UNITED STATES OF AMERICA

DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

NATIONAL ADVISORY COMMITTEE

on

MICROBIOLOGICAL CRITERIA FOR FOODS

Plenary Session

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8-28-02 NACMCF Meeting Participants

Attendees: Chair: Dr. Merle Pierson, USDA

Vice-Chair: Dr. Robert Brackett, FDA

NACMCF Members:

Dr. David Acheson
Mr. Dane Bernard
Dr. Larry Beuchat
Dr. Bob Buchanan
Dr. Catherine Donnelly
Dr. Stephanie Doores
Dr. Frances Downes
Dr. Dan Engeljohn
Dr. Jeff Farrar
Mr. Spencer Garrett
Dr. Tsegaye Hahtemariam
Dr. Michael Jahncke
Dr. Mahipal Kunduru
Dr. Anna Lammerding
Dr. John Luchansky
Dr. Roberta Morales
Dr. Marguerite Neill
Dr. Alison O'Brien
Dr. Skip Seward
Dr. Bill Sperber
Dr.Balasubramanian Swaminathan
Dr. Katie Swanson
Dr. Dave Theno
Dr. R. Bruce Tompkin

Executive Committee: Dr. Art Liang, CDC
Dr. Carol Maczka, FSIS
Maj. Erik Torring, VSA

FSIS Staff: Mr. Victor Cook
Ms. Brenda Halbrook
Ms. Karen Thomas

FDA Staff: Dr. LeeAnne Jackson

NMFS Staff: Ms. Emille Cole
Ms. Barbara Comstock
Dr. Al Rainosek

Outside Participants:

Mr. Tony Corbo, Public Citizen
Ms. Nancy Donley, STOP
Ms. Barbara Kowalcyk, consumer
Dr. Robert Mandrell, ARS
Ms. Felicia Nestor, GAP
Dr. Norman Stern, ARS
Ms.Caroline Smith DeWaal, CSPI

P R O C E E D I N G S

9:17 a.m.

DR. PIERSON: Good morning. We'll go ahead and get started with our meeting.

I'd like to welcome you to the Second Plenary Session for 2002 of the National Advisory Committee for Microbiological Criteria for Foods.

My name is Merle Pierson, and I'm Deputy Under Secretary for Food Safety with USDA, and next to me is Bob Brackett, who is with the Food and Drug Administration.

I will be chairing this Committee. This is my first time to chair the Committee. I believe Kay Wachsmuth was my predecessor. I'm not new to the Committee. Let's put it that way. I served seven years on this Committee, and I see some, I was going to say old faces but I mean that, you know, figuratively. I have had the opportunity to serve with many of you on this Committee and have very fond memories. I know there's a tremendous learning experience being on the Committee and I very much appreciated at that time being able to contribute to documents that then were used by agencies as guidance material for their decision processes and policy and regulations and the

like. So, you know, I thank you for being on the Committee and again well realize the importance of your service.

This session actually brings to a close the current two-year cycle for the Committee. The Committee -- the cycle for the Committee started, the charter started September 6th of the year 2000. Now, does that take care of it for the Committee? No. We are going through the rechartering process again. Brenda knows how to do that quite well, and we will also at the same time be reconstituting the membership of the Committee. The Committee will be rechartered on or before September 6th, and we hope to have a final nominations packet signed by Secretary Veneman within the month or so of the rechartering.

As with any cycle on this Committee, some members rotate off and there are others who do not seek re-appointment to the Committee, and so this time is no exception. We have some people that are leaving the Committee. I very, very much appreciate these people's service on the Committee and the work that they have done. I know it's quite a bite out of your time and, you know, the pay also is not overwhelming. You get free coffee, muffins. That's about it.

Now, leaving us on this cycle is Dr. Mike Jahncke of Virginia Tech. Mike, where are you? Thank you. Margaret Neill of Memorial Hospital of Rhode Island. She's not here? Okay. I know I remember serving on Subcommittees with her. So, she's been on this Committee for quite some time. And Bill Sperber, Cargill. Bill, I saw you. There you are. He's one of the familiar faces from years back, too, on this Committee. And Dr. Swaminathan of Centers for Disease Control and Prevention. There you are across the way.

So, again thank you very, very much for your dedicated service on the Committee and we certainly appreciate all your good work. I know it's been a lot of time and again a lot of time and effort.

On behalf of the full Committee and the federal agencies, again I'd like to thank you for your time, for volunteering to be on this Committee and participating in its various activities. We look forward to those of you who will continue to serve, your continued vested interest in the activities of this Committee and, serving on various Subcommittees.

There are some changes that have been made on the Executive Committee. Major Eric Torring from the Department of Defense Veterinary Service has joined the

Executive Committee in place of Lt. Col. Robert Webb. Eric? There's Eric. Okay.

Dr. Carol Maczka of USDA/FSIS. She's Acting Director of the Risk Assessment Division of the Office of Public Health and Science. Carol? Right here. And we welcome you both to the Executive Committee.

As we bring this two-year cycle to a close, I want to very briefly review the accomplishments of the Committee to date. It's certainly been a very busy two years. Before I became Deputy Under Secretary, I continued to follow the activities of this Committee, also, with great interest. The Committee has provided guidance to FDA on hot-holding temperatures in the Food Code, reviewed the practice of blade-tenderizing steaks and roasts for its relation to contamination with *E.coli* O157:H7, and with this meeting reviewed the Codex Discussion Paper on Proposed Draft Guidelines for Validation of Food Hygiene Control Measures.

Finally, the Committee has undertaken the monumental task of evaluating the existing performance standards for *Salmonella* in ground beef and defining the general principles that are the underpinnings of all future discussions of performance standards that will serve the needs of FSIS and all other federal

agencies that are concerned with performance standards.

Their work is not done, however, as they consider performance standards for other products and evaluate the fundamental issues surrounding performance standards themselves. All of these activities help to answer scientific questions so that sound science-based policies can be made by the respective federal government agencies.

With that, I would like to turn the meeting over to Dr. Bob Brackett who's co-chair.

DR. BRACKETT: Thanks, Merle.

Good morning, and I would also like to welcome both the Committee members as well as the guests in the room and attendees to this Plenary Session.

For those of you who don't know me and I know many of you, I know quite well, I am Bob Brackett, and I'm the Director of Food Safety at the Center for Food Safety and Quality Enhancement at FDA, and I was recently -- excuse me -- Center for Food Safety and Applied Nutrition. Old job.

I was recently asked to serve as co-chair of this Committee with Dr. Pierson, and many of you know that the previous person in this position was Janice

Oliver who is the Deputy Director at CFSAN, and it was really was with mixed feelings that she decided to ask me to do this because she was a tremendous supporter of NACMCF and she greatly appreciates the hard work that all of you have put in to previous deliberations, and I would bet that you will see her on occasion at these meetings just because she does like to come to them.

We have a number of different issues that we're going to discuss during today's meeting. This morning, we will discuss comments on the document entitled "Codex Draft Guidelines for Validation of Food Hygiene Control Measures", followed by the introduction of a new issue for the Food and Drug Administration and that is redefining pasteurization in accordance with the language in the new 2002 Farm Bill. We'll then take a short break and then reconvene and introduce another new issue on *Campylobacter*.

This afternoon, we'll discuss the current status of the Shelf Life Subcommittee, which was included in yesterday's discussion, on criteria for shelf life based on safety and then we'll wrap up things this afternoon with a discussion on *Salmonella* Performance Standards in Meat and Poultry Products followed by a period for public comment.

At this point, I'd like to go around the room and have the Committee members introduce themselves and also state their affiliations and to start this, I think we'll start over on the far side with Katie Swanson.

DR. SWANSON: I'm Katie Swanson with General Mills.

DR. JAHNCKE: Mike Jahncke with Virginia Tech.

DR. DOORES: Stephanie Doores with Penn State University.

DR. THENO: David Theno, Jack-In-The-Box.

DR. LAMMERDING: Anna Lammerding, Health Canada.

DR. LUCHANSKY: Good morning. John Luchansky, USDA/ARS.

DR. O'BRIEN: Allison O'Brien, Uniform Services University Health Sciences.

DR. SWAMINATHAN: Bala Swaminathan, CDC.

DR. ENGELJOHN: Dan Engeljohn, USDA/FSIS.

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

MR. BERNARD: Dane Bernard, Keystone Foods.

DR. TOMPKIN: Bruce Tompkin, recently retired

from ConAgra Refrigerated Foods.

DR. MORALES: Roberta Morales, RTI International.

MR. GARRETT: Spencer Garrett with NOAA Fisheries, and I'm joined at the table by Emille Cole, who's my special assistant that assists me in trying to take the notes at this meeting. Thank you.

DR. ACHESON: David Acheson, University of Maryland.

DR. HABTEMARIAM: Habtemariam, Tuskegee University.

DR. DONNELLY: Cathy Donnelly, University of Vermont.

DR. BEUCHAT: Larry Beuchat, University of Georgia.

DR. FARRAR: Jeff Farrar, California Department of Health Services.

DR. SPERBER: Bill Sperber with Cargill.

DR. BUCHANAN: Bob Buchanan, FDA.

DR. KUNDURU: Mahipal Kunduru with Dole Fresh Vegetables.

DR. TORRING: Eric Torring, DOD Veterinary Services.

DR. LIANG: Art Liang, CDC.

DR. JACKSON: LeeAnne Jackson, FDA, Center for Food Safety and Applied Nutrition.

MS. HALBROOK: Brenda Halbrook, FSIS, Executive Secretary to this Committee.

DR. MACZKA: Carol Maczka, FSIS.

MS. THOMAS: Karen Thomas, FSIS, advisory Committee specialist.

DR. BRACKETT: Okay. Thank you all, and Merle?

DR. PIERSON: What we'd like to do now is to consider the minutes of -- from the January 23rd to 25th, 2002, meeting. I believe all of you have the -- this one page with the minutes on it.

MS. THOMAS: It should have been sitting at your desk, at your table.

DR. PIERSON: I'll give you a couple minutes to find the minutes and scan over them, if you would.

(Pause to review document)

DR. PIERSON: What we'll be doing is making comments on the summary minutes and then, you know, the full transcript from the three days of meetings will be posted on the Web. I'm not sure. Do you want to go through three days of minutes? Dave says no, we're not going to do that.

So, are there any comments on the summary minutes?

MR. GARRETT: Mr. Chairman, I'd move adoption.

DR. PIERSON: Okay. We're with it. Okay. Brenda tells me they're adopted. Okay. If there's no further comment, then we'll declare the minutes as adopted. Thank you.

With that, I will turn the meeting over to Brenda who has some further items to discuss.

MS. HALBROOK: I just have a few housekeeping announcements. Committee members, if you could please make sure you've completed your calendars and we will collect them during this meeting some time today. Either give them to me or to Karen Thomas, so that we can plan the future meetings, both Subcommittee and full Committee meetings. They're of great help to us.

I see you all have figured out the microphones. They need to be turned off and turned on. When you wish to speak, turn them on. When you've finished speaking, please turn them off. That prevents a lot of background noise going to the court reporter.

Then for the members of the audience, we would like you to register, if you plan to make any

public comments at the end of the day. We have a sign-up sheet out at the registration desk. So, if you'd please put your name down, then we can budget the time better for that half hour segment at the end of the day, and if we have many speakers, we'll have to limit the amount of time we allocate to each speaker. So, please take care of that, and as well, when you get up to speak, you'll need to turn the microphone on and off to speak and to finish speaking.

That's all I had to say.

DR. PIERSON: Okay. Before we start with the next item on the agenda, which would be Subcommittee Report by Mike Jahncke, there is one very important announcement I want to make in case you don't already know.

Brenda will be taking another job within USDA and this is her last meeting with the National Advisory Committee on Microbiological Criteria for Foods, and I want you to know that I personally am very, very -- I have great reservations about her leaving, but that's her choice, unfortunately. But she sure does have a great opportunity relative to career advancement and it's one of those mixed emotion situations. You wish the individual the very best and very happy for them to

have these opportunities, yet when someone has done such an excellent job with a Committee leaves, you say oh, my gosh. So I just wanted to publicly thank Brenda for her tremendous work steering this Committee in the right direction and being the glue that holds it together.

Thank you very much, Brenda.

(Applause)

MS. HALBROOK: Thank you very much, Merle, for those very kind words, and I want to say to all of you, it's been a pleasure working with you, and I hope to continue my relationship with each of you as I move on into my new capacity at the Food Nutrition Service.

Thank you all for being such a wonderful Committee and for being so much fun to work with.

DR. PIERSON: Okay. Now, is there anything that I've missed? Are we all right so far? Okay.

With that, then, we'll move to Committee Deliberation on the Codex Discussion Paper on Proposed Draft Guidelines for Validation of Food Hygiene Control Measures and Mike, if you want to lead that discussion?

DR. JAHNCKE: Thank you, Merle.

This document has -- it's almost like the Codex process itself. It's taking geological times to

get to this point. But we are here, I believe.

You all should have -- there's two documents you need to have. One is the original Codex document that was in your packet, “Discussion Paper on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures”, and the next one is, the title, "A Review of the Codex Discussion Paper on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures", and in it, our Subcommittee has addressed and answered the original five questions, plus we addressed three additional questions that were posed to the Subcommittee.

If you remember back in January, we went over the document and we asked those questions and the Subcommittee also took it upon themselves to provide some additional guidance on this document. Our hands were a little tied in that although in this Codex document is a lot of HACCP terminology and concepts with it, we were instructed not to in our discussion and response to the questions not include HACCP-type things. So, it made it a little difficult, but I believe we successfully did that.

Just in a quick review, we provided some guidance on this Codex document, some editorial and

some more substantial comments, things such as suggesting that a scope session be placed into the document, also some rewording of some of the text in the Codex document and all of that is identified in our paper which is the review of this, and back in January, we went through all of those.

If we turn to the fourth page, it starts on the questions that we were specifically asked to address, and the question was: are the stated prerequisites all necessary? Are there prerequisites that are critical that have not been adequately identified? Do all the prerequisites have the same degree of importance? That question refers to the original Codex document on Page 2 and the subtitle of that was "Prerequisites of Validation", and there were three of those.

Our Subcommittee deliberated and just to reiterate, again to bring everybody back up to speed from last January, we identified that the three stated prerequisites were necessary with modifications. We couldn't identify any other prerequisites. We did decide that all the prerequisites did not have the same degree of importance. Number 1 was the most important since, if there were no identified specific hazards to

be controlled, Prerequisites Numbers 2 and 3 would not apply, although the General Principles of Food Hygienic Practices still would apply, even if no specific hazard was identified. That required verification rather than validation, and if there are specific hazards, control measures must be validated.

The second question that was posed to the Subcommittee was stated as: has a scientific basis for the approaches to validation been adequately justified? Are the approaches sufficient to permit the validation of food hygiene control measures? Are there alternate approaches to validation that should be considered? That question applied in the original Codex document on Page 3, the subheading that says, "Approaches to Validation", and under that, there were three discussions on approaches, were placed under those. We reviewed those, and the opinion of the Subcommittee was that of those three that were proposed, Number 1 was -- only Approach Number 1 is a scientifically-based validation activity. We came to the conclusion that Approaches Number 2 and 3 are important but are more -- as written, were more verification rather than validation procedures, although we did indicate that Approaches 2 and 3 may provide useful data for

validation purposes.

We suggested that Numbers 2 and 3 remain part of the document but be reworded to reflect their role in validation. We were not able to identify any other alternative approaches, but in going forward with that, we also concluded that data for validation can include sources beyond experimental trials, such as the literature, regulations, equipment manufacturer validations, etc., and to help clarify that, we suggested that Approach Number 1 needs to have a statement that indicates that control measures are plant-specific and must be validated on a plant-by-plant basis and that perhaps plant-scale trials may become necessary using indicator organisms, and we also concluded that there are alternative approaches for validation that should be considered, that alternative Approaches Number 1 should be considered with appropriate scientific review to ensure that the attributes of performance evaluated is indicative of the status on the control measures of interest, and also we said consideration of alternative approaches to Numbers 2 and 3 in the document should be considered with caution since they relate to verification and not validation as they're currently written.

The third question was with respect to the individual approaches to validation, what elements should be further elaborated, and the Subcommittee felt that we answered this question in our response to Question Number 2.

The fourth question of the original five are factors to be considered in validation complete? Are there additional factors that should be considered? Do all the factors have the same degree of importance? Does the information presented on when validation or revalidation is needed sufficient and reasonable in relation to the simultaneous goals of being protective of public health, fostering scientifically-based food safety programs, developing practical advice on validation of control measures?

That fourth question relates -- starts in the original Codex document on Page 4 under the heading "Factors to Consider in Validation". There were several of those that ran to the bottom of Page 5 in the original Codex document. Our Subcommittee's response to this, the factors as written in the document, are not complete, and we recommended that the information in this section be revised, not eliminated but simply revised and expanded upon. We couldn't

identify, we were unable to identify any additional factors. All -- what complicated this was that all factors are interlinked and we weren't able to rank the factors by degree of importance. We felt that all the factors are important and our Subcommittee could not separate those and rank those in any way.

The fifth question of the original: is the information presented on when validation or revalidation is needed sufficient and reasonable in relation to the simultaneous goals of being protective of public health, fostering scientifically-based food safety systems, and developing practical advice on validation of control measures? And our answer to that question was yes.

So, those were our answers to the original five questions. This past summer, we were given three additional questions that the Subcommittee addressed. The first one was: what role does verification and monitoring have in the revalidation? We struggled with this in that in current HACCP Principles Number 6, validation and implicitly revalidation is really defined as one process and verification.

Coming out of this document and reading through the document, it was evident that the authors

of this original document had the same problem that the Subcommittee members have, and a lot of people have, there's confusion on the use of the terms "verification" and "validation" and "revalidation". Sometimes they're intermixed, intermingled. That happened in the Codex document and that's why we recommended earlier that those Numbers 2 and 3 that were written in verification terms be rewritten so they would be more reflective of validation. We felt that those terms, whenever they're used, really require a lot of consideration, deliberation on the use and definition of these terms.

Question Number 2 was: how many failures need to occur before the system needs to be revalidated? We looked at and discussed this question and assuming that failure means a deviation of a critical control point that requires a corrective action, repeated deviations require redesign of the product or process. We're unsure of how to quantify repeated. In addition, HACCP plans must be revalidated, even if no process or product changes are made and even if no deviations have occurred. Thus revalidation assures auditors that the HACCP plan is current and accurate.

Again, I think the crux of this is that, those terms many times are intermingled, used and confused, and we just recommend that those terms, whenever they're used, really a lot of thought and care goes into it, especially in the Codex document, to ensure that if this is the document on validation, that as it's being written, that it's written in the terms of validation and not so much in verification.

The third question was: if the process is verified, does verification provide the baseline for validation? Our Subcommittee felt that this was an extremely interesting question, and we came to the conclusion that in many commercial operations, it's difficult to validate some of these because of the size and perhaps hazardous nature of the process, and therefore it's difficult to mimic these processes on a pilot plan or laboratory scale, and we also recognized that it's not advisable or permitted to inoculate raw material with pathogens and then run them through a commercial operation to collect data.

Thus, in situations like that, there may be some on-going verification activities, collection of data on an on-going daily basis, that can be used to revalidate a HACCP plan, and this also goes back to

reflect some of the comments that we had originally addressed in the Codex document, and I don't know if other members of the Subcommittee have some additional comments.

DR. SPERBER: Yes, this is Bill Sperber.

On that very last point, I think it needs to be revised a little. This on-going verification is not for the purpose of revalidating the HACCP plan. It's for the purpose of validating that process, the initial validation, which you can't do because the process is very big and hazardous.

DR. JAHNCKE: Any other comments from the Subcommittee?

MR. GARRETT: Thank you, Mike.

I would agree with Bill that it's a process.

DR. JAHNCKE: So noted. That, Mr. Chair, is the report of the Subcommittee.

DR. PIERSON: Okay. Would the change that was suggested, would you reiterate that?

DR. JAHNCKE: Okay. I'll reread that, our response with the suggested change. As I said, this was a question that the Subcommittee felt was a very interesting and important question, and again, due to the size and the hazardous nature of many processes,

it's difficult to mimic these on a pilot plan or laboratory scale, and we recognize that it's not advisable or permitted to inoculate raw materials with pathogens and then place them in a commercial setting to collect data. Thus, in situations like these, on-going verification activities can be used to help revalidate the process. Validate, excuse me, validate the process.

Bob?

DR. BUCHANAN: Thank you, Mike.

While this may seem a little arcane in terms of its language, it would be appreciated it if you could use the phrase "system of control measures" instead of "process".

DR. JAHNCKE: System of control measures?

DR. BUCHANAN: Yes, please. That's more in keeping with the language of Codex.

DR. JAHNCKE: So then, the last sentence would read: "Thus, in these situations, on-going verification activities can be used to help validate the system of control measures?"

Any other comments?

DR. BUCHANAN: In plain language, that means process.

DR. JAHNCKE: Yes. Yes, the process.

DR. SWAMINATHAN: Mr. Chairman, I have a question. Right here.

DR. PIERSON: Okay. There you are.

DR. SWAMINATHAN: Mike, in your answer to the supplementary questions, I'm looking at the answer to Question 2, you're talking about HACCP plans being revalidated even if no process or product changes are made and even if no deviations have occurred.

Would it be possible to provide some kind of a time line for revalidation of HACCP processes? Would people interpret this as 10 years, 20 years, 5 years?

DR. JAHNCKE: I think that part of the difficulty on this again is the use in the Codex world and the time lines on this.

Bill, do you have something?

DR. SPERBER: I'm not sure the Codex document. This is Bill Sperber. But knowing the original HACCP document of this Committee, we suggested revalidation at least annually and that is commonly recommended practice in the industry.

DR. PIERSON: Good. I remind you or ask you to identify yourself and affiliation before you speak for assistance in recording the proceedings. So, can

you do that, please?

Cathy? Katie?

DR. SWANSON: Katie Swanson, General Mills.

Continuing on the discussion of revalidation, I would like to point out that processes, such as thermal process for lower-acid canned foods, have been in place for many, many years, and those are not revalidated on an annual basis. Some of those historically have gone on for many, many years, you know, five years, sometimes 10 years, when no changes have occurred. They will check to make sure that it's the same kind of valve, the same viscosity, etc., but they will not go through the extensive experimental effort on an annual basis to revalidate those systems and we have a lot of history to suggest that that is entirely appropriate and effective in the U.S. canning industry.

So, I would like to make sure that setting a time criteria depends on whether or not there are substantive changes and put that out for discussion for the Committee.

DR. PIERSON: Spencer?

MR. GARRETT: Spencer Garrett, NOAA Fisheries.

I certainly agree with Katie and there are a wide variety of systems that control here, running from low-acid canned foods to pasteurization to other things, and so probably given the breadth of different systems of controls, it would seem to me that you couldn't go much beyond just giving some rather general guidance that should be revalidated at any frequency to ensure sufficient efficacy of the system of controls or something like that. I don't see that because you certainly don't need to reinvent the wheel for low-acid canned foods. So, I'm not sure that given the breadth of the different processes we're talking about here, how you can really come up with an ironclad example, other than just saying that it should be done relative to the nature of the hazard and the efficacy of the system of controls.

DR. PIERSON: Okay. Bill?

DR. SPERBER: Bill Sperber with Cargill.

I don't want to muddy the waters here, and we probably don't want to go really deep into this, but there are reasons for validation within HACCP and presumably two years is for revalidation. One is the first year would be to validate the critical limits at a critical control point. The second would be to

validate the accuracy of the HACCP plan and generally in our HACCP documents and the intent of our response to Question 2 here was revalidation of the entire HACCP plan or the system of control measures, not revalidation of critical limits at individual control points.

Further, I would suggest that canned food regulation in the United States is so rigidly spelled out in the low-acid canned food regulations, unlike the rest of the world, that canned food production in the U.S. is really a separate consideration. But in response to Katie's first comment, which is certainly legitimate for canned food production in the United States, I think our Subcommittee was thinking in terms of revalidation of the HACCP plan or the total system of control.

DR. PIERSON: Okay. Bob?

DR. BUCHANAN: To help you a little bit in the deliberation of this discussion item, in the Codex parlance, a control measure or measures can be as simple as one process, for example, the heating of the food, or it can be as complicated as an entire country's regulatory system for evaluating food safety.

So, you're going to run into some

difficulties if it not restricted to HACCP, it's not necessarily restricted to GMPS. It could be focused on a single step in a process or it could be as big as an entire government. So, as you look at these, you're going to have to be able to keep in the back of your mind that it could be something as specific as a low-acid canned food process or it could be as complicated as a farm-to-fork HACCP plan, and so I would -- the reality is, is that, HACCP plans, we may recommend that they be evaluated on an annual basis but we also don't re-evaluate thermal processes except once every couple of decades. So, we would appreciate if you can keep the language as general as possible.

DR. PIERSON: Bob, you would interpret then the Codex Discussion Paper as going beyond consideration of a very specific HACCP system? You're saying --

DR. BUCHANAN: Correct.

DR. PIERSON: -- it also includes the evaluation of the regulatory capabilities within that country?

DR. BUCHANAN: It could include the regulatory capabilities within that country. It could include the system of import and export inspections or

it could include just something as simple as checking the pH of an incoming ingredient. All of them would have to be covered by this validation document.

DR. PIERSON: Okay. Spencer?

MR. GARRETT: Spencer Garrett, NOAA Fisheries. Thank you.

Then perhaps that re-emphasizes the need for a scope of the document and that might be one way to address it, Bob.

DR. PIERSON: Okay. Katie?

DR. SWANSON: Katie Swanson, General Mills.

Along those same lines, the earlier discussion regarding validation as plant-specific, I think, may be appropriate if you're talking about HACCP plans, but since this is much broader than that, there are certain things like, for example, water activity pH combination to control growth isn't necessarily plant-specific. That could be done in a laboratory and then the plant would have to verify that they achieved those AW pHs. So, I would ask the Subcommittee to reconsider the statements about it must be done on a plant-by-plant basis because some things are more broad.

Second consideration is related to the validation criteria, I forget which page it was on,

where there was three examples, and the current response suggests that only is a true validation activity but Number 2 and 3 are not. Well, for example, if you're doing a hazard analysis and you make the determination that the hazard is not reasonably likely to occur in the absence of control, frequently that is based on epi data and those epi data are what are there to validate that the assumption you're making that it's not reasonably likely to occur is the epi data. So, I would submit that that could be used as validation data as well. The same as if you're trying to establish initial populations, you might need to do some experiments in the Number 2 category to determine what those are.

DR. PIERSON: Yes, Mike?

DR. JAHNCKE: Mike Jahncke, Virginia Tech.

Yeah. I think our response to that was not that they weren't important or -- it was basically on the wording. We wanted them to look at that and put those words, more reflected validation activities. We felt when we reviewed that, it just -- the way it was written, it seemed all to be verification and the title of the Codex document talked about validation. So, it's just a wording thing is how we looked at that

particular issue.

DR. PIERSON: Okay. Thank you.

The -- we're taking an interesting turn here and, of course, we're -- you can see we're scurrying around, hmm, how should we deal with this, and so, Bob Buchanan is going to make a suggestion, I believe, as to how we should deal with this.

DR. BUCHANAN: Thank you, and I know the Committee's desire to make our documents long range and perfect, but we also have an issue here, is that we are now responding to country comments on this document. You have till today to get the document in. After that, we're sending country comments out. So, I would -- we hear the comments. We think that you've done a tremendous job in responding to this.

I would caution you about getting so involved in fine-tuning this document that it is not finished today because if it's not finished today, it will not be considered as part of the country comments that will be going out to all Codex members as the U.S. drafting team evaluates the input that we've gotten from not only this Committee but also a number of different nations and advisory bodies in other nations. It's an instance where we have a real time limit. It's today

or it's probably never.

DR. PIERSON: With that, I'd suggest, Mike, could you, you know, summarize where we're at on the document and we can see what we can do about bringing this to closure?

DR. JAHNCKE: Okay. Thank you, Merle. I believe where we're at right now is the Subcommittee's response to Question Number 2, and I think the crux of that, where there are some comments saying we indicated that HACCP plans must be revalidated. We left it general because, as Bob and others have indicated, this document or our response can deal with a wide variety of different processes and rather than get specific and say that it has to be revalidated on an annual basis or more frequently or longer than -- longer period than that, we left it more general to take into account that there are -- this is a very broad-ranged Codex document, and where we're at right now is the discussion, unless I've missed some of the others, that second question of the new three is where we're at now, determining to either add some additional words, saying how often the plan has to be revalidated or leave it as such, which is more of a general approach.

We did discuss in the Question 3 of changing

-- validating the HACCP plan to change it to validate the system of control measures, but I believe right now, we're on Question 2.

DR. PIERSON: So, I suspect we could just boil this down as to the issue being in Question 2.

Do we have any specific wording, if we need to change the answer to 2, or should we leave it as is? What's the feeling of the group?

DR. SWAMINATHAN: I'm sorry. I didn't plan to cause trouble for our document. All I was -- this is Bala Swaminathan with CDC. All I was trying to suggest was this is too open-ended and perhaps just add as appropriate for the process or system of control or whatever Bob said was the right Codex magic word. That's all I intended to say.

DR. JAHNCKE: So, the appropriate wording would be -- what is that again?

DR. SWAMINATHAN: As appropriate for the process.

DR. JAHNCKE: As appropriate for the process? So, then the document would read: HACCP plans must be revalidated as appropriate for the process? For the system of control measures? How about that? Must be revalidated as appropriate for the system of control

measures, even if no process or product changes are made, and the rest would stay the same. That's what we have. So, that will be the wording.

DR. PIERSON: Okay. That definitely sounds like Codex jargon. There's no question about it. You have it down well, Bala.

With that, Dane, you had a comment?

DR. BERNARD: Thank you, Chairman. Dane Bernard, Keystone Foods.

I could certainly live with the wording that was proposed. I'd just ask the Committee if it is even necessary for us or would it be accepted within the Food and Hygiene Committee to go that way because what we're talking about is a document that modifies the already-adopted HACCP document, and therein the definition of validation and the recommendations that are in the basic HACCP document are really the key to how that's going to be reacted to.

So, we could go with this wording, but I wonder if we aren't going far beyond the scope of this document by doing so because the basic HACCP document lays out the guidance for when.

DR. PIERSON: Well, let me give my take on this, is that, this is advice to, a recommendation to

the U.S. Government. The U.S. Government, of course, will form their, you know, response to the Codex document, and so, you know, such wording shouldn't be a problem.

Bob, you have any comment on that?

DR. BUCHANAN: No. In fact, our original comments back to the Subcommittee was probably not to focus on HACCP as much as you did as was done because substantial amounts of control measures have nothing to do with HACCP on an international basis. In fact, most of Codex activities are focused more on GMPs.

However, the wording, we appreciate what is the underlying thought process that went into developing this document, and it is going to be considered in addition to comments we've gotten from several of our drafting partners around the world. So, I again understand the thought process. I appreciate the fact that we have taken a -- made it a point to say that HACCP plans should be reviewed annually, and my fix on this is if this is a matter of concern, is to remove the term "HACCP plans" and put in a more general term for reviewing your food safety system.

DR. PIERSON: Spencer?

MR. GARRETT: Thank you.

I certainly agree with what Bob's said. I just want to give the Committee a note of information on this document. The Interstate Shellfish Sanitation Conference, which is the state-federal cooperative program to develop model ordinances and rules and procedures for the safety of
-- for the consumption of molluscan shellfish, has a Subcommittee on Validation of Postharvest Treatment and Pasteurization, a subject we're going to get into in a little bit later on today.

I happen to chair that Subcommittee, and this document is being used extensively in determining how one goes about validating postharvest treatment for molluscan shellfish. So, it has more than just an international flavor.

Thank you.

DR. PIERSON: Thank you, Spencer. Do you have any further comment, Mike?

DR. JAHNCKE: I have a question. What have we decided on Question 2 as far as the wording or the removal of HACCP terms? Now, I'm -- there have been comments by Bob and others. I'd just like to know what the final -- what the Committee has decided on the final wording.

DR. PIERSON: Do any others have an opinion on that? Should we leave it as is or put broader aspect to it? Opinions? Spencer?

MR. GARRETT: Spencer Garrett, NOAA Fisheries.

I would agree with Bob that it is broader than just HACCP for an international document.

DR. PIERSON: Okay. So, you agree we talk in terms of food safety systems rather than HACCP. Okay. I see no objection to that.

With that, are there any further comments on the document?

DR. TOMPKIN: I'd like to make a motion that we accept the document with those amendments.

DR. PIERSON: Okay.

DR. SWANSON: Second.

DR. PIERSON: Okay. We have two seconds here. Bruce Tompkin and Katie Swanson. I looked over at the card in front of you, Bruce. It says Robert Tompkin.

DR. TOMPKIN: We have to be flexible.

DR. PIERSON: Change in your name, huh? Okay. Well, with that, I will declare this as a done deal. We've adopted this document. Thank you very

much for your good work.

Okay. Here's Bob Buchanan.

DR. BUCHANAN: Now that the document has been accepted, I would like to take my hat off as a Committee member and put my hat on as the head of delegation for the United States for CCFH and thank the Subcommittee and the full Committee for all the hard work they put in to examining this document, in many cases learning a whole new vocabulary and being able to read the documents, and I think it's always nice when the Committee gets some feedback from the people that have to use their recommendations.

We have received draft copies of this all along. Your comments, including your final changes in wording, are having a very significant impact on the thinking of the drafting, the international drafting panel that's putting this document together, and the recommendations and the thought process as you have followed during the last year are already making an impact and will continue to make an impact as this, what is going to turn out to be a very important guideline for international trade, is put into practice or finalized in the Codex practice.

So, with that, I just want to, you know, end

by again saying thank you very much for all the hard work that went into this work. Thank you.

DR. PIERSON: Thank you very much.

Are you ready? Okay.

DR. BRACKETT: What I'd like to briefly do this morning is just introduce a topic, as I mentioned earlier, that's new to FDA, and this is really not meant for discussion at this meeting but to sort of give you a heads-up of something that we'll be dealing with in the future, and that is, as it says here, what's called "redefining pasteurization", and to give you a little bit of background of where this came from, this is out of our newly-enacted 2002 Farm Bill in which the bill's intent actually is to provide for a common definition of the word "pasteurization", and this is the language out of the bill itself.

Really, there are two main provisions that we might want to be considering here, one of which is that pasteurization as pasteurization would be defined as it is in regulations right now, and there are some examples of that that I'll get to in a moment, but the second part of it is also any other technologies that would provide the same level of consumer protection in microorganism control.

Specifically, the most resistant microorganisms of public health significance that are likely to occur in particular food. So, it does give a little bit of definition to it as to what the parameters are, and as I said, the goal here is so that when one makes the claim that something is pasteurized, that it is in fact defined what that means.

There are some other provisions in the bill as well, such as the period of time that the food is supposed to be on the shelves and remain safe and also notification provisions as well for these products. There are a number of examples of products that now either in regulation or in practice are being done as pasteurized. These are the most notable examples, milk, juice, seafood and eggs and egg products. Probably the best known and the oldest, of course, is pasteurized milk, and in this case, in the Code of Federal Regulations 131, the times and temperatures are actually designated in code, and these are well-known to people in the dairy industry. They know them all by heart because they are so specific.

There is also a provision in there for another term which is ultrapasteurized, which has just a higher temperature and time, higher lethality, so

that in many cases that it's shelf stable. But many of the other cases where pasteurized is used is not necessarily prescribed in that way, an example of which is pasteurized orange juice. In this case, the pasteurization is actually based on enzymatic activity and the number of viable microorganisms, but there is no time-temperature provision for this particular product.

In the case of eggs, it depends on what form the eggs are in. There are guidance documents provided by USDA that designate the pasteurization procedures that are acceptable, both for liquid eggs and egg products, and in the case of pasteurized in-shell eggs, it being a 5-log reduction in *Salmonella* species, one of which has to be a *Salmonella* Enteritidis. So, they differ even from within one product.

There are other examples, some of which are seafood. Blue crab meat is one. Surimi-based products, reduced oxygen packaged food and oysters and in this case, there is a mild heat treatment that is specifically designed to eliminate vibrio vulnificus. So, as you can see, these are not all the same or have the same intent.

Now, all of the previous pasteurization

examples I showed you were thermal in nature, but there are a number of other technologies that could accomplish the same sort of thing; that is, to eliminate pathogens and make for safer food, and these include those that are listed here and actually many of these have been reviewed by a task order that FDA had with IFT and are included within a review document, and there are others as well which is why we have etc., and the intent here is to allow us to look at any kind of treatment that would reduce pathogens in a food.

There are other considerations as well that we thought about as we have to address this issue, one of which is if one renders a product that is ready to eat, that is, if you cook it which is going to eliminate pathogens, is that considered pasteurization? So, that's a definition issue. There are other treatments that have been used in our traditional processes that either have been used or potentially could be used, especially if the right organisms or additives are included, that could accomplish the same thing, including fermentation, drying, various antimicrobials, either those that are in existence now or those that could be developed in the future, and so the definition, could one call that legitimately

pasteurized.

So, what I am going to introduce today is really to tell you what the issue is, which I've done, and also just give you a heads-up on what the future plans will be for the Committee, one of which is that in the future, we will develop a specific charge for a Subcommittee and that is how to address this issue and how to define pasteurization within the scope of the Farm Bill. We'll establish a Subcommittee in the future and then probably convene in the Fall of this year, 2002, to start initiating discussions on how we're going to go about discussing issues, and really that's all I had to say and hopefully now, unless there are any very quick questions, hopefully we'll get back a little bit closer to schedule here.

DR. PIERSON: Okay. Do we have any questions or comments from the Committee?

DR. THENO: Mr. Chairman, Dave Theno.

DR. PIERSON: Dave?

DR. THENO: Bob, do you have a time line when this needs to be done for the Farm Bill or is this open?

DR. BRACKETT: No. Actually, there were two different things in the Farm Bill, one of which had a

time line, and that was educational efforts by USDA, that they actually do have a defined time limit. This does not.

DR. PIERSON: Okay. Do we have any other comments?

(No response)

DR. PIERSON: If not, thank you very much, Bob, and we look forward to developing a Subcommittee to address this issue.

Okay. It's 10:21. So, we'll go ahead and take a break and reconvene at 10:30.

(Whereupon, a recess was taken.)

DR. PIERSON: The next item on the agenda relates to a new charge given to the National Advisory Committee. This new charge relates to *Campylobacter*, its identification and quantification methodologies.

In your packet, you have the specific charge to the Committee. This charge comes from the Food Safety Inspection Service, and let me outline that charge to the Committee. It is to review and compare the methodologies used for *Campylobacter* detection. This would be in USDA/FSIS's 1994-95 and 1999-2000 Baseline Studies in Young Chickens, and to evaluate them for accuracy and precision in providing -- in

assessing the prevalence and quantity of *Campylobacter* on chicken carcasses and to compare the methodologies used in the two studies with recent methodological advances for their ability to provide data on the presence and quantity of *Campylobacter* for application in risk assessment and the establishment of baselines.

So, we have this three-part charge to the Committee. We will have three presentations to discuss baseline methods. First, we'll talk about discussing FSIS's baseline methodology that they used, and then Dr. Norman Stern of ARS will talk about *Campylobacter* methodology, and then Robert Mandrell of ARS will talk about *Campylobacter* aggregation. This charge will be taken by Spencer's Subcommittee and it's an add-on to your already full platter.

With that, I'd like to introduce Victor Cook of USDA/FSIS. He works in the Biosciences Division of the Office of Public Health and Science. He joined FSIS, the Headquarters, in 1998, where he's been involved in a variety of laboratory methodology issues, including *Campylobacter*. Throughout his career, Victor has worked in three FSIS labs, the Eastern Lab, the Beltsville Lab, and the Microbiological Outbreaks and Special Projects Laboratory in Athens, Georgia.

Victor?

MR. COOK: Thank you, Dr. Pierson.

Okay. You should have updated handouts in front of you. I'm going to go through these slides pretty quickly to try to get us back on track here.

We're going to cover the 1999-2000 Young Chicken Baseline Study, I'll skim over that, and the relationship to the '94-95 Young Chicken Baseline Study. Also, I'm going to talk about the *Campylobacter* Methods Comparative Study that was kind of an addendum to the baseline study that used the same samples to compare an ARS method, an ARS-proposed direct plating method to the FSIS-MPN method, and I'm also going to talk about an ancillary study, I'll briefly touch on that, on Nalidixic acid resistant isolates obtained from the above studies.

Okay. The Young Chicken Baseline, what we were trying to accomplish, we wanted to update the data, determine any changes in prevalence and compare the results to the '94-95 baseline. We employed about 1,200 post-chiller/post-drip carcasses over a one-year time frame. Each carcass was rinsed with 400 mls of buffered peptone water. Rinsate was shipped by FedEx overnight and analysis was initiated the next day. All

three field labs participated.

Okay. When we compare the '94-95 and the '99-2000 baseline studies, you'll notice that there were roughly the same number of samples. There was the same MPN method described in Microbiology Laboratory Guidebook Chapter 6 was employed in both studies. Both studies used a 400 ml rinse for the chickens, but there was one difference between the two studies. Whole carcass was shipped for the '94-95 study and rinsed in the lab whereas in the '99-2000 study, the carcass was rinsed at the plant and the rinsate was shipped.

Okay. And this slide shows some data that was used to justify the decision to ship rinsates rather than carcasses. I'll skip on here.

For the *Campylobacter* Methods Comparative Study, as you all may well know, MPN methods are very resource-intensive. They're not amenable to high throughput testing. So, Eric Line of ARS in Athens, Georgia, proposed the use of a direct plating method. We had performed a preliminary study in conjunction with ARS in our Athens SPOSL Lab, and the initial results were promising. So, we made the decision to use baseline -- the '99-2000 baseline samples to -- in an attempt to validate the new methodology.

The ARS method consists of plating one ml over four Campy-Line agar plates. This was a proprietary media developed by Eric Line. The quantitation range it provided was 1 to 3,000 CFU per ml. In order to increase the sensitivity of the assay to make it comparable to the MPN method, it also employed a back-up enrichment of testing 30 ml of rinsate in Bolton Broth with subsequent plating on Campy-Line agar. So, we were able to achieve a theoretical sensitivity of .03 CFU per ml. FSIS MLG method was used for confirmation for what was described, up to 3 to 6 colonies.

Okay. For both baselines, as I said before, the same method was used. It's the MLG Third Edition, Chapter 6 Method that's posted on the FSIS website. It consists of a two-stage Hunt Broth Enrichment and subsequent isolation on MCCDA agar plates, and we implemented that as 3-tube MPN covering 6 dilutions. So, the quantitation range provided there was .03 to 11,000 MPN per ml, and I'm going to skip through these. There's some detail about the FSIS method here, 2-stage enrichment, the gassing and then subsequent plating on the MCCDA plates.

Okay. The MLG confirmation method was used

for isolates derived from both the FSIS and ARS isolation methods. That confirmation method consists of wet-mount direct microscopy examination for typical morphology and darting motility, and there were also catalase tests, oxidase, glucose, and antibiotic profiles using two different antibiotics, resistance to cephalothin and sensitivity to nalidixic acid, which was one of the traditional criteria for speciating the *Campylobacter jejuni/coli*, differentiating them from other campylobacters. So, therefore, nalidixic acid-resistant isolates and therefore most of the fluoroquinolone-resistant isolates were not confirmed as *Campylobacter jejuni/coli* using this test method.

When comparing the FSIS and ARS methods, there was significant disagreement for paired samples. Seventeen percent of the FSIS method positive samples were ARS negative and a similar percentage of ARS method positive samples were FSIS negative. One result could not be used to predict the other. Overall, the FSIS method found that approximately 7 percent more positive samples than ARS method.

Potential sources of variability. Certainly one significant contributing factor was mixed populations of nalidixic acid sensitive and nalidixic

acid resistant *Campylobacter jejuni/coli*. Typically, no more than three colonies were selected because this is a very resource-intensive project and that's all that the methods prescribed, was a minimum of three colonies, and typically if the lab confirmed the first, they would not pursue confirmation of the next two isolates.

So, a significantly-contaminated sample could be negative without exhaustive colony selection, and a subset of our data suggested that about three-quarters of samples containing nalidixic acid-resistant isolates were negative by the MPN and there was a similar percentage for the ARS method as well.

We also have had some concerns about the issue of inconsistent aggregation and co-aggregation of cells and how that might affect the levels and the precision of the levels.

I'm going to defer to Dr. Mandrell on what is aggregation and co-aggregation. That's going to be the topic of his discussion, but again obviously this has a potential -- an obvious effect on the accuracy but perhaps more significantly it has an effect on the precision of the assay and reproducibility and repeatability.

As an addendum to this study, we had Paula Cray of Athens test nalidixic acid-resistant strains that were selected from the study. She used PCR to speciate them, AB Biodisk E-Test to do antibiotic profiling. She found that virtually all of them were jejuni/coli, and she also found that interestingly about 10 percent of the isolates that were found to be nalidixic acid-resistant by our laboratories were nalidixic acid-sensitive in her hands, and I think that Dr. Mandrell will also be addressing that issue. That appears to be due to co-aggregation primarily.

So, in summary, variable sampling and laboratory methodology for *C.jejuni/coli* appears to provide questionable results, but we're not quite clear on to what extent this problem goes. So, the question to be posed to the advisory Committee: Is it scientifically justified to base any conclusions on the data obtained from these studies, and is additional methods research needed? We see that -- my last slide here I'll leave you on, these are some of our possible methodology development research needs as we see them.

A new confirmation protocol to address the nalidixic acid-resistant population of *C.jejuni/coli*, means to mitigate the effects of aggregation/co-

aggregation, simplification of our methodology and also attempt to make it more robust so it would lend itself to high throughput, and perhaps there are sample-handling issues, carcass versus rinse issues, and perhaps we should be exploring non-traditional emerging technologies as alternatives to cultural enumeration, such as quantitative PCR.

Thank you.

DR. PIERSON: Thank you.

What we will do is to have all three speakers and then at the end of that time, we'll have a general discussion and we can ask the speakers questions, also.

So, with that, our next speaker is Dr. Norman Stern. Norman is a microbiologist with the Agricultural Research Service at the Russell Research Center in Athens, Georgia. He's been working with *Campylobacter* and the area of *Campylobacter* research since the early '80s. During this time, he's focused research on characterizing *Campylobacter* distribution in foods of animal origin, developing methods for detection and enumeration of *Campylobacter*, conducting epidemiological studies to describe the transmission of *Campylobacter* from the environment to poultry, and conducting studies of interventions during poultry

production.

Norman?

DR. STERN: Thank you, Merle.

Good morning, ladies and gentlemen. Technology. Distinguished Committee, good morning. Ladies and gentlemen. When I get my slides, I'll know what I'm doing.

(Pause)

DR. STERN: My first comment probably is something having to do with the methodology that exists in the MLG today, and I don't know if it's diplomatic or otherwise, but I don't think I could have a worse nightmare from a microbiologist point of view to have to do 6-dilution of MPNs to -- I think everybody in here has had the introductory classes to microbiology and those of you who have done MPNs or have been fortunate enough to be a TA in a college course have a hard time explaining these 00001 MPN reports and we've all come into that and I think it's a way to confuse things very quickly. So, what I'd like to do is to talk a little bit about methods that I'm familiar with and just present that to you. I can do this, I know it.

(Pause)

DR. STERN: All the methods that might be used within the industry or within regulatory have limitations with regard to time and labor. Cultural bacteriology, immunologic probes or DNA probe methods can only provide an estimate of the actual number of bacteria that are present in any sample, and I think the expression of God only knows is appropriate, although we can't say that here.

It's an estimate and let's remember that. I think what's most important is that within a given process lot and here I'm talking about process lots of 25,000 chickens going through a poultry processing plant, you need to have adequate number of samples so that you have a potential to talk about the mean and the standard deviations that are surrounding that mean, and I will share some data with you to show you what kind of variability does exist within selected process lots.

Somewhere along the way, people who have worked with the organism have made it more complicated than need be. For those of you who know me personally, you realize I'm not a very deep person. I would like to suggest that this is a plausible approach and we can use simpler methods to gain an estimate on the numbers,

and I think it's more important to have an estimate than it is to have a lot of specificity for each one. Yeah. We can do PCRs for detection of *Campylobacter*, also, but I don't know that that is necessary.

What we've been doing in my lab probably the last 20 years has been to rinse carcasses the old-fashioned way, put the carcass aseptically in a sterile bag, add your diluent, and we use tap water. Tap water gains a tremendous amount of nutrients in a very short time and *Campylobacter* is not hurt by these tap waters that then pick up all the diluent, all the components that are part of the processed poultry.

We'll then shake that carcass for one minute and transport it to the lab on chipped ice, make dilutions of the rinse and plate it directly on to Campy-Cefex agar, incubate the agar for 24 or 48 hours at 42 Centigrade under a microaerobic atmosphere. We then take suspect colonies, and this is easily learned after a few hundred plates, you get to know what is a *Campylobacter* and what is not. We'll then do a latex agglutination which costs maybe a dollar or 50 cents per colony, and if we have confirmatory evidence that it looks like a *Campylobacter* on the plate and it looks like a *Campylobacter* under phased contrast microscopy

and we obtain agglutination by specific latex agglutination tests, we call that a *Campylobacter*.

We then make appropriate multiplication having to do with dilution factor and number of colony-forming units that we are estimating and we can come up with an estimate of the number. The good thing about this method, also, is at the end of the day, you do have a colony. That colony is certainly eligible for be it pulsed-field gel electrophoresis or be it for microscopic exam-- you can use the same colony for sequencing so you can be sure that you have -- if you need to do epidemiology on the organism, you certainly can do that.

Okay. Some time ago, we reported on this method that I just described, direct plating versus two then available most probable number techniques, and basically we had equivocal results. It turns out if you run any of these tests multiple times, you'll get more positives, but I don't know that that's the question. The question really has to do with getting an estimate of the numbers. We can get the estimate of the numbers and the colony in less than 30 hours, and I think anyone in this room who's done microbiology could do the same.

The good news, also, is that a given technician who's provided petri plates and who can have somebody do the autoclaving subsequently can easily do 200 carcasses per week and can provide the data on that.

What I wanted to do here was to provide a little sense of what exists in the industry today and these are just -- what we did was to take 50 carcasses and a couple of points need to be made here. These are the levels that we saw in flock X, ranging from about 10 to the 4.5 down to about 10 to the 2.7. This was our limit of detection. If you take one colony on two plates and take the log of that, you'll get 10 to the 2.7. That's our limit. Otherwise, it's non-detectable. So, we assume that that's the level.

So, to get a sense of this flock versus the next flock, here we have clearly a flock that you can tell, again we have a 2-log range, but this particular flock was considerably higher. This had a mean of about 10 to the 4.8 using the methods I've just described. As gross a method as it is, we can distinguish that this flock has statistically greater numbers of *Campylobacter* as compared to the first flock that I shared with you.

Right. Dr. Line reported on Campy-Cefex direct plating equivalent to the FSIS method or the Rosef MPN method and that Rosef is a scientist from Norway, and it's widely used in Europe. The FSIS method uses a charcoal CCDA agar which is opaque and therefore precludes you being able to enumerate in the manner that most of us have become familiar with.

The Campy-Line agar we just heard about and this is a nice agar in terms of differentiating *Campylobacter* as well as selecting for *Campylobacter.* The problem really is, in our hands, that it is quite a selective medium and you can get lower numbers estimated and just compared to a less selective agar, such as Campy-Cefex.

I go back to my history at Virginia Tech and jejuni was always characterized as nalidixic acid susceptible and coli as resistant. For me, it's not a reason to call bacteria by a specific epithet. Today, we certainly have the ability to use molecular methods to distinguish jejuni and coli and they do look like they're different species, although they're both human pathogens, and distinguishing between jejuni and coli probably does not give you enough epidemiologic information to track an organism. So, as I said, I

don't think that resistance or susceptibility is that critical here.

Here's a slide just to give you something else to think about and we took six carcasses in Trial 1, six carcasses in Trial 2, and we obtained numbers and this was a little more complicated. We did centrigation and resuspension, etc. But if you can believe the numbers, they are here for you, and we even went out as far as 40 consecutive rinses and we were still pulling *Campylobacter* back out. So my suggestion here is that we use this first rinse to get an estimate of the level of *Campylobacter* on that carcass, and if you were to sum number 2, 3, 4, 5, 6, 7, 8, 9, 10, we'll probably be able to come up with an equation saying that if we obtain 10 to the 3.65, it's really equal to 10 to the 5. something. I think the numbers are less important than getting an estimate of the level that's on that carcass. I know that this set of carcasses were higher than the second trial and yet this is relevant to the deliberation in front of this Committee.

So, clearly we need accurate enumeration to estimate *Campylobacter* on carcasses. Clearly, we need to sample enough numbers of raw poultry samples so that

we can get a sense of the level of *Campylobacter* within a processing lot, and in my estimation, increased public exposure on raw poultry will provide increased public health concerns. The level that is acceptable still remains to be determined. The level that the industry can provide still remains to be determined. However, with increased exposure, we do see increased disease.

Thank you for your attention.

DR. PIERSON: Thank you very much, Norman.

Our next speaker is Robert Mandrell. He's the Research Leader of the Produce Safety and Microbiology Research Unit at the ARS facility in Albany, California. In the early years of his career, he worked at the Walter Reed Army Institute of Research in Washington, D.C. He continued his research at the UC San Francisco Medical Center after moving to the VA Medical Center in San Francisco, California.

Since joining ARS in 1996, he has been working on microbiological food safety issues. He and his group in Albany work primarily on the molecular biology and ecology of bacterial food pathogens related to produce. Today, however, he's going to talk about some work related to *Campylobacter* in poultry,

specifically the problem of mixed strain cultures that may be caused by the propensity of *Campylobacter* cells to aggregate.

So, as soon as his presentation is loaded, we'll --

DR. MANDRELL: It has a lot of images in it and they always take awhile, but I can get started here.

I'm not a poultry expert, like Norman is. Our work is really focused mostly on produce now. We use poultry as a model for looking at *Campylobacter* because we're very interested in *Campylobacter* as an organism, and a lot of our work is really getting more into the genomics and proteomics of *Campylobacter*. So, we use poultry as a model.

So, what we've done initially was to make some good reagents that would allow us to look at *Campylobacter* on surfaces and biofilms and so forth, and in doing this work, we've run across a couple of little problems, and I didn't mean to make them as much of a problem as I think some might think they are, but I'll present the data here on some issues I think are important for this group.

I've labeled my talk here "Aggregation and

Mixed Strain Cultures". I'll talk a little bit about the aggregation phenomena, which I think anybody that works with *Campylobacter* certainly knows about its ability to aggregate. So, that's not really a surprise to people, and I won't spend too much time on that, but I will talk a little bit about this mixed strain culture issue because that is a problem and I think it is required for certain kinds of surveys, for example, and I think it does require some good care in being able to characterize these strains when doing those kinds of surveys.

So, what we did in our laboratory, Bill Miller is a scientist in our laboratory, and he constructed some plasmids that had fluorescent proteins in them that we put into *Campylobacter*, and we did this because we wanted to be able to look at *Campylobacter* on surfaces and allowed us to look in cell lines, poultry skin and other surfaces, and also would allow us to do co-inoculation studies where we could take different strains, maybe a strain that comes from poultry or a strain that comes from a human patient, be able to mix them together and do very simple studies where we're looking at the fitness of those strains comparing them to be able to identify those strains in

complex systems.

If you could see it, it would be a really pretty image of *Campylobacter* on a chicken skin, but I'm not going to wait for it to come up. It's probably a MAC PC problem here. But you could see these *Campylobacter* cells on chicken skin very nicely. We've been able to see them in cell lines and so on. I'll just go past this in the interest of time.

Also, SEMs of *Campylobacter* show some interesting interactions between the organisms that one might associate with aggregation. We often see these with especially coccoid cells of *Campylobacter*, these fibrils that might be -- they might be flagella, I don't really know what they are, but are certainly something that in certain strains especially seem to be part of an interaction between the organism. In this case, it's from a pure culture.

But what we did then when we did these simple studies with *Campylobacter*, we could take Strain 1 that was one color and Strain 2 that was another color of a fluorescent protein, mix them together, grow them in broth cultures with the very simple goal of trying to see if there were any fitness differences between these organisms. In this case, it was a poultry isolate and

a human isolate, and what we noticed right away is what people have seen before in terms of aggregation, even after vigorous mixing of the strains out of the broth culture or -- and also sonication in this case. The organisms were really tenaciously aggregating and very difficult to get apart. You can see this here where you see the spiral and coccoid forms of two different strains of *Campylobacter* when they're plated and also in just under the microscope.

Now, what we noticed after we plated the organisms was more interesting actually, and in these experiments where we used broth cultures and then plated them out, we noticed that 6 percent of the total colonies on the plate were actually like this and like this. They were a mixture of the two strains. So, therefore, perfectly round single colony-forming units which is the sort of gold standard for pure culture in microbiology were actually mixtures of two strains, and this seemed to be very high, 6 percent seemed to be very high.

We also did experiments where we took the two strains and exposed them to poultry skin, poultry carcass, and then plated those organisms and found that there was even more interaction between the organisms

and they were very hard to separate, but this brought up -- we made this point in the paper but was actually very interesting because of some other work that we were doing in the laboratory with strains that we were sent from outside sources from around the world and also strains sent to us that were part of the NARMs, the Antibiotic Resistance Monitoring Project, from Paula Cray and Mark Englen.

Before I get to that, I just want to mention that we also looked at these organisms that we colonized chickens with and then isolated them from the enteric tissue or from the feces and we didn't see this as much. We didn't see the mixed colony-forming unit, mixed strain colony-forming units quite as much as we did from things like broth cultures or from the poultry skin. Generally, from those samples, the colonies were really clean and pretty pure. Occasionally, we would see problems like this, but if someone were selecting those, you probably wouldn't select one of those colonies anyway.

We did see this occasionally, though, where a colony-forming unit, these are samples that come out of, I think out of feces in this case, it might be from the enteric tissue, we would see colonies that were

obviously a mixture of the two strains. More problematic was that we actually did an experiment where we saved strains that were -- we could isolate -- obviously because of being able to see the two colors, we could isolate a purer colony-forming unit with a single strain and we saved some of these and got them back out months later for additional experiments. They had been stored at minus 80. When we got them back out and replated them, they were actually a mixture of two strains. So, even with measures to be able to identify colonies that were probably not a mixture, we even then ended up with a mixture, indicating there was some apparent contamination even in those colonies.

So, what we have found just in summary is that certain samples were more likely to get these mixed strains, if you're dealing with mixed strains, these colony-forming units that are a combination of the two strains. I think in terms of human isolates, we seldom see this mixed strain problem, and I'm going to describe this in just a moment. With environmental isolates, animal isolates, we tend to see this much more as one would expect because the animals probably have many strains present.

The way that we were able to now see mixed

strains in samples that we get in is we developed a variety of reagents, including monoclonal antibodies, and I won't get into the mass spectrometry, but we can use mass spectrometry to be able to look at single colonies and identify their species based on biomarker ions. Using these kinds of methods in the laboratory, when we get strains in from outside sources, we always confirm that they are what they've been stated to be, and what we have found using these kinds of methods, that some strains that we get in have just been speciated incorrectly or they're a mixture of strains, and this is much more of a problem with *Campylobacter* than things like *E.coli* or *Salmonella* that we get in.

We would be able to observe this by monoclonal antibodies, for example, that are specific for *Campylobacter jejuni* that we have, that we would see with an authentic *Campylobacter coli*, a pure strain, would be baseline binding, but we'd occasionally see with the strains that we get in that they would have a little bit of binding of this antibody. Also, by mass spectrometry, where we can look for biomarker ions, where we can take single colonies and then analyze them by mass spectrometry, we get a profile of ions, and this is a PC problem that

they come out sideways, but here's the profile here. These are just proteins. These are molecular ions of these proteins that we can use by identifying biomarker ions that are specific for that species. We've been able to do this for coli and for jejuni, *Campylobacter lari* and other *Campylobacter*, and these are very good for being able to identify a strain as that species.

However, what we would see occasionally is a mixture of those biomarkers and this is an example here of a strain that we received from an outside source and you can see a biomarker for *Campylobacter jejuni* here and here and biomarkers for *Campylobacter coli*, telling us that this is probably a mixture.

Now, we received some strains that were part of the NARMs project from Paula Cray and Mark Englen, and these are, as those in the FSIS and others know, are strains that are from survey studies looking for antibiotic resistance and then they are sent to Athens, Georgia, and they do drug-resistance, antibiotic-resistance profiles. At some point in this process, these have been selected as single colonies to attempt to get a pure strain. When we get these in, though, we were sent 20 strains of *Campylobacter jejuni* from Paula and Mark, and these were sent to us because they were

multidrug resistant. We wanted strains that were very multidrug resistant because we just wanted to look for plasmids that we could use for engineering plasmids for *Campylobacter* work. So, they were selected in that way only.

We tested them by various procedures, the biochemical assays, monoclonal antibodies and mass spectrometry, and we were able to confirm that seven of those 20 were actually not *Campylobacter jejuni* strains but *Campylobacter coli* strains. So, 35 percent of those particular 20 of the subsets sent to us were not that, the species that was stated.

Now, we told Paula and Mark about this, and they went back and they had seen some ambiguous results themselves with the strains they were getting and they basically went back and retested all 192 isolates that they had and so they recultured them and tested them by a *Campylobacter coli* and *Campylobacter jejuni* specific PCR that they described. Out of that 192, they got 17 strains that were suspicious, and I guess the ones we got were part of that. They actually went to the stock beads that they preserved and did a PCR on that and were able to see in fact that they saw different species than they originally saw and also a mixture as

we were seeing. So, they retested the beads by PCR and they also did passage of the strains, these 17 on media five times, and then retested by PCR each time, and what they found is shown here and they were kind enough to give me their data. The paper's going to be coming out, I think, in a couple of months in Letters of Applied Microbiology on this work.

They compared two types of PCR. I won't get into that. The PCRs that they compared were a commercial PCR and their PCR. I would just state that they gave different results, but what they found is clearly, if you look at this band up here, that's specific for *Campylobacter coli*. So, a coli strain should only give that band. A *Campylobacter jejuni* strain should only give this band and they clearly saw that they were not only seeing differences in what they originally saw in the strains, they also were seeing the mixture and you can see that evident here by where you see an asterisk and also these arrows show, I think, dramatically the change not only in the mixture but also the change after passage in these. So, you can see here where it was mostly a jejuni strain represented there by PCR. You can see now it's a coli and now it's back to a jejuni.

So, here, you see a mixture, almost like an even mixture, based on the PCR products, you see now only a coli and here the mixture back again. So, this is very problematic. These clearly were mixed cultures. That has implications obviously. Now, they reported these 14 strains and the points that are important here, conclusions are that in no case did retesting resolve the inconsistencies. Different PCR systems gave different results, and it appeared that the detection of *Campylobacter coli* strains increased by retesting. So, the jejuni seemed to go away, the colis came up. This may be something about fitness of the strains on passage or something but clearly you're seeing a difference in the ratio of these mixed cultures.

So, mixed strain isolates all had been picked from a single colony at least once. So, what is a *Campylobacter* colony-forming unit? I don't think it's a problem in certain kinds of systems and samples, but it is in others apparently. So, a careful lab technique will usually yield a single strain but not always. So, I want to make the point that certainly this is a problem, I think, in certain kinds of samples.

Now, we clearly can find a mixed species using these kinds of reagents, monoclonal, PCR, etc., but what if you have a mixture of *Campylobacter jejuni* strains, the same species, with different antibiotic-resistance profiles? How do you discriminate that you have a mixture of those two strains, if in fact a colony-forming unit doesn't give you two strains? We're developing methods to be able to do this and I'll just state that using a variety of genetic loci that have lots of variability in them, we will be able to discriminate and identify mixed strains of the same species. I won't get into that here.

So, just the conclusions are that aggregation can lead, probably aggregation, some kind of interaction can lead to these mixed strain isolates. The frequency dependent upon source, perhaps even technical skill and possibly the strains. There may be specific interactions or something. I suspect that certainly when one runs *Campylobacter* from a poultry sample, for example, that you often get swarmy growth. Everybody has seen that, and if you don't have single colonies, someone probably decides to take their sample from something that isn't a single colony and perhaps this is why some cases you can get these mixtures of

strains, but I don't know that for sure.

Ineffective disaggregation will affect quantitation but it's possible that colony-forming units per ml that Norman gets or anybody else gets when they do surveys of poultry carcasses may actually be associated with the actual number of cells that are there and that maybe in those kinds of surveys, you don't care whether it's a coli or jejuni *Campylobacter*, just that it's *Campylobacter.* Selective enrichment, I think, probably minimizes this problem but quantitation wouldn't be as easy. So, the implications for survey studies are, as I said, I don't think if you're doing qualitative assessments that, you know, the percent carcasses contaminated, this data isn't going to matter to that.

Aggregation could affect the quantitation, as I've said, but even there, it may be that the numbers that you get are associated with the actual numbers that are on the carcass. One would have to find that out. But I do think it's important for any kind of survey studies and obviously for biology, those interested in the molecular biology and biology, it certainly has some implications for that. In the NARMs studies, one has to wonder, could the multidrug-

resistance profiles be an additive effect from multiple strains that have different antibiotic-resistance profiles. So, there, I think, you know, certainly Paula and Mark and those in the NARMs project are aware of this.

So, I'll end there. Thank you.

DR. PIERSON: Thank you very much.

Let me point out a correction. I might have misstated where the position of this new charge is. Spencer does chair a Subcommittee that's dealing with performance standards and that that's a very specific charge and they're addressing that and coming as close to conclusion. The charge on *Campylobacter* is a separate charge. It's not something that we're intermingling with the performance standards, the current performance standards charge. This is a separate charge. We're just simply using that same Subcommittee to address the new charge, and with that, I'll briefly turn it over to Spencer so he can give you an outline of where they intend to head with this.

MR. GARRETT: Well, thank you, Mr. Chairman.

I think as we can see from the three presentations relative to the charge and determining the methodologies and the differences and the

utilities, the differences and possible concerns for quantification, qualification, application, dah-dah-dah, our work's cut out for us.

We met August 8th and we had the pleasure of having the presentations by Dr. Walt Hill from FSIS and also from ARS of Dr. Stern, and so one of the things we wanted to do here was to give the full Committee and now we have an additional presentation that we certainly appreciate, Bob, and so now we have to begin to, if you would, collect our thoughts, synthesize this information, perhaps get additional information and so forth.

On August 8th, after we had our two presentations by FSIS and ARS, we kind of went into a brainstorming session and had not only for our Subcommittee members but also for Norman and Dr. Hill as well, and we came up with some thoughts, ideas and suggestions that we might need and some additional expertise and information needs that we felt that we were going to need to begin to address this charge, and I'm just going to very briefly read these out to you.

First of all, determine if additional membership is needed on the *Campylobacter* Subcommittee in order to address the charge. Determine the best

practical method for assessing prevalence and quantification and understanding the difference, if you would, between -- to use prevalence and incidence, we did bring that up again. Review the methods to confirm that they can be used for baseline studies. Determine the variability of the various assays. Determine how the two baselines were designed. Conduct a literature review on additional methods for *Campylobacter* and utilize the utility of the results or how best to utilize the utility of the results. Redistribute the previous NACMCF *Campylobacter* papers to the Committee and Subcommittee and I believe that's been done.

We need to know the variability of the different types and kinds of lab results and why that variability exists. Determine the adequacy of picking only three colonies per plate which is one of the methodology procedures and we can see some of the difficulties perhaps in doing that. Look at the nuts and bolts of the methods, including antimicrobials, as has just been indicated, and sample transport time and strain selectivity in terms of the antimicrobials. Evaluate the relevance of clinical isolations to carcass sampling methodologies.

We need to be provided the '93 and '94

baseline report statistical design and analysis and that's in the process of being done. Determine the reasons for rinse variability and there are differences, so there are variations in the rinse variabilities and what the suitability of how many times do you rinse something. Evaluate the rinse versus purge methods for the purposes primarily for risk assessment. Determine the standardization procedures of plants when samples are actually taken themselves. Review the findings of the May 2000 Chicago meeting on the NACMCF Meat and Poultry Subcommittee and that's being provided to us. Receive additional information from Dr. Hill and Dr. Stern regarding any further suggestions that they may have for our *Campylobacter* Subcommittee and also we would certainly welcome Bob to provide us with any additional information that he thinks that we need to look at, and also, again as Norman brought up, there's -- we also got into some discussions that I certainly don't want to go into today about the difference between precision and accuracy and how that's used in microbiological quantification as well as how do you deal with, as Norm indicated, with MPNs where you're at the lower sensitivity of the test, less than something? How do

you do that? Some people take a log value, other people take the issue of value of one, but it does make a difference in terms of your standard errors and sampling plans and things of that nature.

So, that's pretty much where we are and what we wanted to do here was to give everybody the flavor, if you would, of not only the degree of difficulty relative to the tasks that we're soon embarking upon but also how we're trying to address that task, and I would open it up for any other thoughts, ideas or suggestions or comments.

Thank you.

DR. PIERSON: Okay. Thank you, Spencer.

Allison?

DR. O'BRIEN: Allison O'Brien, USUHS.

I'd actually like to ask a question of the last speaker because it's related to some of the questions you posed. We did not have that opportunity to ask questions of the speakers.

DR. PIERSON: Right. That's what we're going to do now, is ask questions of the speakers as well as comment overall on the charge. So.

DR. O'BRIEN: So, it was for Dr. Mandrell.

DR. PIERSON: Yes.

DR. O'BRIEN: Where is he?

DR. PIERSON: Right there.

DR. O'BRIEN: Oh.

DR. MANDRELL: I don't hear it. Oh, okay. Good.

DR. O'BRIEN: Okay. My question has to do with methodology, and it has to do with the issue of mixed colonies. Did you ever do a quantitative assay comparing, say, real-time PCR data versus colony counts given mixture culture results? Because what we're hearing, of course, from Dr. Stern and from you is that if we do do colony counts, we're not going to be sure that we're dealing with a single colony at any one time. So, I'm just wondering if you've ever done that comparison.

DR. MANDRELL: No. Actually, what we're trying to do is develop the ability to see *Campylobacter jejuni* strains, and we actually have that capability now and we're going to be going back to samples and look to see if we have mixed cultures, not only of coli and jejuni but also mixed strains of jejuni.

As far as quantitation by real-time PCR, there are others in the laboratory that are doing that,

but we -- and that can be adapted to these mixed cultures, but we haven't done that yet.

DR. O'BRIEN: Thank you.

DR. MANDRELL: I think that's something that maybe Paula Cray and Mark Englen may be doing because they've got a lot of the samples that are relevant there.

DR. PIERSON: Cathy?

DR. DONNELLY: I had a question,Cathy Donnelly, University of Vermont.

I had a question for Dr. Mandrell. The entangled flagella that you showed us in micrographs of, to what extent do you think those play a role in this co-isolation of the species?

DR. MANDRELL: I don't know. I showed them because we see them often in SEMs but, I mean, as far as aggregation, we know Campy aggregates, and it's possible that that's part of it, but --

DR. DONNELLY: And I wonder if you're looking at exploring cultural conditions which either promote or --

DR. MANDRELL: No, we're not. We could, but that's -- I mean, it's something that's not our primary objective, but no, we're not. I mean, the way that I

would address this, if I were going to try and get better quantitation, is I would try some -- and we actually are trying this in some of the produce studies we're doing because we're looking at *Campylobacter* on leaf surfaces and in the root structure of plants, and we're using detergents, non-ionic detergents to try and increase the colony counts, and we are seeing some increases, not twofold, but we are seeing some increases using non-ionic detergents to try and just disaggregate the organisms because they are in aggregates on leaf surfaces and in the root structure.

DR. DONNELLY: Thank you.

DR. PIERSON: Bob?

DR. BUCHANAN: This is more as a comment than a question of any of the speakers. I have some concern that we're rediscovering microbiology. The reason why we use the term "colony-forming unit" is because we have a long history of aggregation and it used to be a typical protocol that before you started doing any kind of quantitative study, someone got a microscope out and looked at the cells to find out if they were aggregating, so that you had some idea of whether you were working with single cells or aggregates.

I'd like to make another comment, is that,

PCR and the whole DNA technologies offer some tremendously important tools, but DNA is not a cell, and at some point, whatever the procedure is that's being employed in a baseline study, somebody's got to look at the individual preparations, you know. A microscope is a very powerful tool, and so I have some concerns that we're not using in all of these assays some of the simple things that have been around for a hundred years that really would have answered some of these questions.

DR. PIERSON: Larry?

DR. BEUCHAT: Larry Beuchat, University of Georgia.

I have a comment and a follow-up on Cathy's question to Dr. Mandrell. Oftentimes in running challenge studies or tests for thermal inactivation or sensitivity to sanitizers, we use cocktails. We use a mixture of strains or in the case of *Salmonella* different serovars. I guess it would be reasonable to always test for, for the lack of another word, compatibility or cross-reaction in reference to the observations that Dr. Mandrell has made on this aggregation phenomenon, perhaps not as extensive for other genera but nevertheless to do that, and I think

that's not often enough done.

But my question is a follow-up. I really had the same question as Cathy did. To make in the end more valuable and applicable, practical, the observations that are being developed and made, it would appear that I think the age of the culture, the temperature at which it's grown, whether it was grown on the surface or in media or broth, nutrient availability, would have an impact or could very likely have an impact on the extent of this aggregation phenomenon and even subculturing may well result in the loss or at least change in the ability or extent of aggregation. So, I would hope that Dr. Mandrell or others working in this area would consider these approaches.

Thank you.

DR. PIERSON: John, do you have a question?

DR. LUCHANSKY: Some of the questions -- John Luchansky, ARS, -- I had for Rob have already been asked, but one thing I'd be curious about from some of your other stuff, Rob, do you think this is a situation unique to Campy or with LM or 0157 or *Salmonella*? Would you expect to see similar --

DR. MANDRELL: I can only give you some

information. It doesn't seem to be as much of a problem with some of the other strains. I'll just give you some information on *E.coli* because we've gotten a lot of "O157:H7" strains in from different sources, and in two groups of 55 strains, only 28 of them were authentic 0157:H7, but in another group of strains of a 178, a 168 of them were authentic. So, that's really a methodologic thing.

As far as mixed strains, we did find mixtures of strains in those. Ten percent in one group and the other group, we -- actually, we don't know in the other group because we never really looked because we weren't doing mass spectrometry on those. The way we could find them is by mass spectrometry. We could see the 0157 isolates and then see other *E.coli*, generic *E.coli* that were mixed in there, and we were able to separate them out.

DR. LUCHANSKY: So, then, if I may?

DR. MANDRELL: But I don't think it's the aggregation or the -- it doesn't seem to be as much of a problem with *E.coli*. *Salmonella*, I don't really know.

DR. LUCHANSKY: So, then, do you think, following up on what Larry was saying, do you think

it's a microbiological or a procedural thing or is it a genetic thing?

DR. MANDRELL: If I had to guess, I would say it's a procedural thing with *E.coli*. With Campy, I think what I'm struck by is the number of strains we get in that are a mixture of strains --

DR. LUCHANSKY: So, we just --

DR. MANDRELL: -- from many sources.

DR. LUCHANSKY: Of the LM we sent you last month, were any of those mixed?

DR. MANDRELL: That, I can't tell you.

(Laughter)

DR. MANDRELL: I don't know because, you know, the methods, we haven't been able to get mass spec biomarker ions on the LM. Gram positives are harder to do. We're working on methods to get more ions from those.

DR. LUCHANSKY: And finally, one more, if I may? If you keep following via passage or via whatever, do the coli go back to become jejuni or do the -- do you see any --

DR. MANDRELL: Well, Paula has seen because they've gone in and they have the mixtures, and what we've done is when we get mixtures from other sources,

we just separate them out and we haven't tested them the way Paula did with passage to see in fact do they switch the ratio of those, but I expect they do.

DR. LUCHANSKY: Because that would mean that would be more of a genetic thing rather than a procedural, not so much like phase variation or curl information or something like that but --

DR. MANDRELL: Well, what I'm talking about procedural is the actual getting the mixed culture. I think for Campy -- for *E.coli*, it's just somebody -- you know, it's a procedural thing and Campy, I think it's the same thing. My guess is that what happens is what looks like a single colony-forming unit to somebody that's out in the field doing something, you know, really isn't, and it's likely to be a mixture when you're talking about especially poultry isolates that, you know, in that chiller bath, all of which get rebound to the surface of the animal -- I mean, the carcass, you know. There are many, many strains there. So, it's not hard to imagine that this is what's going on.

As far as the aggregation phenomena and all of that, I don't want to make a point that that's all new. It clearly is not new. What is surprising to me

is that in survey studies that there are mixtures of strains that shouldn't be mixtures of strains. That's my only point. I think we should be aware of that.

DR. PIERSON: Dave?

DR. ACHESON: David Acheson, University of Maryland.

I wanted to come back to Cathy's point about the flagella. There's certainly work to show that flagella are required for aggregation, and it would appear that what is going on potentially is related to glycosylation of flagella proteins. You can have mutants that contain flagella but don't aggregate and probably have mutations in specific enzymes leading to glycosylation. So, the flagella really are the critical element and therefore to get to Larry's point, you could potentially determine mechanisms to inhibit that.

DR. PIERSON: Stephanie?

DR. DOORES: Is there any -- I think this is probably to Dr. Mandrell or to Dr. Stern. Is there any suggestion that it's a requirement for the two strains to be together in order to create the disease? We know certainly that the level of cells is purported to be around 500 cells to create the illness. Would there be

such a situation that if we had the two strains together, that we would have disease caused at extremely low level but if they were different strains or they were separated and apart, you had a higher level of infectivity, and if the two strains needed to be together to create the disease, then maybe it's not a bad thing if we're picking it up on the methods that we currently have now. So, care to comment on that?

DR. STERN: To my awareness, in places such as Northern Europe and in the United States, most of the time, we have pure culture in clinical specimens. I think almost all the time. When we go to developing countries, you can get individuals excreting three, four, five different type of *Campylobacter*. So, I don't think there's anything there to say that to cause disease, you need to have two strains together. I think within the developed world, we consistently have most of our diseases manifested by a single strain.

DR. MANDRELL: I would agree that in the clinical isolates that we've gotten in, they're usually pure cultures. So, not to say that there weren't mixtures of strains there and it's just easier to get a pure culture from a clinical sample, but we have gotten some, and I think we've gotten about four out of maybe

75 to a hundred that are mixtures, but it's less than what we've seen with the animal cultures.

DR. DOORES: Okay. Can I just follow up on that? Is the selection for that organism from a clinical setting using different methods than from poultry, such that you might get a pure culture, a purer culture?

DR. MANDRELL: I don't really know how they do it in the different hospital labs. Someone that knows that -- Bala, maybe you know how that would happen. I don't know what antibiotics and selection systems they use in the hospitals.

DR. SWAMINATHAN: Usually clinical specimens, it's a direct plating on a selected medium, and you don't have the problems that you have with chicken skin and so forth. So, there is nothing unusual about it.

DR. MANDRELL: I mean, the idea of mixed strains causing illness is a very interesting one. It'd be interesting.

DR. PIERSON: Okay. Allison?

DR. O'BRIEN: Yes. Allison O'Brien, USUHS.

I'd just like to follow up on my original question, at least explain what I'm concerned about. I was concerned, particularly concerned in terms of

quantitation when you could not by looking at a colony tell that it was a mixed colony. So, the appearance of your blue and green segmented colonies or whatever, if you by eyeball, without that fluorescent tag, could you have -- did -- could you have detected that it was not a single -- was a mixed colony?

DR. MANDRELL: You mean, in looking at the whole sample?

DR. O'BRIEN: No. Looking at the colony --

DR. MANDRELL: Oh.

DR. O'BRIEN: -- on a plate.

DR. MANDRELL: I --

DR. O'BRIEN: If Dr. Stern was looking at that on a plate or you were looking at it on a plate, would you have realized it was a mixed colony when you were trying to count it?

DR. MANDRELL: Oh, no.

DR. O'BRIEN: Well, that was the point of PCR.

DR. MANDRELL: No. When you look into the light stereomicroscope, that looks like a perfect colony.

DR. O'BRIEN: So, that was my point about asking about PCR, was when you've done all the

visualization that you can do, are you going to be stuck? Are you going to have to -- if you really want an accurate -- let's not get accurate -- precise, but a reproducible count of the actual number of units that you have, are you going to have a problem by the colony that's mixed that you can't see as mixed?

DR. STERN: If I may offer some perspective on this? First off, the direct counts are estimates. Second, when we pick individual sample colonies, we will frequently find three, four, five different colony genotypes by using the sequencing method we employ to determine that in a given flock of birds, suggesting that there may be a number of sources for that flock of birds and that would not be unexpected. Birds do not get sick from *Campylobacter*.

DR. O'BRIEN: Could I just follow up on what you just said? Three or four different genomic types in the same colony or you're just talking about among all the birds in the unit you're looking at it?

DR. STERN: Among all the birds in that unit. We could take 50 individuals and we pick one colony from a plate, we will find different *Campylobacter* strains within that flock.

DR. O'BRIEN: But if there's a difference in

aggregative ability among the various *Campylobacter* for Flock A and Flock B, and in Flock A, the *Campylobacter* tend to aggregate and form a colony that looks like one unit and Flock B, they tend to aggregate less, well, then the relative comparison's skewed.

DR. SWAMINATHAN: This question is for either Dr. Stern or Dr. Mandrell, whoever wants to answer this. Even four out of 75 is quite a bit for clinical strains that you looked at and so I am concerned about it from a clinical isolate standpoint as well, and I'm trying to understand how strong this aggregation is.

I can very easily see how this could happen on a primary isolation plate when you're looking and thinking that you're picking pure colonies, single colony. It may be there may be something under that and it's very easy to obtain a mixed culture. But if Dr. Stern is going to send you some strains, it probably has gone -- been recultured two or three times in his laboratory, and then you are probably plating it out in your own lab and selecting single colonies out of that.

Are you trying to imply that once this aggregation occurs, those cells are difficult to separate even if they are repeatedly cultured?

DR. MANDRELL: I'm not trying to imply that because I don't really know the history of some of these strains that we've been sent that actually were mixtures. I don't know how -- I mean, everybody would like to think that everybody has done the single colony pick multiple times, but I'm not sure it always happens.

As far as them staying aggregated, I mean, if you take that colony that has a mixture and you replate that, you'll see some clean colonies that are -- you know, you don't see mixtures all over the plate. We've done that, taken a colony that is a mixture of two strains, then resuspended it and plated it and you get -- you still get some mixed colonies, still about 3 to 6 percent, but a lot of them have been teased apart and are now single pure strain.

DR. PIERSON: Bob Buchanan?

DR. BUCHANAN: I'd like to follow up on questions for any of the speakers on this one and it's following up a little bit on what Allison brought out, and the purpose for the generation of this data is to determine whether or not we can use it for a performance standard of some sort, and the question becomes are we interested in accuracy or precision in

terms of the methodologies we're looking at?

I guess I'd like to ask the question of any of you. Several years ago, I guess it's going on almost 10 years now, there was quite a bit of controversy in the analysis of poultry by a Holberg rinse for *Salmonella*. The experiments in question were if you took the bird, you put it in a bag with your 400 mls of liquid, you shook it up and you would quantify the number of *Salmonella* that were present on the chicken. If you then took that rinsed chicken and you put it back in a new bag with 400 mls of liquid again and you shook it, you get almost the same number, and you could do this repeatedly. In fact, it was researched. It did come out of the Athens lab.

Are we interested in these methodologies in terms of your ability using whatever method you're using to get a reproducible result or are you interested in getting an absolute number, and then I would wonder, are we using the right methods at all. A whole bird rinse is going to give you something that is reasonably precise. It will not give you an answer that is accurate.

DR. STERN: Well, indeed, that was part of the data that I shared with you and we realized that

we're only getting an estimate on the first rinse, but that if we do consecutive rinses, we can continue to get large numbers of *Campylobacter* out going out to 40 rinses.

I think what happens when you do an initial rinse estimation, you are getting a true estimation of load; that is, if you get a high level at your first rinse, you'll get more coming off later on, and if you have a lower level on the first rinse, then you'll have comparatively fewer in -- when you sum the entire dataset.

So, I think, you know, you're right to say that you can go on a single rinse, the first rinse, and get an estimate or we can come up with the equation of what a single first rinse really means, but I think either way, you're talking about the load on that process lot.

DR. BUCHANAN: So, I interpret that in light of the request that's come in, is that it's more important methodologically to focus on reproducible results, that is precision, than it is to be focusing on the details of accuracy. As long as you have a method that you can continue -- you can rely on to give you an estimate time after time after time, it's more

important than focusing on the details of how accurate that number is in terms of reality.

DR. STERN: I'm not sure. As far as I'm concerned, the words only mean so much to me. What I can say is that I can assess 50 -- I can assess 10 flocks and I know when one flock is significantly more contaminated than a second.

DR. BUCHANAN: I guess the question is, how much effort do you need to get into strain selection, how much effort do you need to get into genome selection, when really what you're looking for is a crude estimate at the front end?

DR. STERN: I would vote for a crude estimate because I think it gives you a pretty good assessment at least what the public exposure is.

MR. GARRETT: Thank you, Mr. Chairman.

Just to point out, though, Bob, that in our charge, we're really not doing this for developing a performance standard, but if you look at the third item down there, it's primarily to compare these methodologies to use in risk assessment and the establishment of baselines, actually, but the issue simply is many of your questions still relate obviously to our purpose.

Thank you.

DR. PIERSON: Thank you.

John, did you still have a question?

DR. LUCHANSKY: Some of this -- this is John Luchansky -- has already been taken up, but I guess I was going to ask the questions to be reframed because if this is a practical constraint to getting numbers for risk assessment, that's one thing. It's another thing if this becomes an academic pursuit to get into the details of what's really occurring here on a microbiological level. So, I was asking for a clearer understanding of that.

MR. GARRETT: Have I given you one?

DR. LUCHANSKY: Well, so you would -- from what you said, you would be looking for precise numbers, so you could better estimate risk.

MR. GARRETT: Well, --

DR. LUCHANSKY: Did I interpret that the wrong way?

MR. GARRETT: -- no, not at all. To the extent that those numbers in fact are suitable for risk assessment, yes.

DR. LUCHANSKY: Is the goal to get a very good handle on the contamination rate and in the number

of antibiotic-resistant samples, be it one colony, two colonies or five colonies, or is it an attempt to get an idea of more the actual exact number of *Campylobacter* strains that are found in a positive sample?

MR. GARRETT: I think it's bits and pieces of both. If we go back to the third bullet, compare the methodologies used in the two studies with recent methodological advances for their ability to provide data on the presence and quantity of *Campylobacter* for application and risk assessment and baseline studies.

So, I think the -- one of the challenges, quite frankly, that we face as a Subcommittee and this Committee faces in general is how do we take all this information and essentially decide what the main thing is and keep focused on the main thing, whatever that is. It certainly relates to -- because we can -- I'm a microbiologist, too, and this can be an exceedingly interesting intellectual exercise and in fact it will be. But again, we're trying to get the determinations made, if you would, and these estimates made that are suitable for methodologies to do baselines and then use that information again for risk assessment purposes.

DR. LUCHANSKY: In that respect then, I don't

-- I guess I would like some insight from you as the chairperson if we are to achieve that, are we to summarily dismiss, for example, the rather elegant experiments Rob described which were great? Are we to embrace that and try to see if we can make them reduce those to routine practice?

MR. GARRETT: No. I think, of course, this is my only second day on the job, but I might point out that I think at this point, we throw nothing out until we determine what seems to be -- and this is in my professional opinion, this will be -- this will parallel the degree of difficulty and the degree of in-depth study by the Subcommittee and then ultimately the Committee itself as we had with performance standards, and let me point out that that's taken over a year.

DR. LUCHANSKY: Thanks.

DR. PIERSON: Dane?

DR. BERNARD: Thank you, Chairman. Dane Bernard, Keystone Foods.

A question for any of the speakers. Is strain-to-strain variation in terms of aggregation, is it -- do they all aggregate to the same degree or is that an issue? I've heard discussions around that, but it relates to Bob's point on precision and

reproducibility.

Thanks.

DR. MANDRELL: I think there are some differences in the ability of strains to aggregate and that would be expected with some of the surface characteristics that are different among the strains. If I could just throw this in, based on what I think your charge is, I don't see that this mixed culture issue is really much of a problem for you all. I mean, I don't see it that way. I think what I'd be interested in, for example, would be Norman's experiments, where he's done the sequential, you know, testing of carcasses and seen if there is an association between the first carcass rinse and the sum of what you get after X number of sequential rinses, and if that association is good, then I don't think it matters that you would have a mixture of coli, jejuni or any mixed strains of jejuni. It doesn't seem like it would matter for that particular issue.

I mean, I see the mixed culture problem as really only a problem for when you must learn something deeper about those strains, antibiotic resistance, for example. So, as far as this issue I brought up, it's certainly an interesting one biologically. It's very

interesting in terms of characterization of strains and the purity of strains when you need to know exactly what the capability of that strain is, but as far as numbers, I would really lean on the side of a crude estimate because if you get into this in depth based on anybody that works with *Campylobacter*, you're going to have a really hard problem to try and get more absolute information about anything related to *Campylobacter* on poultry. So, I would just offer that.

DR. PIERSON: Anna?

DR. LAMMERDING: Anna Lammerding, Health Canada.

I think if we're considering why we're doing this, it's essentially for a public health goal, and in a risk assessment framework, we need to know kind of levels that are causing illness, and we haven't got that quite defined. If you also look at how people are exposed to *Campylobacter* coming from poultry, there is a huge amount of variability and uncertainty in cross contamination and cooking and so on and so forth.

So, I think the variability and uncertainties in those parameters greatly vastly overshadow the need to have an accurate count of *Campylobacter* on the poultry carcass itself. We probably need to have a

good idea, some idea of how much we may be underestimating, but that certainly can be within a couple of logs, I'd suggest.

But on another consideration with the presentation we heard on aggregation, I guess I'm intrigued by any implications for this phenomena to have anything to do with adherence onto poultry carcasses and the implications for any decontamination procedures, based on information that possibly tightly-adhered *Campylobacter* are more resistant to chlorine than artificially-inoculated cells on carcasses, and I think looking at it from that kind of a perspective is relevant to our charge, also.

Thank you.

DR. PIERSON: Tsegaye?

DR. HABTEMARIAM: Thank you, Mr. Chairman. Habtemariam from Tuskegee University.

You reminded me of the example of the FMD outbreak in England recently, and a farmer said let's see how far medicine has advanced when we cannot even diagnose FMD so very well. I'm not a *Campylobacter* expert, but I was sort of intrigued with all the work on *Campylobacter* that methodologies of diagnosis are still problematic, and I think the presenters did an

excellent job of showing the need for more research.

But I just wanted to cast this as an epidemiologist and especially with the idea of the need or the ultimate need for risk assessment as well as baseline surveillance data. This really is a comment really for the chair, MR. GARRETT, to consider. As an epidemiologist and a microbiologist, when the word "sensitivity" comes up, it always is a question in my mind. Microbiologists look at sensitivity as one item and epidemiologists look at it slightly different, and a key issue in these systems that we need to develop, I see clearly a need for two, especially with the sophistication of genomics and proteomics that were presented. We'll need a gold standard undoubtedly, but at the same time, we're going to need an easy and massive application for surveillance and baseline data gathering that would not be expensive and too time consuming. Therefore, there's a need for these two, but we're definitely going to need a good one, a reliable one, a gold standard because out of this, we've got to develop what I would like to throw out as test systems that will provide us good data on sensitivities, specificities, especially false-positive/false-negative issues that are really very

critical in the risk assessment task and the Committee or the Subcommittee experience is to consider, in addition to these methodologies, methodologies that would allow us to establish test systems in terms of sensitivities versus the false-negatives and false-positives would be very useful, and I just want to throw that out for consideration.

DR. PIERSON: Thank you.

Dave, at one time, your flag was up there. Have you backtracked? Our people saw you touch that flag, and you were summarily written down here as wanting to make a comment.

DR. THENO: Well, I'm thoroughly convinced I'm in over my head on methodology here.

(Laughter)

DR. THENO: Although I guess I do have a question that I would put to the presenters. Our charge really is a couple of things. We need to find a good, accurate, easy-to-use methodology if we're going to do something like this, a technique, but if I have three guys where I work present that kind of information and I was thinking about using Campy as a performance standard, I would ask them do you have a better recommendation for me.

This today doesn't look like a streetable proposition and maybe I'm misconstruing it, but do any of the presenters have an idea that what might be a good correlation or, you know, better approach to this than the Campy?

DR. STERN: I'm not running for office, but using the methodology I described and its very preliminary data in the work we're undertaking in Iceland, we can count *Campylobacter* in a rough manner as we do, and we can see differences in human disease response related to different numbers and it's still very preliminary, but we can almost predict that if it's below a certain level, we're not going to see a human disease concern or heck with concern, we're not going to see the human disease.

So, there is some relationship as gross as the method is, but we can see that it -- I don't know if it's a predictor and we're not -- we have not gathered enough data to say that we have a number that I would offer this Committee, but I think that this gross measure has a value.

MR. GARRETT: Thank you, Mr. Chair.

Responding to Dave, I think that given the presentation and the list of brainstorming the

Subcommittee's already gone into and then this additional information here, I think you can readily understand perhaps why the Agency's not asking relative to anything for a performance standard; rather, they're saying is the utility, if you would, in coming up with a methodology that would be appropriate for either baseline studies or in fact risk assessment, and I'm particularly taken by Anna's comments relative to risk assessment and, of course, I have a special place in my heart for microbiological risk assessors, Anna, which also includes Bob Buchanan. So, you see the list there.

(Laughter)

MR. GARRETT: You know, Tsegaye and others. The point simply is that, is there something out of all of this morass, I mean, that's why they got the seafood guy because, you know, we came out of the primordial soup, is there anything that we can actually glean out of all this to make some sense for this for risk assessment purposes and baseline studies?

Thank you.

DR. PIERSON: Very good. Thank you for your excellent discussion, and what we'll do now is break for lunch. Committee members, from what I understand,

you're on your own. Please find your way back here by 1:15 p.m. and we will reconvene at that time.

Thank you.

(Whereupon, at 12:08 p.m., the meeting was recessed, to reconvene this same day, Wednesday, August 28th, 2002, at 1:15 p.m.)

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

1:34 p.m.

DR. BRACKETT: The first thing that we're going to do is have the chair, Bob Buchanan, talk a little bit about a report out on the Subcommittee on Criteria for Shelf Life Based on Safety.

DR. BUCHANAN: Okay. Just for your purposes, this shouldn't take very long, but it's just to provide somewhat of an update of where we stand on the safety base used by Date Labeling Subcommittee that met yesterday and will meet again tomorrow as we work on our document.

Just in terms of a little background, we've been working on a document that at least in its draft form now is entitled "Principles for Establishing Safety Base Consumed by Date Labels for Refrigerated Ready-to-Eat Foods". Boy, this screen is terrible.

This arose out of a request that came from FDA and it in turn arose from the development of the FDA/FSIS *Listeria monocytogenes* Action Plan. As -- in response to some of the things that came out of the *Listeria monocytogenes* Draft Risk Assessment, one of the areas that were identified as a factor that should

be looked at was the potential growth of psychotropic pathogenic bacteria in otherwise adequately refrigerated foods and concerns that the risk of foodborne disease associated with the psychotropic pathogens increased as we extended the storage time.

A Subcommittee was formed. These are the official members of the Subcommittee, though I might note several of the other members of the full Committee have taken an on-going interest in this and have actually attended all of the Subcommittee meetings and have made some very significant contributions, and we encourage anyone in the Committee that has an interest that would like to remain involved in this to please feel free to attend any of the Subcommittees. We do announce the meetings to everyone and, in addition to that, we've had some very excellent input from representatives from different segments of the industry and also from people from academia. For example, Gale Prince made a very interesting presentation to us at the Subcommittee meeting yesterday on a perspective from the side of the retailer.

I might note here that the organisms of concern are the psychrotropic pathogens of most interest, *Listeria monocytogenes*, non-proteolytic

Clostridium botulinum, Yersinia enterocolitica. We still have some questions about whether or not to include *Bacillus cereus* and we've had discussions with CDC about some -- their opinion. Certainly pychrotropic *Bacillus cereus* is an area of concern in Europe. We're not sure what the extent of foodborne disease is here in this country. Then we throw another just a general others. There are a variety of other organisms that have been on one occasion or another suggested as being psychrotropic pathogens. However, most of the concern is with those three top organisms.

We have come to some, you know, general conclusions as we work through this. One is that this is a means of enhancing safety, not a means -- it's not a substitute for HACCP or GMPs. So, the assumption here is, is that, you have an adequately produced, adequately stored product and that we're focusing here on enhancing safety.

We certainly have had the background information that current date labels are primarily focused on quality attributes. However, the perception on the part of the consumer is that this also refers to safety, not just quality. We've learned that there are

different types of date labels and they have different focuses and different sort of strengths and weaknesses. Some of the ones that we're talking about are sell-by dates, use-by dates, and consume-by dates. We are looking now as part of our deliberations yesterday on which of those would be appropriate, at what time, and whether or not we would use more than one of them or would have to.

We have focused on trying to outline what would be the structure of the report and these are the different sections that will be in the report. They are each being worked on independently, some are more advanced than others, but right now, we've focused particularly on getting the scope defined and yesterday's meeting also looked at factors affecting growth, the section on other factors, the section on guidelines for establishing labels. We have -- thanks to Richard Whiting, we have had a fairly detailed example suggested and again we'll be looking at that in more detail.

Interestingly, one of the hardest areas right now is getting definitions for a lot of the different words we're using. It appears that definitions are anything but standardized and definitions vary from

what organization that you're talking to and also what federal agency you're talking with. So, we're going to be working through those issues.

Okay. That's just a real quick snapshot of where we are. It's a work-in-progress. We are making substantial progress. If anything else, if you measure progress by the number of printed pages, we're up to about 30 and just really starting but we'll be slimming that down. We will be meeting again starting tomorrow morning, again working on getting assignments out and on detailing some of the information that we've been generating.

I will be providing -- we got a lot of input yesterday which I'm now busily consolidating on my laptop. An updated version will be printed out late this afternoon and provided to Subcommittee members tonight, so that they can be looking at it in anticipation of tomorrow's meeting.

With that, I'd be happy to answer any questions, if there are any, from the Committee members.

DR. BRACKETT: Thanks, Bob.

Do we have any -- we have really no action to take on this. Are there any questions for Bob or the

Subcommittee?

(No response)

DR. BUCHANAN: Seeing none, I'm going to beat a hasty retreat.

DR. BRACKETT: Okay. Well, on the agenda is scheduled a break, but I don't think we'll do that. So, I think the next that we have up is Spencer Garrett, who is the Chair of the Subcommittee on Microbiological Performance Standards for Raw Meats and Poultry Products, and so at this point, Spencer can report out.

MR. GARRETT: Thank you, Mr. Chair.

I would point out that we have four documents with which we need to concern ourselves as we go through this. The first document is in your folder, and it's entitled "National Advisory Committee on Microbiological Criteria for Foods: Response to the Questions Posed by FSIS Regarding Performance Standards for Ground Beef Products", and it's dated January 25, 2001. If we could get that document? It looks like this.

In that document, if we could turn to Page 15, entitled "Next Steps", and I would like to go to Page 15, Mr. Chairman, to bring the full Committee up

and perhaps those in the audience to indicate what we indicated that we were going to do, and if I may read from those Next Steps, it indicates that "The Subcommittee is nearing completion of its work on data analysis necessary to respond to Question 3 concerning what constitutes scientifically-appropriate methods for considering variations that may be due to regional, seasonal and other factors when developing performance standards."

It goes on to indicate that "Upon completion of Question 3, the Subcommittee will address questions posed in the November 29, 2001, letter from Elsa Murano and Kaye Wachsmuth related to how the standards are working, whether they are helping to ensure the safety of the nation's meat and poultry supply, whether there are more effective alternatives to these performance standards, and what would those alternatives be?" Lastly, the Subcommittee then would address other ground products and other classes and categories, e.g. carcasses.

That is where we started our deliberations in preparing for this meeting. We've met that charge. The second document was passed out earlier. It's dated Draft 8/28/02, and it is Question 3. It indicates,

"What constitutes scientifically appropriate methods for considering variations that may be due to regional, seasonal and other factors when developing performance standards?"

If I may, Mr. Chairman, let me point out that in the earlier, our completed work, the draft that we had you look at Page 15, on Pages 9, 10 and 11 of this document, this report, we have already addressed many aspects of Question 3 relating to variations that may be due to regional, seasonal or other factors when developing performance standards, and if you would go to --

DR. THENO: Mr. Chairman, just looking around the room, and I'm on the Committee, so I know where all this stuff is, I don't think everyone's on the same page you are.

MR. GARRETT: Okay.

DR. THENO: So, we might want to help people get their documents.

MR. GARRETT: Sure. I would like to take us to the report that we adopted on January 25, 2001, that was made available out front this morning, although I noted that there weren't any out there, so I had to borrow Dave's because I lost mine already. Oh, I'm

terribly sorry. I stand corrected. There were some others out there as well. It's the fourth -- it begins on the fourth page of the big document, counting the title page, and I apologize for any confusion. I generally don't do that.

DR. BRACKETT: Spencer, show the front of the document so everybody knows which one you're referring to here.

MR. GARRETT: The front of the document is labeled "Performance Standards Documents".

DR. SWANSON: That is not what the full Committee got. That's what was sitting out there for everybody else to pick up. I think everybody else who's on the Committee got this document in their packet, which says, "National Advisory Committee on Microbiological Criteria for Foods: Response to the Questions Posed by FSIS Regarding Performance Standards for Ground Beef Products, Adopted January 25th, 2001". Is that the one you're referring to?

MR. GARRETT: Yes, and I think they're identical and already it's been pointed out to me that there's a typographical error on the title of the document because it was actually adopted in January 25, 2002, but I would submit that's insignificant for about

what we're going to discuss. Is everybody there, essentially on Page 11? Okay.

You'll see there's -- we go into on Pages 9 and 10 a lot of explanations, but on Page 11, there's -- at the bottom of the page, there's a section on data needs and we indicate what those data needs are and that was the starting point for our deliberations to finish our answer on Question 3.

Also in this big document, Mr. Chairman, we examined probably over a 100,000 data points. There are different types in the kinds of analysis and in this big document, most of it relates to the documents and the data documents upon which we premised our conclusions. It's not my intent to describe all the analysis and so forth. So, that then brings us to our second document, which is our answer to the remaining portion of Question 3. Doing okay?

DR. BRACKETT: This is the one dated August 12th?

MR. GARRETT: Yes, sir.

DR. BRACKETT: Okay.

MR. GARRETT: No, no, no. This is dated 8/28/02. We've had another Subcommittee meeting since August 12th. It was on the table. I have an extra

copy if you'd like one, Mr. Chairman. You got it? Okay.

And in this, this document is only like a page and a quarter perhaps but it is our remaining answer to Question 3, and straightaway, as we address this after examining all the data, we indicate that it is recommended that the '98-2001 HACCP Verification Data not be used to establish new performance standards or a new performance standard for ground beef or to determine either regional or seasonal variability in *Salmonella* prevalence.

We go on to indicate why, inferring that the sampling plans were not designed to provide statistically valid estimates of national prevalence and levels of microorganisms, and for this reason and for the consideration of establishing revised ground beef performance standards, NACMCF recommends that the Agency conduct another nationwide federally-inspected plant microbiological survey for each raw ground product of interest, designed to provide statistically unbiased estimates of the true prevalence of bacteria of concern.

We further recommend that this survey be conducted at least 12 consecutive months, be stratified

by production volume, month and region, and the number of samples analyzed being sufficient to meet Agency-specified discriminatory power for the comparisons of interest. We point out that production volume is an essential factor when considering baseline surveys and should those volumes not be available, estimates must be obtained by other means, such as using appropriate agreed-upon covariants for baseline studies.

We also point out that if there are notable regional and seasonal effects, consideration should be given to increasing the number of samples analyzed to increase the statistical sensitivity to detect significant differences. We also indicate that in the case of ground beef, that an accompanying baseline survey be conducted of trimmings which is the intermediate product stage between the carcasses and the ground product, which would include all source materials with additional consideration for stratification by the various components, such as boneless head meat, low temperature rendered material, advanced meat recovery, lean and fine textured meat, frozen and so forth.

We believe that determining the microbiological profile of the trimmings will better

reflect the prevalence of pathogens and other organisms in source materials for ground beef to establish performance standards, if those are deemed necessary.

Going on to the next page, we indicate that all baseline studies should at a minimum include an identification of the product class and product origin identified by location of manufacture and date. Such information, we believe, will provide the data necessary to address regional and seasonal variations. We go on to point out, though, that there are confounding factors, and we've previously discussed those, I believe essentially on Page 10, perhaps 9, and those confounding factors need to be considered.

We point out that from a practical standpoint, only a limited number of factors are likely to have significant effect on microbial prevalence, and it should not be assumed that the confounding factors will be the same for the different ground products and their source materials. Additionally, the aforementioned baseline studies should include examination for not only *Salmonella* but also for coliforms, *E.coli* and other indicators that may have possible utility as measurements for what we call the cold chain management or process control.

Obviously implicit in this assumption is that the interventions applied to carcasses have the same effect of controlling pathogens, including *Salmonella* as well as *E.coli* and coliforms, and we'll talk more about that particular issue when we address the Murano and Wachsmuth questions.

We further recommend that the statistical estimation procedures used to provide the prevalence estimates and their standard errors be based upon the methods that were used for the '93-94 raw ground product microbiological survey and that survey is footnoted at the bottom of the page. That relates to our answer to Question 3, Mr. Chairman, relative to regional and seasonal variation.

One. We recommend that a new study needs to be done. We indicate how that study -- why we feel a new study should be done, how it should be conducted, and how the results should be analyzed.

Thank you. I'd be glad to answer any questions from the Committee.

DR. BRACKETT: It's probably a good time to stop to answer any questions right now. Does anybody on the Committee have questions for Spencer about this particular part of the question?

(No response)

DR. BRACKETT: Nope. Okay. Move on to the next part.

MR. GARRETT: Thank you, Mr. Chairman.

Then, as we had indicated, we would ask -- we would answer or address, rather, what are referred to as the Murano/Wachsmuth questions. Our answers to those questions are found in another document -- oh, and one other thing I may say on this. We intend to insert our answers to this question in Question 3 on Page 11, okay, under Next Steps.

The Murano/Wachsmuth questions which were twofold and they're also -- it's a four-page document, dated 8/28/02, rather current, entitled "Responses to Question Posed to NACMCF from Drs. Murano and Wachsmuth Regarding Microbiological Performance Standards, November 29, 2001". Everybody there?

We've had a lengthy discussion on these questions and there are actually two. The first question indicates, "How are these standards working, and are they helping to ensure the safety of the nation's meat and poultry supply?", and the second question is, "Are there more effective alternatives to these (and *Salmonella* Performance Standards) and if so,

what would they be?"

I'd like to address these one at a time. On Page 1 of the document that I've indicated, we indicated straightaway again, "As previously indicated in Question 2, General Principle 1, Microbiological" -- from our earlier report that we've already adopted, "Microbiological Performance Standards are intended to effectuate a decrease in the presence of enteric pathogens in raw meat and poultry with the goal of improving public health. NACMCF considers Microbiological Performance Standards an important tool in advancing the microbiological safety of meat and poultry to clearly articulate the Agency's expected level of control of the HACCP system, including sanitation SOPs."

We point out that there really are three criteria we considered in answering this question, and the three are the bulleted items there. Performance standards have stimulated the development and implementation of intervention strategies for reducing the levels of pathogens of meat and poultry.

Secondly, there has been a reduction in the frequency of isolations of *Salmonella* from the verification samples by FSIS, and thirdly, based on

FoodNet data from 2001, CDC's determined that there has been an overall human salmonellosis decrease between 1996 and 2001. We give the reference and also show the 95-percent confidence interval, the upper and lower bounds, of those decrease estimates.

Nevertheless, we point out that the proportion of salmonellosis linked to meat and poultry, the meat and poultry supply, cannot be determined at this time and we'll say more about that in just a moment.

We also noted that existing public health statistics make it very difficult to specifically attribute reductions in enteric diseases to performance standards and point out that the difficulty is due to the wide array of food safety activities underway and in fact the various confounders that affect the linkage between public health and performance standard data and datasets.

We did consider alternative approaches on how the potential impact of the performance standards could be evaluated. The Committees observed that the only data available so far are the *Salmonella* verification results that clearly demonstrate a decrease in the frequency of *Salmonella*-positive samples that are

collected through the Agency's Verification Sampling Program.

We also noted a decreased incidence of *Salmonella* as reflected in the Agency's verification data in raw meat and poultry has not led to a decrease associated with *E.coli* O157:H7 in ground beef. In this instance, the underlying assumptions of the performance standards need to be re-examined. We also point out that before new standards or approaches are adopted, alternative standards or approaches need to be examined and we'll discuss those in the next question.

Relative to Question 1, we have made a recommendation that FSIS should work in collaboration with CDC to measure the impact of the performance standards for raw meat and poultry on salmonellosis and other relevant enteric disease, and we make that recommendation because of the difficulty in trying to, if you would, indicate what the linkage is between those two activities and we described that above, and that is the end of our deliberations on Question 1, Mr. Chairman.

Again, be glad to address any questions anyone may have.

DR. BRACKETT: Okay. We'll take a few

questions on this, if we have any. Bill Sperber?

DR. SPERBER: Yes. This is Bill Sperber with Cargill.

One of your last points, Spencer, had to do with the fact that decreased incidence of *Salmonella* was not reflected in the decrease of 0157 in ground beef. Are those comparing the two separate programs or do you know if these data were collected from the same samples?

MR. GARRETT: It's my understanding, Bill, that they were not collected from the same samples. They are comparisons of different data sets.

DR. SPERBER: Yeah. So, it could in fact be true that a decreased incidence in *Salmonella* would have -- would also effect a decrease in other pathogens, like 0157, but we'd never know that unless we did all of those tests on the same samples.

MR. GARRETT: Yeah. As Peggy points out, -- boy, am I glad to see you. It's not led to a decrease in the disease. We're talking about a decrease in the illness rate, not the decrease in the number --

DR. SPERBER: Okay.

MR. GARRETT: -- of bugs on the carcass, in the product.

DR. SPERBER: Okay. That's my oversight.

MR. GARRETT: Mine, too.

DR. BRACKETT: Any other questions?

(No response)

DR. BRACKETT: Okay. Anything else?

MR. GARRETT: Moving on then to Question 2, Mr. Chairman, and that question asked, are the more effective alternatives to these, and we put in parenthesis (*Salmonella* Performance Standards), and if so, what would they be?

We pointed out, first of all, that regardless of any approach taken to controlling the level of pathogens in raw meat and poultry and obviously other things as well, there should either be an explicit or implicit microbiological criterion underlying the approach taken, and we did consider some alternative approaches, and these, I'll just kind of go through them quickly.

First of all was to use an indicator organism in lieu of *Salmonella* standards, and we have an extensive discussion of that relative to Question 2 in the earlier-referenced report that we've already finished. You could mandate a pathogen control at farm grow-out. Again, these are alternatives. It could be

mandated that antemortem pathogen control be instituted to prevent spread. You could mandate a performance criteria for reduction of pathogens at specific steps in the production of raw meat and poultry products. You could mandate specific proven interventions on raw meat and poultry products, such as thermal treatments, use of organic acids, irradiation and so forth.

You could mandate a continuous improvement requirement or criteria for plant performance within specific time periods, such as, for example, 10-percent reduction in frequency of pathogens on animals on an annual basis until whatever the specific criteria that was selected was met and maintained.

Now, while we've identified some of these outcome-related activities, there was general consensus that performance standards articulate the goals that are expected to lead to improved public health, and the use of the performance standards generally maximizes the flexibility in relation to finding new strategies for improvement. So, one of the points that we're essentially making is the performance standards (1) are technology forcing but (2) they also have the flexibility of letting the industry itself, if you would, determine how best to meet those performance

standards.

We do, however, have a number of recommendations relative to this second question. The first would be for the Government, certainly USDA, to sponsor an analysis to determine the steps in the food chain, say from the farm to the distribution step of raw meat and poultry products, where new technologies could cause major reductions in their frequency of enteric pathogens. In other words, take a big bite, if you would, to try to get reductions before you spend time dealing with diminishing returns.

Secondly, sponsoring agencies should provide stakeholders, and by that, we mean all stakeholders, a summary of the results from on-going food safety research pertinent to this subject.

Thirdly, request ARS and I can never say this, I have to apologize to my colleagues from USDA, -- how do you say that? Cooperative Research and Extension Program. I can never say it. Looks like a seafood to me. You know, in every Greek tragedy, there has to be a little comedy. But anyway, regardless, it's very important that we need to conduct more research at the farm and feedlot level to develop effective control measures and reduce the level of

enteric pathogens on live animals entering the plant. I think we'd all agree with that. Again, request these USDA agencies and industry as well to generate best manufacturing practices, BMPs, to control pathogens from the on-farm level again through distribution.

The last one on this particular page, Page 3, is to re-evaluate the existing policy regarding the degree to which carcass surfaces can be denatured by heat or other treatments with the understanding that increased denaturization on carcasses should translate into an increased kill of pathogens on the surface.

Moving on to Page 4, support research on the use of additives that could control the growth of enteric pathogens and where possible even increase their heat sensitivity in ground products. Evaluate the use of intermittent water treatments for efficacy of pathogen reductions on carcasses after hide removal. Further investigate decontamination procedures, such as electrostatic application of diacetates and so forth, and determine if existing treatments can be further enhanced, and finally as a recommendation, we would request the ARS and CSRES and industry to enhance technological transfer of effective approved treatments from the laboratory to commercial applications, and

while it may not be intuitive at first, what we mean by this is that there are treatments out there that appear to be effective or approved at the laboratory level, but nobody's actually taken them through a commercial application where they could be applied by industry and the request is to try to do this as opposed to expecting other people to do this, and there are a lot of people out there selling these things and so forth, but while they may be effective in a pilot scale level, their utility and effectiveness and efficacy at a commercial scale level have yet to be demonstrated.

Our next steps. What we intend to do is not work anymore on these two questions relative to microbiological -- these microbiological performance standards. Rather, what we would do is to continue our work on the other classes of products, ground chicken and so forth. Nevertheless, though, if the sponsoring agencies wish otherwise, then all we need to do is to be told. Okay. That indicates our answer to Question 2.

Again, any questions or I'd be glad to address any questions.

DR. BRACKETT: Bill?

DR. SPERBER: Bill Sperber from Cargill.

Page 3 of the second question at the bottom, is it the intent of the Subcommittee to introduce a new term, best manufacturing practices, and if so, wouldn't that be confusing with good manufacturing practices? I hear our practices are better than yours.

MR. GARRETT: No. That was certainly not the Committee. I think that's a typographical error, and I believe it's best management practices primarily at the farm level.

DR. SPERBER: Okay.

DR. BRACKETT: Any other questions on Question 2?

(No response)

DR. BRACKETT: With that, also to make sure that that correction is made in the final.

MR. GARRETT: Yes, thank you, Mr. Chairman. We have the correction.

DR. BRACKETT: Okay. Is there anything else, Spencer, that --

MR. GARRETT: Not this week.

DR. BRACKETT: Okay. Just so that we have it on the record, by my reckoning anyway, from Question 1, there is one recommendation, Question 2, there are nine

recommendations, and even though they were not bullets necessarily, I counted six in Question 3, and we just wanted to make sure that the Committee or the Subcommittee is comfortable with all the changes that you have because this will be part of the final document.

MR. GARRETT: Yes, Mr. Chairman, to point out that these are not changes. These are new additions to the final document, and it would be our intent to put these in the final document as I referenced earlier.

DR. BRACKETT: Okay. Do you want the Committee to have more time to think about -- make sure that you're all comfortable with that?

We have a question. Dane Bernard?

MR. BERNARD: Thank you, Chairman. Dane Bernard from Keystone Foods.

Just a small item and Spencer may help me with this, but during the Subcommittee's deliberations, we considered a title change for the main document. Since we do mention things other than ground beef, Spencer, I think we had talked about just changing this to reflect the title to be "For Ground Products With Particular Reference to Ground Beef", and I'd just like to get that on the table before we close discussion on

the document.

Thank you, Chair.

MR. GARRETT: That is correct, Mr. Chairman. That was -- and I'm sorry that I didn't pick that up, but that was -- we were going to amend the title with particular reference to ground beef.

DR. BRACKETT: Any other comments or questions about this discussion?

(No response)

DR. BRACKETT: Okay.

(Pause)

DR. LAMMERDING: Excuse me, Mr. Chairman? Hello? Right here, right across from you, Bob.

DR. BRACKETT: Oh, okay. Hiding. Okay. Anna?

DR. LAMMERDING: Perhaps before we adopt this report, I just want to make a suggestion that we might include the reference to the point of the -- where we state a decrease in disease associated with *E.coli* O157:H7, just to clarify that it is morbidity -- CDC statistic.

MR. GARRETT: Anna, I think it would be helpful for those in the audience and others to -- if you would give the page number and exactly where you

want to put that.

DR. LAMMERDING: At Page 2, the first big paragraph, and the third last sentence from the top third.

MR. GARRETT: And again, what would you like to do?

DR. LAMMERDING: To just insert a reference for the statement that it has not led to a decrease in disease associated with 0157:H7 in ground beef.

MR. GARRETT: Okay. Yes, and I think we should insert that as a footnote as we have the other references in the document, just footnote it and give the reference.

DR. BRACKETT: Okay. To make sure there is no other discussion, what we'll need to do now is have a motion to adopt the additions that Spencer has listed as well as the corrections that have been mentioned because these will be added to the previously-adopted document.

DR. SWANSON: So moved.

DR. BRACKETT: Katie and Cathy. Okay. The Committee is so efficient this afternoon, that we're running ahead of schedule, and so Merle is going to take over from this point on issues.

MR. GARRETT: Thank you, Mr. Chairman, and Merle, before you do, just let me express my and my staff's personal thanks to the Committee members. This was indeed a herculean task that we've taken on here. We've been at it over a year. There's been full and frank discussions on a wide array of subjects, I can assure you, if that's diplospeak, that's what it was, and we just want to thank everybody that participated and frankly the full Committee for adopting it.

Thank you.

DR. PIERSON: Thank you very much, Spencer, and on behalf of the Agencies, we certainly appreciate, you know, your dedicated efforts.

What we'd like to do is to now open the floor to public comment. Certainly it provides some additional time for public comment and, if there are some difficulties with those who want to make comment and in making comment early on, we certainly are willing to accommodate you later, too, but we could proceed with public comment, and those who have signed up could provide comment first. You know, we ask you to keep your comments -- well, please don't give us a two-hour speech because there are others that want to comment, too.

So, if we could have those public comments and possibly limit those to five-10 minutes, we'd appreciate it. I believe you can submit written documents for the record more extensive written documents for the record, and we'd certainly be willing to accept those. I then leave the floor open.

Who was first? Okay. Tony Corbo, are you ready to make comment?

MR. CORBO: Yeah. I actually have a series of questions that relate to the --

DR. PIERSON: If you could identify yourself?

MR. CORBO: Yeah. My name is Tony Corbo with Public Citizen.

DR. PIERSON: Okay. Thank you.

MR. CORBO: I have a series of questions related to the redefinition of pasteurization. The section in the Farm Bill that deals with the issue also sets up a procedure by which companies can submit petitions to FDA for the use of alternative language. Have any such petitions been filed yet?

DR. BRACKETT: The answer is we don't know yet on that. You mean, specific means by which they can do that?

MR. CORBO: Well, there's a procedure by which companies could submit -- that use alternative technologies to use pasteurization in product labeling, and I was wondering whether any such petitions have been received yet.

DR. BRACKETT: Well, no, that's one of the things, I think, that's going to come out of this, is that, a process by which a consistent way that is done will have to be set up.

MR. CORBO: So, in other words, there isn't going to be any petitions approved pending the work of this Committee?

DR. BRACKETT: Under that law, I don't know the answer to that, but one of the things that has been done in the past, for instance, with eggs is a company would actually submit processes under those that are already on the books, if they had to meet the, for instance,5-log reduction in the case of shell eggs or similar.

MR. CORBO: Hm-hmm.

DR. BRACKETT: But in the meantime, I'm not quite sure, to be honest to answer your question, what the procedure will be right now.

MR. CORBO: And if -- I know of at least one

firm that uses an alternative technology that is actually using the term "cold pasteurization" on its product labeling. Is that firm going to be required to change its labeling on packaging while you determine these standards?

DR. BRACKETT: One of the things we're trying to ask this Committee to do is really provide sort of the scientific parameters under which they're going to be done. Until that time, I don't know that there's going to be any changes.

MR. CORBO: Okay. And I know with the issue of irradiation and equating it with pasteurization, both the FDA and USDA have done consumer research on that particular issue. Is the Committee anticipating using any of that in its deliberations on standards?

DR. BRACKETT: Well, it'd be more the scientific parameters; that is, the actual microbiology and the public safety aspects of it rather than perception, although, you know, we'll be giving the Committee whatever documentation that they would require.

MR. CORBO: Thank you.

DR. PIERSON: Okay. Felicia Nestor? Are you ready to make comments, Felicia?

MS. NESTOR: I actually would like to defer for a few minutes, if anybody else is ready to speak. Okay.

DR. PIERSON: Okay. Do you want to go ahead and defer, Felicia, or --

MS. NESTOR: Well, I see that no -- is anybody else ready to step up to the mike? Because I'll step up again, if I want to, later then.

DR. PIERSON: Yes, okay. And if you would like, we could take a short break now to give, you know, some time to people to prepare. Pardon? Yeah. If you'd like to do that, let's -- why don't we take a, oh, 15-minute break and then it'll give people time, you know, to prepare and get ready for this and then -- and, you know, any others that want to sign up, they can do that. Is that all right with you, Felicia?

MS. NESTOR: That's great. Thank you.

DR. PIERSON: Okay. Thank you very much.

(Whereupon, a recess was taken.)

DR. PIERSON: Okay. Felicia, we'll try this again. Felicia Nestor?

MS. NESTOR: Yes. I'm going to ask a favor. Is there any way that I can sit down while I make this comment? Because otherwise I'm going to be throwing my

papers all over the place.

DR. PIERSON: Certainly.

MS. NESTOR: Can I like pull --

DR. PIERSON: Looks like Spencer just gave up a place.

MS. NESTOR: Right. But then, I'm going to have to hold it. Can I pull the chair up under the table or something?

DR. PIERSON: Sure, sure. Why don't you --

MS. NESTOR: Okay.

DR. PIERSON: You could come over here or whatever or go up to the podium. Okay.

MS. NESTOR: Okay. Sorry for all this delay.

I'm Felicia Nestor with Government Accountability Project. I'm Food Safety Project Director, and this meeting went really quickly and so I don't know that my thoughts are absolutely congealed yet.

I distributed to the Committee the report that GAP did with Public Citizen called "Hamburger Hell", and so I want to talk a little bit about that and then just about some general ideas. I guess my main message is that I think the role that we would like this Committee to play at this point is to

strongly advise USDA to improve their implementation of sampling and science. Our report goes into sampling irregularities that we saw that, you know, just don't make sense. They're inexcusable. The charts in the report show that a test that should take two and a half months in eight out of the 26 large plants took up to 26 months. We need science to be implemented more rigorously.

In addition to what's in the report, I also follow other sampling practices of the USDA in implementing HACCP and found some other problems. For instance, the company does *E.coli* sampling itself, and I see in the 1995 document, it seems to me that what is contemplated is that this sampling will be a legitimate measure of process control and that that will be reviewable by FSIS. But what actually happened is the regulation does not prevent the plants from sampling 300 out of 300 carcasses and just reporting the very best result. If this is what's happening -- we know that some companies are doing multiple tests and choosing which results to report. To whatever extent this is happening, the results that FSIS are reviewing are not valid.

Second problem. It took GAP a year of

communications with the Tech Center, the Tech Center's the advisory center for inspectors and plants on how to implement HACCP, to clear up what an inspector should do if he pulls a random sample and it's covered with feces. We called up, asked the expert, the person who would be instructing anyone that called up, what do you do if you pull a random sample and it's just covered with feces, and they said, well, we already know that's contaminated. So, you don't sample it. What you do is work with the plant, get the process back under control. Once the process is back under control, you pull a random sample and that's what you use as your *Salmonella* sample. That again interferes with the validity of random sampling.

I mentioned the ground beef test that should take two and a half months and it took almost two and a half years. The final two things that we mention in our report, and this has to do with Question Number 3, I'm really surprised to come here and see that the Committee recognizes that these sampling programs were not designed to provide statistically-valid estimates of national prevalence and levels of microorganisms. There's a real disconnect between what is being acknowledged by this Committee and what is being

bandied about in the public. We're talking about FSIS press releases and the way those are reported by, for instance, Reader's Digest.

The statistics that are coming out are being repeated that they do reflect a decrease in the national prevalence of *Salmonella*. What we saw was that there was bias going on in the way those sets were analyzed, and we don't know that the specific figures being -- that are in the press release are accurate, and it sounds like you all are very well aware of that. I think there's a real problem if you're talking about information and the public is getting a completely separate and different take on what's happening.

The other thing that sort of I found disturbing about the Committee's recommendations, I didn't get a very clear picture of what you think FSIS should do in the interim while this 12-month new baseline is being conducted. It sounds to me like FSIS could take home the message that it's just discard what we're doing and, you know, back to the drawing board. In this large packet, I see that the 7.5 prevalence for ground beef was first determined in '93-94. It's almost 2003, and we're talking about going back to the drawing board.

I mean, I am fully in support that we have to have good, accurate science. We need that for food safety because there's still too many people getting sick, still too many people dying, and we have a new concern. In order to deal with potential bioterrorist attacks, we're going to have to be using scientific testing, unless USDA gets up to speed and doesn't have the option of making excuses like, well, we just implemented this. It was only five years ago that we implemented this performance standard. We don't know how to do the science. You know, good enough for government work is not good enough anymore, and, you know, the wheels of government turn slowly. Things are -- the situation -- it's very important that USDA comes up to speed in how they use science and comes up to speed really quickly, and I don't know whose role it is to make that happen.

You know, Congress doesn't seem to want to interest itself with implementation. You all have the authority. You have the expertise. I think no matter what you recommend, you should emphasize that USDA has got to ratchet up the integrity of its scientific sampling programs very quickly. There's no point in making recommendations and standing by and watching

them implement shoddy programs.

I'm sorry that it's not more of a cohesive statement, but I think I made my main points.

Thank you.

DR. PIERSON: Thank you, Felicia.

I'd like to recognize that we have some of the members of the National Academy of Sciences group that is conducting a study also on performance standards who are here visiting us. Unfortunately, we've already gone through our discussions on that part, Dr. Hackney. Dr. Hackney is chair of that Committee. Pardon? Okay. But we'd be most happy to provide you with the documents that were discussed and, you know, that the Committee that -- the Subcommittee that was led by Spencer, we certainly would provide those to you. Pardon? Okay. We will provide those to you right now. You could even have an opportunity to join in in the public comment period. However, Dr. Hackney, you would come lower in the list here. You'd have to sign up in order. Okay? Okay.

Next on the agenda here or the order for public comments is Nancy Donley. Nancy?

MS. DONLEY: Thanks very much.

I'm Nancy Donley with STOP, Safe Tables Our

Priority. For those of you who may not be familiar with our organization, we are a national foodborne illness victims organization. Our membership is comprised primarily of families who have had personal experience with food poisoning, including deaths. My own case, I got involved in the issue in the death of my six-year-old son, Alex, from eating *E.coli* 0157:H7-contaminated meat.

I'd like to say that we are an activist organization. I really prefer to call us an actionist organization. We want to sit -- we do sit at the table with you all. We, I think, all want -- I want to make it clear, I think we all share a common goal and the common goal is protecting the public health and safety first and foremost and doing whatever it takes to do it to get those 5,000 deaths a year down from foodborne illness and 76 million illnesses yearly.

So, that said, just a couple quick comments that I'd like to make and a couple are very specific. On this Responses to Questions Posed by Dr. Murano and Dr. Wachsmuth, I'd just like to say I listened with interest, particularly STOP has recognized that there has been a problem for a long time with an oversight at the on-farm portion of our whole food supply and that

that is really where the organisms of concern originate and it's very generally in the intestinal tracts of these animals.

We like the suggestion that said that recommendations to request ARS, CREES, and industry to conduct more research on the farm feedlot level, to develop effective control measures and reduce the level of enteric pathogens on live animals entering the plant. I'd just like to say you may want to consider inserting the words "on and in" animals because we have had members in our organizations who have become sickened from 0157, for instance, because of these very same pathogens not from ground beef but from contaminated lettuce, contaminated juices, swimming in public places where there has been runoff from cattle and in rivers and such like that. So, I'd like to make that as a recommendation.

And then, Number 2 is, I'm watching with great interest on this -- what you're considering as variations that may be due to regional, seasonal and other factors when developing performance standards. I want to make it very, very clear. We consider it absolutely crucial that the highest performance standards be done. We don't give a hoot what time of

year it is, if the animals are dirtier, if there is a problem where you're going to see spikes in incidence of pathogens, that is not the consumer's concern. So, whereas I do understand that we are going to see times when there are these spikes that do occur, that has nothing to do with public health and safety and that's got to come out of the discussion.

So, I just want to, you know, kind of emphasize that point, and once again, I am also on the National Advisory Committee for Meat and Poultry Inspection. I thank you for all the hard work that you're doing. Frankly, I'd like to see a lot of the science get off the ground faster. Also want to reiterate that we are -- we have to, all of us, consider this, industry, government, consumers, that this is an on-going process. We are not ever going to arrive at the point where everyone in this room agrees that we can -- we've got the definitive way of doing something and that we've got the definitive tests that we should be doing. It's an evolving process, and we must recognize that to really protect public health and safety, we need to start doing things now. We need to work with the best science that we have now and keep ratcheting it up and making it better.

So, thank you very much.

DR. PIERSON: Thank you, Nancy.

Next is Barb Kowalcyk.

MS. KOWALCYK: Hi. My name is Barbara Kowalcyk, and I'm from Mount Horeb, Wisconsin. I'm also with STOP.

I thank you for the opportunity to allow me to give a voice to my son Kevin and put a face on all the victims of foodborne illness. Food safety is an issue that touches all Americans and most especially our children which is why your job here today is so important. I would like to tell you about one child, my child, and the impact foodborne illness has had on our family and our community.

On Tuesday, July 31st, 2001, our two-year-old son Kevin awoke with diarrhea and a mild fever. On the evening of August 1st, we took him to the emergency room for bloody diarrhea but were sent home. By the next morning, Kevin was much sicker and was hospitalized for dehydration and bloody stools. Later that afternoon, we were given the diagnosis, *E.coli* O157:H7. On August 3rd, Kevin's kidneys started failing. He had developed the dreaded hemolytic uremic syndrome or HUS. Late that night, he was transferred

to the pediatric ICU at the University of Wisconsin's Childrens Hospital. My husband Mike and I spent the next eight days living in that hospital watching our beautiful son slip away from us.

On that first Saturday in the ICU, Kevin received his first dialysis, a three-hour procedure during which he needed to keep still. That's a tall order for any toddler. So, my husband, the nurse and two of our friends held his arms and legs while they talked and sang songs to reassure him for the entire treatment. Kevin spent the rest of that day and the following two crawling around a crib in agony. He threw up black bile. He became drawn and his eyes were sunken. He looked like a malnourished Third World child, and he smelled a horrible and overwhelming smell, a smell you could never forget. During those long three days, Kevin begged us to give him water or juice, but the doctor said it would only make him worse. He repeatedly asked to swim in his turtle, a pool we used at home. Kevin finally convinced us to give him a sponge bath and as soon as the washcloth came near his mouth, he grabbed it, bit down on it and sucked the water right out of it. It broke our hearts.

On Tuesday, August 7th, Kevin was placed on a

ventilator and continuous dialysis. In hopes of preventing Kevin from remembering this ordeal, the doctors heavily sedated him. As the medication would wear off, Kevin would try to pull the tubes out, so braces were put on his arms. His body began to swell. Doctors inserted tubes to drain fluid off both of his lungs. By the end of the week, he was receiving more medications than we could count to stabilize his blood pressure and heart rate. He had received eight units of blood. Special bed was ordered from Minnesota to help alleviate some of his pain, but throughout it all, the hospital staff remained optimistic. They said that this was typically the way HUS *E.coli* kids got through the illness. But for Kevin, all of this was not enough, and finally, on August 11th, at 8:20 p.m., after being resuscitated twice and his doctors attempted to place him on a heart-lung machine, our beloved Kevin died. He was two years, eight months and one day old. The autopsy later showed that both Kevin's large and small intestines had died, a condition that's a hundred percent fatal.

The week after Kevin died is mostly a blur for us but we do remember some things. We remember telling our five-year-old daughter Megan that her best

friend, her brother, would not be coming home with us. We will never forget the look on her face. We remember meeting with the funeral home director to pick out a casket. We remember going through Kevin's closet looking for his white ring bearer suit so we could bury him in it. We remember walking through the cemetery looking for where we should bury our Kevin, and we remember the day we buried him.

On August 16th, 2001, we didn't just bury our son, we also buried part of ourselves. We will never be the same people we were before. No parent should have to watch their child die the type of death that Kevin suffered. No parent -- our daughter will never be the same again. No one should have to grow up at the age of five. Our community will never be the same again. No preschooler should have to ask to go to a cemetery to visit their friend. But it did happen to our family and our community.

Since Kevin's death, we have been researching foodborne illnesses and what we have learned has appalled us. We did not know that 46 percent of reported *E.coli* O157:H7 cases occur in children under the age of 10. We did not know that it takes less than 10 microbes to make you sick. We did not know that

children under the age of five are at highest risk of developing the deadly HUS from *E.coli* O157:H7. We did not know that once you get HUS, the only thing doctors can do is keep your body alive while the disease runs its course. We did not know that survivors of HUS suffer lifelong medical problems. We did not know that meat recalls are voluntary. We did not know that the USDA rarely shuts down plants that produce contaminated meat. We did not know our meat is not safe. We did not know the risks we were taking by feeding our child a hamburger.

We should have known. Foodborne illness is a children's issue, and it's largely preventable. The CDC estimates that each year, 325,000 Americans are hospitalized due to foodborne illnesses and 5,000 Americans die. As a parent and biostatistician, I was outraged when I recently read a 1990 article from the New England Journal of Medicine, written eight years before Kevin was born, that stated that the incidence of HUS from *E.coli* O157:H7 was 60 percent higher than the incidence of Reye's Syndrome for children under five years of age during the period between 1980 and 1984. This was before they knew the role aspirin played in Reye's Syndrome. Kevin never had aspirin.

Why didn't we know the risks we were taking by feeding him foods that are linked to serious foodborne illnesses? There are groups that would like you to believe that it is our fault that our son contracted *E.coli* O157:H7, that if only we had practiced safe food handling techniques, this wouldn't have happened, but we did practice safe food handling techniques. We were always very careful about cooking our meat. We never ate undercooked meat, always used separate plates and utensils for preparing and serving meat, always cleaned the sink and faucet immediately after cleaning meat and always required our children to wash their hands before eating. We had done what we were supposed to do, but it wasn't enough. We needed the government and the meat industry to do their part; that is, prevent *E.coli* from getting into our food in the first place.

The government and meat industry can do more to protect us. Many argue that demanding stronger food safety policies will be cost prohibitive. To them, I would say this. What cost do you put on a life? In May 2001, the USDA's Economic Research Service estimated that *Campylobacter*, *Salmonella*, *E.coli*, *Listeria* and *Toxoplasma* cost $6.9 billion in medical

costs, lost productivity, and premature deaths each year in the United States. That's a pretty steep figure, but it does not reflect any of the hidden financial costs that victims and their families suffer.

My husband and I were lucky because we both -- we have good medical insurance and we had a life insurance policy on our children. Even so, Kevin's life insurance did not cover the entire cost of his funeral and despite our good medical insurance, neither myself, my husband or my daughter were entitled to grief counseling, which we all desperately needed. It is now a year since Kevin died, and we are still spending $450 per month on grief counseling, and what about the other costs, the losses you can't put a price on? Megan, now six, has lost that feeling of security. She is terrified of being all alone. My two-month old daughter Laura will grow up without her big brother. My husband and I can look forward to growing up with our grief, reliving what should have been every time a milestone is hit. When Kevin should have ridden his first two-wheeler, played his first baseball game, learned to drive a car, graduated from college, gotten married, had children, and society suffers, too. They lost Kevin's contributions, what he could have

accomplished.

The price is too high. No child should be sacrificed just so that Americans can have cheaper meat. Losing a child is a terrible experience, but to lose a child to a preventable situation is an outrage. This is the 21st Century. We have the knowledge and technology to improve food safety. We just need to make it a priority. Young children are at highest risk for foodborne disease. They depend on us adults to make good decisions about their food and they also depend on us to make good decisions about how the government works.

It is imperative that we demand better food safety policies in this country. Despite what some people would have you believe, food safety is not the responsibility of the consumer. While it is impossible for government to regulate safety, it is not impossible for the government to set safety standards. *E.coli* O157:H7 is a pathogen that is harbored in the intestines of animals, in particular cows. If there is *E.coli* in the meat, that means that there is cow manure in the meat and consumers didn't put it there. I don't care how thoroughly you cook it, I don't want to eat it and I certainly don't want my children to eat it.

Americans want safe food.

Because of what happened to Kevin, our family began a grassroots petition asking for safer meat. So far, we have over 4,000 signatures. Obviously Americans want stronger regulations governing the way food is slaughtered, processed and inspected. As a society that values its children, we need to be more responsible for food safety at all levels. You have the opportunity to recommend objective testing and performance standards for pathogens to evaluate the safety of our food. You have the opportunity to put public health first. You have the opportunity to put our children first.

One night shortly before he became ill, I was putting Kevin to bed, and we were talking about how Megan would be going to kindergarten soon. As I kissed him good night, Kevin said proudly, "When I grow up, Mommy, I'm going to kindergarten, too." Kevin should have had that chance.

Thank you.

DR. PIERSON: Thank you, Barb.

Caroline Smith DeWaal is next.

MS. DEWAAL: Thank you.

Caroline Smith DeWaal, Director of Food

Safety for the Center for Science in the Public Interest.

I want to thank Barb Kowalcyk and Laura and Kevin's grandmother, Patricia Buck, who all came in to attend the meeting both yesterday and today. They've taken a big commitment out of their life to try to make an improvement for children, and I know every member in this room has made a big time commitment and a big commitment to be here and to put their best thinking.

I think the take-home message among many is that the decisions made in this room and, more importantly, the decisions made by USDA impact real people. They impact people all over the country, and there is, if anything, I want to help instill a sense of urgency. Good scientists never know enough. They never know everything. They always have more questions, and this Committee and the Committee at the National Academy of Sciences are filled with good scientists.

The question is not do we know enough or do we know everything, but do we know enough to take action, and I think USDA does know enough to take action now to reduce the risk of *E.coli* O157:H7 by implementing more monitoring and testing programs, both

at the carcass level and the trim level. We think they know enough to reduce the risks of *Campylobacter* by requiring monitoring programs and government verification programs in poultry plants for *Campylobacter*. We think they know enough to reduce the risks of *Listeria monocytogenes* in ready-to-eat meat products, again by requiring government and industry monitoring programs and government verification programs.

We don't know everything, but we know enough to reduce the risks, and consumers shouldn't have to wait, and we can't afford to wait and to lose more children like Kevin. USDA should start taking action now to reduce the levels of pathogens in the meat supply. This Committee and the Subcommittee should be commended. They have done a huge amount of work and they have come out with a very impressive report on performance standards and the utility of performance standards for ground beef products, and you know, I can go back and quote from their very report, but I don't need to. They've done their work, but now it's up to USDA to take that and move forward and move forward quickly because consumers can't afford to wait.

Thank you.

DR. PIERSON: Thank you for your comments, Caroline.

Are there any other public comments? Anyone else have anything that they would like to say?

(No response)

DR. PIERSON: Okay. It is clear that we have here, as I sit here and I see all of you and all your backgrounds and professional expertise, that we certainly have the top people in the United States involved here in addressing these food safety issues. We've had an opportunity to hear personal experiences, tragic experiences, related to foodborne illness, and it drives home the immense impact that what we have to do our job in addressing these issues.

I appreciate the work that this Committee is doing in addressing food safety issues and the progress that is being made and the very sound recommendations that are coming forth. So, with that, unless there's any other comments -- Dave?

DR. THENO: Thank you, Mr. Chairman. Dave Theno from Jack-In-The-Box.

I recognize that sometimes people just do their job, they do it exceptionally well, and on behalf of myself and my colleagues on the Committee, we want

to thank Brenda for all she's done for us and wish her well in her new position.

DR. PIERSON: Bob?

DR. BUCHANAN: I'm just reminding that the Subcommittee on Date Labeling is not done. We have another day of meetings. The latest version of the draft document is available for the Subcommittee members, for Committee members, and there should be some copies left over for other people that are interested. I do remind you it is a draft document in its early stages. But Subcommittee members, if you could stop by here, you can pick up a copy, and we'll start tomorrow morning at 9:00 across the hallway, again focusing on working through the sections.

DR. PIERSON: Okay. Again, I thank you very much for your time, efforts, and participation in this meeting.

We therefore stand adjourned.

(Whereupon, at 3:19 p.m., the meeting was adjourned.)