

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31

UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE: NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS

Meeting held on the 20th day of August, 2003

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

TRANSCRIPT OF PROCEEDINGS

8-20-03 NACMCF Meeting Participants

- Chair: Dr. Merle Pierson
- Vice-Chair: Dr. Robert Brackett
- NACMCF Members: Dr. Gary Ades
- Dr. David Acheson
- Dr. Peggy Cook
- Dr. Catherine Donnelly
- Dr. Stephanie Doores
- Dr. Dan Engeljohn

1		Mr. Spencer Garrett
2		Dr. Lee-Ann Jaykus
3		Dr. John Kvenberg
4		Dr. Anna Lammerding
5		Dr. John Luchansky
6		Dr. Carol Maddox
7		Dr. Roberta Morales
8		Dr. Angela Ruple
9		Ms. Jenny Scott
10		Dr. Skip Seward
11		Dr. John Sofos
12		Dr. Katie Swanson
13		Dr. R. Bruce Tompkin
14		Dr. Don Zink
15		
16	NACMCF Executive Committee:	Dr. Art Liang, CDC
17		Maj. Erik Topping, VSA
18		Dr. LeeAnne Jackson, FDA
19		
20	FSIS Staff:	Ms. Gerri Ransom
21		Ms. Karen Thomas
22		Dr. Walt Hill
23		Mr. Loren Lange
24		
25		
26	NMFS Staff:	Ms. Emille Cole
27		Ms. Barbara Comstock
28		
29		Dr. Al Rainosek
30		
31		
32		
33	Outside Participant:	Mr. Tony Corbo, Public Citizen
34		

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24

P R O C E E D I N G S

August 20, 2003, 8:30AM

DR. PIERSON: Good morning. I welcome you to the first plenary session of the 2002-2004 National Advisory Committee on Microbiological Criteria for Foods. I'm Merle Pierson. I'm Chair of the Committee, I'm USDA Deputy Under Secretary for Food Safety and gosh, I know most all of you, so -- and with us, to my right is Bob Brackett, who is Vice-chair of the Committee. He's the Director of Food Safety and Security for FDA, CFSAN. This is not new news, but I wanted to indicate to you that the National Advisory Committee was re-chartered on September 5 2002, and in February 2003, Secretary Veneman appointed new members to serve on the National Advisory Committee. Appointments, of course, go back to September 5, 2002, and they are until September 5, 2004. So we're one half -- we're just about halfway through what, a two-year cycle-- time catches up pretty rapidly and as you can imagine, our Executive Committee, we say how are we going to get these Committee meetings in? But we're doing it. And to that extent, we had our first

1 Subcommittee meetings at the end of June and the new
2 members -- for the new members, there was an
3 informational briefing covering operations and
4 procedures of the Committee. The careful selection of
5 the Committee members was based on their specific
6 expertise, and the Committee's role in providing
7 balanced view-points and scientific advice for our
8 nation's food supply and the safety of the food supply.
9 Now, on behalf of the full Committee and the federal
10 agencies who sponsor the National Advisory Committee,
11 I'd like to thank each of you for your valuable time and
12 the contributions that you will make towards the
13 Committee's activities, your participation, your efforts
14 that you're putting forth will allow us to move forward
15 with the federal government on a number of very
16 essential issues relative to food safety and protection
17 of public health. At this time I think we should go
18 around the table and introduce ourselves and state our
19 affiliation. So we'll go to my left.

20 MS. RANSOM: Okay. Good morning, Gerri
21 Ransom, NACMCF Executive Secretariat, and I'm with FSIS.

22 MS. THOMAS: Good morning, Karen Thomas. I'm
23 the Advisory Committee Specialist from NACMCF/FSIS.

24 MR. LANGE: Good morning. I'm Loren Lange,
25 with FSIS, Office of Public Health and Science.

York Stenographic Services, Inc.
34 North George St., York, PA 17401 - (717) 854-0077

1

2

DR. WALT HILL: I'm substituting for Karen
(Hulebak) today.

3

4

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

5

6

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

7

8

DR. DONNELLY: Cathy Donnelly, University of
Vermont.

9

10

DR. COOK: Peggy Cook, Tyson Foods.

11

DR. SWANSON: Katie Swanson, General Mills.

12

DR. ENGELJOHN: Dan Engeljohn, FSIS.

13

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

14

15

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

16

17

DR. ZINK: Don Zink, Food and Drug
Administration.

18

19

DR. DOORES: Stephanie Doores, Penn State
University.

20

21

DR. MORALES: Roberta Morales, RTI
International.

22

23

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

24

25

DR. ACHESON: David Acheson, FDA.

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 DR. MADDOX: Carol Maddox, University of
2 Illinois.

3 MR. GARRETT: Spencer Garrett, National Marine
4 Fisheries Service.

5 DR. SOFOS: John Sofos, Colorado State
6 University.

7 DR. TOMPKIN: Bruce Tompkin. I'm retired from
8 ConAgra Refrigerated Prepared Foods.

9 DR. ADES: Gary Ades, Foster Farms.

10 DR. LAMMERDING: Anna Lammerding, Health
11 Canada.

12 DR. KVENBERG: John Kvenberg, Food and Drug
13 Administration.

14 DR. LIANG: Art Liang, CDC.

15 DR. TORRING: Erik Topping, DOD.

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

18 DR. BRACKETT: Bob Brackett, FDA.

19 DR. PIERSON: Okay. Thank you very much.

20 It's good to see all of you here and I look forward
21 again to a very productive meeting. I'm pleased to
22 report that all three of our active Subcommittees have
23 gotten off to an excellent start -- or the Subcommittees
24 have gotten off to an excellent start in their work
25 during the June Subcommittee meetings. The three

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 Subcommittees are the Microbiological Performance
2 Standards for Broilers/Ground Chicken; it's chaired by
3 Spencer Garrett. The Subcommittee on Criteria for
4 Shelf-Life Based on Safety, which is chaired by Don
5 Zink, and the Subcommittee on Scientific Criteria for
6 Redefining Pasteurization and that's chaired by John
7 Kvenberg. Now, we have an aggressive work schedule
8 before us and to carry out this week, as these
9 Subcommittees are again meeting. All activities are
10 focused on answering the scientific questions that
11 -- so that sound science-based policies can be made by
12 the respective federal agencies. Believe me, we look
13 very closely at the deliberations of this Committee.
14 These are just not reports that go onto a shelf and
15 gather dust, but we take them very seriously. I'm going
16 to mention performance standards work and then turn the
17 floor over to Vice-chair Bob Brackett. Our Performance
18 Standards Subcommittee has moved beyond their previous
19 work with ground beef and has begun new work on broilers
20 and ground chicken. At this meeting, this Subcommittee,
21 however, was also presented with an additional charge to
22 review FSIS-proposed microbiological baseline study
23 protocols for raw ground beef components. The
24 Subcommittee will concentrate their work on this review
25 during meetings this week and if they can, they'll move

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 on to their previous charge. Before I move on, I must
2 mention that this Subcommittee of the National Advisory
3 Committee recently completed the monumental task of
4 evaluating existing performance standards for *Salmonella*
5 in ground beef and it worked to define the general
6 principles, mechanics, and requirements for setting up
7 performance standards which will serve as the
8 underpinnings for future discussions. This valuable
9 work now appears as a final adopted document that was
10 released in October 2002, titled "Final Response to the
11 Questions Posed by the FSIS -- or by FSIS Regarding
12 Performance Standards with Particular Reference to
13 Ground Beef Products", and this work will serve the needs
14 of FSIS and other federal agencies who are concerned
15 with performance standards. Now I'd like to turn the
16 floor over to Vice-chairman Bob Brackett.

17 DR. BRACKETT: Thank you, Merle. I'd also
18 like to thank all of you for attending and welcome you
19 to the plenary session of the NACMCF Committee. We've
20 got a number of difficult scientific issues before us.
21 Two of the issues that the Committee is addressing were
22 brought to the Committee by FDA, and that is the
23 scientific criteria for redefining pasteurization, which
24 as Merle mentioned, is chaired by John Kvenberg, and
25 criteria for refrigerated shelf-life based on safety,

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 which is chaired by Don Zink. The 2002 Farm Bill
2 contained language amending Section 403(h) of the Food,
3 Drug and Cosmetic Act-- to include that a food is
4 misbranded if it purports to be pasteurized unless "such
5 food has been subjected to a safe process or treatment
6 that is prescribed as pasteurization or has been
7 subjected to a safe process or treatment that destroys
8 the most resistant microorganisms of public health
9 significance that are likely to occur in the food." And
10 the Subcommittee addressing this issue is reviewing
11 alternative treatments to the traditional heat
12 pasteurization, as well as the most resistant
13 microorganisms of public health significance that are
14 likely to occur in each of the foods. The Subcommittee
15 met yesterday to continue to work on a draft document.
16 FDA's also referred the issue of defining the criteria
17 for refrigerated shelf-life based on safety to NACMCF,
18 which they did in 2001. This is an action item in the
19 2001 *Listeria* Action Plan that was released by USDA and
20 the Department of Health and Human Services in January
21 of 2001. And the Action Plan stated that FDA and FSIS
22 will seek advice from a scientific advisory committee on
23 the scientific basis for establishing safety-based use-
24 by-date labeling for refrigerated, ready-to-eat foods,
25 and this Subcommittee will meet on Thursday to continue

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 to work on this draft document. Both the issues I've
2 discussed are challenging tasks, and I look forward to
3 receiving the Committee's final report within the next
4 year. Merle?

5 DR. PIERSON: Thanks, Bob. I'd like to turn
6 the floor over to Gerri Ransom, Executive Secretary, for
7 some additional comments.

8 MS. RANSOM: Okay. Good morning and welcome.
9 I first wanted to mention that if any of the Committee
10 members should need any help, don't hesitate to ask me
11 or Karen Thomas. I also wanted to apologize for the
12 temperature abuse we suffered yesterday. I'm hoping we
13 won't have a repeat of that. It feels okay so far, so
14 keep your fingers crossed. I wanted to mention for
15 those of you who were not at the June meeting, the
16 minutes of the last plenary session appear under tab
17 five of your notebook. We also have copies out on the
18 table. These minutes were previously released on the
19 FSIS website and also at the June meeting. These were
20 issued as chair-certified minutes, therefore, we will
21 not be adopting these at today's meeting. This was done
22 in order to get them out sooner to you. Again, as Dr.
23 Pierson mentioned, our microphones are constantly live,
24 so keep that in mind and, of course, we've got easy
25 operation, so that helps. Next, I wanted to mention

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 that anyone wishing to make public comment, guests,
2 please sign up outside --- at our registration desk. We
3 will limit comments to 10 minutes, but again, make sure
4 that you do sign up. Finally, I wanted to point out to
5 our guests that outside on the table we do have
6 available a number of NACMCF work related documents, so
7 feel free to take any documents that interest you. I
8 wanted to point out that this table is reserved only for
9 those documents approved by the NACMCF Executive
10 Committee. If guests do wish to distribute any
11 materials, we ask that you please use the table that is
12 a little further down past the refreshments. This table
13 is specifically for guests to distribute materials. I
14 also ask that you do not put any materials on the table
15 up here, on the Committee's table. Okay. Finally, I
16 wanted to mention to the Committee Karen has given you
17 calendars, so please make sure to fill those out at some
18 point. You may give those to her at the meeting or fax
19 them later on, but we need to know your availability for
20 scheduling future Subcommittee meetings. Okay, and with
21 that, I'll turn the floor back to our Chair.

22 DR. PIERSON: Thanks, Gerri. I'm going to
23 turn the floor over to Spencer Garrett to provide an
24 update on the Performance Standards Subcommittee work.

25 MR. GARRETT: Thank you, Mr. Chairman. As you

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 had indicated at -- immediately prior to this meeting,
2 or some time prior to this meeting, our Subcommittee was
3 given an additional charge relating to the conduct of
4 microbiological baseline studies and I think that it
5 would be appropriate for the USDA and Loren(Lange)in
6 particular, perhaps, to go ahead and give us that --
7 charge to the full Committee, if you would like, and
8 then we'll -- and I'll be glad then to tell you where we
9 are on that, Mr. Chairman, as well as on the previous
10 charge.

11 MR. LANGE: Good morning. I'll start with
12 just a sort of brief background where USDA has been in
13 terms of microbiological baselines and lead up to
14 identifying the four areas that we have asked the
15 Committee to comment on some plans we have for doing
16 baseline studies starting in the next fiscal year.
17 FSIS, or its predecessor agencies, have probably been
18 doing micro surveys or micro studies back, I think, into
19 the '60s, but something technically what we would call a
20 microbial baseline study, that sort of officially
21 started -- the first one probably started with, I think,
22 steer and heifer carcasses in 1992. And as -- a
23 baseline study, I guess, we would call a microbiological
24 survey or study that generates sufficient data that one
25 can make estimates of national product prevalence and

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 the variability of the distribution of microbial
2 pathogens in the products, so where there has been a lot
3 of work -- but previously, there wasn't an ability to
4 come up with estimates like -- an estimated x percent of
5 this commodity, you know, is positive for *Salmonella* or
6 positive for generic *E.coli* and distribution, so --
7 that's what we consider a baseline study. There were
8 about 13 baseline studies conducted throughout the '90s
9 by FSIS. Some of those baseline studies resulted in
10 performance standards that were published in 1996.
11 There were steer/heifer carcasses, cow/bull carcasses,
12 chicken carcasses, young chicken carcasses, turkey
13 carcasses and the three ground products, ground chicken,
14 ground turkey and ground beef. As we moved later into
15 the full implementation of HACCP by the year 2000, when
16 very small establishments were starting to be required
17 to meet the performance standards, the Agency had gotten
18 to the point where its regulatory testing was consuming
19 what was about a full capacity of about 90,000
20 microbiological samples a year. At that time we
21 considered -- we sort of had possibly excess resources--
22 in addition to our regulatory programs, that we could
23 conduct at least one on-going national baseline study.
24 In late 1991, with a new Undersecretary for Food Safety,
25 we got our first direction that we should start looking

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 at conducting a baseline study for beef trim. The
2 Department, at that time, was getting a lot of comments
3 from ground beef producers. There are a large number of
4 federally inspected producers of ground beef, somewhere
5 between 1500 to 1600. They were under the performance
6 standard for ground beef and a very common comment was,
7 their suppliers of trim or raw materials weren't
8 required to meet any microbial standard. They were
9 purchasing stuff on the market and being held
10 accountable for meeting a ground beef standard and the
11 trim they were buying wasn't being held to any sort of
12 performance standard. There was --at the same time,
13 there were certainly a lot of comments and a lot of
14 concerns that some of the ingredients that go into
15 ground beef might have high levels of different
16 microorganisms. There were basically no data on
17 microbial profiles of the ingredients, so we were given
18 this direction in late 2001. In 2002 we engaged in a
19 lot of discussions with the Agriculture Research Service
20 (ARS). Dr. Luchansky was involved in that. As we
21 started out, I was looking at some old email in my
22 folder -- Outlook's great for keeping history. I think
23 late in 2001 I saw an email from Gerri Ransom here
24 saying, oh, trim, you know, I've heard people do purge -
25 - I heard people do core samples and stuff, so we've

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 come a long way and we know a lot more now, and we did
2 put some people in charge of coordinating this effort.
3 Then throughout 2002, we worked with ARS because we knew
4 that they had been working with different parts of the
5 industry. They had been studying different methods of
6 collecting trim samples, so we're working with them.
7 Over 2002 we developed protocols that everybody was
8 given prior to this meeting to perform. And we had full
9 intentions of moving ahead with FSIS doing a trim study
10 that-- I'll mention it later grew into a "raw ground
11 beef component study". At the same time in 2002, about
12 the time, I guess in the spring, when we start thinking
13 about budget initiatives, the agency put forward -- our
14 Micro Division put forward an initiative where we would
15 ask for funds so that we could do some ongoing baseline
16 studies, some cyclical studies every three or every five
17 years on the commodities that we'd already looked at:
18 the beef carcasses, the hog carcasses, chicken and the
19 ground products. So as we put forth a budget
20 initiative, asking for 1.7 million dollars, we were
21 thinking in terms of redoing the baseline studies we'd
22 already done and we were going to do this trim study in-
23 house. Well, as it turns out, this food security became
24 a bigger and bigger issue and we were starting to direct
25 more and more of our resources in our labs toward

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 looking at methods to do food security testing and some
2 ongoing monitoring of the food supply. It sort of
3 became clear that we were not going to be able to do any
4 in-house study of trim and continue with our initiatives
5 on food security, so -- and at the same time we were
6 getting positive signals that we yes, indeed, were going
7 to get this -- a line item appropriation to do baseline
8 studies using a private sector lab under contract. So
9 the things that have occurred in the beginning, we
10 diverted what we thought would be the cyclical baseline
11 studies for what we've done in the past and said we will
12 plan to use this newly appropriated money beginning on
13 October 1 to do raw ground beef component studies. And
14 we've already developed a request for proposals that
15 should be on the street fairly soon and we intend to
16 have the responses from contract labs by the end of
17 September, I think, is our current schedule. There were
18 four areas that we have asked the Committee to
19 concentrate on and I'll just identify them very
20 generally in terms of what we've asked for comments on.
21 The first one was this protocol for collecting samples
22 and this is at issue. If you're looking at what was
23 called traditional beef trim, you'd collect small pieces
24 from a large number of pieces of trim, and you'd take
25 what people have described as a core sample. If you had

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 a 2000 pound what they call combo bin of trim, you could
2 just take a core through the middle and analyze that and
3 there were other people that had looked at trim -I mean
4 collecting the purge, the drippings from the bottom of
5 the container. So this is one of the areas we asked --
6 we had been working with ARS, and had come to some
7 conclusions that were handed out in the preliminary
8 paper. As I mentioned earlier, we started out thinking
9 of trim as what people, I think traditional trim as it
10 comes off a carcass and it's anything that doesn't
11 probably result in a steak or a roast. As our team got
12 into this, they identified eventually 18 different raw
13 ground beef components, everything from product from
14 advanced meat recovery to low temperature rendered
15 products, to head meat, cheek meat, weasand meat, which
16 is the meat that surrounds the esophagus, but it's been
17 made clear, now it's not the esophagus itself that's
18 used as casings, and there are several other products.
19 So our team -- internal team -- had taken those 18 and
20 divided them down into five sub-groupings with some
21 preliminary indications of priorities and that is a
22 second area we've asked for comment on. The third area
23 is our whole sampling design area. We don't want to
24 spend a million dollars analyzing laboratory samples if
25 we can't use those to come up with good national

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 estimates, so we've talked about at least a preliminary
2 survey that we've already sent out to the field. We'll
3 be getting back data on production levels and current
4 microbial interventions that are used on these five
5 groups of components. We are sure that the information
6 will help us design our surveys. As we go back, I'll
7 just mention those earlier surveys. The Agency has
8 always had detailed information on carcasses -- numbers
9 of carcasses slaughtered. We have an information system
10 that tells us by week, what each plant -- how many
11 steer/heifer carcasses are slaughtered, how many young
12 chicken carcasses are slaughtered. We do not have
13 production information centrally located on any of the
14 raw ground beef components, nor ground beef. There just
15 hasn't been a -- information production requirement that
16 the Agency has had, so the survey is our first attempt
17 to get an idea of what the production levels are in the
18 industry. If you go back to those earlier baselines I
19 mentioned in the '90s, there were only two ways to do
20 the sampling plan. On the ground products we didn't
21 know the production, but we had a list of plants we
22 thought produced the product, so we sent them a sample
23 collection form, asked for the sample, and then asked
24 the inspector to give an indication of the production
25 volume represented by that sample or the weekly

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 production. In those carcass surveys, we had the weekly
2 production, monthly production, quarterly production --
3 the sampling forms actually were randomly picked and
4 weighted by the production level, so the statistical
5 sampling plan was built in when the forms -- actually,
6 how many forms went out to each plant over the year. So
7 those are options that we have under consideration of
8 trying to collect production information up front and to
9 design the survey by then, scheduling based on
10 production or, just by identifying who makes the product
11 and then send out sample collection forms and collect
12 information at that time, and that was the third area.
13 And finally, the last area we asked for comment on was
14 the organisms that we were going to test for in the
15 baselines and our preliminary decision was to test for
16 *Salmonella* and *E. coli* O157:H7, both positive, negative,
17 and do a quantification on all positive samples and for
18 other organisms. We were going to look at generic
19 *E. coli*, Enterobacteriaceae, coliforms, and those are
20 the four areas we've asked the Committee for comment on
21 and they were all covered in the materials that were
22 sent out ahead of the meeting and we discussed yesterday
23 in the Subcommittee. So with that, unless there's any
24 other questions, I'll turn it back.

25 MR. GARRETT: Thank you. Mr. Chairman, with
York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 that introduction and explanation, then I would report
2 briefly where we are and I also want to point out that
3 there was an additional request by FSIS that we complete
4 this particular examination during this week of August
5 18 and so that's why we deferred our previous
6 discussions on ground chicken and have focused in this
7 new effort. And I'm pleased to report that we've made a
8 great deal of progress, far more progress than I thought
9 possible, and quite frankly, we're very near completion.
10 It's not my intent to go through our report in detail
11 yet, because there are still some things that we're
12 fleshing out obviously. But we have looked at the, as
13 requested, the prioritization of the five components or
14 categories, for example, we've tweaked back some. We've
15 looked at the sampling plans, we've based the general
16 recommendations, and I might point out one general
17 recommendation, as well, is that since the field
18 inspection force will be heavily involved in actually
19 collecting these samples, that we felt that some sort of
20 standardized training program, either on CDs or videos
21 or something like that would be very, very helpful in
22 assuring the uniformity and integrity in the sample
23 collection process itself. We've gone through each of
24 the questions. We have some recommendations that we've
25 come together with, but we worked in two different sub-

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 working groups. We've now put the report together.
2 Nobody's seen the report combined as yet in the sub-
3 group and that's what we're going to be doing right
4 after this plenary session and then I feel confident
5 that we can bring a report to the full Committee for
6 Friday. As a matter of fact, for those that are staying
7 in this hotel at least, we'll try to get that Committee
8 report to you -- delivered to your room, so you'll have
9 some advance time to read it. Having said that, I might
10 also say that we have a previous charge with six
11 questions relative to ground chicken and it would be our
12 intent to go back to that, possibly this afternoon when
13 we finish this new charge and possibly even finish that
14 charge to bring to the full Committee. That's just
15 depending upon how the discussions go, so I think we're
16 -- moving ahead with all deliberate speed, as we say,
17 and hopefully we can bring at least one finished report
18 to the full Committee Friday. Thank you.

19 DR. PIERSON: Thank you, Spencer. It sounds
20 like you're making very good progress and I sit here
21 thinking how we keep throwing things at Spencer and his
22 Committee, we just try to keep him charged, but he just
23 keeps gobbling it up. You're doing a good job there.

24 MR. GARRETT: Mr. Chairman, let me apologize.
25 It's been pointed out to me it's actually broilers, not

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 ground chicken.

2 DR. PIERSON: Okay. I'd like to turn the
3 floor now over to Don Zink, who -- chairs the Shelf-
4 Life Based on Safety Subcommittee and -- so he can give
5 us his report.

6 DR. ZINK: By way of background, there have
7 been, in the past, some food-borne disease outbreaks due
8 to -- caused by psychrotrophic pathogens and the vehicle
9 was a refrigerated, ready-to-eat food with a substantial
10 refrigerated shelf-life. If at some point, in the
11 future, it becomes desirable to look at limiting the
12 shelf-life of products based on safety, the questions
13 arose what sorts of considerations or criteria would be
14 applied in making that happen? How would you actually
15 go about doing that? And this Subcommittee has been
16 charged to answer five questions related to this. We
17 have answered almost all of the five questions. We
18 still have more work to do, some sections to flesh out
19 and we want to include some data from the 2003 FDA Risk
20 Assessment when it's published, but I believe that with
21 this week's session, we can substantially complete a
22 draft and I'm hopeful that we'll then be able to have
23 something ready to submit to the full Committee,
24 probably within a few weeks after these meetings this
25 week.

1 DR. PIERSON: John Kvenberg, who is the chair
2 of the Redefining Pasteurization Subcommittee.

3 DR. KVENBERG: Thank you, Chairman. Well, as
4 the Vice-chair had initially, in his opening remarks,
5 basically reviewed the reason for seeking advice on
6 alternatives to pasteurization being keyed into a new
7 act that revised the Food and Drug Administration's law.
8 The Subcommittee was formed --a working group and
9 introduced the charge to NACMCF at the meeting in June
10 of 2003, and we met as a working group, and at that time
11 we reviewed the potential technologies that would be
12 applicable to microbial reductions in a process that
13 would be covered under this new fabric of pasteurization
14 definition. There were some dozen technologies that we
15 uncovered that were basically reviewed by the Institute
16 of Food Technology in a report that we used as a basis
17 for that. I will report out on the Committee's working
18 group's deliberation then on Friday at length. I won't
19 take the time to do that now, but just to introduce what
20 was reviewed by individuals and discussed at our working
21 group meeting yesterday, the technologies of microwave
22 and radio frequency, ohmic and inductive heating, high-
23 pressure processing, pulsed electric and high-voltage
24 arc discharge technologies, pulsed light, oscillating
25 magnetic fields, ultraviolet light, ultrasound, x-rays

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 and irradiation, steam and hot water and chemicals. So
2 the Committee can see that there are a lot of potential
3 technologies that are applicable to what we're doing. I
4 must say that basically, what the -- what our working
5 group is now trying to grapple with is a working
6 definition of the term pasteurization, because the way
7 the Act -- if I could just take a moment just to go
8 through and reiterate some of the material you have --
9 if it's clear to us that if it is subject to a
10 regulation that is prescriptive and promulgated, that
11 the Agency defines as pasteurization, that is an obvious
12 hurdle. Also, a food that could be subjected to a safe
13 process or treatment, in the words of Congress is
14 reasonably certain to achievement of destruction or
15 elimination -- of the most resistant microorganisms of
16 public health significance that are likely to occur in
17 food -- well, that's a large task. We are currently
18 looking at that in terms of what the risks may be. It
19 also goes on to say that within the same section of
20 that, that the effective period of this process to
21 redefine pasteurization be effective for a period at
22 least as long as the shelf-life of the food when stored
23 under normal or moderate abuse conditions. There are
24 two points here. Number one, we're not really sure if
25 there's a definition of moderate abuse conditions. That

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 came up and we will have to be concerned with that, but
2 I think more importantly, there's a cross-linkage
3 between the shelf-life that we're looking at and the
4 pasteurization, because there's a requirement, although
5 the language does say achieve destruction or
6 elimination. The language also states effective for at
7 least a period of, which would mean that it would be
8 below the level of detection. So those are the general
9 concepts that we're still working through. Also, to
10 report back that we understood in the Executive
11 Committee that there was sufficient dollars this fiscal
12 year for a potential for a trip and -- in working with
13 the working group calendars, the people in our working
14 group, it looks like the third week in September would
15 be possible to take a trip to Chicago to FDA's combined
16 consortium center there at -- called the Moffett Center
17 and a potential to visit -- one processor so we can be
18 exposed to that technology. Also, there's going to be,
19 it was a consensus that we need to have in the next
20 fiscal year, definitely need to schedule a working group
21 meeting of this Subcommittee to go back and further
22 refine our working report, because we have, in essence
23 now, a dozen technologies that are going to be reported
24 on. We're going to try to put that together, so that's
25 our desire for the fall before the next plenary session,

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 at least one working group session. I can't estimate
2 our progress on one working group meeting. There has
3 been an offer from FSIS, you know, for a potential visit
4 to Minnesota, so one possible alternative to locating
5 the working group meeting in Washington would be
6 possibly to have a working group meeting in Minneapolis,
7 but -- that's not a consensus, but I'm just advising the
8 Chair that's a potential request for a working meeting.
9 Thank you.

10 DR. PIERSON: Thanks, John. I need to
11 recognize Brenda Halbrook, who joined us. Is she back
12 there? Brenda? Stand up. Brenda was Executive
13 Secretary up until last year. When did you -- start at
14 that -- in the position?

15 MS. HALBROOK: September 9, I started at the
16 Food and Nutrition Service.

17 DR. PIERSON: Food and Nutrition Service.
18 Then how long were you the Executive Secretary at the...

19 MS. HALBROOK: Well, let's see. It seemed
20 like a long time. I think I was unofficially associated
21 as of April of when would that be? 2001? Until
22 September, 2002.

23 DR. PIERSON: Okay. Well, we appreciated the
24 good work that you did for this Committee. You
25 certainly need to be recognized. Yes, she's now with

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 Food and Nutrition Service. It's good to have you here.
2 Okay. Although it's just slightly early, I think we can
3 move on to the public comment portion of the program.
4 Officially, it's open from -- this is 9:30 to 10:00
5 a.m., then a break, so we only have one person signed up
6 for public comment and they can present that public
7 comment now or -- if you're ready, if not, we'll take a
8 break and then come back at 9:30. But if you're ready
9 to -- Tony Corbo, a public citizen.

10 MR. CORBO: Good morning, I'm Tony Corbo from
11 Public Citizen, a consumer group.

12 DR. PIERSON: Um-hum.

13 MR. CORBO: In June and yesterday I've been
14 sitting in the working group on Redefining
15 Pasteurization and can really appreciate the daunting
16 task that this working group has. I realize that
17 they're dealing with the scientific criteria for
18 redefining pasteurization, but as we all know, whatever
19 recommendations comes out of this Subcommittee, could
20 eventually impact labeling on products and that's been
21 our concern from the get-go on this particular section
22 of the Farm Bill. We opposed the section of the Farm
23 Bill as it eventually was passed, as well as most of the
24 other consumer organizations, because we felt that it
25 could cause consumers to become confused over the

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 definition. In particular, we believe that the
2 motivation behind this was an attempt by the food
3 irradiation industry to try to hide the word irradiation
4 and use the word pasteurization to try to gain consumer
5 acceptance. And it was interesting when we made that
6 charge, when the Farm Bill was being debated, that a
7 number of industry groups said no, you know, there are
8 other technologies out there that we would like to see
9 the use of the term pasteurization applied. I've
10 brought a couple of visual aids. At the time, one of
11 the technologies that industry was saying is that, you
12 know, for example high-pressure, you know, technology
13 could be used as a pasteurization technique. I've
14 brought a box that contained guacamole that uses hydro-
15 static pressure to treat it. My wife likes it and so
16 we've been regular consumers of this product for about a
17 year and a half. Up until the middle of June, the box
18 contained the following statement: fresh under pressure,
19 a state-of-the-art -- a cold-pasteurization technology.
20 And cold-pasteurization was mentioned on three sides of
21 the box. In mid-June, a new box appeared in the store,
22 it's larger, has a greater quantity of guacamole, but
23 this time the word -- the term cold-pasteurization has
24 disappeared. So I phoned the company to find out why
25 they dropped the term and what they said was they've

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 received a number of consumer inquiries about whether
2 this product was irradiated and if it were irradiated,
3 they weren't going to purchase it. So they have dropped
4 using the term cold-pasteurization. So as far as the
5 working group, I commend you for the work, but you're
6 going to be up against quite a bit of consumer
7 skepticism on trying to redefine pasteurization. Thank
8 you very much.

9 DR. PIERSON: Thank you. Do we have any other
10 comments? Comments that anyone would like to make?
11 Okay, if not, we can go ahead and take our break now.
12 Yes, John?

13 DR. KVENBERG: I should have mentioned it
14 during my report, but I'm asking for the clarification
15 of the Chair and Vice-chair on the charge to our working
16 group, and I think I know the answer, I just -- I guess
17 what I really want is an affirmation that I'm correct in
18 my assumption on the charge.

19 DR. PIERSON: Um-hum.

20 DR. KVENBERG: The fifth question that was
21 asked was "What biological hazards might be created as a
22 consequence of pasteurization and treatment?" It came
23 up in discussion. My interpretation of that question is
24 that we're talking about microbial contamination that
25 might cause enteric disease or sequelae as opposed to

York Stenographic Services, Inc.

34 North George St., York, PA 17401 - (717) 854-0077

1 some other alteration of the product that would be a
2 safety concern by consumption, but it was a discussion
3 in the Committee. I just want to have an affirmation
4 that I'm correct in my interpretation of that charge.

5 DR. PIERSON: Yeah, John. I think you're
6 right. It's really what's concerned more for changes in
7 the microbial ecology of the product that would allow
8 something that would normally not have been a hazard to
9 become one.

10 DR. KVENBERG: Thank you.

11 DR. PIERSON: Any other comments or questions?
12 Okay. Spencer, if it's all right with you, we'll take a
13 short break and then you can resume your Subcommittee
14 deliberations.

15 MR. GARRETT: Yes, as we say in the Naval
16 Services, the flogging will continue, I guess. But
17 we're going to be in here.

18 DR. PIERSON: Okay. We'll be meeting in here.
19 Okay.

20 ***

21 [End of Proceedings, 9:15AM]

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38

CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

IN RE: National Advisory Committee on Microbiological
Criteria for Foods Committee, Plenary Session

HELD AT: Washington, DC

DATE: August 20, 2003

We, the undersigned, do hereby certify that the foregoing pages, numbered 1 through 32, inclusive, are the true, accurate and complete transcript prepared from the reporting by the reporter in attendance at the above identified hearing, in accordance with applicable provisions of the current USDA contract, and have verified the accuracy of the transcript by (1) comparing the typewritten transcript against the reporting or recording accomplished at the hearings, and (2) comparing the final proofed typewritten transcript against the reporting or recording accomplished at the hearing.

Date:

Karen D. Martini, Transcriber
York Stenographic Services, Inc.

Date:

Sarah Mowrer, Proofreader
York Stenographic Services, Inc.

Date:

Tim Wagner, Reporter
York Stenographic Services, Inc.