UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MICROBIOLOGICAL CRITERIA FOR FOODS

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PLENARY SESSION

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June 4, 2007
1:00 p.m.

USDA Cafeteria
(Conference Room)
1400 Independence Avenue, S.W.
Washington, D.C.

CHAIRPERSON: DR. CURT MANN
Deputy Under Secretary for
Food Safety, USDA

EXECUTIVE COMMITTEE MEMBERS:
ROBERT E. BRACKETT, Ph.D., Vice-Chairperson
LEEANNE JACKSON, Ph.D., FDA Liaison
GERRI RANSOM, MS, Executive Secretary
KAREN THOMAS-SHARP, Advisory Committee Specialist

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COMMITTEE MEMBERS:

DR. GARY ADES
DR. SCOTT BROOKS
DR. PEGGY COOK
DR. UDAY DESSAI
DR. DANIEL ENGELJOHN
DR. TIMOTHY FREIER
DR. WALT HILL
DR. MICHAEL JAHNCKE
DR. JULIE ANN KASE
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DR. JOSEPH MADDEN
DR. ALEJANDRO MAZZOTTA
DR. JIANGHONG MENG
DR. ELI PERENCEVICH
MS. ANGELA RUPLE
MS. VIRGINA (JENNY) SCOTT
DR. ROBERT TAUXE
DR. IRENE WESLEY

ALSO PRESENT:

DR. EVELYNE MBANDI, FSIS

I-N-D-E-X

Note: Due to technical difficulty the initial portion of the transcript was reconstructed from speaker notes. The reconstructed portion of text, on pages 4-12, is in italics.

P-R-O-C-E-E-D-I-N-G-S

DR. MANN: Good Afternoon, I would like to welcome our members and guests to the first plenary session of the 2007-2009 National Advisory Committee on Microbiological Criteria for Foods (NACMCF). I am Dr. Curt Mann, NACMCF Chair and USDA Deputy Under Secretary for Food Safety.

To my left is our NACMCF Vice-chair Dr. Robert Brackett, and Director of FDA's, Center for Food Safety and Applied Nutrition.

As I mentioned, today's session is the first meeting of the full Committee of the 2007-2009 NACMCF. We are at an exciting point with this newly formed Committee, as new and returning members were recently appointed by the Secretary of Agriculture and we will be starting out this term with some new work charges.

Before I go any further, let me say that this Committee is performing an invaluable service to the supporting Federal food safety agencies, those being: the USDA Food Safety and Inspection Service, the HHS Food and Drug Administration and the Centers for

Disease Control and Prevention, the Department of Commerce, National Marine Fisheries Service, and the Department of Defense, Veterinary Service Activity. NACMCF is providing scientific advice to our Nation's food safety programs. On behalf of the sponsoring agencies, I would like to thank each of you for your willingness to share your valued expertise, and time in support of the activities of the Committee.

Our previous 2004-2006 NACMCF Committee was very successful and I wanted to make mention of some their completed work.

The Committee completed the final reports: One: The Analytical Utility of Campylobacter Methodologies, and two: Response to the Questions Posed by FSIS Regarding Consumer Guidelines for the Safe Cooking of Poultry Products. Both these reports can be found on the FSIS website and were published in the Journal of Food Protection. Both reports had immediate and direct application to FSIS program needs.

The Campylobacter report has been used extensively by our baseline studies design teams to establish methodology for upcoming microbiological

baseline studies for broilers/young chickens, and turkeys, respectively. This report was used to assist in selecting and validating a Campylobacter testing protocol for these studies, and also for study design issues, including sampling plans. This report will assist future baselines as well.

The poultry cook report was timely because of the need for FSIS to immediately consider the recommendations in the report related to an ongoing outbreak at that time associated with a raw-breaded poultry product (the product type addressed in the report), and there was also an urgent need for FSIS to convey safe poultry cooking procedures to consumers and industry regarding avian influenza. The Agency also used this report to support new labeling policy for raw breaded chicken products. The report's focus on the need for validated cooking instructions for consumers is critically important information. This report is being used as a resource document for FSIS inspectors as well as industry.

NACMCF is moving forward, and as I mentioned this Committee will tackle some new work areas. The following subcommittees will be active as this

Committee term starts up: One: Determination of Cooking Parameters for Safe Seafood for Consumers; two: Assessment of the Food Safety Importance of Mycobacterium avium subspecies paratuberculosis; three: Parameters for Inoculated Pack/Challenge Study Protocols; and four: Determination of the Most Appropriate Technologies for the FSIS to Adopt in Performing Routine and Baseline Microbiological Analyses.

As you are aware, the seafood cook subcommittee has been an on-going workgroup and they will bring their draft final report to the full Committee on Friday for deliberation and adoption, thus we anticipate that they will be wrapping up this work. Spencer Garrett, of the National Marine Fisheries Service is the subcommittee chair of this group.

The Mycobacterium subcommittee work began last Committee term and the group has been making much progress. This subcommittee potentially could finish their work by our September 07 meeting, but we will have to wait to hear from the group on Friday for a more to definitive status report. Dr. Don Zink of

FDA, will serve as the chair of this subcommittee this term.

Moving on, before we have Committee members introduce themselves, I would like to turn the floor over to our Vice-chair, Dr. Bob Brackett.

DR. BRACKETT: I would also like to welcome everyone to our first plenary meeting with a newly appointed Committee. I would like to thank our returning members for their continued service and also to thank the new members for volunteering their time and expertise in support of the activities of the Committee. Your participation and effort will allow us to move forward on a number of public health protection and food safety initiatives. I look forward to many insightful discussions.

At this time I would like to go around the table and have Committee members introduce themselves and state their affiliations.

(Introductions around table)

DR. BRACKETT: I would now like to turn the floor over to Gerri Ransom our Executive Secretary who will provide some additional information.

MS. RANSOM: Good afternoon and again, welcome. As always, if I or Karen can assist members with anything, please do not hesitate to let us know.

A note on some meeting procedure for today. If you would like to participate in discussions, please take your name card and set it vertically so our Chair will be alerted to call on you. Please also remember to state your name and affiliation for the record, as the session is being recorded to create a transcript. Thank you.

For any guests wishing to make public comment, we ask that you please register with us at the front desk. We have a sign-up sheet at the registration desk. Each registrant will be allowed up to 10 minutes for their remarks.

I also want to point out to our guests that we have a table out front where you can find copies of various documents related to NACMCF. So feel free to pick up copies of materials that interest you. For those guests who wish to distribute any materials please check with our folks at the sign-in desk and they will assist you. We thank you for your cooperation on this.

Related to NACMCF business, I have a few items to mention. A NACMCF charter was approved on August 3, 2006 and on March 23, 2007 the Secretary of Agriculture appointed 30 members to the Committee for the 2007-2009 2-year NACMCF term. Unfortunately one of the NACMCF appointees had to decline their appointment due to a new appointment within FDA that has given him a new set of responsibilities. Dr. David Acheson will not be serving with you on NACMCF this term. We anticipate that another appointment will be made from within FDA to fill this slot on the Committee.

And one administrative note: Please check your entry in the member address list in your meeting notebook and let Karen know if any updates or corrections are needed in your contact information.

I am looking forward to working with you this week and I hope you find this NACMCF term enjoyable, rewarding, and challenging.

And I will now turn the floor back over to Dr. Mann.

DR. MANN: Thank you, Gerri. And now I will move us into today's work. This afternoon we will

receive introductions on the two new work charges being presented to the Committee today, and these subcommittees will begin working this term. These subcommittees include:

Parameters for Inoculated Pack/Challenge Study Protocols. This is an FDA work charge and the subcommittee will be chaired by Dr. Don Zink of the FDA. Dr. Bob Brackett of FDA will present this charge today. A draft of this charge was previously presented to the Committee for comment at the September 2006 NACMCF plenary session. This subcommittee will not be meeting this week, but they will commence work this summer.

Our other new work area is on the FSIS topic of Determination of the Most Appropriate Technologies for the FSIS to Adopt in Performing Routine and Baseline Microbiological Analyses. This subcommittee will be chaired by Dr. Uday Dessai of FSIS and he will be presenting this charge today. The group will start work this week. Please note that NACMCF was also asked to Comment on a draft version of this charge at the September 06 plenary session and the

charge provided to you today incorporates comments received.

And now I call upon Dr. Bob Brackett to introduce the FDA inoculated pack charge. Bob…

(Start transcript at 1:15 p.m.)

DR. BRACKETT: By way of background, the restaurant and retail food store industry routinely uses inoculation/challenge testing to determine whether a specific food requires time and temperature control for safety, and these are referred to as TCS.

And when the laboratory testing is used to support a change to what the Food Code could do and how the product is handled in the establishment and the examples we used here is refrigerated to unrefrigerated holding for some types of food or vice versa, or perhaps if they can extend the shelf life, these sorts of handling issues. Usually they will send the data to either a state or local regulatory agency or in some cases directly to the Food and Drug Administration, in what's known as a form of a

variance in support of the Food Code to allow them to do that.

And in these cases, the submitter must ensure that the study is appropriate for the food in question and also for the pathogens of concern that might be in those foods, or that's considered to be in a lot of those foods, and then obviously incorporate whatever necessary elements into the study that would yield a valid design. And this is something that has not been consistent in the industry and something that really needs to be addressed and to be transparent and much more science-based.

The definition of potentially hazardous foods or the time/temperature control necessary for food safety was amended in 2005 in the FDA Food Code and in that, it included both consideration of pH and A_W interaction tables. And so this allowed the use of the hurdle concept to be used to determine whether a temperature control for safety of food is necessary or not.

When the pH and the A_W interaction controls

and the framework that's used to determine that the food does not require further refrigeration, sometimes further product assessment is necessary using inoculated pack or challenge study testing. So it's for these, that the study protocol, that we are bringing forth to this Committee, is dealing with.

So the charge for the Subcommittee for this particular task is summarized here. Because of the many different questions that have been raised by regulatory entities as well as industry users, on the definition of potentially hazardous foods and whether the time/temperature control is needed, this Committee is asked for its guidance to clarify these issues. And, again this has to do with science that's involved in it.

So the questions are listed in the next couple of slides, and you also have a copy of them in your binder as well.

The first is, what are the appropriate criteria that must be considered for an inoculated pack/challenge study to determine if a food requires time/temperature control for safety? And for

example, pathogen species, strain selection, whether or not to use a surrogate organism, the number of pathogen strains used, inoculation level or levels, incubation temperatures, length of incubation/duration of studies, all of these different factors are put in an inoculated pack study.

Secondly, what are the appropriate uses of mathematical growth and inactivation models of which there are a number? Under what condition can these models be used as a substitute for actual experimental laboratory inoculated pack/challenge studies? Of the models that are currently available to us, which ones are the most suitable for this use, and what are the limitations of these models?

Thirdly, what are the limitations for applying results of an inoculated pack/challenge study to one food versus another similar food? Sometimes they're close enough that they seem like they would be interchangeable, but not always.

Fourthly, of the existing inoculated pack/challenge study protocols, and there are some

available, some of which are published by the American Baking Association, NSF International, as well as others, including some -- this Committee, which are most suitable for application to a wide variety of foods, and then what are the limitations of these protocols if they were to be used? And are there existing protocols that are apparently for specific food-pathogen combinations?

Fifthly, and this involves developing a decision tree to aid in the design of an appropriate inoculated pack/challenge study. This allows investigators to test or desk-check the decision tree using the following five foods, and these are just examples: meat-filled puff pastry, baked cheese pizza, chopped lettuce, cheeses (either blocks or slices), and lemon meringue pie.

Sixthly, identify the basic knowledge, skills, education, training, experience and abilities necessary for a multidisciplinary work group or individual to be qualified to design, conduct or evaluate studies such as these and the pursuant results. So this really deals with the expertise of

the individuals involved in the study itself.

So that pretty much summarizes what has been charged. I think there's a lot of different items to address, and it is going to be challenging for the group to do that.

And so at this time I would reserve some time here if you have any questions, or clarification I can give to you.

(No response.)

DR. MANN: Any questions for Dr. Brackett?

DR. BRACKETT: Okay. Very good. Thanks.

DR. MADDEN: I've got a question for Dr. Brackett. What exactly --

UNIDENTIFIED SPEAKER: Name and affiliation.

DR. MADDEN: Joe Madden, Neogen Corporation. What exactly does a Committee member do to be considered for a Subcommittee appointment if you choose to be on a Subcommittee?

DR. BRACKETT: Typically -- if you're not on the Subcommittee but you'd like to be. Is that what you're asking?

DR. MADDEN: Yes, sir.

DR. BRACKETT: I think what we have is a very open system. That is, if you have time and you would like to be on the Subcommittee, we've had sort of the tradition that you just go and participate in that Subcommittee even if you're not an actual official member.

DR. MADDEN: Thank you.

DR. MANN: I'd like to jump in on that a little bit. The Executive Committee has been thinking about that, the goal is to have a certain productivity and maintain a certain momentum, with a certain number of members so inevitably there will be situations where we have Committee members serving on two different Subcommittees and I think in the past, there's even been some instances where there's been three. The thing we're asking in the future of our Subcommittee chairs is to recognize that, discuss this with the folks who are serving on two different Subcommittees, try to accommodate scheduling as much as possible. When it comes to that inevitable situation where you can't be in two places at the

same time, that the Subcommittee chairs would, with advice from the member, would assign a primary duty and a secondary duty, if you will, so that you don't want to slow down a Subcommittee's momentum. You can always catch somebody up. So it may be useful to -- after the fact if someone was --

Are there any other questions of Dr. Brackett?

(No response.)

DR. MANN: Okay. Thank you. That's important work there, and we look forward to the product of Dr. Zink's Subcommittee.

Now I'd like to call upon Dr. Uday Dessai, and we will discuss the other new Subcommittee, the New Technologies charge. Dr. Dessai.

DR. DESSAI: Thank you, Dr. Mann. This charge was presented, like Dr. Mann said earlier, and we got extensive comments on this charge. We have the transcripts of those, and also there were some e-mail communications and feedback on the charge. Given that the charge was presented in a new technology format, we were kind of focused on SMEs (subject

matter experts) kind of technology. Now we've taken into account all the comments that we received thus far, and the charge has been revised to reflect those comments.

This Committee has the following members. I won't read the names of everyone here, but basically the charge is aimed at providing FSIS recommendations about what is out there in terms of new technologies and what would be suitable for FSIS given that FSIS is a regulatory agency. I'm not going by the text here. We are on Tab 8. I'm just talking about the general issues, and I'll come to the charge of the Subcommittee in a little bit.

So what is out there and what would be applicable to FSIS in terms of doing what we do faster, that's detection of pathogens or for process control indicators, how can we do it faster? How can we do it in a cost effective manner? And how can we do it in such a way that the data is available to us to do many other things, not just regulatory issues, but for attribution and other kinds of models? So that was the focus of this charge.

The points summarized here are consider the following when you are deliberating on this issue, specificity and sensitivity of the methodology that you'll be looking at, adaptability to various matrices including -- human clinical samples, the scope of the analyses, that is species identification, the current serotype -- and antibiotic resistance, PFGE or any other methods that get to virulence of an organism potentially.

Then enumeration has been a major issue because most of our risk assessments, data driven risk assessments, need not just the prevalence, but the prevalence and the numbers of organisms.

Then like I said, speed is an issue for us, and easy acquisition of the data and transfer. It is very important data be in a format where it can be transferred very easily into the existing data system of FSIS.

Cost and resource efficiency is, of course, prime importance.

The charge is broken down into six points here, and I will read these. These have been

slightly modified and rearranged from the previous questions, taking into account the comments that we received.

The first part is what are the most appropriate technologies FSIS should consider for improved microbiological analysis? What are the most promising methods that could replace or complement those currently used at FSIS? What are the important parameters to be considered in determining the suitability of a method for a particular application such as laboratory analysis versus pathogen and in-plant testing? Routine versus baseline testing and enumeration of all pathogens. We've combined this, actually baselines, as well as the routine testing, because baselines, after we get the baseline, the methodology generally is validated for other laboratories to be used for regulatory testing.

Item two is: what are the advantages and disadvantages of these newer technologies, all methods, when selecting newer technologies or methods, consider that the FSIS approach of reliance on culture confirmed positives for target organisms

in the context of method correlation, substitution and degrees of confidence. For instance, if the technology does not measure or coordinate with -- cell presence, can reasonable decisions be made about the safety of the product? Now this was a point we added after we got the comments with the last presentation.

Item three, when adopting new technologies and testing platforms, what considerations must be made regarding sampling protocols, how that sampling (sites, site rinse, et cetera), impact assay sensitivity, specificity and limit of detection? Are there any practical ways (concentration technologies, et cetera) that could be adopted to compensate for the potential loss in specificity, sensitivity and detection limit requirements for microbiological targets? This is again a modified point from all the comments that we got.

Item four, consider specifically the accuracy, applicability and validation of an assay capable of detecting thousands of single nucleotide polymorphisms, SNPs, in a single reaction. Would

such an assay be timely, cost effective and capable of screening specimens to monitor process control? Would it be capable of differentiating multiple microbial species in a single sample? Could it have application for differentiating bacterial subspecies particularly relevant for *Salmonella,* which are particularly characterized by serotypes, or detecting and antibiotic resistance genes and virulence factors? Determine the suitability of incorporating SNPs in meeting the current and future testing needs of FSIS. Now this charge has not been altered except adding the last part of this charge.

Item 5, when selecting a new technology, what factors should be considered such that the data generated will be useful in an expanded manner to include attribution/risk profiles and models for human illnesses?

And the last item is, what issues will need to be considered to make newer and promising technologies reality in FSIS? FSIS future testing for pathogens and indicator microorganisms. For technologies that may be useful in the future,

identify research gaps that need to be addressed prior to implementation. The last part of this charge has been added on because of the comments.

That finishes the presentation of the charge and we will take questions.

DR. MANN: Any questions for Dr. Dessai?

(No response.)

DR. MANN: I have one. You're going to focus on the laboratory part of this at first rather than the in-plant or in-field type of technologies? What are you going to try to focus it on?

DR. DESSAI: Well, what we did was we left it to the Subcommittee to decide what they want to focus on based on the amount of work and the time that we needed, but we had thought initially that in-plant would be a focus to start with, but we'll leave it to you to decide.

DR. MANN: So you haven't decided?

DR. DESSAI: No.

DR. MANN: Okay. You think you're going to focus on in-plant first?

DR. DESSAI: Yes, that was the thought

process.

DR. MANN: Okay. Thank you. Any other questions for Dr. Dessai with regard to the charge?

(No response.)

DR. MANN: Okay. Thank you.

DR. DESSAI: Thank you.

DR. MANN: So these are two new charges for this term. We potentially might have some replacement charges coming up at the next session, but we'll stay tuned on that and we'll -- work on what we might have available as we close out some of the other subcommittees.

We're moving along fairly quickly. So we're ahead of schedule. At this point in time, you have a choice of whether you'd like to take a break and go to public comment or just go right to public comment. We have some audience here. We can go to public comment. I will follow the druthers of the Committee here.

I think we're going to move forward. So we'll check and to see if anybody has any further comments. Is there anyone in the audience who would

like to make a comment for the Committee's benefit?

(No response.)

DR. MANN: All right. Well, hearing none, it looks like that closes our public comment period, and that's winding us down for this morning. We have a week ahead of us. I want to thank all the Committee members for coming in, and being a part of this Committee again, and we'll have a pretty active schedule the rest of this week. We'll meet again as a full Committee on Friday.

So again, I want to thank you for being part of the Committee that we're trying to drive some additional life into because it is one of the best advisory committees on public health protection from foodborne illness. It's a unique advisory committee, given the fact that it's sort of co-owned by many different food safety agencies. So your skills and your technical advice are very important to these regulatory agencies.

Irene.

DR. WESLEY: I have one question. Do you have a timeline for the new methods technology? Are

you going to allow time for a baseline survey? Are they in 2010, 2009?

DR. MANN: Could you just rephrase your question with the microphone on to make sure our transcriber is getting it?

DR. WESLEY: Do you have -- Irene Wesley, ARS. Do you have a timeline when you'd like to have some of the recommendations from the Committee incorporated into the FSIS --

DR. DESSAI: I will be happy to comment on -- and then it's also specific. So we have not decided concrete on this but as we go along, with other meetings, we will then sort out immediately and then say after we present to the body here that these are things you can do short-term and the rest of the things you can do long-term.

DR. MANN: Dr. Engeljohn.

DR. ENGELJOHN: This is Engeljohn with FSIS. And I would just follow up what Wesley already said, and just opined that I think the Agency would be grateful to get short-term and long-term perspectives as to what might be able to be

accomplished near-term and then longer term, and we define in the Subcommittee what those terms mean, but clearly whatever the Agency could be using now to be developing or studying or assessing -- methodologies would be quite helpful.

So we would be looking to the future because it would be a major modification to the design and support that we have in place, but if there are things that we can do short term, we clearly would want to know that and start doing that.

DR. MANN: As we close out, are there any other comments that our Executive Committee members would like to make at this time?

(No response.)

DR. MANN: Okay. Well, again I just look forward to this week's meetings. I wish you all a productive week. On Friday, we'll reconvene and we'll hear about the seafood cook document that hopefully we'll get a final approval on and then hear reports from the Subcommittees.

So I adjourn the meeting. Thank you.

(Whereupon, at 1:37 p.m., the meeting was

concluded.)