

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS

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PLENARY SESSION

+ + + + +

September 28, 2007
9:00 a.m.

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

DR. ROBERT BRACKETT
Vice-Chair, NACMCF

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DR. TIMOTHY FREIER
DR. KATHLEEN GLASS
DR. LINDA HARRIS
DR. WALT HILL
DR. MICHAEL JAHNCKE
DR. LEE-ANN JAYKUS
DR. JULIE ANN KASE
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DR. JIANGHONG MENG
DR. ELI PERENCEVICH
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DR. DONALD SCHAFFNER
MS. VIRGINIA (JENNY) SCOTT
DR. JOHN SOFOS
DR. DONALD ZINK

I-N-D-E-X

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

2 (8:59 a.m.)

3 DR. BRACKETT: I'm pleased to welcome both
4 our members and guests to today's Plenary Session of
5 the 2007-2009 National Advisory Committee on
6 Microbiological Criteria for Foods, or NACMCF as we
7 call it.

8 I'm Bob Brackett, NACMCF's Vice-Chair and
9 the Director of the FDA Center for Food Safety and
10 Applied Nutrition. And, regretfully, Dr. Dick
11 Raymond, who is our NACMCF Chair, and also USDA's
12 Under Secretary for Food Safety was unable to be with
13 us today, but he does send his regards and says that
14 he is well aware of the long hours that Committee
15 members have worked in order to accomplish the work
16 tasks this week.

17 As you know, NACMCF was established in 1988
18 in response to recommendations of the National
19 Academy of Sciences for an interagency approach to
20 microbiological criteria for foods. The Federal
21 agencies sponsoring NACMCF started funding this
22 Committee, and we began the great NACMCF journey that

1 has continued for all these years.

2 Since NACMCF has been rechartered every two
3 years, in accordance with the Federal Advisory
4 Committee Act, a number of Committees have served
5 before this one. At each interval that the Committee
6 was up for renewal/rechartering, the Secretary of
7 Agriculture approved continuation of the Committee.
8 This continuation underscores the importance of the
9 valuable service that NACMCF has provided through
10 expert advice, which is incorporated into the
11 nation's food safety programs advancing public
12 health.

13 Each and every Committee has provided
14 valuable guidance and recommendations to both the
15 Secretary of Agriculture and the Secretary of Health
16 and Human Services regarding the microbiological
17 safety of foods. And so to each member of the
18 current Committee, whether you are new to NACMCF or
19 you have served on past Committees, I and the
20 sponsoring agencies thank you for your service and
21 for your commitment to food safety and public health.
22 It is much appreciated.

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1 Before we move forward, I want to turn the
2 floor over to Dr. David Goldman. As you know,
3 Dr. Goldman is a member of the NACMCF Executive
4 Committee and Assistant Administrator for the Office
5 of Public Health Science at the Food Safety and
6 Inspection Service at USDA. David.

7 DR. GOLDMAN: Thank you, Bob, and let me
8 add my greetings to all of you and my thanks for the
9 work that NACMCF has done this week and in the years
10 past as well.

11 I did want to add the regrets sent by
12 Dr. Raymond. He is actually right at this time this
13 morning making a presentation to all of our frontline
14 inspectors at a meeting. This is a meeting that is
15 very important to the Agency, as the Agency is
16 considering some new initiatives in the realm of
17 inspection. And so he will be unable to join us. He
18 does send his regrets, and he is looking forward to
19 reading the reports that come out of today's meeting
20 and the upcoming reports from future work.

21 I did want to echo what Bob just said about
22 the importance of NACMCF, and from the perspective of

1 FSIS in particular. The most recent Committee that
2 was convened from 2004 to 2006 worked very diligently
3 in developing and then adopting two papers that are
4 of great importance to us. One was the "Analytical
5 Utility of *Campylobacter* Methodologies", and the
6 second was a "Response to the Questions Posed by FSIS
7 Regarding Consumer Guidelines for the Safe Cooking of
8 Poultry Products."

9 I just wanted to let you know that these
10 two reports have been directly applied to the
11 activities of this Agency. The *Campylobacter* report
12 was heavily relied upon to guide our baseline studies
13 group regarding *Campylobacter* methodology for
14 nationwide microbiological baselines. In fact, we
15 have an ongoing baseline right now with young
16 chickens or broilers, and that baseline started at
17 the end of June. The *Campylobacter* methodologies
18 that were endorsed by this group have been very
19 central to the activities of that baseline.

20 In addition, the Poultry Cook Report that
21 was adopted with the last Committee as well, was
22 available to inform manufacturers of products, about

1 how to design reliable cooking instructions for
2 consumers that would result in a safe product.

3 So I think these two reports highlight the
4 importance of the NACMCF activities to our Agency,
5 and we will continue to provide you hopefully
6 challenging work charges that will help this Agency
7 move forward.

8 So with that, I want to turn the microphone
9 back over to Dr. Brackett, and thank you for your
10 service to the Committee.

11 DR. BRACKETT: Thanks, David. I have an
12 important business item to take care of before I ask
13 the Committee members to introduce themselves. I
14 want to welcome a new appointed member. Dr. Kelly
15 Bunning, of FDA, was recently appointed by the former
16 Secretary of Agriculture, Mike Johanns to fill a
17 vacant slot on the Committee. And so, Kelly,
18 welcome.

19 Note that in front of you is the
20 Certificate of Appointment from NACMCF along with a
21 letter from Chuck Connor, but that is actually in the
22 mail as Gerri tells me. So we don't have it with us

1 this morning. So even though you're supposed to have
2 it in front of you, the certificate is in the mail,
3 Kelly, but it official. So that's the important part
4 of this. And I noted that you have attended
5 subcommittee meetings this week. So you are well on
6 your way to getting up to speed on some of the issues
7 that we have to discuss. And I'm sure you'll enjoy
8 your time, Kelly, with the Committee as anybody who
9 has served on the Committee has in the past. We look
10 forward to you bringing the expertise that you bring
11 to the Committee.

12 So let me also take the opportunity to
13 welcome and introduce Lieutenant Colonel (LTC) Tim
14 Stevenson, right over here, who was recently assigned
15 to the NACMCF Executive Committee, to serve as the
16 new Department of Defense Liaison, replacing LTC
17 Brad Hildebrand who many of you know, and so welcome,
18 Tim.

19 At this time, I'd like to go around the
20 table and have the Committee members introduce
21 themselves and state their affiliation and please
22 make sure the microphone is on so we can hear you.

1 So we will start I think with Dr. Meng.

2 DR. MENG: Jianghong Meng, University of
3 Maryland.

4 MS. KOWALCYK: Barbara Kowalcyk, Center for
5 Foodborne Illness Research and Prevention.

6 DR. BUNNING: Kelly Bunning, FDA, Center
7 for Food Safety and Applied Nutrition.

8 DR. CLIVER: Dean Cliver, University of
9 California, Davis, until Sunday (Will be retiring).

10 LTC KING: Robin King, Department of
11 Defense, Veterinary Services Activity.

12 DR. COOK: Peggy Cook, Safe Foods
13 Corporation.

14 DR. MADDEN: Joseph Madden, Neogen
15 Corporation, Lansing, Michigan.

16 DR. ENGELJOHN: Dan Engeljohn, U.S.
17 Department of Agriculture, Food Safety and Inspection
18 Service.

19 DR. BROOKS: Scott Brooks, Food Safety Net
20 Services.

21 DR. KASE: Julie Kase, North Carolina State
22 Laboratory of Public Health.

1 DR. FREIER: Tim Freier with Cargill.

2 DR. HILL: Walt Hill, Institute for
3 Environmental Health.

4 MS. SCOTT: Jenny Scott, Grocery
5 Manufacturers Association/Food Products Association.

6 DR. ADES: Gary Ades, G&L Consulting Group.

7 DR. JAHNCKE: Mike Jahncke, Virginia Tech.

8 DR. PERENCEVICH: Eli Perencevich, VA
9 (*Veteran's Administration*) Maryland Health Care
10 System.

11 DR. JAYKUS: Lee-Ann Jaykus, North Carolina
12 State University.

13 DR. SCHAFFNER: Don Schaffner, Rutgers
14 University.

15 DR. SOFOS: John Sofos, Colorado State
16 University.

17 MS. RUPLE: Angela Ruple, NOAA (*National*
18 *Oceanic and Atmospheric Administration*) Fisheries.

19 DR. GLASS: Kathy Glass, University of
20 Wisconsin-Madison, Food Research Institute.

21 DR. HARRIS: Linda Harris, University of
22 California, Davis.

1 DR. ZINK: Don Zink, Food and Drug
2 Administration, Center for Food Safety and Applied
3 Nutrition.

4 LTC STEVENSON: Tim Stevenson, Department
5 of Defense, Veterinary Service Activity.

6 DR. LIANG: Art Liang, CDC, Atlanta. I'm
7 on the Executive Committee.

8 DR. JACKSON: Lianne Jackson, FDA, Center
9 for Food Safety and Applied Nutrition, Liaison to the
10 Executive Committee.

11 MS. RANSOM: Gerri Ransom, Food Safety and
12 Inspection Service and NACMCF Executive Secretary.

13 DR. DESSAI: Last but not least, Uday
14 Dessai, FSIS, USDA.

15 DR. BRACKETT: Thank you. Of course,
16 you're last but not least.

17 Now at this time, we're going to hear from
18 three subcommittees who have been working quite
19 diligently on their assigned charges this past week
20 in particular. Two subcommittees are early in their
21 tasks, and this includes the group working on the
22 FSIS New Technologies charge, and the group working

1 on the FDA Inoculated Pack Challenge Study Protocols
2 Project.

3 Our other subcommittee working on an FDA
4 charge has been tackling the subject of the food
5 safety importance of *Mycobacterium avium* subspecies
6 *paratuberculosis* or MAP. And the MAP group has
7 brought us a draft final report for review,
8 discussion and consideration for adoption. And I
9 know a number of you will be having to leave early so
10 we're going to move along quickly so that we can
11 actually get that adopted while we have a quorum of
12 members here at the Committee meeting.

13 Before I go any further, I'd also like to
14 pause and take care of some of the basic housekeeping
15 issues that we do when we meet, and so I'm going to
16 ask Gerri Ransom, who is our Executive Secretary, to
17 mention a few of these items.

18 MS. RANSOM: Good morning again and welcome
19 again.

20 As always, I just wanted to let you know
21 that please come see Karen or me if you need any
22 assistance with anything. In order for us to have a

1 smooth productive meeting today, I wanted to mention
2 a couple of items.

3 Just a reminder on some meeting procedure
4 for today. If you would like to participate in
5 discussions, please take your name card and set it
6 vertically so that our Vice-Chair will be alerted to
7 call on you. Please also remember to state your name
8 and affiliation for the record each time you're
9 addressing the Committee as the session is being
10 recorded to create a transcript.

11 I wanted to mention that for any guests
12 wishing to make public comment, we ask that you
13 please register with the folks out front. We have a
14 signup sheet and each person will be given 10
15 minutes.

16 I also want to point out to our guests that
17 we have a table out front where you can find copies
18 of various documents. The MAP or *Mycobacterium*
19 document is out on that table and available for you.
20 There's both a clean copy and a track changes copy
21 allowing you to follow along and take a look at the
22 last edits that were made.

1 If any guest would like to distribute
2 materials, please see our folks out front and they'll
3 assist you with that.

4 On the NACMCF business side of things, I
5 have a few items to mention. I have a status report
6 on the Seafood Cook document. This report was
7 adopted at the June meeting. Its full title is
8 Response to the Questions Posed by the Food and Drug
9 Administration and the National Marine Fisheries
10 Service Regarding Determination of Cooking Parameters
11 for Safe Seafood for Consumers. The full Committee's
12 comments have been incorporated into this report, and
13 my office is now working on the final formatting of
14 the report. We're going to be submitting it to the
15 Journal of Food Protection soon for publication and
16 as soon as possible, we'll get the report out on the
17 web, the FSIS website. This is a great work
18 accomplishment of this Committee. So congratulations
19 on that.

20 Now we are working on scheduling future
21 NACMCF subcommittee and plenary meetings. So you
22 should have received an e-mail from Karen. We've

1 repeated that information for you in your meeting
2 book. I have heard during this week that maybe it's
3 a little bit overwhelming to try to determine what
4 your schedule is from January through September. So
5 we'll be working with you on that. We'll try to
6 narrow down some dates for subcommittees, some
7 months, weeks for subcommittees and also for the
8 potential to plenaries that we'll have in 2008.

9 We're looking at maybe a spring or early
10 summer plenary and possibly a September plenary. So
11 we'll see how we go in terms of needs for adoption of
12 documents and things of that nature.

13 Now a number of Committee members have
14 asked about the next work charges for NACMCF. The
15 sponsoring agencies and the NACMCF Executive
16 Committee have been discussing several priority
17 charges for NACMCF, but these are not yet fully
18 developed. The finalization of the next work charges
19 for NACMCF may not fall right in step with the next
20 plenary. So what we're going to do in order to start
21 work on these charges is get these issues out by e-
22 mail and also posted upon the web. That's going to

1 allow for subcommittees to begin to work on these
2 next charges.

3 And finally, very importantly, as soon as
4 you are able to fill out your travel expense sheets
5 for this meeting, please do so. The needed
6 information is in your meeting book. We are the end
7 of our fiscal year. So Karen is really going to be
8 cracking the whip to get the information in so she
9 can get you reimbursed.

10 And, of course, if you have any questions
11 or need assistance, get with Karen or me on this.

12 So I wish you a good meeting today, and now
13 back to Dr. Brackett.

14 DR. BRACKETT: Thank you, Gerri. So we'll
15 get going rather quickly here, and we're going to
16 start by hearing from Dr. Uday Dessai with a report
17 from the Subcommittee on the Determination of the
18 Most Appropriate Technologies for the FSIS to Adopt
19 in Performing Routine and Baseline Microbiological
20 Analyses. So, Uday.

21 DR. DESSAI: Thank you, Dr. Brackett, and
22 welcome.

1 We have two documents in front of you. One
2 is the slide presentation for the report of NTSC,
3 which is the New Technologies Subcommittee of NACMCF.
4 As far as the slides are concerned, I'm not going to
5 go into the details of each slide. I'm just going to
6 summarize the slides.

7 The meeting was held September 24th through
8 the 28th. There were 13 Subcommittee members and a
9 number of specialists, invited specialists and
10 presenters who were at the meeting. Six
11 presentations were held to expand the understanding
12 of new technologies for the Subcommittee, and the
13 discussion that happened over the three days was
14 towards narrowing down our understanding of the
15 charge. The charge in itself is very large in scope.
16 So the Subcommittee deliberated a number of times to
17 condense the charge so the charge can be addressed in
18 a meaningful manner.

19 The six presentations were done to further
20 explore the dimensions and the depth of the topics
21 shown on slide number 3.

22 Slides 4 to 7, the Subcommittee debated on

1 the approach and the focus for the charge.

2 And on slide 9, we have the final approach
3 in the form of an outline. This is an outline of the
4 report. The report is going to look similar to what
5 you see on slide 9. The items might change very
6 slightly, and we will make reference to the charge
7 questions and sub-questions in the report in item 1,
8 2, 3, 4, as it applies.

9 Now slide 10, we've listed all the invited
10 speakers as well as invited experts, and you see a
11 number of those who are from FSIS, FDA, as well as
12 the invited speakers from different areas with
13 different levels of expertise in topics that were
14 relevant to this Subcommittee.

15 And with that, I'm open to questions.
16 Subcommittee members do contribute when needed if
17 there are questions.

18 DR. BRACKETT: Do we have any questions
19 about the report?

20 (No response.)

21 DR. BRACKETT: Apparently not. So thank
22 you very much, Uday.

1 The work that this Subcommittee has been
2 doing is very much appreciated and is of interest to
3 a lot of people that are outside this room as well.

4 The second report we'll hear is from
5 Dr. Don Zink, who is the Chair of the Subcommittee on
6 Parameters for Inoculated Pack/Challenge Protocols,
7 and this Subcommittee is also early in their work, on
8 their assigned charge, and so I will turn it over to
9 Don to give the report on that.

10 DR. ZINK: The Subcommittee met for the
11 first time since receiving the charge on the 26th and
12 27th of this month. What we found initially is that
13 all of the prior attempts to do this type of a
14 document usually either centered very narrowly on a
15 particular organism or type of food or else the
16 recommendations were of a general nature or
17 guidelines for performing these types of studies.

18 It's our intent to write something that's a
19 good bit more specific and what we've realized is
20 that there's a certain amount art and experience that
21 goes into these kinds of studies, and it's not an
22 easy matter to convey that in the written word and in

1 an organized way. But I think we're off to a great
2 start. We've already put quite a bit of words on
3 paper and devoted quite a bit of time to charts or
4 tables or visual ways of presenting the information.
5 So I think we're off to a good start, and we'll be
6 able to come up with a unique and comprehensive
7 document.

8 DR. BRACKETT: Okay. Thank you, Don.
9 We're going to look forward to some of the further
10 developments from this Subcommittee as well as you
11 tackle this very important food safety issue in the
12 future.

13 According to the agenda, we are scheduled
14 for a break, but I don't think we'll do that. We'll
15 pass on that and move into something where we
16 actually have some deliberations to do. And so we're
17 going to back to Dr. Zink again.

18 The final report that we'll hear today is
19 one that will be up for adoption as well, and this
20 will be Dr. Zink who is also the Chair of the
21 Subcommittee on Assessment of the Food Safety
22 Importance of *Mycobacterium avium* subspecies

1 *paratuberculosis*, and we will go through the report
2 as is traditional, page by page, with comments, and I
3 will turn this over to Don for the discussion and
4 deliberations.

5 DR. ZINK: Before we go through this on a
6 page by page way, I'd like to make mention of two
7 aspects.

8 One, most microbiologists are mindful of
9 the fact that the vast majority of microorganisms on
10 the face of the earth actually cannot be cultured or
11 have not been cultured in pure form on our official
12 media. And for these bacteria, we have no idea what
13 they're life is like in the real world. I would
14 characterize *Mycobacterium avium* subspecies
15 *paratuberculosis* as an organism that's on the fringe
16 of just having been cultured in pure form on
17 artificial media. It's a very difficult organism to
18 work with. It takes a very long time to culture the
19 organism on solid media or even in liquid media, and
20 this fact has been a factor in confounding a lot of
21 the methodology, the efficacy of the methodology in
22 recovering and enumerating the organism. And it adds

1 in my opinion a fair degree of uncertainty to the
2 body of literature on MAP.

3 Certainly things have improved over the
4 years and the Committee focused and limited itself to
5 what we felt was the most recent and most relevant
6 literature. We also paid special attention to the
7 quality of the sources of information that we used.
8 In many cases, we did have to use abstracts or
9 proceedings papers that did not appear in peer
10 reviewed articles. And when we did that in the
11 report, we tried to specifically identify the source
12 as a non-peer reviewed source, an abstract or meeting
13 proceeding.

14 The second point is the conundrum of MAP is
15 that there are a number of excellent studies that
16 show that current milk pasteurization processes
17 inactivate the organism. Depending on which study
18 you read and how that study was conducted, these
19 studies demonstrate anywhere from a 4 to a 7 log
20 reduction of the microorganism when given the minimum
21 pasteurization requirement typical of Europe or the
22 United States.

1 I would point out, too, that most milk
2 producers give their products more than the minimum
3 requirement (for pasteurization) that is listed in
4 Europe or U.S. regulations. However, there are
5 several studies that clearly show that this organism
6 can be recovered from a small percentage of retail
7 pasteurized fluid milk products and the percentage of
8 this ranges as high as 2.8 percent in one study.

9 It is tempting to conclude that the
10 organism survives pasteurization but if you go back
11 to my earlier remarks about how very little we know
12 about how this organism really behaves and lives in
13 the environment, the Committee was of the opinion
14 that a more conservative interpretation was warranted
15 and that the possibility of post-process
16 contamination is very real and hasn't really
17 adequately been investigated.

18 So for the present, we have no certain
19 explanation of why we have an organism that is
20 apparently significantly reduced in numbers by
21 pasteurization processes yet is present in low
22 numbers in a small percentage of fluid milk samples.

1 So with that, I'd like to begin. And
2 actually we begin on the title page. The Committee,
3 as committees often do, changed the title of the
4 report. You'll recall that we were tasked to
5 specifically avoid delving into the role of MAP as a
6 human pathogen. And so we changed the title from
7 Assessment of the Food Safety Importance of
8 *Mycobacterium avium* subspecies *paraTB*, to Assessment
9 of Food as a Source of Exposure to *Mycobacterium*
10 *avium* subspecies *paraTB*, since we made no attempt to
11 determine whether or not this organism was or wasn't
12 a food safety risk.

13 I guess I'd like to move into the Executive
14 Summary which begins in your document on page 4.
15 Does anyone have any comments on page 4?

16 DR. SCHAFFNER: Actually, it's not on page
17 4. It's a minor point, but the Table of Contents is
18 not right.

19 DR. BRACKETT: State your name and
20 affiliation, Don.

21 DR. SCHAFFNER: Don Schaffner, Rutgers
22 University. It's not on the Executive Summary

1 actually. The Table of Contents, the numbering is
2 not correct. It's a minor point, but it needs to be
3 fixed.

4 DR. ZINK: Okay. Thank you.

5 (No response.)

6 DR. ZINK: No comments on page 4. How
7 about page 5?

8 (No response.)

9 DR. ZINK: Page 6?

10 (No response.)

11 DR. ZINK: Page 7?

12 (No response.)

13 DR. ZINK: Page 8?

14 (No response.)

15 DR. ZINK: Page 9?

16 (No response.)

17 DR. ZINK: Page 10?

18 (No response.)

19 DR. ZINK: Page 11?

20 (No response.)

21 DR. ZINK: Page 12?

22 DR. BRACKETT: Walt Hill.

1 DR. HILL: Walt Hill, Institute of
2 Environmental Health. I have a question about the
3 word "potential" in line 232, "potential sample," and
4 also coupled with the verb past tense "has." So it
5 seems to me there's kind of a contradiction on
6 something being a potential sample but that has been
7 looked at.

8 DR. ZINK: Okay. What line was that on
9 again?

10 DR. HILL: Line 232 and 233.

11 MS. SCOTT: Can we clarify are we working
12 off the document with or without tracking. This is
13 Jenny Scott.

14 DR. ZINK: I'm working off the document
15 without track changes.

16 DR. HILL: It's on page 13.

17 DR. ZINK: There were no comments on 12.
18 So we're on 13. Okay.

19 DR. HILL: It's line 231 and 232.

20 DR. ZINK: Okay. Okay. You're saying
21 change -- what were the changes again?

22 DR. HILL: Well, the statement "potential

1 sample" to me had kind of a funny ring to it, and I
2 guess what is meant by that is that something could
3 be tested, and if it was tested, then it would be a
4 sample, and then the use of the past tense verb "has"
5 because potential seems in the future.

6 DR. ZINK: How about if we delete the word
7 "potential" and change "has" to "have"?

8 DR. HILL: Fine.

9 DR. ZINK: Is everybody okay with that?
10 Jenny.

11 MS. SCOTT: Just before you change "has" to
12 "have," I think that just removing the word
13 "potential" solves the problem, and the ability to
14 culture has been limited by significant challenges is
15 what we're saying.

16 DR. ZINK: So leave it as "has."

17 MS. SCOTT: Yes.

18 DR. ZINK: Is everybody for leaving it as
19 "has"?

20 MS. SCOTT: My mistake.

21 DR. ZINK: "Have."

22 MS. SCOTT: It's "have." The ability to

1 culture and detect. "Have," right.

2 DR. ZINK: Okay. "Have" it is. Any
3 further comments on page 13?

4 (No response.)

5 DR. ZINK: Page 14?

6 (No response.)

7 DR. ZINK: Page 15? Lee-Ann?

8 DR. JAYKUS: Lee-Ann Jaykus, North Carolina
9 State University. On page 15, line 280, I just
10 suggest removing "before transfer into growth media"
11 because it's redundant from the previous sentence.

12 DR. ZINK: You want to delete "before
13 transfer into growth media."

14 DR. JAYKUS: Because you say exactly the
15 same thing in the previous sentence.

16 DR. ZINK: Okay. Is everyone okay with
17 that?

18 (No response.)

19 DR. ZINK: Okay. Any more comments on page
20 15?

21 (No response.)

22 DR. ZINK: Page 16?

1 (No response.)

2 DR. ZINK: Page 17? Lee-Ann?

3 DR. JAYKUS: Lee-Ann Jaykus, North Carolina
4 State University. I'm working off two different
5 documents. So I think it's page 17, it would be line
6 326. Can we change that to "cell number" rather than
7 quantity?

8 DR. ZINK: You want to change the word
9 "quantity" to "sum."

10 DR. JAYKUS: "Cell number."

11 DR. ZINK: "Cell number."

12 DR. JAYKUS: I think it's a little clearer.

13 DR. ZINK: Is everyone okay with that
14 change?

15 (No response.)

16 DR. ZINK: Okay. Any more comments on page
17 17?

18 (No response.)

19 DR. ZINK: Page 18?

20 (No response.)

21 DR. ZINK: Page 19?

22 (No response.)

1 DR. ZINK: Page 20? Jenny?

2 MS. SCOTT: We had some comments sent in by
3 Irene Wesley, and I guess I can bring them up as we
4 come to them, but in line 400, she recommended adding
5 "potentially" between "can" and "enter," so that it
6 says, "MAP, which is shed in the feces of infected
7 animals, can potentially enter the food supply,"
8 which I think is a good change.

9 DR. ZINK: Okay. Is everyone all right
10 with inserting the word "potentially"?

11 (No response.)

12 DR. ZINK: In reviewing the document
13 yesterday, the Subcommittee also found something on
14 line 405 that they wanted to change. If you look at
15 the sentence that begins, "Since MAP has an obligate
16 intercellular pathogen," this is an incorrect
17 statement. MAP is not an intercellular pathogen, and
18 we propose changing that sentence to, "Since MAP is
19 an extremely fastidious pathogen (requiring
20 *Mycobacterium J* for in vitro culture), it is unlikely
21 to grow in the environment or food." Is everyone
22 okay with that change?

1 UNIDENTIFIED FEMALE SPEAKER: Can you read
2 that again please?

3 DR. ZINK: The sentence would read, "Since
4 MAP is an extremely fastidious pathogen (requiring
5 *Mycobacterium J* for in vitro culture), it is unlikely
6 to grow in the environment or food." Okay.

7 Any comments on page 20?

8 (No response.)

9 DR. ZINK: Page 21? Lee-Ann?

10 DR. JAYKUS: Lee-Ann Jaykus, North Carolina
11 State University. I believe that on line 429, well,
12 the sentence that begins on 428, should read,
13 "Because the study focused on positive herds, the
14 2002 NAHMS Dairy Study cannot be used to accurately
15 estimate the true prevalence of positive animals in
16 the U.S."

17 DR. ZINK: Okay. Change the word "herd" to
18 "animals." Is everyone okay with that change?

19 (No response.)

20 DR. ZINK: I think that's correct. Okay.

21 Page 22?

22 (No response.)

1 DR. ZINK: Page 23?

2 (No response.)

3 DR. ZINK: Page 24?

4 (No response.)

5 DR. ZINK: Page 25?

6 (No response.)

7 DR. ZINK: Page 26? Tim.

8 LTC STEVENSON: Tim Stevenson, Department
9 of Defense, Veterinary Service Activity. I had a
10 question if the Subcommittee ran across any numbers
11 if an infected cow were milked, just one cow, what
12 would the levels be in the raw milk, and I realize
13 that there's a lot of dilution in the bulk tank, but
14 did you run across numbers from an infected cow per
15 ml?

16 DR. MADDEN: Joseph Madden, Neogen
17 Corporation. The problem that you have with this
18 organism is you have to go through a decontamination
19 step and enrichment steps. So quantitatively that's
20 one of the problems we had when we were reviewing all
21 of the data on this organism and culture method. So,
22 no, we did not find any real quantitation.

1 However, there are some that says it's
2 probably less than 1 to 10 per milliliter.

3 LTC STEVENSON: And that was my assumption
4 as a veterinarian and some understanding of the
5 disease that it's not shed in the milk in extremely
6 large quantities, and then when you take the dilution
7 with the bulk tank and the milk going into the whole
8 herd, probably the levels going even into the
9 pasteurization process would be extremely low. And I
10 thought that would be valuable if we could put that
11 in, if that's an important part of data, but if the
12 research can't support that, then I guess we can't
13 put that in.

14 DR. ZINK: As I recall, all the references
15 to numbers we saw were very low.

16 LTC STEVENSON: Okay.

17 DR. ZINK: Jenny?

18 MS. SCOTT: To Tim's question, Jenny Scott.
19 I don't think that we had anything that was
20 specifically a single cow from a positive herd or
21 fecal positive cow and that the milk was from that
22 cow. The closest to this would come in the Gao study

1 (Gao et al. 2002. Effect of pasteurization on
2 survival of MAP in milk. J. Dairy Sci.) where they
3 looked at quarter milk samples of infected herds, but
4 again, they were pooled, too. So I think that in
5 order to enhance the detection, they were pooling
6 milk from positive herds or positive cows.

7 DR. ZINK: Robin King has her flag up. Did
8 you have a comment?

9 LTC KING: Robin King, DOD, VSA. Actually,
10 I was wanting to go back to page 21 to clarify that
11 change, in changing that one word "herd" to
12 "animals." I thought that the NAHMS 2002 Study was
13 based on using only positive herds and it was herd
14 prevalence that we were concerned about, and so we
15 couldn't use that study to determine true herd
16 prevalence because they were only focusing on the
17 positive herds in the country and not to try to
18 figure out, you know, statistically how many herds
19 were positive. So if we change that word to
20 "animals," then we've changed the meaning of that
21 sentence.

22 DR. ZINK: Right. The statement is true

1 that you can't use that study to determine the number
2 of or prevalence of positive animals in the U.S., and
3 you also can't use it to determine the prevalence of
4 positive herds in the U.S.

5 DR. BRACKETT: Dean Cliver and then Jenny
6 Scott. Dr. Cliver.

7 DR. CLIVER: Dean Cliver, UC Davis. In the
8 immediate thing, it seems to me you could say "herds
9 or animals" and cover both contingencies. It's not
10 an either or proposition, I mean in the context.
11 What I actually wanted to comment on and I don't have
12 a specific place for it, but my Ph.D. before NOAA was
13 on physiology and milk secretion. Implicitly in the
14 way some of these samples were collected by quarter
15 and so on, it seems to me that the supposition was
16 that the agent was being shed via the mammary gland
17 but there were other places where there was an
18 outright statement that what if this was fecal
19 contamination in the milk. And it seems to me that
20 those are two very different modes of contamination.
21 At some point, the suppositions ought to be
22 reconciled or else if we're saying it is either this

1 or it is that. That ought to be stated explicitly
2 because it just kind of sneaks in here and there.

3 DR. BRACKETT: Jenny?

4 MS. SCOTT: I think we've complicated this
5 sentence, and we need to do a fix here. The sentence
6 before specifically indicates the percentage of
7 animals in the positive herds. So it is reasonable
8 to suggest that that percentage is not accurate
9 because it focused on positive herds, but then we
10 continue with that sentence and say that the 2007
11 NAHMS Study may provide more accurate information on
12 herd prevalence of MAP. So we do need to figure out
13 whether it would be herd or animals in both
14 instances. And maybe the best fix would be to say
15 that it can't be used to accurately estimate the true
16 prevalence of either positive herds or animals, and
17 that the 2007 study may provide more information.

18 DR. ZINK: I think the proposal is to
19 change that to "positive herds or animals." If
20 everyone agrees, we'll --

21 DR. BRACKETT: Just for the sake of
22 recordkeeping, what would the wording be again,

1 Jenny, that you're suggesting?

2 MS. SCOTT: I think that it would be that
3 "The study cannot be used accurately to estimate the
4 true prevalence of positive herds or animals in the
5 U.S.," and then the next sentence would also have to
6 be changed to say that "The 2007 NAHMS Study, yet to
7 be published, may provide more accurate information
8 on herd or animal or herd and animal prevalence of
9 MAP."

10 DR. ZINK: Okay. Is everyone in agreement
11 with those two pages?

12 (No response.)

13 DR. ZINK: Okay. Previously we were on
14 page 23.

15 (No response.)

16 DR. ZINK: 24? Linda Harris?

17 DR. HARRIS: Linda Harris UC Davis. Line
18 498, you say "natural water." I wasn't entirely sure
19 what natural water was as opposed to unnatural water.

20 DR. ZINK: Yeah, I see it.

21 DR. HARRIS: I think you could just say
22 water as opposed to sediments, right? I think that's

1 what you mean, water versus sediment.

2 DR. ZINK: Okay. Everybody okay with
3 deleting the word "natural"?

4 DR. HARRIS: Well, Kathy has whispered in
5 my ear. She said as opposed to meaning municipal
6 water. So environmental sources of water I guess is
7 perhaps --

8 DR. ZINK: Jenny?

9 MS. SCOTT: Could we fix it by saying both
10 water and water sediments from the environment?

11 DR. ZINK: Is everyone in agreement with
12 that change, to delete the word "natural" and insert
13 "from the environment" at the end of the sentence?

14 (No response.)

15 DR. ZINK: Okay. Page 25.

16 DR. BRACKETT: One moment. Scott.

17 DR. BROOKS: Just a minor clarification. I
18 noticed that it was attributed to reference 61 and
19 the title of 61 says "Survival of MAP in Dam Water
20 and Sediment." I don't know if that helps clarify it
21 or not.

22 DR. ZINK: So presumably a lake or a very

1 large pond. Yeah.

2 Page 25? Kathleen?

3 DR. GLASS: Kathy Glass, University of
4 Wisconsin-Madison. I guess the only one I'm looking
5 at is municipal water treatment, number 5, 11 line
6 number, it says "municipal water treatment." That's
7 assuming that this is going to be standard treatment
8 with chlorination or are there other municipal water
9 treatments that we haven't considered besides
10 chlorine? That's more of a question.

11 DR. ZINK: Jenny.

12 MS. SCOTT: Yeah, there are all of the
13 flocculations, filtrations and other treatments that
14 were in that, not just chlorination, especially since
15 MAP is fairly resistant to chlorine. It is more a
16 removal process that went in there.

17 DR. ZINK: Kathy, do you want us to clarify
18 that in some way by inserting the phrase
19 "particularly filtration or flocculation"?

20 DR. GLASS: I think it would be important
21 to identify what kind of water treatment you'd be
22 looking at. So it's not considered just chlorination

1 because I don't see anything else within the above
2 statements that would suggest that unless you go back
3 to the source, the references.

4 DR. ZINK: Dean and then Jenny.

5 DR. CLIVER: Dean Cliver, University of
6 California, Davis. I've worked with EPA on these
7 things. By definition, complete drinking water
8 treatment for public water supplies, if the water is
9 of surface origin or ground water under the influence
10 of surface water, it has to include coagulation,
11 filtration, sedimentation and then disinfection. If
12 the water is of ground water origin and not under the
13 influence surface water, it may just be chlorinated.
14 But I think in the context, of what we're doing here,
15 if water had been defined first as surface water, why
16 then the EPA standard for community drinking water
17 treatment would subsume all of those steps.

18 DR. ZINK: I'd make one comment that may
19 influence your comments, Dean. Lee-Ann just pointed
20 out that the data in the preceding text of the
21 paragraph is all from outside the United States.
22 Would you expect that similar requirements or

1 situations would prevail?

2 Okay. Jenny?

3 MS. SCOTT: Jenny Scott. I think that this
4 came up in our discussions, and we went back to the
5 papers and looked at what treatment was used there,
6 and it was some long name that we decided to -- it
7 was like counter current blah, blah, blah, I think
8 basically a sedimentation and filtration type of
9 system, but then we are using that information to
10 make a statement here. So I think that the Committee
11 could conclude that municipal water treatment
12 according to current EPA requirements would be
13 sufficient to reduce the numbers of MAP in water.
14 That would be a true statement if we wanted to make
15 the change along those lines.

16 DR. ZINK: You're proposing inserting the
17 phrase, "according to U.S. EPA requirements."

18 Okay. Is everyone in agreement with that?

19 (No response.)

20 DR. ZINK: Okay. Page 26?

21 (No response.)

22 DR. ZINK: Page 27?

1 (No response.)

2 DR. ZINK: Page 28? Tim.

3 LTC STEVENSON: Tim Stevenson, DOD. I'm
4 assuming that after having been assigned to Europe
5 for the past 6 years that many of their cheeses are
6 made from raw or thermised milk, and at the bottom of
7 the page, line 586 through 588, it cites retail
8 cheeses from Greece and the Czech Republic. Does
9 anyone on the Subcommittee recall, did the reference
10 state whether those cheeses were made from raw milk
11 or thermised milk or pasteurized milk?

12 DR. ZINK: Jenny?

13 MS. SCOTT: We looked for that, and there
14 was no indication unfortunately whether the milk had
15 been pasteurized or heat-treated in any way.

16 LTC STEVENSON: Perhaps we could add that
17 statement in that it was unclear from the reference
18 whether or not these cheeses were made from
19 pasteurized milk.

20 MS. SCOTT: Could I suggest we say that the
21 study did not report whether or not the milk used in
22 manufacturing the cheese had been heat treated in any

1 way.

2 LTC STEVENSON: Great.

3 DR. ZINK: To add specific wording, "The
4 study did not report whether or not these cheeses
5 were pasteurized or heat treated," or "the milk," in
6 the report.

7 MS. SCOTT: Jenny Scott. I think you have
8 to say, "whether the milk used to manufacture these
9 cheeses had been heat treated."

10 DR. ZINK: Okay. So the sentence would
11 read, "This study did not report whether or not the
12 milk used to manufacture these cheeses had been heat
13 treated." Okay. No further comment?

14 (No response.)

15 DR. ZINK: Page 29?

16 (No response.)

17 DR. ZINK: Page 30?

18 (No response.)

19 DR. ZINK: Page 31?

20 (No response.)

21 DR. ZINK: Page 32?

22 (No response.)

1 DR. ZINK: Page 33? Tim?

2 LTC STEVENSON: Line number 700, it talks
3 about milk processing with turbulent flow. Just a
4 small point of clarification, but our PMO
5 (*Pasteurized Milk Ordinance*) would normally classify
6 that as laminar flow and they try to prevent
7 turbulent flow through a normal processing system.
8 Could we replace that word "turbulent" with the word
9 "laminar flow"?

10 DR. ZINK: Any objections? Jenny?

11 MS. SCOTT: I think we ought to go check
12 that. Tim, did you go back and look at the PMO on
13 that? Or does it just require you to do the
14 calculations based on laminar flow which would be a
15 worse case situation because I think in practice, the
16 process would actually be turbulent flow.

17 LTC STEVENSON: There may be some
18 turbulence in the entire process, but the holding
19 tube is laminar flow, and there's many requirements
20 describing the engineering therein to prevent
21 turbulent flow because with turbulent flow, you can't
22 have accurate time recording for the processing. You

1 can't track the time that the particles in milk go
2 through the holding tube unless there's laminar flow.
3 So there are excruciating design details to ensure
4 the laminar flow at least in the holding tube. I
5 wouldn't argue that somewhere in the system there's
6 turbulence certainly in the homogenizer, but the heat
7 step and the holding tube are laminar flow. And the
8 PMO would support that.

9 DR. ZINK: I'm thinking that for any system
10 that has a holding tube, it probably would be laminar
11 in the tube. I guess it would be turbulent in the
12 heat exchanger. There are degrees of turbulence in a
13 laminar flow and, Jenny, I'll let you talk about
14 that.

15 MS. SCOTT: Jenny Scott. It's kind of a
16 past life there, and could I suggest that we fix this
17 by deleting the "using turbulent flow" from that
18 sentence and then we can go back and look it up. I
19 don't really think that it is critical to what we're
20 trying to say there. I'm just not comfortable with
21 just changing it to "laminar flow" because I really
22 think that it is turbulent flow in there.

1 DR. ZINK: Your proposal is just to delete
2 the word "using turbulent flow"?

3 LTC STEVENSON: But I do think that it's a
4 lead in to the rest of the paragraph where we're
5 talking about different effects of heat treatment,
6 whether or not it's a placid system sitting in a
7 batch versus turbulence or somewhere through the heat
8 processing system, that impacts the effect of heat on
9 the organisms. So I think there's value in having
10 that in the introductory sentence there. I just
11 don't want to confuse that part with -- maybe we
12 could say there's certainly, and I wouldn't disagree
13 that there's turbulence somewhere in the modern
14 pasteurization processing systems, but I just don't
15 want that to be a point of confusion in the holding
16 tube.

17 DR. ZINK: Dan Engeljohn, you're next.

18 DR. ENGELJOHN: Engeljohn with FSIS. Well,
19 perhaps you could put the word "flow" in front of
20 "processing." So it's "continuous flow processing
21 system."

22 DR. ZINK: Don Schaffner has his card up as

1 well.

2 DR. SCHAFFNER: Don Schaffner, Rutgers
3 University. I would have to agree with Jenny. I
4 think if we just strike the phrase using "turbulent
5 flow," it makes that sentence not create the
6 controversy, and there is a statement later on page
7 34 about the degree of turbulence, distribution of
8 residence times, and I think we all agree that that's
9 important, and the issue of batch versus continuous
10 processing is also important but again, I would say I
11 would agree with Jenny. Just striking those three
12 words from the sentence on line 700, I don't think by
13 doing that you failed to set up the rest of your
14 paragraph.

15 DR. ZINK: So the proposal is to -- are you
16 okay with inserting the word "flow" after
17 "continuous," Don?

18 DR. SCHAFFNER: No comment.

19 DR. ZINK: Jenny, are you okay with that?
20 So we would change the sentence to end, "continuous
21 flow processing systems."

22 MS. SCOTT: Yes.

1 DR. ZINK: Okay. Page 34?

2 (No response.)

3 DR. ZINK: Page 35? Tim?

4 LTC STEVENSON: Tim Stevenson, DOD. Line
5 number 739, the last part after the last clause of
6 that sentence, "as well as potential for laboratory
7 contamination during sample analysis." I assume that
8 came out of the reference, but it just seems to come
9 out of left field to me and it wasn't set up and
10 normally we wouldn't expect laboratory contamination.
11 We wouldn't just make that assumption. So I'm
12 wondering why the importance of that and possibly we
13 can just strike that last clause.

14 DR. ZINK: As I recall, the Subcommittee
15 members can chime in, there were instances in earlier
16 studies where laboratory strains appeared to
17 contaminate samples. And I think we found it was
18 particularly important for laboratories to take
19 control measures and verify that strains they
20 recovered did not, in fact, come from their own
21 laboratory. That was why that was put in there. And
22 the article specifically does make, if you look at

1 reference 214, the article's entitled "*Mycobacterium*
2 *bovis* Cultured from Commercially Pasteurized Cow's
3 Milk: Laboratory Cross-Contamination." Robin?

4 LTC KING: Robin King, DOD. Actually what
5 that study recited really is just dealing with TB.
6 They didn't mention MAP in there at all but there was
7 a possibility because of the cross-contamination in
8 using other types of *Mycobacterium* and there was a
9 possibility that, you know, that could always happen
10 with MAP. I don't know if we had any other studies
11 that indicated cross-contamination with MAP in the
12 laboratory.

13 DR. ZINK: Okay. Jenny?

14 MS. SCOTT: Jenny Scott. As I recall that
15 study, they had been looking for both TB and paraTB.
16 It was the TB that was the cross-contamination
17 problem. They had been using the hood for some
18 tissue samples from some TB positive cows I think
19 previous to that, and that's where the cross
20 contamination came from. It probably is a remove
21 scenario. Well, I wouldn't have any heartburn with
22 removing that.

1 DR. ZINK: As I recall, one of the earlier
2 grant papers, there were some allegations or
3 indications that some of the positive pasteurized
4 milk samples could have been strains from her own
5 laboratories. Does anybody have that recollection or
6 comment on that?

7 (No response.)

8 DR. ZINK: Well, the proposal is to just to
9 strike that phrase or do you want to leave it?

10 LTC STEVENSON: Tim Stevenson. I'm fine
11 with the explanation and the context certainly if it
12 happened with one type of *Mycobacterium*, and with the
13 difficulty working with the organism, the laboratory,
14 it certainly could be. It just didn't pop up
15 immediately as to why that was important. I see it
16 in the reference, and I'm happy with that. So I
17 withdraw my comment, and I think it's okay to leave
18 it.

19 DR. ZINK: Okay. We'll leave it as is?

20 (No response.)

21 DR. ZINK: All right. Page 36? There was
22 a Committee comment on line 758, ends with the two

1 words, "of course." A suggestion that we strike
2 those two words. Any further comments on page 36?

3 (No response.)

4 DR. ZINK: Page 37? Lee-Ann Jaykus?

5 DR. JAYKUS: Lee-Ann Jaykus, North Carolina
6 State University. Even though I was on the
7 Subcommittee, I didn't read through this paper, and
8 I'm referring to the sentence between line 791 and
9 794, at the end of the page. The last phrase in that
10 sentence, "utilizing an identical aliquot as
11 control," it doesn't make any sense at all, but I
12 don't know the context because I didn't read the
13 paper. Is there anyway we can clarify it?

14 DR. ZINK: I'm assuming that they used an
15 aliquot of milk for which they did not have
16 macrophages containing MAP.

17 DR. JAYKUS: But then if you read the next
18 sentence, it says the results demonstrated a
19 difference between the survivable MAP in macrophages
20 when compared to the control free bacterial cells.

21 DR. ZINK: Yeah, why is in one, the MAP
22 were in macrophages and in the other, they were not.

1 DR. JAYKUS: Right. So I think you
2 probably can change that to say utilizing, you know,
3 non-macrophage -- I mean, I don't know what the right
4 word is free MAP as a control. But I want to make
5 sure that that's what they actually did.

6 DR. ZINK: How about if we go back and
7 check that reference and verify that that's what they
8 did. As I recall, they were looking at the
9 difference between intracellular and free MAP.

10 DR. BRACKETT: Dean Cliver and Robin King
11 also.

12 DR. ZINK: Okay.

13 LTC KING: I was just going to say that,
14 Robin King, DOD, that we could maybe put in there
15 just utilizing non-infected macrophages, but I kind
16 of agree with Don, that maybe we should check the
17 reference and see what it was they actually used.

18 DR. BRACKETT: Dean.

19 DR. ZINK: Dean.

20 DR. CLIVER: Dean Cliver, UC Davis. I bit
21 my tongue when I read that sentence. I review a lot
22 of manuscripts for publication in journals and the

1 word "aliquot" has been used to death. My dictionary
2 says it means something that when you divide
3 something into an even number of parcels with no
4 remainder, each of them is an aliquot. This is a
5 sample.

6 DR. ZINK: Then whatever we do with that
7 phrase, we'll get rid of "aliquot" and change it to
8 "sample." I think we should probably look and see if
9 we use aliquot anywhere else. We'll do that.

10 DR. BRACKETT: So just to repeat, we're
11 going to go back and check the references. Is that
12 correct?

13 DR. ZINK: Yes. Check the reference and
14 clarify it. Don?

15 DR. SCHAFFNER: Now that we've decided to
16 go back and check the reference, can I just suggest
17 that we just strike that phrase because it's clear
18 from the following sentence what the control in the
19 experiment was. So if you just have it read,
20 "containing MAP were added directly to the milk
21 samples, the results of the study demonstrated no
22 significant difference between the survival of MAP in

1 macrophages when compared to the control."

2 DR. ZINK: Is everyone all right with that?
3 It certainly takes care of the "aliquot" issue, too.

4 DR. JAYKUS: Lee-Ann Jaykus. I would still
5 feel comfortable if you guys would check that
6 reference please.

7 DR. ZINK: Okay. We'll check the reference
8 and verify that that was indeed the nature of the
9 control, and if it is, we'll just strike the last
10 part of that sentence. Okay. All right. Page 38?

11 In review its work, the Subcommittee found
12 on line 810 where it says, "properly operated and
13 validated pasteurizers operating at 72 degrees."
14 We're going to change that to so that it would read,
15 "validated pasteurizers treating milk at 72 degrees
16 Centigrade for 15 seconds."

17 Is everyone okay with that change?

18 (No response.)

19 DR. ZINK: No further comments on page 38?

20 (No response.)

21 DR. ZINK: Page 39? Joe?

22 DR. MADDEN: Joseph Madden, Neogen

1 Corporation. Thank you, Mr. Subcommittee Chair. I
2 just have a question and a proposal for the full
3 Committee that ends the section and line 820 on
4 pasteurization of milk. Do we want to make a
5 conclusion at this point that as written in the
6 Pasteurized Milk Ordinance, the time temperatures
7 appear to be adequate for the elimination or whatever
8 of this organism so that we do not want to change
9 those time temperature parameters because we have
10 uncertain data based upon the culturing techniques
11 used, and everything else. And I propose we put some
12 type of conclusion at the end of this section and
13 then at the conclusion of the report regarding
14 pasteurization, and I had a statement if I could read
15 it that I would propose and then turn it over to the
16 Subcommittee Chair, if the Committee agrees.

17 DR. ZINK: Okay.

18 DR. MADDEN: What I propose is putting a
19 sentence in there that says, "It is the consensus of
20 the Committee to recommend based upon the efficacy of
21 methods used to-date for the detection of MAP, the
22 prevalence in milk products and the thermal

1 inactivation studies performed to-date, including the
2 possibility of post-process contamination, to
3 conclude that it is premature at this time to
4 recommend the time temperature parameters for the
5 pasteurization of fluid milk currently in place as
6 stated in the Pasteurized Milk Ordinance not be
7 changed until further investigations with
8 standardized methodologies be instituted by
9 investigators and the public health significant of
10 MAP is determined."

11 DR. BRACKETT: Coming from FDA's
12 perspective, I would oppose that language simply
13 because the objective of the Subcommittee is to
14 determine exposure in this case, with the title, not
15 to make policy recommendations. I would just leave
16 that out for that reason. Could you consider
17 modifying your statement? It's important, I think,
18 to have it in there about the efficacy of
19 pasteurization but just to leave it as a statement of
20 fact rather than recommendation.

21 DR. MADDEN: Joe Madden, Neogen
22 Corporation. Are you proposing I strike the last

1 part of that sentence which says, "until
2 investigations with standardized methods be
3 instituted by investigators" and then strike "and the
4 public health significance of MAP is determined"?
5 Strike that phrase?

6 DR. BRACKETT: Yeah, it would actually be
7 helpful to see what your written text is. I think
8 what we want to avoid is where the Committee is
9 actually making recommendations about what a policy
10 decision should be made, rather than a statement of
11 scientific fact about the organism itself.

12 Jenny Scott?

13 MS. SCOTT: Could I propose some simpler
14 wording along the lines of "the data do not indicate
15 a need to change the recommended times and
16 temperatures for milk pasteurization at this time"?

17 DR. ZINK: Joe.

18 DR. MADDEN: Joe Madden, Neogen
19 Corporation. That would be acceptable to me. No
20 problem.

21 DR. ZINK: Jenny, you want to repeat that
22 sentence?

1 MS. SCOTT: "The data do not indicate a
2 need to change the recommended times and temperatures
3 for milk pasteurization at this time."

4 DR. BRACKETT: I would counter propose that
5 maybe say, "The data do not indicate that the current
6 pasteurization conditions are ineffective" or
7 something to that effect, because again yours still
8 has an element of policy recommendation in it. I
9 guess the point here is that you're suggesting that
10 there's no data to say that pasteurization is not
11 working to eliminate the organism, and you can come
12 to say some statement like that full stop.

13 DR. ZINK: You had some suggested changes
14 in the wording, Jenny?

15 DR. BRACKETT: And also we have a comment
16 by Uday here as well.

17 DR. DESSAI: Uday, FSIS. I would say, "The
18 data are insufficient." That's what I heard in the
19 earlier case. It's not that the data do not
20 indicate, but it's insufficient at this time.

21 DR. BRACKETT: Jenny?

22 MS. SCOTT: Jenny Scott. Can I try then,

1 "The data are insufficient to suggest that the
2 current times and temperatures for milk
3 pasteurization are inadequate."

4 DR. BRACKETT: Since there's a lot of
5 wordsmithing going on with this, what I would
6 suggest, we're at the break time, that we break for
7 15 minutes and during that time, actually have
8 something written in front of us so that we can
9 respond to it appropriately. Does that sound
10 reasonable?

11 DR. ZINK: Yeah.

12 DR. BRACKETT: Okay. So it is now,
13 according to my watch, 10:12, or the official clock
14 up there is 10:12, let's reconvene at 10:25.

15 (Off the record.)

16 (On the record.)

17 DR. BRACKETT: At this time, Dr. Zink, do
18 you want to continue with this?

19 DR. ZINK: Okay. Jenny has put on the
20 screen up there a sentence for your consideration.
21 Does anyone have any comments on including this
22 sentence? Eli?

1 DR. PERENCEVICH: Just what does
2 "occurrence" mean? Is it prevalence? Is it
3 instance? Is it levels?

4 DR. ZINK: Jenny?

5 MS. SCOTT: Jenny Scott, GMA. I would
6 think that it would be both, and we could change it
7 to say "impact the prevalence or numbers of MAP in
8 milk."

9 DR. ZINK: So is the proposal to change
10 "occurrence" to "prevalence"? Would that be okay
11 with you, Eli?

12 DR. BRACKETT: Scott Brooks, comment?

13 DR. BROOKS: This is Scott Brooks of Food
14 Safety Net Services. Not to be too picky, but it
15 might be appropriate to use the term "incidence"
16 rather than "prevalence." You would be looking at
17 the number of new incidents, cases of contamination
18 of MAP in milk. It could be an argument that might
19 go on for a while about the --

20 DR. PERENCEVICH: Perencevich, VA Maryland.
21 Yeah, that's why I asked the question because it
22 could be interpreted a number of ways, but I think

1 what we mean is levels.

2 DR. BROOKS: Right.

3 DR. ZINK: By levels, do you mean numbers?

4 DR. PERENCEVICH: Numbers.

5 DR. ZINK: Peggy?

6 DR. COOK: Peggy Cook, Safe Foods. I'm
7 asking more of a question. Would we want to use the
8 word "increasing" or to suggest that changing the
9 pasteurization? And it's more of a question for the
10 Committee, which word.

11 DR. ZINK: I think the Committee, the sense
12 of the Committee was, and why this has come up, is
13 that there is concern that people will look at the
14 reported literature finding this in retail samples of
15 raw milk and even look at a few reports that showed a
16 pilot and commercial scale equipment that the
17 organism came through the pasteurization process, and
18 that some would conclude that there is a need to
19 increase pasteurization times and temperatures. And
20 our sense is that there are so many confounding
21 issues and variables and uncertainties with this
22 organism that we wanted to forestall such an implied

1 conclusion on anyone's part and, you know, say that
2 it would be premature to do that. So the concern was
3 that someone would want to increase pasteurization,
4 and that's what it intended to address with a
5 sentence like this. Kathy.

6 DR. GLASS: Kathy Glass, UW Madison. I
7 think it's real important for us to fine-tune and
8 make sure that we understand these are U.S.
9 pasteurization temperature and times, because I don't
10 know if that's the same all the way across the world,
11 too. And if people are, we're pretty U.S.-centric
12 here, a lot of the data is going to be coming from
13 outside, too, and people outside the U.S. are going
14 to be looking at it.

15 DR. ZINK: Certainly we could clarify that
16 it's a U.S. document, but what they do in Europe is
17 very, very similar. Jenny?

18 MS. SCOTT: I just want to point out that
19 in Europe, they did increase the time of
20 pasteurization to address the issue of MAP in milk
21 and it didn't make any difference.

22 DR. ZINK: Lee-Ann.

1 DR. JAYKUS: Lee-Ann Jaykus, North Carolina
2 State University. Could we say, "At this time there
3 are insufficient data to conclude that increasing
4 pasteurization times and temperatures would change
5 the incidence and/or levels of MAP in milk"?

6 DR. ZINK: Okay.

7 DR. BRACKETT: Do you want to repeat that
8 again?

9 DR. JAYKUS: "At this time there are
10 insufficient data to conclude that increasing the
11 pasteurization times and temperatures would change
12 the incidence and/or levels of MAP in milk." And
13 those of you who are the experts just can tell me if
14 those terms are correct. It really should be
15 "incidence and/or numbers." Numbers.

16 DR. BRACKETT: Barbara, you have your flag
17 up.

18 MS. KOWALCYK: Barbara Kowalcyk, CFI.
19 Actually I tried to make it more general, the
20 suggestion that I was going to propose is, "There's
21 insufficient data to draw inferences about the effect
22 on pasteurization times and temperatures on the

1 numbers of MAP in milk." And that would address the
2 European differences, I guess, versus U.S. that
3 somebody was talking about earlier.

4 DR. ZINK: Do you want to read that again,
5 and maybe we can put it up there.

6 MS. KOWALCYK: "There is insufficient data
7 to draw inferences about the effect of pasteurization
8 times and temperatures on the numbers of MAP in milk
9 or reducing the numbers of MAP in milk."

10 DR. ZINK: How about on "reducing
11 prevalence and/or numbers of MAP in milk"?

12 DR. BRACKETT: And it would be our
13 insufficient data.

14 DR. ZINK: "Incidence," not "prevalence."
15 Tim?

16 LTC STEVENSON: May I suggest that we just
17 take out the word "prevalence" or "incidence" because
18 it could be a debate, but we just put we're concerned
19 about the level or number of viable MAP in milk.
20 Incidence and prevalence is really describing disease
21 in the animal, and we're not concerned with that.
22 We're looking for level of viable bacteria in the

1 milk. So I think we still get the point, the number
2 or the level, when we take out that "incidence" or
3 "prevalence."

4 DR. BRACKETT: Uday, a question?

5 DR. DESSAI: Yeah, Uday, FSIS. I think we
6 should stay away from "prevalence," "levels" and
7 "incidence" in this case. Also the numbers, we may
8 have to use a qualifier, like "suspected numbers
9 anticipated," something, because this assumes that
10 there are those numbers all the time. So there might
11 be a qualifier needed to say whatever that is,
12 anticipated, suspected or expected numbers, something
13 like that.

14 DR. ZINK: What if we use the word
15 "occurrence" because in the studies we looked at --

16 (Laughter.)

17 DR. ZINK: Seriously, no one was
18 enumerating the organism in these retail milk
19 samples. It was either there or not there.

20 DR. BRACKETT: Barbara?

21 MS. KOWALCYK: Maybe rather than
22 "occurrence," "presence."

1 DR. ZINK: "Presence." She proposes -- I
2 guess your sentence would read, "There is
3 insufficient data to draw inferences about the effect
4 of pasteurization times and temperatures on the
5 presence of MAP in milk."

6 Anyone have any comments on these two
7 proposed sentences?

8 DR. BRACKETT: This is Bob Brackett. The
9 only problem with reducing is that you're talking
10 about an inference about pasteurization times and
11 temperatures. You could actually increase the
12 survival if you lowered the temperatures and times.

13 Art?

14 DR. LIANG: Yeah, how about influencing.

15 DR. ZINK: Proposed on influencing. Let's
16 say Dean, Robin and then Peggy.

17 DR. CLIVER: "Data are," not "data is."

18 DR. COOK: Peggy Cook. My question
19 concerning the word was regulatory-wise, you know, so
20 that kind of takes that out of it. You're not giving
21 direction as far as, you know, anything regulatory-
22 wise. So I like that as far as changing that word

1 particularly.

2 DR. ZINK: Robin.

3 LTC KING: Robin King, DOD. Personally I
4 think that second phrase is a little too general, in
5 that earlier in the document we say that it
6 decreases, "it appears that the number of
7 microorganisms are decreased at 4 to 7 log." So I
8 mean I think we have to deal with the change, any
9 kind of change in current practices. If we have to
10 refer to that, it needs to be a little more specific.

11 DR. ZINK: Linda.

12 DR. HARRIS: That was similar to my
13 comment. Linda Harris, UC Davis. The second one, it
14 almost says that there isn't enough data to even
15 recognize that there's any reduction of MAP when you
16 pasteurize milk, and I think the previous conclusion
17 or statements from the Committee is that there's a
18 demonstrated reduction of MAP when you apply
19 pasteurization temperature in milk. So I wouldn't
20 want people to dismiss pasteurization with that
21 sentence.

22 DR. ZINK: John.

1 DR. SOFOS: Sofos. I agree with that
2 because the paper actually concludes that there is
3 evidence for a 4 to 7 log reduction.

4 DR. ZINK: Bob, how do you feel about
5 these?

6 DR. BRACKETT: We have Jenny Scott here,
7 too.

8 MS. SCOTT: I'm just wondering if we, Jenny
9 Scott, GMA, if we couldn't go back to the first one
10 and modify the end of that as we have changed the end
11 of the second one, to say that "at this time, there
12 is insufficient data to conclude that increasing the
13 pasteurization times and temperatures would reduce
14 the presence of MAP in milk."

15 DR. ZINK: Bob? Uday.

16 DR. DESSAI: Uday, FSIS. I would still
17 think the number needs to be qualified, low numbers
18 or infrequent and low numbers. There should be
19 something there because this doesn't give us the
20 sense of what is the prevalence, what is the number.
21 It just assumes it. So there should be some
22 qualifier: low numbers or ordinarily low numbers,

1 existing low numbers. Something that qualifies it.

2 DR. ZINK: We were talking about the -- in
3 this part of the document, we report literature
4 findings of the organism in up to what, 2.8 percent
5 of retail pasteurized milk, and we don't have any
6 numbers of the organisms in those milk samples, but
7 we have only the mere, you know, presence, if you
8 will of it in the milk. Eli?

9 DR. PERENCEVICH: Perencevich, VA Maryland.
10 Presence, not prevalence.

11 DR. ZINK: Uday, did you have a further
12 comment?

13 DR. DESSAI: Yeah, 2.5 percent, could that
14 be then equated to prevalence, not the numbers of
15 organisms, in terms of --

16 DR. ZINK: Right.

17 DR. DESSAI: -- but that could be
18 prevalence.

19 DR. ZINK: I'll refer to our experts on the
20 correct use of "prevalence" or "presence" or
21 "occurrence" or --

22 DR. DESSAI: There are two aspects. Number

1 one is of the 100 samples, let's say 2.5 are
2 positive. The second issue is of those 2.5 which are
3 positive, once you apply pasteurization and there
4 were -- numbers, those numbers getting reduced, not
5 getting completely eliminated. So there are two
6 aspects to this which need to be captured.

7 DR. ZINK: Don?

8 DR. SCHAFFNER: Don Schaffner, Rutgers
9 University. I would argue to leave it as "presence"
10 because we're really talking about numbers that are
11 pretty squishy and not real solid, and by saying
12 presence, we're just being I think sufficiently
13 general. I don't want to really talk about
14 prevalence in concentration, because we're just not
15 real confident in those numbers.

16 DR. ZINK: Is there a consensus that the
17 Committee can live with that first sentence as it's
18 now written?

19 (No response.)

20 DR. ZINK: Okay. If there are no fall on
21 the sword objections, then we'll insert that sentence
22 at line 820 and go on. Are there further comments on

1 page 39?

2 (No response.)

3 DR. ZINK: Page 40? Eli?

4 DR. PERENCEVICH: Perencevich, VA Maryland.

5 At the end of this, kind of going through the cheese,
6 I wanted to take us back unfortunately to page 6, but
7 it's relating. So I can't get Carl Sagan out of my
8 head. He said absence of evidence isn't evidence of
9 absence, and I think that line 128 through 130, which
10 were recently inserted by the Subcommittee, does the
11 Committee feel we have sufficient numbers of studies,
12 quality of studies, to make this statement, summary
13 statement. The summary statements begin, "Cheese
14 made from pasteurized milk is unlikely to be a
15 significant source of exposure to MAP." And I think
16 we don't have enough studies to say that yet.

17 DR. ZINK: I can tell you the thinking and
18 discussion that went into it or that was behind it,
19 and I throw this out for the rest of the Committee's
20 consideration.

21 We have said and determined that there is a
22 4 to 7 log reduction by pasteurization itself. There

1 were indications in the literature, and it was our
2 sense, that the cheese manufacturing process itself
3 further reduced any organisms that might survive
4 pasteurization if such a phenomenon occurs. This
5 reduction occurs two ways.

6 One, when you make cheese, you're
7 concentrating it, if you will. You're taking a solid
8 portion and a whey portion, and you can have
9 microorganisms that are removed from the cheese to
10 the extent that they're with the whey fraction that's
11 taken away.

12 The other is that during the ripening
13 process, there is a die-off of some microorganisms
14 during cheese ripening.

15 So that was the thinking that went behind
16 the statement, but I'll throw it open to the
17 Committee and Subcommittee members to add to that.

18 Kathy?

19 DR. GLASS: Kathy Glass, UW Madison. I
20 would agree with, you know, the potential die-off
21 during the ripening. I'm not sure if I necessarily
22 agree with whisking away some of the cells and the

1 whey portion and the protein portion. I think that
2 there have been a couple of studies that indicate
3 that actually, depending upon what the protein and
4 what the bacterium is, that you actually may be
5 concentrating it in the curd rather than reducing it
6 during that cheese making process, and so it might be
7 premature to say that overall, it would get away with
8 the whey.

9 DR. ZINK: Yeah. Tim?

10 LTC STEVENSON: If you put that in the
11 context of the whole paper, I think that that
12 statement is sufficient. As Don mentioned, there is
13 and they do qualify that for pasteurized milk, cheese
14 made from pasteurized milk, there's the reduction
15 there, and there certainly are, in the separate
16 studies, cited additional die-off during the ripening
17 period. So I think it's even safer than pasteurized
18 milk, fluid milk.

19 DR. ZINK: Eli?

20 DR. PERENCEVICH: Perencevich, VA Maryland.
21 I guess underlying this is that we don't know what
22 the safe level would be. So to say something like

1 unlikely to be a significant source, gets kind of
2 outside of the charge of this, I mean, you know,
3 prevalence, numbers. It sounds like we're making a
4 statement about the safety with that.

5 DR. ZINK: I don't think there was an
6 intention to make a comment about the safety. The
7 intention was to put it in the context of not really
8 rank order, but to give some sense of how it compared
9 to say pasteurized milk. Our attempt was to rank it
10 lower than pasteurized milk as a potential source.
11 Maybe there's a better way we can say that. Jenny?

12 MS. SCOTT: Jenny Scott, GMA. I think you
13 are correct in that the point we were making here is
14 whether or not cheese is going to be a source of
15 exposure to MAP, and the conclusion was because of
16 pasteurization and the further inactivation of other
17 inhibitory factors in the cheese that it's unlikely
18 to be a significant source. I don't think that that
19 does reflect safety or not safety because we have
20 tried to stay away from that everywhere in this
21 document and that's why it was phrased in terms of
22 whether or not it was a source of exposure to MAP.

1 DR. BRACKETT: Uday.

2 DR. DESSAI: I would think we need to
3 simply add "compared to pasteurized milk," at the end
4 of the sentence, "exposure of MAP compared to
5 pasteurized milk."

6 DR. ZINK: So how would the sentence read?

7 DR. DESSAI: "Cheese made from pasteurized
8 milk is unlikely to be a significant source of
9 exposure to MAP compared to pasteurized milk." So
10 you're trying to show that cheese has a lower degree
11 of potential exposure compared to pasteurized milk
12 itself.

13 DR. BRACKETT: I think what you're trying
14 to say, "compared to the milk from which it was
15 made."

16 DR. DESSAI: "Compared," yes. Yes.

17 DR. ZINK: How does the group feel about
18 that? Jenny?

19 MS. SCOTT: Jenny Scott, GMA. I think we
20 focused throughout this document in trying to
21 determine where people are exposed to MAP, and
22 clearly the first focus was on milk because that's

1 where all the data are. Our conclusion there is
2 pretty much that milk is unlikely to be a highly
3 significant source unless it's not been pasteurized.

4 DR. ZINK: Pasteurized milk, yeah.

5 MS. SCOTT: Pasteurized milk is not going
6 to be a significant source, and I'm afraid that by
7 taking those words on in the cheese part, it could
8 imply if it's taken out of context that milk is a
9 significant source of MAP which is not what we
10 concluded. And I think that the way this is phrased
11 is exactly how we intended it, that we don't think
12 people are going to ingest a lot of MAP in cheese
13 products.

14 DR. ZINK: Eli?

15 DR. PERENCEVICH: I think we summarized the
16 data really well in the document, but I think by
17 putting this here, we're overstating the amount of
18 evidence available. There haven't been enough
19 studies to make that statement. I mean only a couple
20 of types of cheeses were studied. I'm just, you
21 know, you couldn't do a meta-analysis on these three
22 sentences and come up with this. We kind of --

1 DR. ZINK: What if we put a statement in
2 there that said, "Although data are limited, cheese
3 made from pasteurized milk is even less likely to be
4 a significant source of MAP than pasteurized milk
5 from which it is made," something like that.

6 DR. PERENCEVICH: Yeah, I like that.

7 DR. ZINK: Lee-Ann, did you have a comment?

8 DR. JAYKUS: Lee-Ann Jaykus, North Carolina
9 State University. Yeah, I like the copy out based on
10 current data and I did a little bit of wordsmithing.
11 So, "based on current data and compared to other
12 products, cheese made from pasteurized milk is
13 probably not a significant source of exposure to MAP
14 compared to other products," well, milk and --

15 DR. ZINK: So the sentence might read,
16 "Although data are limited, cheese made from
17 pasteurized milk is probably not a significant source
18 of exposure to MAP, but the potential to exposure to
19 MAP from milk products made from raw milk is
20 unknown."

21 DR. JAYKUS: That's fine.

22 DR. BRACKETT: Do you want to repeat that

1 again please?

2 DR. ZINK: "Although data are limited,
3 cheese made from pasteurized milk is probably not a
4 significant source of exposure to MAP, but the
5 potential to exposure to MAP from milk products made
6 from raw milk is unknown."

7 Okay. We will modify that sentence
8 accordingly. We left off on page 40. Are there any
9 further comments about page 40?

10 (No response.)

11 DR. ZINK: Page 41?

12 (No response.)

13 DR. ZINK: Page 42? Jenny.

14 MS. SCOTT: Jenny Scott, GMA. Irene Wesley
15 had suggested we needed an introductory sentence to
16 "the research needs" rather than jumping right into
17 this, and based on what she submitted, some of the
18 Committee members came up with, "Based on a review of
19 the literature, including the research needs
20 identified by other groups (references 1 and 196),
21 the Committee identified the following research
22 needs."

1 DR. BRACKETT: Could you restate that again
2 please, Jenny, slowly?

3 MS. SCOTT: "Based on a review of the
4 literature, including the research needs identified
5 by other groups (1, 196)" --

6 DR. BRACKETT: Hold please. Starting from
7 "including the research."

8 MS. SCOTT: Do you want me to start from
9 the beginning?

10 DR. BRACKETT: Yes.

11 MS. SCOTT: "Based on a review of the
12 literature, including the research needs identified
13 by other groups (1, 196), the Committee identified
14 the following research needs."

15 DR. BRACKETT: Do you have that written
16 down on a piece of paper?

17 MS. SCOTT: I can give it to you in a
18 readable format, yes.

19 DR. BRACKETT: Okay. Thank you.

20 DR. ZINK: I've got it written down on my
21 copy, too.

22 There was an additional suggestion on 896

1 when the Subcommittee reviewed it to insert the
2 words, "and enumerate" after the word "detect." So
3 it would read, "in standardization of rapid,
4 sensitive and specific methods to detect and
5 enumerate MAP in a variety of matrices."

6 Is there any further comment on page 42 or
7 these two suggested changes?

8 (No response.)

9 DR. ZINK: Okay. Page 43?

10 (No response.)

11 DR. ZINK: Page 44?

12 (No response.)

13 DR. ZINK: Page 45?

14 (No response.)

15 DR. ZINK: Page 46? Tim? And John?

16 LTC STEVENSON: On page 46, line number
17 987, there's a reference to vaccination. I'd like to
18 recommend that we change that last part of that
19 sentence, "a promising control technology would be
20 vaccination but this is currently only being used in
21 a limited," you know, "under controlled
22 circumstances" or something along those lines and in

1 a limited manner because there are programs in a few
2 states where they're using herd control which you've
3 cited up previously in lines 981, 983, testing of the
4 animals, and in conjunction with those two
5 procedures, there is a limited vaccination program
6 being carried out and the initial results look to be
7 promising but it's a developing program. So I wish
8 we could put in a term like that, "that vaccination
9 is currently being used sparingly or under controlled
10 situations."

11 DR. ZINK: Would you say it's being used
12 experimentally?

13 LTC STEVENSON: Could you say in a pilot
14 program or something like that? Is in the initial
15 stages or early stages of implementation or something
16 like that. It's not like an experimental
17 vaccination. It's being used under controlled
18 situations.

19 DR. ZINK: Maybe change the phrase to, "but
20 this is currently in the early stages of
21 implementation."

22 LTC STEVENSON: Yes.

1 DR. ZINK: Okay.

2 DR. BRACKETT: Jenny?

3 MS. SCOTT: Jenny Scott, GMA. On line 979,
4 Irene is suggesting putting reference 236 at the end
5 of the sentence. And in line 981, changing "newly
6 born" to "newborn."

7 DR. ZINK: There was also a suggestion from
8 Irene that a sentence be inserted before line 973.
9 That sentence would read, "Cost effective preharvest
10 controls by which to restrict or eliminate the
11 transmission of MAP within cattle populations have
12 been described, reference 236 and reference 93. The
13 goal of the recently implemented uniform program
14 standards for the Voluntary Bovine Johne's Disease
15 Control Program is to reduce its prevalence in the
16 national cattle herd, reference 93."

17 The intention there was to give recognition
18 to and whatever encouragement we can for these
19 programs.

20 Are there any comments on these proposed
21 changes to page 46?

22 (No response.)

1 DR. ZINK: Okay. All right. Page 47?
2 Jenny Scott.

3 MS. SCOTT: Irene has suggested a reference
4 168 at the end of the sentence that ends on line
5 1005.

6 DR. ZINK: We did verify that that
7 reference is relevant, very relevant. Any discussion
8 about page 47, and the proposed change?

9 (No response.)

10 DR. ZINK: Page 48? Dean.

11 DR. CLIVER: Dean Cliver, UC Davis. Line
12 1008, we have a Cast 2006 citation in there. If
13 that's meant to be a reference citation, it ought to
14 be in numerical format. If it's not, it's pretty
15 meaningless.

16 DR. ZINK: That line is -- which line
17 again?

18 DR. CLIVER: 1008 I should say.

19 DR. ZINK: 1008.

20 DR. CLIVER: Yeah, parenthetically it says
21 Cast 2006. If that's in your list of references, the
22 number should be given here. If not, it needs to be

1 added to the list of references.

2 DR. ZINK: That's an oversight. Yeah, we
3 would convert that to a numerical reference. In
4 fact, I should say we will have to go through the
5 references once more very carefully to make sure that
6 everyone we cite is used in the reference and put it
7 in whatever format is required for publication.

8 Page 49?

9 (No response.)

10 DR. ZINK: Page 50? Uday.

11 DR. DESSAI: Yes. I have a couple of
12 comments here. One would be on 1054 line, we would
13 want to consider adding "viable MAP in ground beef."

14 DR. ZINK: Okay. How would it read? It
15 would read "viable" -- okay.

16 DR. DESSAI: The next sentence or
17 continuation from, "however, cull dairy cattle are
18 likely to have a significant higher prevalence of MAP
19 infection compared to beef cattle." I did not see
20 that being mentioned either on page 13 or page 43,
21 unless I missed it. Because this is a concluding
22 part, I was looking for --

1 DR. ZINK: Talking about -- back to where
2 we talked about incidence in cattle. Let's see.
3 What page was it?

4 UNIDENTIFIED SPEAKER: Page 43.

5 DR. ZINK: We did have those numbers before
6 us in the deliberations, estimated MAP prevalence in
7 U.S. beef herds is 7.9 percent and on line 913, MAP
8 prevalence in U.S. dairy herds is estimated at
9 approximately 22 percent. So in terms of herd
10 prevalence, the herd prevalence is higher for dairy
11 herds than it is for beef herds. We thought the
12 primary reason for this, on average, these dairy
13 cattle are much older. That was the basis for that
14 statement, that cull dairy cattle likely have a
15 significantly higher prevalence of MAP compared to
16 beef cattle.

17 DR. DESSAI: Okay. Going to same page 50,
18 1059, the last -- the sentence which starts with,
19 "Unfortunately there are limited data available on
20 the prevalence of," I would like to add, "viable
21 MAP," there.

22 DR. ZINK: That's true. There's no data on

1 viable MAP. Do you want to say that there are no
2 data available on the prevalence of viable MAP in
3 ground beef? As I recall, there are no data that
4 have cultured the organism from ground beef.

5 DR. DESSAI: That would be good. Then on
6 1060, "The potential for exposure of MAP by
7 consumption of ground beef is credible but needs
8 further study." I think that first part is very
9 strong, credible, because even on page 30 I noticed
10 that right up front, second line, 613, it says, "Beef
11 should be considered a potential source of exposure
12 to MAP." And if I understand right, under the
13 conditions of disseminated infection in cattle, then
14 that would be the route to get MAP into beef, because
15 so many studies with (*Escherichia coli*) O157 show
16 that the gastric route is not a route for
17 contamination under the current processing
18 conditions. It's the hide. So I would kind of look
19 at this very carefully.

20 DR. ZINK: What our thinking was, to the
21 extent that cull dairy cattle are more likely to be
22 infected with MAP, and to the extent that at least

1 two lymph nodes can be included in ground beef made
2 from these cattle, and the organism is known to
3 localize in lymph nodes, that was the trail of logic
4 we used to think that ground beef could be a source
5 of it.

6 Now I have to agree with you that we may
7 well have worded this more strongly than we should
8 have, but -- John, do you want to weigh in on that?

9 DR. SOFOS: Sofos. I would suggest to
10 change the sentence to say that "potential exposure
11 to MAP by consumption of ground beef needs further
12 study."

13 DR. DESSAI: That's acceptable.

14 DR. BRACKETT: Jenny.

15 MS. SCOTT: Jenny Scott, GMA. Did you make
16 a change to say that there are no data available on
17 the prevalence of viable MAP.

18 DR. ZINK: In ground beef, yes.

19 MS. SCOTT: I wonder if that does not
20 disregard the two studies where they did look at
21 ground beef but they didn't find any. By making that
22 change, does that suggest that there aren't any

1 studies and that's why the limited data was in there
2 before?

3 DR. ZINK: Well, there's no data on the
4 prevalence of viable MAP. There's those two studies,
5 yes, but --

6 MS. SCOTT: But I could read that to
7 suggest that there weren't studies to look at the
8 prevalence, and that's why there are no data.

9 DR. ZINK: Do you want to leave it as
10 limited?

11 MS. SCOTT: So say there are no studies
12 that have detected viable MAP?

13 DR. ZINK: So you would change it to read,
14 "Unfortunately, there are" -- well, you would take
15 "Unfortunately" out.

16 MS. SCOTT: "There are no studies that have
17 detected" --

18 DR. ZINK: There are no data -- "there are
19 no studies that have detected viable MAP in ground
20 beef and none on its potential survival after
21 cooking."

22 DR. BRACKETT: Uday, did you have a

1 comment?

2 DR. DESSAI: Yes. On 1060, the last
3 sentence, "The potential for exposure to MAP by
4 consumption of ground beef is credible but needs
5 further study." Maybe this sentence -- "needs
6 further study" is perfect, but "credible" needs to be
7 softened I would think.

8 DR. ZINK: How about if we delete it. I
9 think there was a proposal to delete it to read, "The
10 potential for exposure to MAP by consumption of
11 ground beef needs further study."

12 DR. DESSAI: Right.

13 DR. ZINK: Lee-Ann?

14 DR. JAYKUS: Lee-Ann Jaykus, NC State. Can
15 we go back to the previous comment on, I think it was
16 "no studies." Can you read that back please?

17 DR. ZINK: The last proposal was, "There
18 are no studies that have detected viable MAP in
19 ground beef and none on its potential survival after
20 cooking."

21 DR. JAYKUS: Okay. "None of the studies
22 have detected viable MAP," because there were two

1 studies.

2 DR. ZINK: Okay.

3 DR. JAYKUS: "None of the studies."

4 DR. ZINK: Okay. "None of the studies have
5 detected viable MAP in ground beef and none on its
6 potential survival after cooking."

7 DR. JAYKUS: And there are no studies on
8 its --

9 DR. ZINK: Okay. "There are no studies."
10 So it would read, "None of the studies have detected
11 viable MAP in ground beef, and there are no studies
12 on its potential survival after cooking."

13 DR. JAYKUS: Good.

14 DR. ZINK: Dan?

15 DR. ENGELJOHN: Engeljohn, FSIS. Don, I
16 think you made an important point about the lymph
17 nodes, and there are programs available today where
18 lymph nodes are not allowed in ground beef by
19 purchase specs. So I think if we could in that last
20 sentence then add "particularly containing lymph
21 nodes" after the word "beef," that that will then
22 actually help focus perhaps some research. The

1 School Lunch Program, as an example, does not allow
2 lymph nodes in ground beef.

3 DR. ZINK: So that sentence would now read,
4 "The potential for exposure to MAP by consumption of
5 ground beef, particularly containing lymph nodes,
6 needs further study." Okay. Is there -- Barbara?

7 MS. KOWALCYK: Barbara Kowalcyk, CFI. I'm
8 sure everybody wants to move on from this previous
9 comment on lines 1058 and 1059. I just wanted a
10 clarification. Were those two studies designed to
11 determine the prevalence of MAP?

12 UNIDENTIFIED SPEAKER: Uh-huh.

13 MS. KOWALCYK: They were. Okay. Thank
14 you. That's all I wanted. Then I'm fine with the
15 sentence as it reads.

16 DR. ZINK: The only caveat we have on those
17 studies is it is so very difficult to recover this
18 organism from sources that have a lot of competing
19 microorganisms, and when you see a study with MAP and
20 a negative result, this is an organism that begs
21 having similar studies from many other labs over a
22 period of time verify those results. It's, with this

1 organism, hard to have confidence in a negative
2 result.

3 MS. KOWALCYK: Well, my concern was, and I
4 don't have this sentence written out in front of me,
5 is it says that "none of the studies." It could be
6 interpreted that we have confidence that it's not
7 there, and it gets back to the comment Eli made
8 earlier, absence of evidence is not evidence of
9 absence.

10 DR. ZINK: Right.

11 MS. KOWALCYK: And, you know, I just want
12 to make sure that that sentence doesn't imply that we
13 have confidence in the number of studies that we
14 reviewed.

15 DR. ZINK: I think we have as much
16 confidence in it as we do any study in anything
17 reporting the absence of the organism. Don?

18 DR. SCHAFFNER: Could we perhaps say none
19 of the limited number of studies? Neither of the
20 studies. There we go. Neither. Excellent.

21 DR. ZINK: So we have a proposal to make it
22 read "neither of the studies." Are we okay with

1 that?

2 (No response.)

3 DR. ZINK: I think you'll agree with us,
4 this area needs further study. No further comments
5 on page 50? Eli?

6 DR. PERENCEVICH: Perencevich, VA Maryland.
7 The sentence that begins on 1045, "The Committee
8 believes that pasteurization and ripening combined to
9 greatly reduce the risk of human exposure to MAP,"
10 and I suggest changing that sentence to, "The
11 Committee believes that pasteurization and ripening
12 combined to greatly reduce the numbers of MAP from
13 pasteurized milk cheeses." Because we didn't look
14 specifically at human exposure.

15 DR. ZINK: Well, I would go back to our
16 earlier discussion about the word "presence." Do we
17 mean numbers or presence?

18 DR. PERENCEVICH: Numbers, presence, fine.
19 "Reduce the presence of MAP."

20 DR. ZINK: Is there a consensus that we
21 change the sentence? Is "presence" preferable to
22 "numbers"?

1 DR. PERENCEVICH: And then you have to
2 change "from" to "in" pasteurized milk cheeses.

3 DR. ZINK: It would read then, "The
4 Committee believes that pasteurization and ripening
5 combined to greatly reduce the presence of MAP in
6 pasteurized milk cheeses." Is that -- Tim?

7 LTC STEVENSON: Could we also insert that
8 word "viable," presence of viable MAP, the word
9 "viable" before "MAP"?

10 DR. ZINK: Okay. Is everyone okay with the
11 changes proposed on page 50?

12 (No response.)

13 DR. ZINK: Okay. Page 51?

14 (No response.)

15 DR. ZINK: That concludes the text of the
16 document. Does anyone have any comments on the cited
17 references?

18 (No response.)

19 DR. ZINK: Again, we'll double-check those
20 very closely.

21 I would like to comment on the tables.
22 You'll notice that the tables included with this are

1 fairly extensive. I think the Subcommittee, it's
2 fair to say, feels that we still need to go over
3 these tables and perhaps assure consistency of
4 abbreviation, reduce the number of words there if we
5 can, by being a bit more terse. These tables came
6 about because in order to get our hands around the
7 many aspects of various foods and environments we
8 considered, we realized early on the tremendous
9 impact methodology had on the results that
10 investigators reported. We constructed these tables
11 as something that was necessary for us to be able to
12 write the darn report, and then we came to like the
13 tables quite a bit and felt that they should be
14 included and published with the report. Is there any
15 discussion of that or the inclusion of these tables
16 extensive though they are? Bob?

17 DR. BRACKETT: Brackett, FDA. One of the
18 work products or many of the work products that have
19 come from this Committee are the publications of
20 reports, and they have been pretty much become gold
21 standards, but they've also been a real help to the
22 research community and to the public health

1 community, going back and finding the same sort of
2 information.

3 I think including these tables in a
4 published document would be very, very helpful to
5 audiences all around the world.

6 DR. ZINK: Okay. Well, if the Committee
7 agrees, then we will include the tables. We'll clean
8 them up as necessary. Jenny. I'm sorry.

9 MS. SCOTT: Jenny Scott, GMA. There are a
10 number of changes that need to be made in these
11 tables if we're going to publish them, and I think
12 it's going to require some work by some Committee
13 members to help you out here. There is some
14 information in the tables that is wrong that needs to
15 be fixed, in addition to the formatting changes and,
16 in addition, there are parts in some of the tables
17 where because they were done by different people, the
18 information gets very sketchy in some places, where
19 it's very fleshed out in others. So I would
20 volunteer to help format these tables if we're going
21 to keep them in there.

22 DR. ZINK: Yeah, I didn't mean to soft

1 pedal the work that those tables took. They took a
2 lot of work.

3 All right. With that, I guess it
4 concludes. I'll turn it back to you, Bob.

5 DR. BRACKETT: Do we have any more
6 questions about the document itself just as a last
7 once here?

8 (No response.)

9 DR. BRACKETT: During the process now, what
10 we will need to do is actually adopt this document,
11 and in order to do so, we will need to have a first
12 and second motion to do so. Do we have a motion to
13 accept the revised document with tables being
14 corrected?

15 DR. CLIVER: (University of California,
16 Davis) Move.

17 DR. BRACKETT: Dean Cliver adopt, first.
18 Second motion?

19 DR. SOFOS: (Colorado State University)
20 Second.

21 DR. BRACKETT: Second by John Sofos.

22 Okay. So we do have the first and second

1 motions made. At this point, we will take a vote.
2 All those who are in favor of adopting the document
3 as described, signify by saying aye?

4 COMMITTEE MEMBERS: Aye.

5 DR. BRACKETT: Any opposed?

6 (No response.)

7 DR. BRACKETT: Okay. Then the document is
8 adopted.

9 Well, one thing I have to say about this,
10 you know, just in concluding about this document, it
11 seems to me that this is probably one of the more
12 complex and difficult issues that the Committee has
13 had to address but nevertheless, I really want to
14 commend you all for doing that. It's been a good
15 help for us.

16 DR. ZINK: I'd like to make special mention
17 of Dr. Mike Collins (University of Wisconsin) and
18 Dr. Roy Radcliff (Marshfield Clinic), who took time
19 out of their schedules to come and participate in
20 most of the Subcommittee meetings, and I think it's
21 fair to say that we would not have been able to get
22 our arms around this organism the way we did without

1 their guidance and help and clarification. It was
2 extremely valuable.

3 DR. BRACKETT: That's well put. Well, this
4 does come to the end of the third Plenary Session or
5 meeting of this Committee, and I do want to give my
6 thanks to everyone who participated and there has
7 been a lot of participation as well. But we also as
8 part of our normal Committee structure, allow time
9 for public comment. We really have no one signed up
10 yet for public comment, but I would like to ask
11 anybody in the room if they do have a comment at this
12 time.

13 (No response.)

14 DR. BRACKETT: It appears there are none.
15 So again, thank you to all the members of the
16 Committee who have shared a lot of brainpower and
17 scientific expertise for the purpose of advancing
18 food safety and we do appreciate that.

19 So I will wish you safe travels back to
20 your home, and I now call the meeting adjourned.

21 (Whereupon, at 11:18 a.m., the meeting was
22 concluded.)