Vibrio parahaemolyticus* in Raw Molluscan Shellfish." There were eleven excellent presentations during that day.

And what I saw as our role as the subcommittee -- we were there at this point to listen to their presentations and be there to offer scientific guidance, suggestions, to ensure that what they were doing was scientifically sound, that if they were missing any type of data that we would have some suggestions of where they should obtain additional data, or if they had incorrect data, to address that.

We were there to help keep them on track and let them know they were proceeding along sound scientific methods. The real -- when the rubber's going to hit the road on this -- they have been collecting available data. They're still in the process of collecting data. But over the next two or three months, I believe at the September meeting, they're going to be coming back and making a presentation. They're collecting the data and they're

assembling the risk assessment models. At that point, I think as a subcommittee, we'll really be able to look at the outputs on that and the outcomes on that.

On the first risk assessment that was done, the scope of the risk assessment -- the purpose of it and the scope was to determine the relationship between molluscan shellfish and *Vibrio parahaemolyticus* in illnesses. The risk assessment, the goal of it, was to produce estimates of illnesses for levels of pathogenic *Vibrio parahaemolyticus* like to be exhumed by different subpopulations. And within that context, as I indicated, there were eleven presentations that addressed various issues.

The risk assessment working group was collecting information, asking for information to help them address the following questions: what is the frequency of occurrence of pathogenic strains of *Vibrio parahaemolyticus*; what parameters, if any, such as water temperature, salinity, nutrient profiles can be used as indicators of its presence; what is the frequency of occurrence of pathogenic strains of *Vibrio parahaemolyticus* in molluscan shellfish and numbers of pathogenic organisms at the time of consumption; are levels at the time of consumption related to levels in the growing water?

There were data shown indicating that -- and it's

temperature dependent, season dependent, indicating that at time that the concentration within the tissue of the oyster is much higher than what was found in the water. During the winter months, few of the organisms were found in the oyster tissue and/or in the water column, but there were quite a few in the sediments.

What is the dose-response relationship from outbreak epidemiological animal or in vitro studies? What are the dose-response differences between different strains and serial types and among the different human susceptible subpopulations? What is the role of post-harvest handling that may be influencing the numbers of *Vibrio parahaemolyticus*?

And this is more, as I see it -- this last question's more about -- as Peggy mentioned this morning, there was a little confounding of some risk management actions and also some risk assessment that was confounded in some of these presentations. One of the questions that I think is more of a risk management or mitigation issue than an assessment issue but was one of the questions they're looking for, can reductions in risk be achieved through depuration of relay? And some of these issues were brought up at the time.

When the presentations first started, there were

three questions that were posed to the subcommittee, and I alluded to them when I started this presentation. One of the questions that was posed, what data are needed? As I indicated, they -- and for some of these items, there's not a lot of data out there. And I think one of their challenges as they assemble this risk model is to make decisions on which data needs to be included and which won't. Some of that's going to fall out as they put it together, and as new additional studies are coming in they could use that to look at the outputs and determine what type of data needs to be included and what type doesn't.

The other question was, is their scientific approach sound? That was asked to our subcommittee. They're making the presentations. We're supposed to be answering these questions, and any other comments and suggestions.

They started out with their introduction statements describing the outbreak illnesses in 1997 that involved about 209 individuals in the Pacific Northwest, from California to British Columbia. Again, in 1998, more than 500 individuals from the Gulf Coast, Northeast, and Pacific Northwest reportedly became ill after eating raw molluscan shellfish and the single serial type of 03K6. This was identified as predominant in the 1998 outbreak. So

they discussed these issues.

Other presentations talked about FDA's program with states, currently with the National Shellfish Sanitation Program. Again, some of the questions that were brought up in this assessment, at least at some point in the process -- or after this process is done, perhaps the next step would be to look at some of the FDA's current allowances. They currently allow -- that cannot have levels of greater than 10,000 cells per gram in *Vibrio parahaemolyticus* in oysters at the current time. Some of the recent outbreak data indicates that some of these illnesses may have been caused by few organisms in these oysters.

They also indicated that during these outbreaks, FDA didn't rely on those levels to open or close it. They relied upon changes in season and temperatures that have historically shown that they have not been associated with illness, and they also relied upon absence of particular strains of *Vibrio parahaemolyticus*.

One of the questions asked was -- there are many federal laboratories that are able to do these analyses -- how effective or efficient are the states in these? And the response was they're getting better. There are training programs. Again, this is outside the risk assessment scope,

but there are programs in the states to allow them to be better at detecting various strains. Information was also presented on differences between virulent and non-virulent *Vibrio parahaemolyticus*, and possible pathways into the water from ship ballast water or relaying.

There were discussions on the effect of physiology of the oyster and *Vibrio parahaemolyticus* numbers, and perhaps the possible effect of -- you deplete the glycogen, you drop the pH, and the possible effect on *Vibrio* numbers. There was also discussion on information, the data collected. Again, we're looking at not necessarily the effect of time and temperature on growth rates but what type of data is available at the end product that can be used in this risk assessment?

There is some data on *Vibrio parahaemolyticus* numbers at the retail level versus the harvest level, and discussions went into effect of are those really reflective as what really comes out of the water at the time, or are they more reflective of time-temperature relationships? Andy DePaola gave some information on the effect of refrigeration on *Vibrio* numbers showing that refrigeration really did not have that much of an effect in reducing *Vibrio parahaemolyticus* numbers. Basically, I think by placing these things under temperature control and cool them

down, you decrease the rate of increase in growth, but you don't necessarily decrease the numbers that are currently there.

One of the presenters described the seven case series and four outbreaks that have occurred. Data on consumption was presented. And the last presentation focused on dose-response models, described some of the earlier human feeding studies conducted in Japan, I believe, with graduate students. They also covered animal feeding studies and some of the limitations associated with trying to correlate animal feeding studies to humans.

The working group discussions -- we commented about regarding dose-response consumption patterns and relationship of risk to special subpopulations. Discussions went on about regarding the need for multiple biological end points risk assessment, including gastrointestinal illnesses, septicaemia, and perhaps even death. There was discussion regarding pre and post harvest modules and again, we fell into some mitigation outside the assessment scope of things, but looking at potential intervention methods, including relaying of shellfish from one harvest area to another.

There was also even talk about somehow even treating ballast water in ships, which for the most part,

becomes quite impractical on some of these large vessels.

During the public comment period, some industry members offered to provide data regarding consumption patterns, looking to such things as stratification by where it's eaten, urbanization, education, and income. There was a lot of discussion and there was concern saying, Why do we have to have this done by July 6? And everyone said there's more data coming out. Why not wait? And the answer was -- and I think it's a very good answer -- this is a start and there has to be a time when you go with your best available data and start the process.

But this is not -- because it's starting doesn't mean it's going to end in September. As new data is being developed, this will be incorporated into the risk assessment and it will strengthened and grown from there. But the base will be there. The structure will be there, which would hopefully make it easier, as new information comes in, to help build the models.

Again, I saw the role of the subcommittee basically to offer scientific guidance and advice to the risk assessment working group, and to make sure that they're on track; that their approaches are sound, their methodologies made sense. And again, in September, we will see their output from this.

Any comments? That was basically a summary of the presentation on Wednesday on *Vibrio parahaemolyticus*.

MS. WACHSMUTH: Okay. Are there any observations by subcommittee members who were there or questions by committee members who weren't there or any comment from FDA?

MR. POTTER: Thank you. As Mike pointed out, the principal input FDA was seeking in the *Vibrio parahaemolyticus* risk assessment was whether or not the approach was sound and whether all available data were being appropriately included in the data base. The next step will be presentation of the draft risk assessment at our September meeting, so that they can get a final read from the committee before they go forward to write the final risk assessment.

As Mike also pointed out, the final risk assessment will still be a work in progress. As new data come in, they will be plugged into the framework that's developed.

MR. JAHNCKE: Thank you. And yesterday, there were presentations made for *Listeria monocytogenes*. The risk assessment working group presented a document that was called, "Structure and Initial Data Survey for the Risk Assessment on the Public Health Impact of Foodborne *Listeria monocytogenes*."

In this session, there were five presentations. Similar to the previous day's process, they initially asked three questions, similar questions: is the scientific approach sound; do we have all the right data; and have we overlooked anything? That was charged to our subcommittee as we listened to the presentations.

The first presentation provided introduction material to the risk assessment process. Also, they addressed that other countries such as Canada and Denmark do have different policies concerning *Listeria monocytogenes* levels in foods. They wanted to describe that their risk assessment was seeking four types of information: information on the level of *Listeria monocytogenes* in foods and consumption levels of these foods -- that was their exposure assessment -- and information on the epidemiology of foodborne Listeriosis and human health consequences of such exposure; their dose-response information.

They want to use this risk assessment to determine the frequency of occurrence of *Listeria monocytogenes* primarily in ready-to-eat foods. And they hope to collect information on the numbers and types of organisms associated with these foods at the time of consumption. They're going to be using food consumption data bases to assess the amount of these foods that are

consumed and analyze epidemiological data concerning food implicated in outbreaks in sporadic cases. A dose-response model is planned to be developed and the information may come from the literature and/or epidemiological animal or in vitro studies.

One of the more lengthy presentations was the -- well, one of the first presentations was on the food contamination module, and that module was responsible for collection *Listeria monocytogenes* food contamination data and using this data -- the thought was to use this data in conjunction with dietary intake data to determine the intake of pathogens in certain foods. Again, the emphasis was on ready-to-eat foods, and they're looking at data primarily from 1980 to the present, to include both qualitative and quantitative data.

The data they're looking at was primarily of U.S. origin, although they were not going to rule out data from other countries. It was pointed out that there are different products in different countries, some of them higher salt contents and other things that may make it a little more difficult to relate it back to the U.S. type food and products. Indicated that Listeriosis is a relatively rare disease, but there can be considerable mortality associated with it.

Most commonly affected populations, pregnant women, neonates, elderly, the immune-compromised. I went over a little bit that there's seven species of *Listeria* with at least 13 serial types, of which the 4b, the 1/2b, and the 1/2a are responsible for most of the human Listeriosis.

They indicated that additional information is needed for numbers of *Listeria monocytogenes* in some specific product areas, indicated that information for fruit juices at the current time is -- data is fairly scarce. In the dairy area, they indicated the available information is fairly good. Sea foods -- information is available but needs sorting by type and preparation, and seafood is sort of lumped together. In red meats and things, the available information is fairly good. Sandwiches -- there's some European data available but additional quantitative data is also needed.

Much of the data is of the type of presence or absence, but it's still useful, but additional studies are needed to provide quantitative data. Work has begun by the working group to develop a data base addressing frequency and numbers of *Listeria monocytogenes* in specific commodity groups.

One of the larger presentations that went on

yesterday was on the consumption data module. I think one of the drawbacks of that consumption data module is just the amount of information that's out there, and I think their challenge is going to be how they're going to take that data and break it into useful groups. Somehow they're going to have to come to grips with that, and that's -- I don't know how they're going to get their hands around all that, but it's going to be a tough job.

Consumption data was going to look at foods that present the greatest risk of being contaminated with *Listeria monocytogenes*, and that data's going to be examined in light of consumption data. And as Mary pointed out, there were two important sources of consumption data using the analysis, the Agricultural Research Services continuing survey of food intakes, and the other is maintained by CDC's National Center for Health Statistics. They may have a little difficulty trying to merge these two.

The information on there that they have for these specific groups -- they have data on amount eaten per person per day per gram. And as I indicated, these data bases have a lot of information on numerous categories of foods. And there are limitations. There is some under reporting. Some of these are done by surveys. Some of these are done by telephone survey, so there can be under reporting of

consumption data. And they're going to have to come in and come up with some type of waiting factors as they try and blend these two data bases.

They also have consumption data for different kinds of products that are kind of mixed dishes. They're going to have to somehow sort out -- you've got a sandwich that's got meat and vegetables, and somehow they're going to have to tease that out or come to some type of relationship with that.

Discussions were held on how to provide additional information for the consumption data base. There was -- at that point, there were offers from people on the NAC committee and also later on from some industry groups, that there is some additional information on consumption in different food types that can be made available, that can be part of this risk assessment. There were talks about a market basket survey. And as I said, some industry members like the Dairy Association and others that agreed to provide data for the consumption model efforts.

Again, information on products from other countries are available, but they caution that there may be some significant product differences: higher salt levels; different types of processes; little different pH's and things like this that they're going to have to look at if

they're going to include this in this type of data base.

The public health module part of the working group addressed the epidemiology of *Listeria monocytogenes* outbreaks and characteristics of dose-response. That module they indicated was going to focus on three data points: virulence characteristics for host factor susceptibility or immune satisfactors -- and this is taken into context with the food matrix -- data for this models are going to come from some outbreak and case reports or animal or in vitro studies.

Information was presented during the day on the pathology of *Listeria monocytogenes* and information was also provided on the epidemiology. And information was also provided on describing some of the characteristics of people that are susceptible to Listeriosis, and virulence characteristics of *Listeria monocytogenes*. And the discussion was also, as we're using animal models -- and if you look at the susceptibility of some of the populations, elderly being more susceptible to Listeriosis -- of developing animal models that may have to reflect that. Again, it's difficult to sometimes take animal models and translate it into human studies, but identify those characteristics in elderly people may make them more susceptible and try and develop your animal model to reflect

some of that, to get some data that may be more applicable.

Information was given on the type of food vehicles responsible for Listeriosis, along with again, information on susceptibility of various groups of people.

The working group discussions -- there was a lot of discussion on what type of data's needed for this risk assessment and that the presenters acknowledged that quantitative data is the most helpful. And there was suggestions from the subcommittee group and also later on from the public on suggestions of how to acquire additional data.

A fourth area identified in these presentations was a consumer preparation practices. There were some discussions on how are you going to address this in your model? Another subcommittee member offered to provide data regarding methods that are more likely to recover injured cells. Other suggested sources of data included some United Kingdom and German data, and perhaps even some Norwegian data.

Again, we got back to the point of, what's the rush for July 6, and there was concern later in the public comment that there's not sufficient data. We might as well wait for all this data -- is going to be in before this model is developed or this assessment is completed. Again,

the group was reminded that given the best available data at this current time -- and, I might say, in this particular risk assessment working group, there's a lot of information out there, that it is time to start developing the risk assessment. Again, as more data comes in, this information can be used later to modify, to build on to it, to substitute the data that's currently in there, so it is a living, breathing, operation.

There was a suggestion also that maybe part of the background section of the document be expanded to compare some of the policy issues of the U.S. and other countries, and look at that as far as Listeriosis in each country. Again, the issue of multiple biological end points was discussed, as far as the risk assessment.

There's the general question of how to supply the data and where to send it, and I think that's a very valid question. The spokesperson for the working group indicated that summary data is acceptable, but they prefer primary data, as much detail with that data as possible, identifying food vehicles, the analytical methods, sensitivity of the methods used; these types of things. They indicated that where the data needs to be sent is to -- one person is Dave Linebeck, University of Maryland, also to anyone in the steering committee here at NAC. And this information then

will be given to Richard Whiting and his group as they develop the risk assessment.

There are data gaps. There's going to be data gaps. Again, in September, as the working group takes the information that they have and start putting it together, what's going to happen is that they're going to be able to do a better assessment of the quality and the types of data that they have, and they're also going to have a better assessment of the types of data and studies that they're going to need to help make their model -- their assessment model more robust.

That is a summary of what took place yesterday. Again, all these presentations from both days were excellent presentations. I really would like to commend both working groups, both the *Vibrio* one and the *Listeria* working group on doing an outstanding job of binding this material and presenting the material. It's a very difficult area. It's a very challenging area, but it's also a very exciting area, and we certainly are looking forward to seeing their document in September and see what they do with the current information. And looking forward to, as a -- risk assessment subcommittee is looking forward to again looking at their output at that time.

That concludes my report.

MS. WACHSMUTH: Questions or comments from the committee members?

I think one thing I wanted to say, just in terms of background, I only attended the *Listeria* session yesterday but apparently, these are two -- these approaches are different. One is more of a ranking approach and the other is more of a qualitative, specific pathogen, specific product, and the outcomes will be quite different.

Maybe Bob, Dick, someone would like to describe that a little bit so we'll know what to expect as an output a little more.

MR. BUCHANAN: Yes, I'd be happy to. I just wanted to clarify one thing. In the Federal Register notices, are the names of the heads of the risk assessment teams and how to send data to -- if this is problematic, then there were some alternative approaches that were discussed, but you should really contact the individuals indicated in the Federal Register if this is a problem. But Dick Whiting and Mary Ann Miliotis are the leads of the two teams, the *Listeria* and the *Vibrio* respectively, and that's where most of the -- if at all possible, the data should come into.

These are two distinctly different types of risk assessments. The one on *Vibrio* is to answer some very

specific questions about *Vibrio parahaemolyticus* in raw molluscan shellfish, is what is referred to as a product pathway analysis. And they're designed to answer some very specific questions about those commodities. *Listeria* risk assessment is a total diet risk assessment where we're looking to determine the foods that represent the greatest risk to the U.S. consumer and regard to Listeriosis.

This is referred to as a risk ranking. We are trying to identify among a broad group of products which ones we should be focusing our efforts on, and so the outputs are very different. And we'd be happy to go into more detail than that.

I would, before Mike leaves, like to thank him for all his work he did in helping FDA go through these two public hearings.

MS. WACHSMUTH: I'll echo that. Have a good trip, Mike.

MR. JAHNCKE: Y'all have a nice holiday.

MS. WACHSMUTH: Okay. Any other comments, expectations? We -- Angela?

MS. RUPLE: I'd just like, as a member of the subcommittee, like to echo Mike's comments on the excellent job that the two risk assessment teams did. I think those of you who didn't get a chance to hear the presentations

will be very surprised at the amount of work that they have done in such a short amount of time, and I think everyone should look forward to their report to the September meeting.

MS. WACHSMUTH: Dane?

MR. BERNARD: Thank you. I'll echo what Angela said. They were excellent presentations, well-organized, and the presenters all should be complimented for the job they did. It was truly impressive.

I know that both these risk assessments will move ahead as rapidly as possible. However, I'd like to remind those on the teams that there's a particular urgency felt on the part of the industry for the *Listeria* risk assessment. Dr. Kvenberg and I last week were at a consultation where *Listeria* was also on the table and it was specific to seafood, but our trading partners are a bit confused about *Listeria* policy in the U.S. I think some clarity that may come from using the results of this risk analysis to reexamine our total management strategy we think is imperative.

And in that regard, there was a comment during the session on *Listeria monocytogenes*, and I think Bruce made the point -- and I didn't hear it in Mike's summary, although I may have missed it -- that as you go through the

risk ranking, it would be desirable to look at segmenting products into those where the organism has a probability of growing where it doesn't appear that it will grow, and where maybe you have a question mark as to whether it will or not. I think that would be of great utility as you begin to look at risk management decisions that might depend on a risk assessment.

Thanks.

MS. WACHSMUTH: Mike?

MR. OSTERHOLM: I think one of the areas that all of us would like a lot more information on, but I see it coming through over and over again, as we define Listeriosis as that which we find, i.e., the invasive disease issue, the more severe cases. And I think there still are legitimate questions about the burden of actual disease out there that's non-invasive disease that we just have a very hard detecting. And so I urge that that be carefully looked at, because we're trying to do some work right now in fact in that very area to further define that.

And as you all know, the difficulty of isolating it out of just common diarrhea and how frequently that occurs -- and so that can't be lost, because I think that's part of the overall burden. We need more data on it. I just didn't hear addressed -- and it wasn't in the Federal

Register either.

MS. WACHSMUTH: It was in the presentations --

MR. OSTERHOLM: Oh, was it? Okay. Good. Great.

MS. WACHSMUTH: Yes. It was a pretty significant -- several slides, but I still don't think there was a great deal of data.

MR. OSTERHOLM: Yes. There isn't.

MS. WACHSMUTH: Bob?

MR. BUCHANAN: There was also a very strong message sent by the advisory committee that multiple end points should be examined in the risk assessment, and that was heard by the risk assessment teams.

MR. OSTERHOLM: Good.

MR. BUCHANAN: Do you have any good data?

MR. OSTERHOLM: No. Actually, part of the problem is methodologically trying to figure out how to acquire those data and how to prospectively look at it. One of the things that the group in Minnesota are doing right now is trying to get at that other 98 percent of diarrheal disease that's out there other than *Salmonella*, *Campylobacter*, and *E. coli*, and that's one of the hot ones to look at.

We're also looking at *Helocobacter* [phonetic]. There's a number of different organisms, other *E. colis*,

that are not in the category. The group just in the last year and a half has discovered three additional new *E. coli*s that don't fit into any of the current categories of a pathogenic *E. coli*. And I think there's just a lot there yet to be found, and *Listeria* I think is going to be one of them. From our initial data, it looks like *Listeria* clearly is going to be some role.

MR. BUCHANAN: This is Bob Buchanan. Just to reinforce a comment I sort of made off the cuff, certainly there is a feeling that the disease that we call Listeriosis is probably only the small percentage of total cases, the septic cases of a wider disease syndrome. If anyone has any data on the -- just the gastrointestinal involvement, this is very important to us in terms of an overall estimate of the incidence of the disease.

MS. WACHSMUTH: I'm going to turn it over to you, because the next item is -- and there will be full day, at least right now that's the way we're thinking, for each of these in September, so we'll be looking at those exact data and can critique it, looking specifically for the things that we all think might be most important. It's a good opportunity. The -- looking at the specific pathogen commodity combination will then fall to any particular regulatory agency.

For instance, if USDA is going to look further at deli meats and hot dogs, we will have to take it from where the ranking has presented that relative risk to us. But that means a lot of the base work is done, so those next assessments shouldn't be as time consuming as most of them have been in the past.

Okay. I'm turning it over to Dr. Potter now to discuss bare hand contract proposal.

MR. POTTER: Thanks, Kaye.

The Conference for Food Protection is an organization of state food safety regulators who meet every other year, and among their responsibilities is to discuss brought up by guidance presented to them in FDA's food code.

In the 1998 Conference for Food Protection, there was considerable discussion of guidance in the food code that would prohibit bare hand contact of ready-to-eat foods to prevent transmission of foodborne disease. While there were some data discussed in that meeting, the discussion was heavily-weighted toward anecdotes and strongly-held personal beliefs. And in an effort to civilize the debate and to elevate its scientific quality, FDA is asking the National Advisory Committee to help assess some of the issues of science involved in the transmission of disease through bare hand contact with ready-to-eat foods.

In April of this year, FDA published in the Federal Register a request for data on transmission of disease through bare hand contact and issued a number of questions with that request. Based on the information at hand and the information that's forthcoming from that request, FDA is going to prepare a white paper on bare hand contact with ready eat foods, and will provide that white paper to members of the National Advisory Committee for your review before the meeting in September.

Part of the meeting in September will be a public hearing with the committee on the issue of bare hand contact, so the committee members can be exposed to more of the debate and then more limited debate by the committee itself on these issues to provide guidance to FDA going into the next Conference for Food Protection in the year -- in April of 2000.

Mike?

MR. OSTERHOLM: First of all, I really congratulate FDA for taking this stance. I think this is a very important issue, particularly as we see the ever-changing picture of who is serving our food and the increasing role that cold food plays in our public settings. I think that's an important issue.

I guess one of the areas though that I think

that -- this is not a held belief. It's really a question -- is that oftentimes I've heard the study referred to as looking at the risk of bare hand contact. And I think that we would rather see the focus, at the risk of just hand contact, period, because I think what it's going to ultimately be is a cost benefit issue, where it may be that gloved hand contact may play a role also in how gloves become contaminated, whether basically hand liquor gets involved.

As you know, we know from the health care studies that we have real concerns about that, that if you wear a glove long enough, you do some very interesting things to the microflora of the hand with all the sweat and dead skin that breaks off and the leakage that occurs. And having worked a lot with blood-borne pathogens, we're very familiar in that side. That can play a role too.

So I think that I would look at this as kind of taking the known hypotheses, that it doesn't matter what you do with the idea that you're actually trying to show one or the other is less a risk with one or the other and what are the circumstances, opposed to assuming bare hand's the problem, glove's not or vice versa. I think they're both going to contribute. It's just a matter of how much and under what conditions each contribute.

MR. POTTER: Thanks, Mike. And that is an important consideration.

If the committee looks behind Tab 11, the questions that are being asked are there, and in fact that is question number 4, what are the positive and negative aspects of using gloved rather than bare hands, and under that question, whether pathogens can increase in number on gloved hands and if so, whether there are additional procedures -- whether gloves are likely to become a source of contamination and so forth.

MR. OSTERHOLM: But could I add one piece? I think that one of the areas that we really don't have a good handle on -- and actually, Katie, you raised it today about the issue of *Staph* and *Strep* -- our sense is that there may be a lot more *Staph* and *Strep* foodborne illness today that could be associated with gloved hands because of the microflora, and we know that from the health care side, where we have seen the substantial change in the flora of the hand based on long-term gloving.

And so I would only add here that this is talking about pathogens on the glove, which is an important consideration, clearly, because of cross-contamination that can occur. There's nothing worse than going into a store and watching somebody pick their nose with their gloved hand

and then just keep going. Their hand's protected, they think. They're fine.

But I think it's also the issue of what's inside the glove and what changes over time, which is an interesting dynamic that is somewhat different than you see with the ungloved hand.

MR. POTTER: One of the presenters in September will be someone who comes from the hospital infection control environment and has studied the issue of what's on the outside of the glove and what's on the inside of the glove that can dump out when there's a rip in the glove.

So again, this is the kind of discussion that we're looking for. These are the kinds of issues we want raised so that we can go into the next Conference for Food Protection armed with the best science that we can that will support an appropriate public health guidance.

Other questions? Dane.

MR. BERNARD: Thank you. Does the committee have a vote as to whether we want to do this or not?

MR. POTTER: No.

MR. BERNARD: I was afraid you were going to say that.

MR. OSTERHOLM: Can I ask Dane a question? Do you have a problem with doing this? Are you concerned about

this?

MR. BERNARD: I'm just anticipating the -- how did you introduce this -- the anecdotal information and especially the strongly-held personal beliefs, which those of us who watch a certain list serve get inundated with -- constantly, and I know it's going to show up. So we'll do it. I don't want to do it --

MR. OSTERHOLM: That's why you have to do it, Dane, because of that. We got to get some answers. I think we really owe it to ourselves to have those answers.

MR. POTTER: We will give you an extra percentage of what we pay you for the normal duties -- Earl Long, do you have a -- okay.

Other comments, aside from Dane?

(No response.)

MR. POTTER: Okay. I'll turn it back over to Kaye.

MS. WACHSMUTH: Okay. Everyone's forewarned then. I think this will be the -- probably the first day and a half of the next meeting. But it is important -- extremely important.

Okay. We can talk about potential future activities. We don't -- other than the things that we mentioned for the next meeting, we weren't prepared to go

through any specifics today except to give you a heads up that there is now an interagency interdepartmental task force to look at antimicrobial resistance. And Karen Hulebak is the representative from USDA, and this has been quite a response from USDA, which as many agencies are interested in this particular problem. And the effort is lead by CDC, NIH, and FDA. And I'll let Karen give you a little background.

We don't have anything specific, but I'm sure some things will come to this committee from those discussions.

MS. HULEBAK: Thanks, Kaye.

As Kaye mentioned, CDC, NIH, and FDA are co-chairing a task force to develop a public health action plan to combat antimicrobial resistance. Their concept of this action plan is that it should focus on human health prevention behaviors, human health drug prescription behaviors, the human health end of the dynamic that results in the development of antimicrobial resistance.

They recognize that agricultural uses of antimicrobial drugs also contribute to the problem to some degree, and that it's important for agriculture to be engaged in the discussion. So we will be taking part, and as Kaye mentioned, I will be the department's representative

on the task force.

The task force is made up of one member of virtually all the public health service agencies with an interest in this issue, not just CDC, NIH, FDA, but also AHCPR, Agency for Health Care Policy and Research, HCFA, HRSA, DOD, VA -- what am I forgetting? EPA, as well. So it's attempting to be a pretty comprehensive effort.

I'll have to tell you all that this is a huge job. The task force is going to attempt to identify actions that need to be taken and implementation steps that are realistic and achievable. In order to do that, the task force has had to restrict the focus of its considerations to domestic issues. It recognizes that this resistance problem is a global problem. DOD's input to this task force is -- DOD's issues are global, infections acquired overseas and brought back to this country. But the task force has to focus, at least to start, on domestic issues.

I believe the life span of the task force is going to be about nine to 12 months from now. There will probably be recommendations, suggested implementation steps that will be relevant to FDA and to USDA in such a fashion that the agencies consider actions that will be perhaps brought to this committee. So we wanted to give you a heads up about this important undertaking of the federal agencies

and give you some sense that maybe in a year or so or a year and a half, there will be items from that task force that this committee will hear about.

Any observations on any of -- from any of your perspectives on this?

MS. WACHSMUTH: Peggy?

MS. NEILL: Peggy Neill. I guess I address this to either of the triumvirate up here. Would it be appropriate then to ask Karen to give a debriefing, if such is the correct term, in September, if --

MS. HULEBAK: Sure. I'd be happy to.

MS. NEILL: -- there are items to be debriefed?

MS. HULEBAK: Sure. I'd be happy to.

MS. NEILL: You've had one meeting?

MS. HULEBAK: The task force has had one initial organizational meeting. The first real event will be July 19, 20, and 21 in Atlanta, a public meeting. And there will probably be one more public meeting, but that's not for certain.

MS. WACHSMUTH: Some of you may be involved. There will be some expert elicitation, I'm sure.

Okay. Well that's -- any comments about future activities from any of the committee? Any requests from the sponsoring agencies? Mike?

MR. OSTERHOLM: As some of you are aware, I raised a concern after the last meeting about some of the structure of the committee and activities, and I just want to, in light of that, congratulate you for what has been a wonderful follow-up. And I think this group was more informed and had more information before this meeting than I think in any of the previous I remember over the last many years.

And I just want to congratulate you for responding in such a very thoughtful and helpful way. It really makes it a lot easier for us to know what to anticipate and be able to do our home work in advance, and I congratulate you.

MS. WACHSMUTH: Thank you. Just keep your fingers crossed that we can maintain it.

Bruce?

MR. TOMPKIN: A year or so ago the small group of the advisory committee did have a meeting to discuss various aspects of HACCP, and we developed a guidance -- there wasn't a guidance -- some recommendations actually to the agency with regard to HACCP implementation. And the regulation was being interpreted and applied and so on, and that seems to have been set aside or something has happened or not happened.

I'd just like to know what the status of that is and we were to have finalized it -- or actually, it was put off and -- it was to have been decided upon or passed as a recommendation from that subcommittee by the full committee. And I think that should have occurred, probably at the previous meeting.

I just wanted to know where we were with that and if you wouldn't want to let that slip by.

MS. WACHSMUTH: We'll ask Dr. Engeljohn to check into the subcommittee historical activities. We lost Margaret and Mike Robach as well, so we lost our memory. But, yes. We'll try and resurrect that.

I know there was at least one meeting where the FSIS policy group had prepared a side by side, and we got into some of those discussions, but I really don't know where that is right now.

MR. TOMPKIN: Several of -- a couple of us, at least -- Katie and I were both present --

MS. SWANSON: Dane was there as well.

MR. TOMPKIN: -- Bob Buchanan was there. Dane. Yes.

MS. SWANSON: And some of us have copies of our notes.

MS. WACHSMUTH: We'll reconstruct this.

Okay. Anything else? Okay. I think -- oh, Dane. Sorry.

MR. BERNARD: Thank you. In the same vein of things that have come up at past meetings where we haven't decided whether we need to follow up or whether there is a way forward, at the November '98 meeting, the suggestion was made that the *Campylobacter* document might be reopened for discussion to see if there were a need for updating that document in light of the FoodNet results, which seem to be demonstrating quite a predominance of that particular organism and problems from that. There were recommendations in that report that might need to be reviewed and might be of some benefit. And I don't recall a follow-up on that.

And at the meeting in March of this year there was a suggestion to reexamine at least the recommendations in the 1991 NACMCF *Listeria monocytogenes* document. And so I just wanted to bring those suggestions up again, Madame Chair. Thank you.

MS. WACHSMUTH: Right. And we distributed those -- both of those documents I think at the last committee meeting, and we did ask for any comments from the committee on the *Listeria* recommendations, specifically, and I'm not aware that we received any. Again, we can check and make sure that in the change of leadership of the

subcommittee and responsibility for that we didn't lose something.

But, Dane -- of this quizzical look --

MR. BERNARD: I'm not sure that the document was in fact distributed. The subcommittee met at the March '99 meeting, specifically looked at methodology and investigational techniques --

MS. WACHSMUTH: But I think the white paper was included in the general binder. It was included in mine, but I can't testify --

MR. BERNARD: You're right. I stand correct. It was distributed, but the suggestion to take another look at it in terms of its recommendations came up at the plenary session --

MS. WACHSMUTH: Right.

MR. BERNARD: -- at the closing plenary session at the March meeting.

MS. WACHSMUTH: Right. If -- Katie?

MS. SWANSON: The minutes might reflect this, but we were supposed to have gotten comments to Dick Ellis, as I recall, by I think it was tax day. And I was negligent in doing that.

MS. WACHSMUTH: I think we may need to send out a reminder, but we can follow up on that as well. It would be

a good time for it. There are quite a few meetings right now to determine how to prioritize some *Listeria* research and studies. There's money available through several industry groups. So to have -- if there are any things that we want to get out there, that we feel are needs, this might be a good way to do it.

We'll try to follow up with something in writing between now and the next meeting, but we're going to have quite a full meeting the next time I think.

Okay. Karen has some administrative matters, ideas, and then we will move to public comments.

MS. HULEBAK: Thank you, Kaye.

I just have a few items I'd like to discuss with the committee. I was able to talk with a number of you individually by phone before this committee meeting and raise some of these ideas to you, but since you're all more or less together now -- we're losing people minute by minute -- I did want to cover some points and see if we can get some discussion going. But before we move to the sublime, I'd like to spend a little moment on the mundane and ask those of you here to double check the information on you in the committee list, make sure it's right. If it's not, let us know.

This is your last chance to have a look at your

subcommittee assignment. We have to keep the -- I'm assuming that they are correct because I haven't really heard anything from anyone that they're not. But have a look at that. We need to maintain balance on those committees, but let us know if there is something that you'd like to discuss with us. And the mundane having been covered, we'll move to the sublime.

I had some ideas about -- been thinking about ways to streamline committee procedures, make life easier for you as committee members with a lot of hard work to do in your lives outside this meeting. It seems that most of the committee is pretty comfortable working with e-mail and electronic document distribution, and I would like to try to move in that direction as much as possible.

Is that a general sense? Are most folks comfortable working through e-mail and perhaps even document distribution through e-mail? Well then, that's good. Quorum of nodding heads -- because I'd also like to explore the possibility of establishing a web site for the committee. This would be in large part of public access web site. We get questions occasionally about whether this committee has a web site: post news notices about what the committee's got going on, when its next meeting is, make documents available to the public or drafts available to the

public, as they are now, of committee documents on that web site.

I think it's also possible to establish a place on the web site, and I'm moving into territory that I'm not real knowledgeable about here. But I think it's possible to establish a place on the web site where the committee could actually work on documents that would become publicly available, but a password protected spot where people could work. That may be pushing the technology that FSIS has available to it right now, but I'd like to try to at least see if that's possible.

Is that the kind of thing the committee might be interested in having access to?

VOICES: Yes.

MS. HULEBAK: Okay. Good.

MR. TOMPKIN: I was on the program committee for AMSA and they set up a web site with password protected -- and it was a matter of keeping up with all the e-mail. That was the only problem, but it works well.

MS. HULEBAK: Well, as a federal advisory committee, we need to make sure that our work takes place in the sunshine, and we need to make sure that our drafts are available to the public. I think we can do both of these things and remain well within compliance with that.

Now, on to a slightly more touchy issue. I have the sense that organization of material in these binders is more or less useful to folks, that it's accessible, it's an organized way to get material. It is however, to my way of thinking, bulky and sort of uncomfortable to carry around. So I wanted to just try a thought out on you that instead of big binders, that we might distribute material organized in a file folder like the accordion files with tabs so that you could bring with you what you want, bring to a given meeting just that file folder's worth of material, easily file it in files at home, because it seems to me like if one stays on this committee for a few years, your office could easily be overtaken by these binder notebooks.

But on the other hand, I know that a lot of people are pretty comfortable with these binders. So you don't have to tell me now, but think about it and I might poll you in a month or so, and if there's a majority in favor, we might move in that direction. It struck me that it might be a little more flexible. It might lend to ease of filing back at home in your offices.

Any thoughts on that point now?

MR. ANDERS: I'm a little late -- on the first e-mail. I have no problem with the e-mails. I do get lots of e-mails. One of the problems though that is happening that

I'm seeing, getting from CDC and from Washington and wherever, is that if people send at a higher level than you have, you can't open that document.

So the smart thing to do is send a lower -- say you have Word 6.0 and you send a Word '98, they can't open that document.

MS. HULEBAK: Right.

MR. ANDERS: So I think that needs to be kept in mind.

MS. HULEBAK: Right.

MR. ANDERS: I sent an e-mail the other day and someone said they couldn't open any WordPerfect. So the issue really becomes a problem of what is in -- someone said, Well, if you have any question, you send it in rich text format. Everyone can open it.

MS. HULEBAK: Okay. Well, having had experience with mass distributions of documents through e-mail, I know that that's a problem. I know that we need to find something that works for virtually everybody, but we may have to send it in -- any given document in two forms.

John. No? And I'm sure I'll find out what rich text format is.

MR. KOBAYASHI: Yes. It's one of the options in your save as versions.

MS. HULEBAK: Okay. I can do that.

MR. KOBAYASHI: I'm not sure if it's appropriate to bring up another subject, but if anything can be done to expedite travel reimbursements or if nothing can be done, what about travel advances, pre-paid hotels, whatever?

MS. HULEBAK: We're really working hard on getting any smoothness into the path on travel reimbursements and travel assistance. I urge you to take -- since what we might like to have is a final solution to that problem we can't achieve overnight, take advantage of the folks who are here today to try to do your -- even finish your form today, or get it as far towards final as possible, that we can do the best we can go get that reimbursement turned around.

MS. WACHSMUTH: We're plagued with difficulties in this area, not just for the committee. It's just not a very user-friendly system.

MS. HULEBAK: But even -- I'm not sure that we're stuck with all aspects of the system we have to live with now. Changing it's going to take a few months.

MR. KOBAYASHI: At least as far as I'm concerned, it would help out a lot if we didn't have to pay for the hotel bills. It's one thing to carry around cab fees and what not -- meals for a few months, but the hotel bill gets

a little bit burdensome.

MS. WACHSMUTH: Yes. Thank you.

MS. HULEBAK: I had one last point. I talked with a number of you who seemed to think that it would be useful to have a fact sheet on this committee, because sometimes people you work with ask for just a quick summary of this committee and what it does and what its major chartered issues are, and so we prepared that fact sheet. I think it may be out on the table. It's one page. It covers all the major facts about this committee, and it should be pretty useful to those of you who've said you might be interested in having such a thing.

Well, that covers my list of menu items. Any other thoughts from any of you? Mel?

MR. EKLUND: Yes. On behalf of the committee -- I'm sure I'm speaking on behalf of the committee -- I want to congratulate the group for organizing this, the supporting group. I think it's been a fantastic meeting. And I know last night we worked on the thing for the QTF, and we left it with Leon and Don Kautter. And I came back last night picked it up, I was shocked at how nice they had put this thing together in a professional way. So I think they all deserve a great congratulations on this.

And I have to say too, since I'm retired, this

has stimulated my blood back into research and things like this, so I'm really, really, pleased, and I think many of us are. So congratulate all of you.

MS. HULEBAK: Well, thank you very much. And I just say what I said at the beginning. I've never worked with a committee that's worked harder and more -- in a more committed fashion and just really pitched in than I have in the last three days with this committee. So thank you.

MS. WACHSMUTH: Thanks, Karen. Stephanie?

MS. DOORES: Stephanie Doores. It would be helpful to me, since this is only the second meeting that I've been to, if we had some kind of a flow chart for the different agencies to know where all the people that are up in the front are in the whole scheme of things, because we do have FDS and FSIS and USDA, and I'm not quite sure on who's reporting to whom and where the comparable levels are.

MS. WACHSMUTH: Okay. Organizational charts?

MS. DOORES: Sort of, yes. That would be great, especially since people move in and out of these roles too.

MS. WACHSMUTH: Okay. The most recent is on the first page of --

MS. DOORES: Yes. But I kind of wanted to know who your bosses are.

MS. WACHSMUTH: Oh, that kind of chart? You want

organigrams for each of the agencies. Okay. That's not a problem.

All right. Any other issues? Any comments from anyone who still remains in the audience? Oh, we do have a comment?

MR. FORMAN: Hello. I'm Eric Forman. I'm with the Agricultural Marketing Service. I feel reminded of a statement of President Kennedy in the -- when he was in office, and he was hosting a group of Nobel Prize winners. And he said he never -- the White House never had such a concentration of brain power since Thomas Jefferson dined alone. And I want to extend my thanks and thanks of my colleagues and my agency for the hard work of the staff and of all you folks in particular on the questions we raised that have come up in the course of administering our QTV program.

So that's all I have to say. Thank you.

MS. WACHSMUTH: Thank you. I know the group did work very hard. I popped in once or twice yesterday and they were in deep discussion.

Okay. Well, that's about it. We look forward to seeing you in September, and if anything comes up between now and then, feel free to contact anyone on the steering committee, but Karen probably most of all.

Does anybody else on the steering committee have anything else to say?

(No response.)

MS. WACHSMUTH: Okay. Good job.

(Whereupon, at 2:14 p.m., the meeting was concluded.)

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REPORTER'S CERTIFICATE

MEETING OF: National Advisory Committee on Microbiological Criteria for Foods

DATE: May 28, 1999

LOCATION: Chicago, Illinois

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the National Advisory Committee on Microbiological Criteria for Foods.

Date: 06/11/99

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