UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE: National Advisory Committee on Microbiological Criteria for Foods

Meeting held on the 22nd day of August, 2003

at 8:30 a.m.
Hotel Monaco
700 F Street, N.W.
Washington, DC 20004

TRANSCRIPT OF PROCEEDINGS

8-22-03 NACMCF Meeting Participants

Chair:	Dr. Merle Pierson
Vice-Chair:	Dr. Robert Brackett
NACMCF Members:	Dr. David Acheson
	Dr. Peggy Cook
	Dr. Catherine Donnelly
	Dr. Stephanie Doores
	Dr. Dan Engeljohn
	Mr. Spencer Garrett
	Dr. Robin King
	Dr. Mahipal Kunduru
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	Dr. Anna Lammerding
	Dr. John Luchansky
	Dr. Carol Maddox
	Dr. Roberta Morales
	Dr. Eli Perencevich
	Ms. Angela Ruple
	Ms. Jenny Scott
	Dr. Skip Seward
	Dr. John Sofos
	Dr. Katie Swanson
	Dr. Don Zink
NACMCF Executive Committee:	Dr. Art Liang, CDC
	Maj. Erik Torring, VSA
	Dr. LeeAnne Jackson, FDA
	Dr. Carol Maczka, FSIS
FSIS Staff:	Ms. Gerri Ransom
	Ms. Karen Thomas
	Dr. Walt Hill
	Dr. Karen Hulebak
FDA Staff:	Mr. Don Kautter
NMFS Staff:	Ms. Emille Cole
	Ms. Barbara Comstock
	Dr. Al Rainosek
Outside Participant:	Mr. Sam Ankrah, VA Tech

P R O C E E D I N G S

August 22, 2003, 8:40AM

DR. PIERSON: We can go ahead and get started with the Closing Plenary Session of the 2002-2004 National Advisory Committee Meeting of Microbiological Criteria for Foods. I'm Merle Pierson. Again, I'm Chair of the National Advisory Committee on Microbiological Criteria for Foods and of course, as you know, this is Dr. Bob Brackett, who is Director of Food Safety and Security for FDA, CFSAN. He is the Vice-chair for this Committee. You've had a very productive week and again, I appreciate all the time that you've taken to deliberate during this week on the issues that were before you and I look forward to hearing the reports of the Subcommittee chairs. I know we did this earlier in the week, but let's go ahead again and go around the table and introduce ourselves. I guess we can go to the right this time.

DR. BRACKETT: As Merle said, I'm Bob Brackett, FDA.

DR. JACKSON: LeeAnne Jackson, FDA, Liaison to the Executive Committee.

DR. LIANG: Arthur Liang, CDC Food Safety

Office.

DR. TORRING: Erick Torring, DOD representative to the Executive Committee.

DR. KVENBERG: I'm John Kvenberg, Food and Drug Administration.

DR. LAMMERDING: Good morning. Anne Lammerding, Health Canada.

DR. KUNDURU: Mahipal Kunduru, Dole Fresh Vegetables.

DR. SOFOS: John Sofos, Colorado State University.

MR. GARRETT: Spencer Garret, The National Marine Fisheries Service.

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

DR. MADDOX: Carol Maddox, University of Illinois.

DR. ACHESON: David Acheson, FDA.

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

DR. MORALES: Roberta Morales, RTI International.

DR. PERENCEVICH: Eli Perencevich, University of Maryland, Baltimore.

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

DR. DOORES: Stephanie Doores, Penn State University.

DR. ZINK: Don Zink, FDA.

MS. RUPLE: Angela Ruple, NOAA Fisheries.

DR. ENGELJOHN: Dan Engeljohn, FSIS.

DR. SWANSON: Katie Swanson, General Mills.

DR. COOK: Peggy Cook, Tyson Foods.

DR. DONNELLY: Cathy Donnelly, University of Vermont.

MS. SCOTT: Jenny Scott, The National Food Processors Association.

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

DR. HILL: Walt Hill, FSIS.

MS. THOMAS: Karen Thomas, Advisory Committee Specialist, FSIS.

MS. RANSOM: Gerri Ransom, NACMCF Executive Secretariat, FSIS.

DR. PIERSON: Thank you. I'll turn the microphone now over to Gerri and she has some details here to take care of to keep us all glued together.

MS. RANSOM: Okay. Good morning and welcome

to your last day of our meetings. I wanted to mention for our guests that anyone wishing to make public comment, please sign up with us outside at the table. Guests will be given up to 10 minutes for comment, so make sure you sign up, if you're interested. I also wanted to point out that outside in the hallway we do have a table set up containing documents related to NACMCF work, so any of our guests who are interested in picking these up, feel free. Again, I would like to mention that this table is reserved only for documents approved by the Executive Committee. We do have a separate table set up for documents that guests can use for distributing documents -- again, please feel free to use that. Also, please don't put any documents on the table up here, okay? And I want to give you one last reminder, Karen Thomas has given you calendars and under one of the last tabs in your notebook. Please leave with us your availability, enabling us to schedule Subcommittee meetings, or if you wish, you can fax it at a later time. Okay, thank you and we'll turn the floor back over to Dr. Pierson.

DR. PIERSON: Okay. Thanks, Gerri. This week the Performance Standard Subcommittee as chaired by Spencer Garrett was tasked with an additional charge and

this was to review the FSIS proposed microbiological baseline studies for raw ground beef components. As this Subcommittee has recently begun new work on performance standards for broiler and ground chicken, we're especially appreciative of their flexibility and effort -- extra efforts they've taken in addressing this additional charge, so I look forward to hearing from Spencer and the progress that has been made. Also, this week was the Subcommittee on Criteria for Shelf-life Based on Safety, chaired by Don Zink and the Subcommittee on Scientific Criteria for Redefining Pasteurization as chaired by John Kvenberg and of course, we're looking forward to the reports from the Subcommittees. And to begin with, I'll turn the floor then over to Spencer Garrett, who will report on the work of his Committee -- Subcommittee.

MR. GARRETT: Thank you, Mr. Chairman. We have before us a report from our Subcommittee that's out of NACMCF response to USDA/FSIS request for guidance on baseline study design and evaluations for raw ground beef components, dated August 21, 2003. Our Subcommittee worked diligently on this document. Unfortunately, the full Committee members only received the document this morning and so I'm not certain if

you've had time to read the document. It's only eight pages of which three -- two and half to three are the background and the title page, so we can either take 15 minutes out and everybody read it, or I'd be guided by the will of the Committee. Do you want to go through it now, or do you want to read it? Seeing that there's no objection to going ahead, I think I'll just go through the document.

MS. RANSOM: I think we did get a request over here for allowing us to read the document.

DR. PIERSON: Who did it? No, that's perfectly fine. Why don't we take 15 minutes then and read it? Fun. You can't even know when you're done. Excuse me, when you're finished. You'll never be done.

MR. GARRETT: Fifteen minutes...

DR. PIERSON: ...a notation, so we'll take just a couple of more minutes to...

MR. GARRETT: Mr. Chairman, I think we probably can proceed and the way that I would like to proceed to facilitate us through this -- let me remind us all that in our charge, and when I get to that, you'll -- that the Committee was requested, actually, to give the recommendations back this week, so as we go through this, it's with a view toward adopting the

document when we finish our discussions in any deliberations and modifications. The first page, or actually page two, is the background statement and was indicated by Loren Lange in the opening of our session. FSIS, in keeping with our pathogen reduction rule -- and also, in response to recommendations-- made by this Committee relative to earlier. They've indicated we will receive funding to do more baseline studies and we plan to perform microbiological baseline studies and are asking us for our advice on the design of those studies. They've indicated that the first phase of their baseline studies will be to determine the microbial profile for raw ground beef components. They've indicated that when they looked at what makes up the raw ground beef components, they selectively grouped those into five categories for baseline studies. They've indicated the baseline studies would be staggered over time and at the middle of the page there, they presented us, as a Committee, with what USDA/FSIS perceived as the highest priority relative to public health risk. And that list was, first of all, weasand, head and cheek meat. Secondly, advanced meat recovery (AMR) products. The second, low temperature rendered product (LTRP), partially defatted chopped beef. Domestic trim and

subprimals destined for ground beef. And then imported beef. They indicated that they intend to identify the contribution of these components to the prevalence of pathogens such as *Salmonella* and *E. coli* O157:H7, and to measure indicators of process control. And as they begin their experimental design for these baseline studies, they indicate to us that they're also doing some preliminary surveys to help them, in fact, zero-in on what they should be doing. They indicated the first survey will identify and quantify producers for each of the components, and then the second survey will identify how much each component is typically used in ground beef production, pointing out that the goal of the survey is to provide a picture of the diversity and prevalence of the various components used in ground beef. They've indicated that the objective of their baseline survey program is to collect data that will be used to develop general microbiological profiles for all types of ground -- RGBCs for select microorganisms, that --representing various degrees of public health significance. They indicate that the information will be used for risk assessment activities for developing regulatory strategies to reduce the prevalence of enteric pathogens in raw ground beef and it will also provide data on

potential indicator organisms to provide a basis for guidelines to verify process control. Did you see the projected outcomes there I mentioned? They will inform the Agency's risk assessment and other scientific analysis, thereby supporting the Agency's science-based risk management programs including possible performance standards development -- for performance standards, rather, and other regulatory options. Our databases will be merged to support performance standards development and evaluation criteria allowing determinations on relationships among microorganisms and assisting in identifying industry practices which are effective in pathogen reductions. The effect of certain variables, geographical location, seasonality, plant size, production volume on the prevalence levels of particular bacteriological pathogens will be taken into account, which then brings us to our specific charge. And our charge -- and I realize we read this, but I'm going through it again very deliberately. And not only for ourselves as a Committee, but for the general public. An FSIS goal is to strive to determine the optimum study design configuration for each project satisfying the needs of both risk assessors and policy developers. It is part of this process for NACMCF to

provide feedback on certain aspects of the proposed baseline study designs. Plans for RGBC testing are now being submitted at this time and we, being FSIS, would like this feedback by way of review and comments. FSIS's request that NACMCF specifically comment on the approach and concepts of the proposed RGBC baselines, relative to the four points below. NACMCF has been asked to complete this review and comment task at the meetings scheduled for the week August 18, 2003. By the close of the meetings, August 22, FSIS requests that NACMCF provide completed draft comments on the points below and a revision to the draft comments is requested by September 12. Specifically, we are asked to provide feedback on 1:protocols for collecting samples of RGBCs; 2:priority selection and grouping of RGBCs into five distinct baseline categories chosen by the proposed rankings and groupings based on perceived associated public health risks appropriate and; 3:sampling plan design, and they point out that although the sampling plan design for the studies is incomplete and the results of the two surveys that I mentioned, "What are the most important elements to consider?". And finally: selected test organisms for RGBC baselines. And you'll note that this report that we have before us references

the Committee, because if we're talking about although this is a Subcommittee report, but if we do adopt this report then it would become the Committee report. And so we recognize in our deliberations the dual nature of the FSIS charge, which seeks advice on developing baseline studies which would provide information for use in the development of regulatory strategies, as well as for use in risk assessments. As a means for addressing both needs, the Agency representatives and the Committee agreed to modify the charge in the order of the questions submitted to us to make a more logical presentation for discussion and resolutions, therefore we ordered the questions in the following order. And all we did is just merely flipped one and two. And that seems to be very -- we seem to be very consistent, because we've done that the last two times, as well. So I'm not going to read those charges again. And so the following narrative represents our deliberations, comments and general recommendations and what we've done is we've made some general recommendations overarching recommendations, if you would. And then for each question in which we're asked, we make very specific recommendations. So with the indulgence of the Committee, what I would like to do is stop here and ask

if there are any questions on the background? It would be my intent to proceed then first, with the general recommendations followed by each question and what our specific recommendations are. Yes? John Kvenberg.

DR. KVENBERG: If I could, Spencer, draw your attention to general recommendation E on...

MR. GARRETT: We haven't gotten there yet.

DR. KVENBERG: Oh, I'm sorry. You're not -- you said background. I apologize. I'll hold the question until you're there.

MR. GARRETT: We're now at general recommendations.

DR. KVENBERG: Got you. There will be paybacks.

MR. GARRETT: I'm sure.

DR. KVENBERG: Let me draw your attention to general recommendation E on page five. From the onset, I applaud the overall effort and -- but only offer it may be beneficial in that recommendation to include the Food and Drug Administration's involvement with the States through the Food Code and its Executive Committee. We totally endorse the idea of doing exposure components of risk assessments. I think it would be a very positive aspect in assisting FSIS and

certainly would be useful to make that conference aware of that activity. Thank you.

MR. GARRETT: If, in fact, I could offer one comment. I certainly agree with that and we will go back, folks, to the other general recommendations. But could you just merely say likewise, FSIS and FDA should assess the importance. How do you go about doing that?

DR. KVENBERG: Well, specifically, my thought was that basically we -- and FSIS does play a role in the Conference for Food Protection and development of the Food Code. It's a vehicle for the Conference of Food Protection to work with the many States and local jurisdictions so there may well be benefit in number one, informing them that including baseline studies work at retail, what's going on and offer any assistance that could be put to FSIS's exposure component of the risk assessment. So I think the words I would like to have in there is not just FDA, but the Conference of Food Protection.

MR. GARRETT: How about if we put -- how about if we -- would you like FSIS and FDA in the first sentence? Then I'm going to suggest a follow-on sentence. The follow-on would say furthermore, FSIS and FDA should inform the Conference on Food Protection of

these -- of this proposal.

DR. KVENBERG: That was my intent.

MR. GARRETT: Yeah.

DR. KVENBERG: I don't know if others have any comments on it, but thank you.

MR. GARRETT: Yeah. And recommend making their members aware of these activities and offer advice and counsel. Anna? Anna?

DR. LAMMERDING: I think I'd like to see a little bit more positive language that may have to do with -- engaging. The -- for protection. Conference members...

MR. GARRETT: You want to change informing to engaging?

DR. LAMMERDING: Yes. Yes. Thank you.

MR. GARRETT: Jenny?

MS. SCOTT: Spencer, would you read that back, because I'm not sure it reads quite right if you just change the word inform to engage, because you're not going to engage the CFP of this proposal.

MR. GARRETT: In this proposal -- on this -- engage in this proposal.

MS. SCOTT: Or perhaps engage them in the proposed work.

DR. KVENBERG: MR. GARRETT, I just want to reiterate. My initial request was, basically, it went to informing them as to opposed actual -- whether or not they're engaged, I think would be a matter for assessment by FSIS and in consultation -- and I hope they will do that with the Food and Drug Administration and the Conference. My intent of the initial one was to make them aware and see what could be offered for assistance. I understand that the design of this exposure assessment and the risk assessment has to be coordinated through -- FSIS is a part of the larger picture. So that was the intent of -- my initial thing was to inform.

MR. GARRETT: The thought comes to mind, as I put my cheaters on here, that -- it's true. I don't wear contact lenses. But I think it's also -- it would be the -- rather than saying engaging, I think the Conference itself may want to play a role in that because I think probably informing would be better, but I don't feel strongly one way or the other.

DR. LAMMERDING: How about collaborate with?

MR. GARRETT: Okay. Let me try to read it, then.

MS. SCOTT: We like that.

DR. ENGELJOHN: As long as you're happy.

DR. PIERSON: If I could make an intervention as the Chair, just a procedural thing, if the Committee members would identify themselves before they make a comment?

MR. GARRETT: Further FSIS and FDA should seek collaboration from the Conference of Food Protection relative to the proposed activities -- these proposed activities. Now, if we could, I'd like to go back to the page four. We have three general recommendations there. Are there any comments on those general recommendations? Seeing none. Returning to page five, we now come to question one, which is priority selection and grouping of RGBCs into five distinct baseline categories chosen. Are the proposed rankings and groupings based on perceived associated public risk appropriate? We make six specific recommendations. The first is that the Committee found that categories defined by FSIS do adequately reflect possible raw ground beef components with the addition that the imported category should include fresh components. The Committee reordered the priority ranking of the categories provided by the USDA/FSIS based on volume, the perceived contribution to the risk of illness,

expert opinion on the use of the components of ground beef, and processing variables such as chilling rates during production. Plus the category of domestic trim and subprimals are identified by this Committee as representing the highest perceived risk as described above -- below. Secondly, the Committee recognized that setting priority based on volume and perceived risk and other variables was -- compromised to some extent by the lack of data. The Committee, therefore, recommends that FSIS consider the use of pilot surveys to assist and prioritize in categories other than this Committee's leading category of domestic trim and subprimals. It is recommended that the USDA prioritize the rank order for engaging in baseline studies as follows: domestic trim, AMR, LTRP, imported frozen and fresh beef, cheek and head meat. We point out that the domestic trim and subprimals are considered by this Committee as the number one priority, since those components comprise the largest volume of raw materials used in ground beef and are known to contain *E. coli* O157:H7. AMR may be an ingredient included at levels nearly 10 percent in approximately half the ground beef being sold at retail. So the more AMR a manufacturer -- is manufactured under various processing conditions that could lead to

differences in microbiological contamination and growth. Jenny, I'm sorry. Go ahead.

MS. SCOTT: Before you go on. The next statement you're about to read actually looks like it applies to AMR when it really applies to LTRP.

MR. GARRETT: Yeah, I have -- fix that there. Moving on, on page -- on top of page six, and these three, as Jenny points out -- now that was Jenny Scott from the National Food Processors Association --it says this Committee recognizes that some of this production -- we'd like to get rid of the two words of this and insert in lieu thereof -- the LTRP. So it would read the Committee recognizes that some -- it should be of the LTRP production -- and this goes on -- occurs at dedicated facilities and recommends that these facilities be included in any baseline studies along with sampling that is critical. That a record should be made of any antimicrobial interventions. And the way that I would like to go through this is each recommendation at a time and I kind of operate by Jeffersonian rules of order like legislatures do and so -- without exception, so you know, slow me down. Don't let me -- of course, some people think I'm too slow anyway. But I am deliberate. The next recommendation:

imported fresh and frozen beef is used in domestic ground beef production. The Committee recommends that the country of origin for the raw material must be included and whenever possible, information be made available to USDA on a government-to-government basis -- excuse me -- and whenever possible, the interventions used during the production of the raw material. Such intervention information may be available to USDA on a government-to-government basis from the -- that should be from the exporting country. Sampling frequency should be related to import volume, specifically; fresh product needs to be included in the design of the imported product case study. The Committee recognizes that cheek and head meat are generally not used in large quantities for ground beef production, especially by large establishments, therefore, we encourage FSIS to gain a better understanding of the production and disposition of these products. It may be that a single component of this category, such as head meat, would be a good indicator for the overall category. This would be an excellent category for which a pilot study should be undertaken before embarking on a baseline study. And then finally, for question one, the Committee recommends that consideration be given to linking -- to the linking

of samples, i.e. trim and subprimals and head and cheek meat and weasand meat from the same lot of animals. The Committee recognizes that this may be premature. It could provide useful information in future baseline studies. Moving on to question two -- and I'm assuming that we're agreeing with the wording -- protocols for collecting samples for RGBC. We made four specific recommendations. For domestic trim and subprimals, FSIS should proportionately allocate by production volume the total number of samples to three classes of trim, e.g. low fat, greater than 90 percent lean, medium fat, less than 90 percent and greater than 50 percent and high fat, 50-50. Proportionality relative to the production volume should be used to determine the numbers of samples to be taken from each selected establishment, monthly over a 12-month period and from each region, and some minimum number of samples to be determined by FSIS required from each region -- excuse me -- for each -- from each month/region. Inspectors should specify estimated lean content of combo bins when not identified by the plant based on FSIS examples to be developed regarding subprimal cuts, knuckles, claws, chucks, grounds and skirts. Further, the Committee recommends that FSIS consider age of the animal as an additional

stratifying factor for sample collection. Anna?

DR. LAMMERDING: Maybe your -- I mean, do you think we should include in this sentence age of animal less than 30 months, over 30 months as a clarifying statement?

MR. GARRETT: I brought that up in the Subcommittee meeting -- frankly, I think you probably should. If there is, in fact, a -- I mean, 30 is the magic number. It's kind of like 3.6 *E. coli*, you know, is a magic number. Detectable limit. So I would mention it, but I'd be guided by the will of the Committee.

DR. ENGELJOHN: This is Engeljohn with FSIS. Let me just point out that in the general recommendations -- it specifically stated there that the age of an animal would be over/under 30 months, so I don't think it's necessary, but it certainly doesn't hurt to repeat it, either.

DR. LAMMERDING: Anna Lammerding, Health Canada. I'll leave it up to you, Dan. Just to clarify -- we don't want to know how -- as you said, travel passport of an animal, necessarily -- we don't need to know the exact ages, it's that cut-off limit, and if it's clear enough, once it's defined in the general

recommendations, then I'll go with that.

MR. GARRETT: And I think also -- I think we should remember that they're also going to be recommending -- and we'll get to that in just a minute. There'll be inspectors' instructions and inspector training, videos and CDs made, too, so I think it would be well captured, frankly.

DR. ENGELJOHN: This is Engeljohn again. I think for transparency and the fact that the question was raised, that -- it's easy just to go ahead and add it in.

MR. GARRETT: Okay.

DR. ENGELJOHN: So let's just add it.

MR. GARRETT: So then, Anna -- since she brought it up, where would you like for it to go?

DR. LAMMERDING: I went over -- it specified the age of the animal and I think they have that in a couple of categories.

MR. GARRETT: E.g., 31.

DR. LAMMERDING: It just -- they were over or under...

MR. GARRETT: Above and below -- older and younger than 30 months.

DR. LAMMERDING: Correct.

MR. GARRETT: Okay. Thank you. The next specific recommendation under question two. For AMR and LTRP, the Committee recommends that the samples be allocated by production volume and stratified by region and month with some minimum number to be determined by FSIS for each region/month. Further, the Committee recommends that FSIS consider age of the animal -- what have I done? I repeated it, yeah. As an additional stratifying factor for sample collection. And we'll repeat that, okay? Turning then, on to page seven, the next recommendation was for weasand meat. Weasand, head and cheek meat, FSIS has -- proportion to be allocated by production volume the total number of samples to each component based upon microbiological pilot studies and surveys. And we recommended that earlier. Proportionality relative to production and volume should be used to determine the number of samples to be taken from each selected establishment, monthly over 12 month period from each region with some minimum number of samples to be determined by FSIS required from each month/region. Further, the Committee recommends that FSIS consider age of the animal as an additional stratifying factor for sample collection. And we'll add the over and under 30.

DR. PIERSON: Spencer?

MR. GARRETT: Um-hum?

DR. PIERSON: Merle Pierson. I have a question then for the meat industry folks here. When it comes to, you know, we say it should consider age of animal, but if when we say over and under 30 months of age, is that data, in fact, easily collected? What's the difficulty in collecting that kind of information?

DR. SEWARD: This is Skip Seward with the American Meat Institute. I think in some cases it would be obtainable and in some cases it might be more difficult. I think it will depend when the inspectors charged with collecting that sample, if there's communication between them and the establishment, that that would help facilitate making sure that that information is available for the particular lot of animals which are being sampled. So I would say in most cases that is going to be able to be done, but they'd want to know in advance of that sampling effort so they could adequately conduct that on the animals that would be slaughtered. Especially if you're looking at harvesting or sampling products from that animal that was slaughtered the day before, for example, obviously you need to make that assessment at the point of

slaughter, not the day after at the carcass level or at the fat level. Does that answer your question, Dr. Pierson?

DR. PIERSON: Um-hum.

MR. GARRETT: Dr. Lammerding?

DR. LAMMERDING: Anna Lammerding, Health Canada. The Subcommittee deliberated on this, I mean, because there have been differences noted between cows, bulls, steers, heifers and calves, and we wanted to make it as simplified as possible and I think simply because of the BSE, and we talked about age of animals and categories that we came to the conclusion or -- yeah, conclusion that thing of 30 months cutoff, upper, under was an easy cut. When the information's available. Is that -- Skip, is that right? I mean -- as easy as possible. We didn't want to complicate things too much.

MR. GARRETT: Any other comment? Moving on then, to the last recommendation under question two. Inspectors should collect composite samples as described in appendix one up to a minimum of four pounds in the plant, gently mix and divide into two portions and ship to FSIS and contract labs. Appendix one, you'll notice the footnote. There is a proposed instruction to inspectors on how to do the sampling, collecting the

sample, determining the numbers, samples to take, and this document now will have to be changed as a result of the deliberations of our Committee that we're talking about now, so FSIS will then provide the appropriate reference when they change the document.

DR. LUCHANSKY: Spencer?

MR. GARRETT: Um-hum?

DR. LUCHANSKY: John Luchansky. I'm just curious to note in the appendix -- I didn't have time to go through all of it. Was there a piece in there about how -- or what will be sampled, you know, we talked about the core, purge, trends -- I don't know if I saw that in that appendix.

MR. GARRETT: I think it's also coming later, slice.

DR. LUCHANSKY: It's going to be slice?

MR. GARRETT: Yeah, um-hum. But yes, it will be described in -- any other questions? Moving on to question three. Sampling plan design -- although sampling plan design for RGBC baselines is incomplete, pending the results of the two surveys mentioned, what are the most important elements to consider? We've made five specific recommendations. The first, the Committee recommends the use of probability sampling techniques,

e.g., stratified random sampling by month and region to assist in obtaining representative samples for each month/region. Secondly, for allocation of the number of samples to be taken from each plant by month and region. Refer to the first three specific recommendations under question two. We just didn't want to repeat them again. Three, the Committee recommends that the agency provide a transparent document that explains how the total number of samples were determined and identify how the number of samples are to be allocated in the establishments. And then we go on to indicate that the Committee notes that the FSIS has plans to test approximately 2000 samples of each category for all of the listed pathogens and indicators, appears to be based on the expected low prevalence of *E. coli* O157:H7. The Committee noted that variation due to regionality and seasonality could be significant factors in determining the number of required samples for each component category. We also made a recommendation, the statistical estimation procedures used to provide the prevalence estimates and their standard errors be based on the methods used by FSIS for the 1993-1994 program product microbiological survey data to increase the sensitivity of the statistical hypothesis testing,

applications, and the precision of estimates of prevalence. FSIS should also aggregate the monthly data in each region to quarterly in -- seasonal groupings, groups. And then finally, under question three, the Committee recommends that FSIS consider the collection of additional samples to account for possible high numbers of discards and non-return rates, which you always have in national sampling progams. Any questions? Without exception, moving to question four. Selected test organisms for RGBC baselines. We have one specific recommendation and one suggestion. We recommend that the following organisms be selected by FSIS for the baseline studies. That *E. coli* O157:H7 and also 0157, the nonmotile strains. Secondly, *Salmonella*, thirdly, generic *E. coli*, fourthly, total coliforms, fifthly, Enterobacteriaceae and then finally, aerobic plate counts. Also, we suggest that FSIS should consider the development of a protocol to investigate the prevalence of non-0157 STECs, particularly 0111, 026, 0103, 0121 and 0145. There may be an opportunity to incorporate such an investigation into the baseline surveys. As chairman, seeing no objection, we submit our report. It would be our intent, as the next step now, to make the technical corrections that we've done here and then

submit it formally to FSIS.

DR. PIERSON: Okay.

MR. GARRETT: Secondly, let me say we also made progress on our original charge, and though we did not complete that, we did get through the first six pages -- eight pages and what we're looking for the Committee's -- for the Subcommittee's understanding, what we'll be doing will be taking everybody's comments that we've already received, plus what we already did and get that back out in a couple of weeks so the Subcommittee can continue working on that. Thank you, Mr. Chairman.

DR. PIERSON: Thank you, Spencer. So your intent is that we adopt? -- the Committee adopts this report without objection and that you'll be making technical corrections for...

MR. GARRETT: And just the notations we've made.

DR. PIERSON: Do any Committee members object? Okay. So we need a motion to adopt without objection.

DR. SWANSON: First motion.

DR. PIERSON: Is there a second?

DR. KVENBERG: Second.

DR. PIERSON: Okay. Are you all in favor?

MS. RANSOM: Should we get the names for the

record?

DR. SWANSON: Katie Swanson.

DR. KVENBERG: John Kvenberg, second.

DR. KVENBERG: Mr. Chairman?

DR. PIERSON: Yes?

DR. KVENBERG: If that matter of business is closed, I would just like to mention one thing before you move on your agenda.

DR. PIERSON: Certainly.

DR. KVENBERG: Thank you. At the -- I think that the working group should be applauded for work and being very adaptive this week and especially give recognition to its chairman. The National Advisory Committee, being a -- somewhat agent now and as a group that has its own traditions, I would address -- recall to many plenary sessions ago when I was a working group chairman on a particular thorny issue, that the fail factor was also associated at that time and you made mention earlier, during this week's deliberations that you were given a new charge and you were moving onward, so in the traditions of this Committee and plenary session, I'd like to present this award on behalf of this group, the coveted "Onward through the Fog Award".

MR. GARRETT: I accept this award as a mystery

in the midst of the fog in which it's offered. I like that.

MS. RANSOM: Can I order a dozen of those, please?

MR. GARRETT: Thank you very much.

DR. PIERSON: Well, Spencer, congratulations on your most well-deserved award and again, we thank you for your excellent work and the Subcommittee's excellent work and has been very expeditious in addressing this charge. So with that, I'd like to turn the floor over to Don Zink and he'll report on the Shelf-Life Based on Safety Subcommittee.

DR. ZINK: I'm going to be very brief. Our Safety-Based Date labeling document is still a work-in-progress, but we've made quite a bit of progress since our last meeting. The document is mostly complete as far as writing assignments go. We have some additional work to do -- considerable work to do with the epidemiologic data. One of the things the Committee did this session was to go through CDC food commodity codes item by item and determine which we considered ready-to-eat foods that could support the growth of psychrotrophic pathogens and we'll be going back to CDC asking for data that encompasses all of these food items

and that will help us better assess safety-based date labeling. It might have an impact on public health outcomes. We still have a few writing assignments to go to flesh out some sections that are pretty thin or that have gaps. I think that we would like to meet in the next session for perhaps two days. I think that I'm not going to make any great predictions, but I think with a couple of days more work can -- provided -- that we can do quite a bit of work between meetings, that we should have a draft document for the full Committee after then. Thank you.

DR. PIERSON: Thank you. What we can do now -- we're well ahead of time. Why don't we -- let's go ahead and hear from John Kvenberg and his Subcommittee and the after that we'll take a 15 minute break and then following that, we'll have public comment.

DR. KVENBERG: Thank you, Chairman. Well, as I reported at the initial meeting of the plenary session, this working group met on Monday and I was going to expand somewhat a little bit more during the time allotted this time to brief the full Committee on the activities of the working group on pasteurization. We had asked for and received -- and I want to thank the working group for the hard work that was put into a

review of the technologies that was put forward. We discussed those documents and they were made available to the full Committee and to the observers of this Committee and in our review of those documents, I will go through briefly the considerations of the working group in our next steps. One of the issues that we dealt with was what we needed to -- we considered what we needed to be a working definition of the term pasteurization and I'll just read out to you what I think the consensus language of that was in the view of the working group at the time. Pasteurization, for the purposes of our consideration, we are considering is the process or treatment or combination thereof that is supplied to reduce -- an added word -- to the most significant microorganism of public health significance to a level that is not likely to present a public health risk throughout the shelf-life of a food under normal and moderate abuse conditions. Now that being said, the reason for that modification was the initial language that was provided in the act that modified the Food and Drug Administration's language basically prescribed for a process that is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganism of public health significance.

And it was the considered opinion of the working group that what actually intends is below the level of detection because you have the log reduction process, if I'm expressing the views of the working group correctly. And further on in the act that was passed, it basically goes on to say for a period of time that is effective for at least as long as the shelf-life of a food when stored under normal and moderate abuse conditions and in the language that was provided in the act actually acknowledges it's a log reduction issue, so I wanted to make you aware of that. The technologies that we reviewed were microwave and radio frequency and we received a report that was put together by Dr. Lee-Ann Jaykus and Stephanie Doores, ohmic and conductive heating, which was reported by Roberta -- Dr. Roberta Morales. Dan Engeljohn was also assigned to that particular group. High-pressure processing was reported on by Dr. Carol Maddox. Collaborating on that is Dr. Cathy Donnelly, Dan Engeljohn and Angela Ruple. Pulse electric field and high-voltage arc was reported on by Dr. Anna Lammerding. Pulsed-light was an effort Dr. Kathy Swanson -- Katie Swanson -- and Jenny Scott. Oscillating magnetic fields, again, Dr. Lammerding. Ultra-violet light and again, that was a task that was

addressed by Dr. Swanson and Jenny Scott. Ultra-sound was reported on by Dr. Larry Beuchat. X-ray and irradiation, Skip Seward, along with steam and hot water, which was identified and chemicals, which was reported also by Skip and Dan Engeljohn were in collaboration on the chemicals. So that was an overview of the technologies that we had addressed. Our next step is -- I announced before -- was intention -- at least some of the working group members to take a visit to Chicago before the end of the fiscal year to the National Center for Food Safety and Technology and in regard to that, one visit is being proposed and I believe if we'd be able to coordinate that with a food processor that is dealing with E-beam irradiation so that the working group can take a look at that particular technology. Again, I express our desire and we'll wait until the calendars are reviewed on scheduling of an additional working group session of this group next to further address what the further development of a draft document on this recommendation would be. We would definitely need a week's working group to do that and I'll wait for coordination of the timing vocation of that. One of the things that the working group was struggling with that I think I should

put forward is the definition, per se, of what we're trying to deal with these various technologies and I'd like to get a consensus, I guess, from -- specifically, the Vice-chair on the concept of what constitutes pasteurization itself. I think we struggled quite a bit with that concept and in consultation, we had drawn back to the language of the
-- which you'll find in the pasteurized milk ordinance that speaks to every particle of the food having the -- the process reach to it and that may be a guiding thing that may help this working group, if that's agreed upon. That would be -- because some of the technologies that we were looking at did have an application to surface disinfection or surface pasteurization, if you will, that didn't go to every particle of the commodity and further, I guess, is in examining the charge, I think there is great utility in examining the latter issue, but as it fits to full pasteurization, it may not be the same issue. So if the working group has the latitude to explore these technologies in light of what separate applications that would be useful. So I guess I will just leave it at that, but that's our current -- at least, trying to lift our fog factor, if you will, on exactly what our charge would be. I'd like to go on a

bit and then we can come back to that question to see if we're on the right track. In addition, the working group was wondering what our next steps ought to be relative to the questions that were posed -- and I will go through very briefly just to give you a feeling for some of the comments that were put forth on the technologies that we did evaluate. But in essence, it's a very daunting task to evaluate exactly what our recommendation ought to be for which organism depending on which technology and it's further confounded by the fact that multiple technologies might provide a hurdle barrier in order to achieve the intended result at the end, so whatever recommendations we come up with in this working group, we have to sort through: are we going to take certain technologies that would apply time and temperature as traditionally known, even if it's introduced by a different method versus another technology that doesn't use heat and the time of heat dwell in the actual technology because the organisms that may become less resistant will then change and the way you measure that would change. In the simplest sense, I guess we're looking at what goes into the process and what kind of reduction you achieve at the other end of the process, that was proposed. Further,

the working group does not have a -- we have reviewed the certain requirements, be they called process requirements or -- I don't call them food safety objectives necessarily, but the certain requirements normally expressed in D-value reductions of certain processes that define -- for instance, you have this in low-acid canned foods, you have it in the pasteurization process of milk, pasteurization process of eggs and the reduction value is measured in order to define pasteurization is variable in its destruction value and variable in organisms, so that's rather an overview of what we're facing. That being said, just let me go through some -- as an example, a few questions that the Committee had received in reviewing the reports. The first question we were asked is: "What were the scientific criteria that should be used to determine if a process is equivalent to pasteurization?", and the comments were reviewed by the Committee in light of looking at high-pressure technology in this case. We felt that one of the areas we would be working in is the scientific criteria to be used to determine the process should be easily measured. I think that may cut across. The validation is product and organism-specific, another cross-cutter. No guidance exists, but we can be

-- we can basically find out if validation can be conducted through microbiological experimentations or biological challenges to this. Again, there's no road map to exactly what would constitute a valid methodology to determine the technology, just as -- I'm just picking on high-pressure because a lot of discussion was based on that. And then the next question that was asked is: "What if any further research is needed to determine the criteria?", and I think we're on soundest ground when you have time and temperature with heat associated with the group. That seemed to be what our working group came down to is we find comfortable ground where there is a lot of prior history in publications, but where no standardization exists, I think we need guidelines to how to -- and research, perhaps if there's a lacking void in to how you standardize publications so we can assess better what it is that is actually being measured. Another area of research -- and I'll use high-pressure is somewhat far along, but again, if we go back to the idea of pasteurizing a particular product and we buy into the concept that it has to reach the entire food, we have uniform application. In the case of high-pressure, the group is looking at yes, the pressure is uniform and probably will get throughout the

process and to the core of the food to be examined. We had certain questions when it came to processes such as microwave technology and perhaps irradiation if you had cold spots or shadowy-type effects to where research may be needed, or at least protocols need to be developed so that there is an assurance that the intended effect was achieved. Third question that we were asked is what's the most resistant microorganism of public health concern for each process and I will digress a little bit from high-pressure, but mention that as one of the major ones. Dr. Lammerding pointed out in -- was it pulse light? I think one of the discussions we had that the technology there, again, would -- we have a void of actually understanding what the most resistant organism would be relative to the mode of action of what the technology applies to it. In that case, there's a cell membrane destruction and the organism expires in that case, so there's work to be considered on the resistant microorganism dependent on the technologies that we put forward. We were asked about the data needs that would be needed to scientifically acquire and validate the adequacy of the proposed technology and here again, depending on which technology you have, I think there's a desire from the working group to come forward with --

there needs to be some scientific basis on how you evaluate current studies or put forth new ones to verify and validate the adequacy of a proposed technology so the rules are the same and uniformly applied. The fifth question was: “What biological hazards might be created as a consequence of pasteurization with the treatment?” -- and you may recall, I asked for clarification of the Chair that that was limited to the actual microbial hazards that might have some competitive advantage. Here again, depending on the technology that you’re looking at, biological hazards through lack of competition or injury repair and recovery may play depending on the technology that you have. In the instance of the initial document that I was talking about, which is high-pressure, you may not have the issue of reintroduction of pathogens if you have -- if you can apply a treatment, such as high-pressure to a -- through a final package that is already sealed up to where you don’t have cross-contamination coming back, but any pasteurization process that is vulnerable to post-pasteurization recontamination would present that hazard, but sort of what I think the Committee was looking at. The last question we were asked basically needs a lot more work before we move on. What types of

commodities could be used to achieve the pasteurization to be applied. This is going to take some work depending on the technology or combination of technologies that we've been faced with. That's an overview, Chairman, of the progress of the workgroup. Thank you.

DR. PIERSON: Thank you for your report, John, and what we'll do now is we'll take a 15 minute break. We'll reconvene at 10:00 a.m.

MR. GARRETT: Mr. Chairman.

DR. PIERSON: Yes?

MR. GARRETT: Before we take a break, I'd like to make one observation on the report.

DR. PIERSON: Sure.

MR. GARRETT: And I make this observation as the chairman of the Validation/Verification Subcommittee of the Interstate Shellfish Sanitation Conference, which was just adopted in Oregon three weeks ago? Our report dealing with how you go about validating, if you would, a -- in fact, pasteurization or how you'd define pasteurization. And as we had our deliberations, we were assisted, certainly, by FDA and the statisticians of FDA, Dr. Blodgett, Dr. Rainosek, our statistician, and they did a very elegant piece of work with how to

deal with if you're talking about non-detectable levels and the method requires an MPN measurement, a most probable number measurement, which is merely a population estimate itself, but with wide variation. How, in fact, you would determine the number of samples to actually take to insure that you were way, way, way, way below the infectious dose of a particular organism and so I thought we would bring that information forward to your Subcommittee, John, to -- it might be helpful in some of your considerations. Thank you.

DR. KVENBERG: Mr. Chairman, if I could -- it's John Kvenberg again -- I don't know what the agenda is, but I think it would be appreciated by the working group that at some point before we adjourn from plenary session any comments that the Committee may have for guidance on our next proceedings on what we reported on so far. If I could also address some of Spencer's concerns. Just to underscore part of our lack of clarity, we're moving -- in the case of shellfish, which a lot of work was done relative to how you validate it. Here, again, it underscores the question that we were asked, which I'm -- we're trying to remain focused on, which is what constitutes proper application of the term pasteurization? In a particular instance that was

mentioned, the Subcommittee did look at, as a potential model for review, the situation of shellfish commodities, as well. In that regard, they're looking at a specific pathogen – *Vibro vulnificus* in that particular case to provide a treatment that would reduce to whatever level that would be considered safe, but that does not -- I don't think -- going to the thinking that we're putting forward here constitute in itself a pasteurization process in the normally understood terms of the word, because the various technologies are aimed pathogen reduction to provide additional safety. That's why I mentioned on the front end of the charge that it may be useful for this group to consider one example of it that the recommendation of the charge for pasteurization itself might be one thing, but pathogen reduction technologies is a subset that may not come up to pasteurization. Thank you.

MR. GARRETT: Just a follow-up. That particular...

DR. PIERSON: That's Spencer Garrett that's following on.

MR. GARRETT: That's Spencer Garrett, National Marine Fisheries Service. The -- just so I'm not misunderstood when I said way below infectious dose.

It's actually at nondetectable levels in the case of one of those treatments or actually, all of those treatments. So it is reduction to nondetectable levels as defined by one, methodology, and two, the sample plan.

DR. PIERSON: Okay.

MR. GARRETT: But nevertheless, we'll make all that information available to you and do -- do with it what you will.

DR. PIERSON: Okay, now we'll take the 15 minute break and then what we'll do afterwards is come back and have comments, and John, your Subcommittee...

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[Off the Record]

[On the Record]

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DR. PIERSON: Let us go ahead and reconvene. I know -- John Kvenberg has come back? We don't have John here. Is he coming? Okay. I know that the charge John's Subcommittee has is a very challenging one and one that is rather complex. There was a report done for FDA two, three years ago on these technologies that he's talking about and you know, they're cutting-edge technologies and since that time there's been a

considerable amount of work that has been done and when you have developing -- scientific information such as that, it's a challenge then to try to filter all that out and make heads or tails out of it and answer those questions. I feel we can certainly appreciate the challenge that the Subcommittee has. Given that, I'd like to know if there's any comment that the full Committee has relative to the charge and where they're headed. Question?

MS. SCOTT: Jenny Scott, NFPA. Just a brief comment about the comment John made about considering application of the treatment to every particle in the food. We're going to have to think about that a little bit in our Subcommittee because I know we do want to consider surface pasteurization treatments for some types of products and we wouldn't want to rule that out and I think ultimately, what we're trying to get at is that the products have the same level of safety regardless of what process is used to provide that.

DR. KVENBERG: Jenny, one of the things the Committee might want to consider is perhaps, rather than every particle, to every particle that might reasonably be contaminated with a pathogen.

DR. PIERSON: And yeah, I know too, some of

these technologies, for example -- and you have this surface treatment, but also somewhere you're even treating fluids within some type of compartment. There is a distribution of the dose of that treatment within that particular chamber and so not all particles get equal -- get the equal effect. Any other comments? John, do you have any specific questions that you'd like to raise?

DR. KVENBERG: At this point, I do not unless -- I don't see any hands coming up from the rest of the working group. I don't have any further at all.

DR. PIERSON: Okay. If not, I'd like to move to open the floor to public comment. We had one person to sign up, Sam Ankrah. Sam, are you here? Let's see, I think our limitation is 10 minutes. Pardon? Yeah, and he, of course, is again -- identify yourself again and then your affiliation and then you have 10 minutes or less. Thank you.

DR. ANKRAH: My name is Sam Ankrah from Virginia Tech. I work for the Center for Food Nutrition….Alexandria, Virginia. -- I think the Committee has done great work and I have to compliment the Committee for that. I have two questions. My question is actually towards the sampling and the size

of the sample, so it's mainly directed towards the statisticians, so in your draft report on the Risk Assessment for *E. coli* O157:H7 which I read on the web-- the plan was based on information from the CDC sentinel sites and if you look at the sampling plan, it is actually very broad and it has no statistical validity at all because of the sample size. Now, if the samples -- if your sampling is based on that information, which is ultimately based on the CDC sampling plan, then I think you may want to take a second look at the sampling that you have. Secondly, increasing the sample size to, I think...

DR. PIERSON: Could I ask you a question? You said the risk assessment on *E. coli*?

MR. ANKRAH: Yes, sir.

DR. PIERSON: The Committee wouldn't have done a risk assessment on *E. coli*...

DR. PIERSON: What are you referring to?

MR. ANKRAH: The FSIS report. FSIS has a report on the risk assessment of *E. coli*.

DR. PIERSON: The draft risk assessment?

MR. ANKRAH: Um-hum.

DR. PIERSON: That's FSIS and...

MR. ANKRAH: Right.

DR. PIERSON: ... that would not be this Committee.

MR. ANKRAH: Okay. I'm sorry. Okay, this Committee is actually going to take 2000 samples and first of all, I wanted to find out from how many plants, how many retail stores? Is it 2000 samples coming from -- secondly, you mentioned using a random sample, a technique actually to collect the data. The question is if you have visited 1,900 plants, about 100,000 retail stores and by using sampling -- random sampling to collect your data, I think that's a problem right there. I don't know how many -- the 2000 divided among so that no more plants and no more retail stores. I think you may want to consider comparing the random sampling technique with other competing sampling that takes up the other. Thank you.

DR. PIERSON: Okay. Thank you. Before we're done -- you have your report we've adopted and the FSIS would take these comments into consideration in conducting their baselines. So do we have any other -- we don't have any other registered public comments. I would still keep the floor open for any other public comments. Spencer's going to make a comment as a Committee member or as a public...

MR. GARRETT: No, just before you adjourn, I would like to make a comment.

DR. PIERSON: Okay. I guess next on the docket is to adjourn. I -- so I'll give you the last second just before we adjourn. First of all, I want to thank you very much for your excellent work and I thank very much Gerri Ransom and Karen Thomas for the organization of this meeting, making sure that we have the facilities and things go well and smoothly and that you have all the documents that you need for conducting your work. You know, it's a challenge always to find a place or venue to have meetings and this is -- I don't recall when we'd ever had anything in this hotel, so it was a different venue. If you have comments or whatever, let Gerri know and that helps in our further consideration of venues. The next full Committee will be what? February 9, 2004 and we're trying to work out the location for that Committee, taking various factors into consideration, but we'll let you know at a later date the location. In the interim, though, we anticipate there will probably be Subcommittee meetings and of course, the chairs and Gerri and Karen will be coordinating that. You will be submitting your calendars to Karen so that she can get the scheduling

worked out. There is a lot of work on the -- placed on all three Subcommittees and so again quite a bit before them and we look forward to their answers and their colleagues in FDA, as well as us, we always like the answers yesterday that we can use the answers as quick as you can get them, but you have to give them all due consideration, deliberation and we do appreciate your conscientious work. Here again, I very much thank all the Committee members for their work. This takes a lot of time out of your activities and I want to reassure you that this work does not go unnoticed. We do take it very seriously and do use it as a -- as an important reference and -- in our deliberations and provides a good scientific analysis of the issues. And with that, Bob, if -- let's see, if I -- I don't have to give it to Spencer now or give the floor to...

MR. GARRETT: I'd be remiss if I didn't say that I engage in a lot of different activities and I must say I consider this the most intellectual one I do and truly, it's a delight to, you know, when you're a manager you don't often get a chance to have these intellectual discussions, if you catch my drift, you know. But -- so you know, and I'm a person who doesn't take praise well, but I'd certainly by remiss if I didn't

also ask that we also thank Emille Cole, sitting on my right, who's our Special Assistant for Extra Activities and Programs and also, Barbara Comstock, who's our Visual Information Specialist...

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[Tape 2]

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MR. GARRETT: ...a great staff and I'd just like to publicly -- thank them.

DR. PIERSON: Well, Bob, do you have anything you'd like to say?

DR. BRACKETT: I guess I would just like to thank the Committee, as well. Each one of you was specifically chosen and picked to be on this Committee because of your expertise and your experience and I've been here as much as I could every day to notice how hard you work and it is difficult to get away to do something this long of a time period away from your offices and it is appreciated.

DR. PIERSON: Well, with that, I will wish you a very wonderful weekend and a very safe trip back home. The meeting is hereby adjourned. Thank you. 10:20AM.

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IN RE: NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS PLENARY SESSION

HELD AT: WASHINGTON, DC

DATE: August 22, 2003

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