

UNITED STATES OF AMERICA
DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NATIONAL ADVISORY COMMITTEE
on
MICROBIOLOGICAL CRITERIA FOR FOODS

Omni Shoreham Hotel
2500 Calvert Street, NW
Washington, D.C.

Friday
January 25, 2002

The above captioned meeting convened at 9:00 a.m.

Chairperson:

Kaye Wachsmuth
USDA-FSIS, OPHS Deputy Administrator
Washington, DC 20250

Executive Committee:

Vice Chair:

Janice Oliver
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FDA, CFSAN

College Park, MD

Centers for Disease Control Liaison:

Arthur P. Liang, MD, MPH
Director, Food Safety Initiative Activity, CDC
Atlanta, GA

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LeeAnne Jackson, Ph.D
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Commerce Department Liaison:

E. Spencer Garrett
Laboratory Director
National Seafood Inspection Laboratory
National Marine Fisheries Service
Pascagoula, MS

Defense Department Liaison:

LTC Robert Webb
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Executive Secretariat:

Brenda Halbrook
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Advisory Committee Specialist:

Karen Thomas
USDA, FSIS, OPHS
Washington, DC

Committee Members:

Dr. David Acheson
University of Maryland
Department of Epidemiology & Preventive Medicine
Baltimore, MD

Mr. Dane Bernard
Food Safety and Quality Assurance
Keystone Foods LLC
West Conshohocken, PA

Dr. Larry Beuchat
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Dr. Robert Buchanan
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Dr. Catherine Donnelly
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Dr. Stephanie Doores
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Dr. Frances Downes
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Dr. John Kvenberg
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Centers for Disease Control & Prevention
Atlanta, GA

Dr. Katherine Swanson
The Pillsbury Company
St. Paul, MN

Dr. David Theno
Jack in the Box, Inc.
San Diego, CA

Dr. Robert Tompkin
ConAgra Refrigerated Foods
Downers Grove, IL

Audience participants:

Ms. Caroline Smith-DeWaal
Director of Food Safety
Center of Science in the Public Interest

P R O C E E D I N G S

9:00 a.m.

1
2
3 DR. WACHSMUTH: I'm hoping everyone can stay
4 until noon. I'm hoping we can finish by noon. To that
5 end, if there are no objections, I'd like, instead of
6 taking a break -- if someone needs coffee, or needs to
7 get up, just do that as you see a time in the debate.
8 If there's not, I'll for a short break. We don't have
9 to. Okay, we have most of the council, and I see
10 several people with Caroline Smith-DeWaal's report.

11 Okay, I think what I'd like to do is start
12 the way we discussed yesterday, start with the hot
13 holding document. I think we were -- the Committee was
14 in agreement with the document except for question four
15 and the subcommittee has revised that. I'll ask Dan if
16 he has any comments, and then just open it for
17 discussion.

18 DR. ENGELJOHN: This is Engeljohn with FSIS.

19 Before you, you should have a redline strikeout
20 version of modifications to the draft that you got
21 yesterday, and to give you an overview of what's here,
22 my attempt was to incorporate the concept that if, in
23 fact, an operation was capable and had data to support
24 that they were controlling their process to insure

1 their product is at least 130 degrees or higher at all
2 times, that time may not need to be a factor in that,
3 but that requires there to be data.

4 So within the document that you have, the
5 changes I made, the first one relates to just
6 clarifying that we used the FDA survey information that
7 is contained in the background material. The middle
8 portion, the large section that was added, added the
9 concept about data to support 130 degrees minimum
10 without time, and then the concept in the bottom half,
11 incorporates the concept that time and temperature are
12 important when there's non-continuous monitoring or
13 there is no data at the time to support that 130
14 degrees is, in fact, the minimum temperature.

15 So, should I read through it, or just take
16 comments from the group?

17 DR. WACHSMUTH: I think I'll just open it up
18 for discussion now. If there are any objections
19 particularly -- David?

20 DR. ACHESON: Yes, David Acheson. I was just
21 wondering why like halfway down, the should got changed
22 to a could in relation to the margin of safety could be
23 increased through the use of both time and temperature
24 control?

1 DR. ENGELJOHN: I made the change really
2 because -- as a recommendation. I didn't see the could
3 or should mattered, but do you see a difference there?

4 DR. ACHESON: I did see a difference, and I
5 just -- I presume the subcommittee is recommending that
6 it should be? Should just says it a little stronger
7 than could. That's my point.

8 DR. ENGELJOHN: Okay, I see some nods, so
9 should.

10 DR. WACHSMUTH: Okay, any objections? If
11 not, I'll change it back to should. Okay, I think it
12 was a good job, subcommittee, and we'll complete that
13 report.

14 DR. ENGELJOHN: Can I ask, Madam Chairman, do
15 I just send that to Brenda -- the revised document with
16 all the changes? Is that what I need to do?

17 DR. WACHSMUTH: Yes.

18 DR. ENGELJOHN: And we just accept that as
19 the document, then?

20 DR. WACHSMUTH: Yes, the changes that we
21 agreed on.

22 DR. ENGELJOHN: Okay, within the other parts
23 of the document refer to the subcommittee, so I'll
24 change that to Committee. The other questions that

1 were there -- so I'll just make those kind of
2 formatting changes. Okay.

3 DR. SWANSON: I have one -- one last thing.
4 It's Katie Swanson. The last sentence. It's only what
5 has been called a potentially hazardous food that is
6 held under those temperatures would be considered
7 hazardous. You might have like a tomato soup that
8 would have a lower pH, so this is a pretty absolute
9 statement, and I don't really think it's appropriate.

10 DR. WACHSMUTH: Could you -- at this point --

11 DR. SWANSON: Okay, I'll suggest a change.
12 "concluded that any potentially hazardous food
13 maintained during hot holding at lower temperatures."

14 DR. WACHSMUTH: Okay, if there are no
15 objections, that will be done. Bob.

16 DR. BUCHANAN: We would prefer if you don't
17 use the term potentially hazardous food.

18 DR. SWANSON: Okay.

19 DR. WACHSMUTH: Katie?

20 DR. SWANSON: Any food that supports the
21 rapid and progressive growth of --

22 DR. BUCHANAN: We would prefer if you don't
23 use rapid and progressive growth.

24 DR. SWANSON: Any food that supports the

1 growth of pathogenic -- food borne pathogens. How's
2 that? Without time/temperature control for safety.
3 I'm dreaming again.

4 DR. WACHSMUTH: Well, I think that's --

5 DR. SWANSON: Did you get that, Dan?

6 DR. ENGELJOHN: No.

7 DR. SWANSON: Okay, "any food that requires
8 time/temperature control for safety that is
9 maintained."

10 DR. ENGELJOHN: Okay.

11 DR. WACHSMUTH: Okay? Good job,
12 subcommittee. In fact, to the whole Committee, I think
13 you by your individual subcommittees and then some
14 people had to do double duty -- you've done a great
15 job. I was reading documents this morning -- some very
16 nice work.

17 Now the next document we'd like to finalize -
18 - it has been a rather extensive rewrite, but the
19 subcommittee seemed very true to the charge they were
20 given from the full Committee, the requests for
21 changes, and that's the blade tenderizing document.
22 John, would you want to say anything -- introduce this?

23 DR. KVENBERG: Thank you, Madam Chair. Yes,
24 the -- we received comments in full Committee and had

1 some actual drafting text provided by Dr. Neill. The
2 subcommittee subsequently reviewed that and inserted
3 into the document the additional comments that were
4 made there. Before we get into general comment, I have
5 two what I would consider to be editorial changes of
6 one word -- minor, just to point the Committee to.

7 On page three of the document, the seventh
8 recommendation, "quantify D and Z values for strains of
9 E. coli 0157". What we really didn't address was Dr.
10 Buchanan's comment relative to the cocktail, and if we
11 inserted the word "individual" in front of the word
12 "strains for E. coli", I think that would get the
13 intent of what the Committee was driving at, because
14 there is some variability in the D and Z values -- the
15 valuation data that was presented in that thesis report
16 for review. Just so we're clear on our recommendation,
17 I think the "quantification of individual strains"
18 would be a good insertion on that -- just the word
19 individual.

20 And above that, it's clearly editorial,
21 because our changing from a subcommittee to a Committee
22 report, under questions three and four on that page,
23 just strike the word "sub" as it appears on question
24 three and four, and just merely say "the Committee

1 concluded". If there's no objections to those
2 statements.

3 Also if we could, I would suggest we go --
4 discussion on this document page by page as an
5 editorial nature, just to save time, Madam Chair.

6 DR. WACHSMUTH: That was my point. I thought
7 what I might do is just go section by section. If
8 there are any changes in that introductory paragraph,
9 or any suggestions for that. John. And when you make
10 -- we would like to finalize the document, so when you
11 have a comment, give us a very specific -- specifically
12 worded statement that we could insert, or something you
13 want to delete, so we can keep the document intact. If
14 we have to make too many changes, we won't be able to
15 finalize it. John.

16 DR. LUCHANSKY: If I may, just for accuracy,
17 I have a couple suggested changes to make. The last
18 paragraph on page one, second sentence, steaks, when we
19 look at the actual case writeups for those illness
20 incidences, in Canada was actually a steak and a roast,
21 so for accuracy, I would propose to have it read
22 "incidences associated with steaks and roasts in
23 Canada".

24 DR. KVENBERG: Madam Chair, can I just ask

1 for exactly where the insertion goes in that sentence?

2 DR. LUCHANSKY: One second, please. The only
3 point I'm trying to make is that in Michigan it was
4 sirloin steak, and in Canada, it was a roast and a
5 steak, and so I think the document should reflect that,
6 rather than as it is now, saying that it was steaks in
7 both Canada and Michigan.

8 DR. WACHSMUTH: They were different kinds of
9 steaks?

10 DR. LUCHANSKY: It was a roast in Canada.

11 DR. KVENBERG: Madam Chair, can I propose
12 then that in the Canadian incidence, and then insert
13 "involving steak and roast" -- would that be --

14 DR. LUCHANSKY: That's fine. I'm sorry --
15 one -- I also think for clarity, that the last sentence
16 where it says, "There was no further investigation of
17 the beef product" -- I would put an "s" on product, and
18 I would insert the word "Canadian beef products",
19 because in the Michigan incident, there were able to
20 identify the fact that it was tenderized. So for
21 clarity, "Investigation of the" -- insert "Canadian
22 beef" -- and put an "s" on "products".

23 DR. WACHSMUTH: Alright. Any other comments
24 on the first page?

1 DR. MADDOX: Carol Maddox. The second to the
2 last paragraph, second line should be --

3 DR. WACHSMUTH: Can you pull up the mike?

4 DR. MADDOX: I don't have a mike.

5 DR. WACHSMUTH: Sorry, we need a microphone.

6 DR. MADDOX: Carol Maddox, and second to the
7 last paragraph, second line, should read,
8 "investigations do not include questions on consumption
9 of steak or roasts".

10 DR. WACHSMUTH: Oh, okay. Anyone else, any
11 comment on the first page? Okay, let's turn the page.
12 John.

13 DR. LUCHANSKY: I was on the subcommittee, so
14 that's why I'm a little more familiar with this one. I
15 propose that under question number two, the third
16 paragraph beginning "Following inoculation" that "a
17 five strain cocktail" gets hyphenated. I also propose
18 in the next paragraph that the second sentence,
19 beginning, "While data" be deleted because a statement
20 on what occurs at 140 degrees directly follows in the
21 next sentence.

22 I also propose that the last paragraph
23 beginning, "The Committee felt" be moved under question
24 one because it comments on epidemiological information

1 and all of that is dealt with under question one, so I
2 propose that we move that to under question one. And
3 I propose that the sentence "Of the two situations
4 discussed", where it says, "Item one, additional data
5 is needed" -- I propose that that be struck because I
6 think, unless I'm wrong, we have all the data we're
7 going to get about the Michigan and Canadian illness
8 episodes, so I don't think it's accurate. I'd be happy
9 to reiterate the suggested changes if they aren't
10 clear.

11 DR. KVENBERG: Madam Chair, John Kvenberg,
12 I'd appreciate that, as I'm trying to capture what he's
13 saying.

14 DR. LUCHANSKY: Okay, under question two, the
15 third paragraph beginning "Following inoculation with a
16 five strain cocktail". The next paragraph beginning,
17 "This presents" -- delete the second sentence beginning
18 "While data published by Sporing" and simply have it
19 run contiguous with the next sentence beginning, "Non-
20 intact blade tenderized".

21 DR. WACHSMUTH: I think the first one is
22 editorial. This is not exactly editorial. I'd like to
23 make sure everyone's in agreement. I'm seeing some
24 nods. Does anyone disagree with that change?

1 DR. ENGELJOHN: I don't disagree, but I'd
2 just like to get another reading of it so that I
3 understand.

4 DR. WACHSMUTH: Okay. John Luchansky is
5 proposing that we delete the sentence that begins
6 "While data published" and simply move the next
7 sentence paragraph up to follow "individuals" because
8 they seem to say the same thing. But it's not exactly
9 the same thing, that's why I'm raising --

10 DR. SWANSON: I think it helps to have the
11 reference so that, from a historical perspective,
12 somebody can go back and determine how that conclusion
13 was made.

14 DR. LUCHANSKY: The reference -- that could
15 be clarified, if I may, Katie. We're right directly
16 under question two, "The following statements are based
17 on scientific data published in the Master's thesis" --
18 that's the Sporing reference right there, so if it
19 would help to put Sporing up in that sentence --

20 DR. SWANSON: Well, from the perspective of
21 someone who did not sit on the Committee and go through
22 the deliberations, I think it's clearer this way and
23 more justifiable, so I'd recommend keeping this as it
24 is.

1 DR. WACHSMUTH: Stephanie?

2 DR. DOORES: I may have missed it, but I
3 don't see the Sporing reference actually written out in
4 the back under the other references.

5 DR. LUCHANSKY: The Sporing reference is in -
6 - I'm sorry -- is in the first paragraph of this
7 document, and we could indeed list it as a bona fide
8 reference in the back under references. That was
9 another suggestion I was going to make later.

10 DR. WACHSMUTH: I think since some -- there
11 is at least one person thinks that the information is
12 helpful, that we should leave it in. I don't think it
13 hurts anything. Also, now that you do have a reference
14 at the end, formatting wise, it would be appropriate to
15 put Sporing in as well. Bob?

16 DR. BUCHANAN: Just a minor point in regard
17 to scientific publications. Is this Master's thesis
18 truly published? Is it available? Is it archived
19 appropriately? Typically, Master's thesis are not to
20 be considered -- are not considered published
21 documents, nor are they citable, typically because most
22 people cannot gain access to those unless you were on
23 the Master's thesis or unless the university is going
24 to make this available, unlike dissertations, which are

1 centrally brought together by an organization. So I
2 have some reservations about using the term published
3 and in fact, citing it as a scientific reference.

4 DR. WACHSMUTH: Sorry, Bob, I wasn't
5 connecting that it was just -- not just -- that it was
6 a thesis.

7 DR. LUCHANSKY: That's one of the central
8 points of our deliberations in that that's the only
9 study that's --

10 DR. WACHSMUTH: It's not peer reviewed.

11 DR. LUCHANSKY: And it's not peer reviewed,
12 that's a key point.

13 DR. WACHSMUTH: Okay, so we do need to leave
14 it -- you should not put it in the references. But I
15 think we should retain the information.

16 DR. BUCHANAN: And you should not refer to it
17 as a "published document".

18 DR. KVENBERG: Madam Chair, I will attempt to
19 fix, John, if it's alright?

20 DR. WACHSMUTH: I think it's fixed. We're
21 going to leave it alone.

22 DR. KVENBERG: But one word change on Dr.
23 Buchanan's comment, and I think the word "published" is
24 the problem you're seeing there, so if you strike the

1 word "published", it says, "While data by Sporing".

2 DR. LUCHANSKY: Or "contained in" --

3 DR. WACHSMUTH: Yes, that's good.

4 DR. LUCHANSKY: "contained in the" --

5 DR. KVENBERG: "While data contained in the
6 thesis by Sporing" would fix his problem with
7 "published" -- the one word.

8 DR. MADDOX: We leave the sentence in?

9 DR. WACHSMUTH: So we'll leave it -- yes,
10 we'll retain the sentence. The next suggestion --

11 DR. MADDOX: Then -- I'm sorry. If we do
12 leave the sentence in, there's a modification that
13 needs to be made to it then. There was a
14 misinterpretation that the E. coli was only eliminated
15 from the surface, and that's not true, it was totally
16 eliminated from the steak. So strike "the surface of",
17 so it reads, "broiling to an internal temperature of
18 140 degrees Fahrenheit eliminated E. coli 0157H7 from
19 inoculated steaks that had been blade tenderized."

20 DR. LUCHANSKY: And I think if it stays,
21 which again I don't favor, but I think we have to
22 clarify the term eliminated. I don't have the exact
23 data in front of me, but I believe they were able to
24 achieve a six-log reduction, but it doesn't comment as

1 to whether they were or were not able to recover the
2 pathogen by enrichment. So -- I think that word
3 eliminated should be quantified.

4 DR. SWANSON: May I withdraw my request not
5 to eliminate the sentence. It's not worth the
6 discussion we're having.

7 DR. WACHSMUTH: It's not. Let's delete it.

8 DR. KVENBERG: Madam Chair, this is
9 clarifications to where we are then, that John
10 Luchansky's recommendation to delete the entire thing
11 is where we are?

12 DR. WACHSMUTH: We took it.

13 DR. KVENBERG: Thank you.

14 DR. SWANSON: One more comment was pointed
15 out, the second paragraph after question two refers to
16 scientific data published in the Master's thesis. I
17 suggest just delete the word "published".

18 DR. WACHSMUTH: "Published", okay.
19 Substitute contained.

20 DR. BUCHANAN: Just eliminate "published".

21 DR. WACHSMUTH: Okay, John, your next
22 recommendation was to move --

23 DR. LUCHANSKY: I was going to make the
24 recommendation that the last paragraph, "The Committee

1 felt there was a paucity of epidemiological data" be
2 moved under question one which is where we articulated
3 the epidemiological component of our deliberation. And
4 I would suggest that it would be in that first
5 paragraph under question one, "The Committee concluded
6 that there was sufficient data to answer question two
7 but not three". I would start that paragraph off with
8 the sentence from page two, "The Committee felt there
9 was a paucity of epidemiological". I'm sorry, LeeAnne,
10 what?

11 DR. WACHSMUTH: Okay, so we would move "The
12 Committee felt" we would move that sentence and what's
13 below that just above question two?

14 DR. LUCHANSKY: With the exception that I
15 would strike the second sentence, "Of the two
16 situations discussed by the subcommittee, the consensus
17 was" -- that sentence needs to be struck for the
18 following reason, point number one, additional data is
19 needed is no longer valid because I think we have all
20 the data we're going to get from the Michigan and
21 Canadian outbreak -- is that true, John? John
22 Kvenberg?

23 DR. KVENBERG: Yes, unfortunately Frances
24 Downes is not here but I think we have all we're going

1 to get. There was a subsequent clarification of the
2 equipment that was used, we had as a document, but I
3 think Dr. Luchansky's right, there is nothing more
4 going to be forthcoming from Michigan. We have what we
5 have.

6 DR. LUCHANSKY: Or Canada.

7 DR. KVENBERG: Or Canada.

8 DR. WACHSMUTH: Okay, if we accept that,
9 you're proposing to move that sentence and strike --

10 DR. LUCHANSKY: "Of the two situations
11 discussed".

12 DR. WACHSMUTH: "Of the two situations".

13 DR. LUCHANSKY: And I explained why I thought
14 item one was no longer needed.

15 DR. WACHSMUTH: Right. You want to go to
16 item two.

17 DR. LUCHANSKY: Item two, to me, I think, is
18 needed, but I think perhaps it could be moved under --
19 to under "Research needs".

20 DR. WACHSMUTH: Become number eight?

21 DR. LUCHANSKY: If that's what you would like
22 or suggest.

23 DR. WACHSMUTH: Any objections to that?

24 Okay. Anything else on question two? Katie, is your

1 flag up or down.

2 DR. SWANSON: Oh, I'm down.

3 DR. WACHSMUTH: Okay. Alright, question two
4 we've modified now. Editorial changes, we changed
5 "published" to contained in the first sentence under
6 the question we've hyphenated "five strain" in the
7 third sentence.

8 DR. BUCHANAN: Kaye, before you go, I --

9 DR. WACHSMUTH: Bob?

10 DR. BUCHANAN: I have one final question
11 about question two.

12 DR. WACHSMUTH: Okay.

13 DR. BUCHANAN: And again, this is based on
14 only a cursory reading of the supporting summary of the
15 Master's thesis. You have in question two, in the
16 sixth paragraph, the paragraph that reads "Although
17 data were more variable at temperatures below 140, it
18 is possible to achieve a 3.2 log reduction for blade
19 tenderized, and a 5.2 log reduction for intact beef
20 steaks at 120 degrees Fahrenheit." I do have a
21 question how that value was obtained? Was that based
22 on taking the entire steak that was inoculated and then
23 blade tenderized and then calculating it -- grinding up
24 the whole steak and achieving the results? Or was that

1 based on taking the core sample at the coldest point in
2 the steak and determining the value there?

3 If it was the former, then you really
4 shouldn't be citing these numbers because the point
5 you're looking for is what was the D value in the
6 internal components, and this is artificially
7 indicating what is the level of contamination that was
8 removed.

9 DR. KVENBERG: Madam Chair, John Kvenberg. I
10 think -- and Committee help me here -- basically they
11 punched a -- I guess you would call it a core sample of
12 the steak, they didn't do the whole steak.

13 DR. LUCHANSKY: Bob, I -- if I may, or Carol
14 perhaps, that's --

15 DR. WACHSMUTH: Just identify yourself.

16 DR. LUCHANSKY: John Luchansky. That was one
17 of the concerns that we had about the study, and you
18 very astutely picked it out, which is why, in the
19 research need, under item two, we list "We must
20 determine the survival of 0157 in the core", so --

21 DR. BUCHANAN: Well, it's fairly obvious when
22 you only had 10^3 in the center, and you had a 5.2 log
23 reduction at 120 degrees Fahrenheit, the numbers don't
24 add up. So --

1 DR. LUCHANSKY: Interestingly, there was a
2 greater kill at 130 for the tenderized compared to the
3 non-tenderized, so we tried to preface our remarks by
4 saying below 140 the data were variable.

5 DR. KVENBERG: Madam Chair, can I request
6 invoking a rule here as to can we get a suggested
7 changing to the words so we can move on?

8 DR. WACHSMUTH: Yes, I mean this is a good
9 point, but I think -- I don't know how deeply we want
10 to get into the data at this point. Do you have a
11 suggestion, Bob? Do you want to eliminate something or
12 add a sentence clarifying what kind of sample, or
13 something specific?

14 DR. BUCHANAN: One second.

15 DR. LUCHANSKY: Could I -- Bob, perhaps
16 attack a phrase on the end articulating that "as
17 determined by taking a core sample" -- you know, just
18 spell it out how the microbiological analysis in
19 actuality was conducted?

20 DR. WACHSMUTH: While Bob's working on that,
21 are there any other comments?

22 DR. BUCHANAN: I'll come back.

23 DR. WACHSMUTH: Carol -- sorry, I didn't see
24 it.

1 DR. MADDOX: I believe -- Carol Maddox -- I
2 believe that that was actually a cross-sectional sample
3 through the center of the steak, and I propose that we
4 add that description to the end of this sentence.

5 DR. WACHSMUTH: To read?

6 DR. MADDOX: To read that "the 5.2 log
7 reduction for intact beef steaks at 120 degrees was
8 determined from a cross-sectional --

9 DR. WACHSMUTH: "Sample".

10 DR. MADDOX: "samples", I guess.

11 DR. BUCHANAN: That's fine.

12 DR. KVENBERG: Madam Chair, can I ask for a
13 repeat of the actual language? I don't have it. Thank
14 you, John Kvenberg.

15 DR. WACHSMUTH: Okay. Let's see if I have
16 it. It was simply to add at the end of the sentence
17 that "Although data were variable at temperatures below
18 140, it was still possible to achieve a 3.2 log
19 reduction for blade tenderized and a 5.2 log reduction
20 for intact beef steaks at 120 degrees Fahrenheit as
21 determined from a cross-sectional sample."

22 DR. KVENBERG: Thank you.

23 DR. WACHSMUTH: Is that okay, Bob?

24 DR. BUCHANAN: Can I just recommend, it's

1 "based on a cross-sectional" -- "based on cross-
2 sectional samples" -- I assume more than one was done
3 -- "of inoculated steaks".

4 DR. KVENBERG: Got it.

5 DR. WACHSMUTH: Okay, it now ends with "based
6 on cross-sectional samples of inoculated steaks".
7 Alright, any other comments on two? What about three
8 or four? Those conclusions are still the same.
9 Research needs? We have moved what was part two under
10 question two, is now number eight under research needs.
11 Carol, is your flag up?

12 DR. MADDOX: Yes, Carol Maddox. Just some
13 minor points in the research need section, under number
14 five, it should read, "proportion and quantity of blade
15 tenderized beef" to be consistent with the other
16 request.

17 And in addition to modifying number seven to
18 read "individual strains of E. coli 0157", I would
19 propose that these -- the individual strains be
20 identified and are characterized.

21 DR. WACHSMUTH: Okay, so we would add another
22 sentence that says "Individual strains should be
23 identified and characterized"? Is that the proposal,
24 Carol?

1 DR. MADDOX: Yes, that would be acceptable.

2 DR. WACHSMUTH: I think that was a suggestion
3 made by Larry yesterday. If there are no objections,
4 we'll take that. Dane.

5 DR. BERNARD: Thank you. Dane Bernard. With
6 the list of research needs here, I'm wondering if what
7 we shouldn't really recommend is that the -- a study
8 similar to what was done by Sporing be repeated? We've
9 talked about doing the D and Z values on the strains
10 used in the Sporing study; we've talked about
11 characterizing them. But I think it's worth noting
12 that, at least in my opinion, that even if the D and Z
13 values were now calibrated, it may bear little
14 resemblance to what was run in the Sporing study -- the
15 state of those organisms at that time. I'm not sure
16 that what we're asking for here, we're really, at the
17 end of the day, if we did it, would give us what we
18 need. And I'm just asking my fellow Committee members
19 if it wouldn't be more appropriate just to recommend
20 further studies of the type done by Sporing, wherein
21 you could collect the heating data on the steaks in a
22 more accurate way -- we've got that recommendation in
23 here -- all of it should be run kind of at the same
24 time so that you get the best data. So I'm just asking

1 a question of my colleagues.

2 DR. KVENBERG: Madam Chair, may I address
3 that?

4 DR. WACHSMUTH: John.

5 DR. KVENBERG: I think that, just to be
6 clear, and I understand your point, and I personally
7 agree with it, the study that was reported on was
8 broiled steaks only, so the language we should use, I
9 guess, would be repeating of the study by Sporing on
10 broiled steaks -- would be -- that's the only data set
11 that exists -- that would be the repeat, just for
12 clarification. Additional studies need to be done on
13 other types of steaks and on roasts.

14 DR. LUCHANSKY: Madam Chair?

15 DR. WACHSMUTH: John Luchansky.

16 DR. LUCHANSKY: On page four, under
17 recommendations, perhaps we could broaden that to
18 accommodate what Dane was suggesting. "Point one, FSIS
19 should consider requesting NACMCF to develop guidelines
20 for validating the process and to" -- you know, add on
21 to there -- "and to reproduce the results already" --
22 you know, something there to the effect that the trial
23 with the steaks needs to be reproduced and with the
24 roasts need to be conducted.

1 DR. WACHSMUTH: I think it's probably not a
2 bad idea for a location, because you are recommending
3 that the Agency --

4 DR. LUCHANSKY: Ask for it.

5 DR. WACHSMUTH: -- ask for. The Agency can't
6 do it. I'm not sure -- can somebody help us with some
7 words here?

8 DR. LUCHANSKY: "That additional studies be
9 undertaken" --

10 DR. WACHSMUTH: "That the Agency request
11 additional studies" --

12

13 DR. LUCHANSKY: "That additional research is
14 needed to --"

15 DR. WACHSMUTH: Well, under this, you're
16 recommending to the Agency.

17 DR. LUCHANSKY: There's -- one thing that
18 they're -- the first recommendation was to, if a study
19 was going to get conducted, have somebody set
20 guidelines so that whoever would do that study would be
21 using a standardized protocol and would be addressing,
22 essentially, all the items that we've been talking
23 about under research needs: look at the effect of
24 strains, look at the effect of fat, watch where you put

1 the thermocouples, how many strains you should use --
2 that basically begins to set guidelines for conducting
3 a validation study.

4 It's a different point to say additional
5 studies are needed.

6 DR. WACHSMUTH: Okay, if we had another
7 sentence, then, with one -- or continue that -- "that
8 the Agency request additional studies" -- and just
9 leave it that nebulous? Would that -- add anything?
10 Would that help any?

11 DR. BERNARD: I think at the same time we
12 make that recommendation, Madam Chair, we may express,
13 I think, some -- and I don't want to diminish the
14 importance of the Sporing study. What I guess I'm
15 trying to avoid here is having it appear that the
16 Committee thinks that the Sporing study is all that
17 needs to be done. So I think with that suggestion, we
18 may point to some additional things that we would have
19 liked to have seen done along with the Sporing study,
20 and in order to fill those gaps, we think that
21 additional work needs to be done.

22 DR. WACHSMUTH: The reason that I thought
23 John's suggestion was a good one is that the Committee
24 is saying that we need to develop guidelines and ways

1 for validating, and if you tag onto that that the
2 Agency should also request additional studies using
3 these guidelines, I think that will get you what you
4 want. I'm not sure. David?

5 DR. ACHESON: Suggested wording, as a third
6 point under the recommendations, "That FSIS request
7 additional studies be undertaken to reflect the
8 research needs." And if we haven't got all those needs
9 covered under the research needs to bring up Dane's
10 point, then we should add an eighth or ninth research
11 need specifically. So that would be a third -- just to
12 recap, a third point under recommendations "That FSIS
13 request additional studies be undertaken to reflect
14 research needs."

15 DR. WACHSMUTH: And follow the guidelines --
16 or do you want to add anything to refer back to the
17 fact that this Committee thinks that there is a certain
18 rigor that needs to be introduced into this?

19 DR. ACHESON: Yes, we could add that.

20 DR. WACHSMUTH: Okay, somebody's got to help
21 me with the words. They're not coming. The third
22 recommendation will be "FSIS requests additional
23 studies be undertaken to meet the research needs and to
24 be conducted according to guidelines from number one."

1 PARTICIPANT: "Above guidelines."

2 DR. WACHSMUTH: Carol?

3 DR. MADDOX: That sounds fine. Could make
4 that -- I think that sounds fine, could be "FSIS
5 requests additional studies that reflect the research
6 needs mentioned and follow the above guidelines."

7 DR. WACHSMUTH: Okay, "follow above
8 guidelines" -- and we'll put a number one after that.
9 Are there any objections? Is that -- does that help?
10 Bob, are you up?

11 DR. BUCHANAN: Yes, I am, Kaye, and I have
12 two comments. One is related to research needs and my
13 apologies, but I would like to return to question three
14 at some point. In terms of the research section in
15 recommendation number six, I'd like to suggest that it
16 be rewritten more in an engineering perspective and
17 "request a better understanding of the heat and mass
18 transfer characteristics of blade tenderized meats
19 cooked by various means."

20 DR. WACHSMUTH: Okay, could you do that again
21 more slowly?

22 DR. BUCHANAN: Right. "better understanding
23 of the heat and mass transfer characteristics of blade
24 tenderized meats cooked by various means." And there's

1 a verb -- it's not a complete sentence, but I didn't
2 try to fix that.

3 DR. KVENBERG: Madam Chair, John Kvenberg.
4 Can I get you to restate the sentence so I have it?
5 Thank you.

6 DR. WACHSMUTH: Okay, I think I have it.
7 Under research needs, "A better understanding of the
8 heat and mass transfer characteristics of blade
9 tenderized meats cooked by various means and the
10 variability of the internal temperatures in cooked
11 steaks" -- I inserted it, Bob.

12 DR. BUCHANAN: It's not necessary.

13 PARTICIPANT: Don't need the last part.

14 DR. WACHSMUTH: Just eliminate the last part
15 of the sentence.

16 DR. BUCHANAN: Just eliminate the last part
17 of the sentence.

18 DR. WACHSMUTH: Okay, so it would then read,
19 "A better understanding of the heat and mass transfer
20 characteristics of blade tenderized meats cooked by
21 various means."

22 DR. KVENBERG: Thank you.

23 DR. WACHSMUTH: Okay, anything else in the
24 document, in general?

1 DR. BUCHANAN: Yes, Kaye, I would like to
2 return to question three.

3 DR. WACHSMUTH: Okay.

4 DR. BUCHANAN: After having read question
5 three over several times, I must -- I find the response
6 there sort of unsatisfying. It doesn't -- I guess,
7 based on your consideration of the issue in steaks, and
8 based on the subcommittee's, or this Committee's
9 knowledge of meat and poultry products, or blade
10 tenderized products, I guess I expected one to be able
11 to extrapolate, based on the best science we have
12 available some statement more than just "insufficient
13 data were available". And while I realize that you may
14 have had no data on roast to consider, I'm trying to
15 grapple in my own mind why -- why a roast would have
16 been different than a steak, other than the fact that
17 there may be some heat mass transfer characteristics
18 that differ. And just to say that you couldn't come up
19 with it, I don't know, it --

20 DR. WACHSMUTH: This -- if this Committee's
21 report will be read in total, without pulling the
22 question out of context, at the top of page two, that
23 second paragraph after the epidemiological data, it
24 says, "thus, the available evidence shows that steaks

1 and roasts can transmit E. coli 157H7 infection, but
2 does not allow discrimination for relative contribution
3 of the commodity type." The reference to Rodrigue in
4 the back is a roast that was not blade tenderized. I
5 think what Dr. Neill was trying to do was show both
6 could be vehicles and we just don't have the
7 information to make the -- to discriminate between
8 them. John.

9 DR. KVENBERG: Sure, just in response to
10 this, I think we have to base our recommendations on
11 the science we have. Where we don't have the science,
12 we say it. So interpolating information from non-
13 existent data is somewhere the subcommittee just
14 couldn't go. Maybe the response is rather terse, but
15 we defer to the research needs that this needs to be
16 developed in order to make a recommendation. There was
17 nothing to draw from. So I'm at a loss as exactly how
18 to modify our response on question three, or engage in
19 speculation of what we might have to say about roasts.
20 We just simply don't have the scientific data to say
21 anything.

22 DR. WACHSMUTH: Dave?

23 DR. ACHESON: Can I just support John on
24 that? There really was no data, and sure we could

1 speculate, but we didn't feel that we should do that.

2 DR. WACHSMUTH: Okay. I think they went as
3 far as they could go, Bob. John Luchansky, for this?

4 DR. LUCHANSKY: I was going to bring up a
5 different topic, but I do concur, Bob, we just were
6 uncomfortable speculating.

7 DR. BUCHANAN: I guess I
8 find it a little limiting in the fact that there has
9 been a great deal of research done on reformulated
10 roast, and there's a great deal of information about
11 the thermal characteristics of roast in the elimination
12 of Salmonella, and also there's a great deal of
13 information on Clostridium perfringens in that regard,
14 was the basis of the current cooking requirements for
15 roast beef. And you know, I don't have it at my
16 fingertips -- all of the data that were generated on
17 the cooking characteristics of roast and meats. But if
18 you have an organism X number of inches inside the
19 roast, and you have the characteristics associated with
20 the cooking of roast, it's a pretty straight
21 engineering calculation to determine what the heat
22 transfer is going to be.

23 DR. LUCHANSKY: And again, that would be a
24 calculation and a prediction, rather than an X log

1 kill, so I think -- or hopefully, one of the take home
2 points of this document would be the paucity of
3 epidemiological information, the adequate -- or the
4 need for adequate studies to fully validate either
5 steaks or roasts, and hopefully that message comes
6 through here.

7 DR. WACHSMUTH: Yes, I think at this point in
8 the deliberations, that we need to bring specific data
9 to the table -- more studies and things the
10 subcommittee can consider, then we need to supply those
11 to the subcommittee, otherwise I think we have to take
12 their assessment of the situation. Dan, is it to you?

13 DR. ENGELJOHN: Yes, Engeljohn. Maybe -- I
14 have a potential fix here that may help the situation.
15 We did have some information to look at, and I think
16 the real issue here related to slow roasted prime rib.
17 We did have some preliminary information about that,
18 not on 0157, but on other organisms which did present
19 us with some insufficient information. So possibly, if
20 we could just add to the end of the response, the
21 statement, "particularly as it relates to slow roasted
22 prime meat -- or rib". Maybe that would help get at
23 the issue, that that was the issue that, as I recall,
24 was coming forward potentially from the Conference for

1 Food Protection issues related to slow roasted prime
2 rib. The issues related to Clostridium perfringens
3 being of primary concern, and not having enough
4 information there as well as 0157. Does that get at
5 the issue?

6 DR. WACHSMUTH: I'm not sure --

7 DR. BUCHANAN: Well, I'm not going to beat a
8 dead horse on this one. I'm not going to fall on my
9 sword over it. It's just, one of the basic principles
10 of food microbiology and food engineering is that you
11 don't have to do every product every way. That once
12 you've established some characteristics and it's a
13 basis for almost all of our process controls throughout
14 the industry, once you've established these
15 characteristics, you can have a reasonable evaluation
16 based on those characteristics. And the heating
17 characteristics of roast are well known, the thermal
18 resistance of these organisms are well known, and
19 unless you're getting into extreme examples, such as
20 evaporative cooling, going through some normal cooking
21 cycle would give you a pretty good idea of what the
22 temperature's going to be in a roast if you're
23 penetrating it even to a level of an inch. And you can
24 -- while you may not be able to have specific data on

1 all of it, you could get a pretty good estimate of the
2 number of D values that would have been achieved at any
3 one point in that roast based on the cooking time and
4 temperature.

5 DR. WACHSMUTH: Okay, I think at this point,
6 if we're going to deal with the data, the subcommittee
7 needs to see data and deal with it, or to take a
8 certain approach. What the subcommittee is saying
9 under recommendations is that they need to revisit
10 this. There are data coming out of the Cattlemen's
11 meeting; there are data that they know we will have
12 access to soon. I think everyone on the subcommittee
13 would like to continue to work on this, so I think what
14 we need to do is make sure Bob comes to that meeting
15 and we get the particular approach and the data that
16 he's talking about to the subcommittee. Carol, were
17 you putting your flag up? No?

18 DR. MADDOX: Unless we do make a response to
19 that answer to question three, that the Committee just
20 again, reiterate, "feels that there's maybe
21 opportunities as this new data is generated to respond
22 better to this question."

23 DR. WACHSMUTH: Okay, any other comments on
24 this. I see that the Committee noted the Cattlemen's

1 meeting yesterday and we'll get that.

2 DR. KVENBERG: Madam Chair?

3 DR. WACHSMUTH: John, go ahead.

4 DR. KVENBERG: Before you leave that
5 question, just for clarity of editorial purposes, Dr.
6 Maddox made a suggestion -- are we leaving question is
7 as stated, or is there additional -- as stated?

8 DR. WACHSMUTH: I think as stated. I think
9 Dan was trying to help, but it was a little beyond the
10 question.

11 DR. KVENBERG: I just wanted a clarification.

12 DR. WACHSMUTH: Okay. Okay.

13 DR. LUCHANSKY: Kaye? Or Madam Chair?

14 DR. WACHSMUTH: John, I'm sorry.

15 DR. LUCHANSKY: May I make a suggestion for
16 the Committee to consider because maybe it fits better?
17 What you identified now as point eight, which is the
18 original point two on the top of page three --

19 DR. WACHSMUTH: Right.

20 DR. LUCHANSKY: Would it be better to place
21 that under recommendations to FSIS and simply say --
22 pick it up where it says, "FSIS should request that
23 state and local" -- does that seem like a better fit?
24 Presently it's listed as a research need, but it may be

1 more appropriate to list it under recommendations to
2 FSIS.

3 DR. KVENBERG: Madam Chair, John Kvenberg. I
4 would endorse that -- that was a problem for me in my
5 head, also, to identify it as a research need, because
6 I think this is a recommendation. That FSIS follow up
7 with CDC. It's not really a research need.

8 DR. LUCHANSKY: So my -- I propose to strike
9 the first phrase of that sentence, "If an outbreak ...
10 CDC in cooperation with" -- strike that component of
11 it, and just simply start it, "FSIS should request that
12 state and local" and then move that to under
13 recommendations to FSIS.

14 DR. WACHSMUTH: I think you'll need to put
15 FSIS with CDC.

16 DR. LUCHANSKY: I'm sorry. Okay.

17 DR. WACHSMUTH: Yes.

18 DR. LUCHANSKY: I was on formatting there,
19 but okay. Maybe I think now if David's point number
20 three, make this point number four.

21 DR. WACHSMUTH: Any objection to that? Skip?
22 Anybody? Okay, this is now a recommendation and it
23 will be number four under the recommendations. It says
24 that "FSIS with CDC should request" and so on. Skip?

1 DR. SEWARD: Yes, thank you. Just for a
2 point of clarification. You suggested that the
3 subcommittee would continue to work on this, and I just
4 wanted to clarify that, because yesterday I was left
5 with the impression that this subcommittee was
6 finished, or that -- was being disbanded. So I just
7 want to make sure -- I think it should go on, but I
8 just wanted -- you know, you suggested that it was, so
9 --

10 DR. WACHSMUTH: Once we form these
11 subcommittees they just go on forever.

12 DR. SEWARD: Okay, fine.

13 DR. WACHSMUTH: The point that we made
14 earlier was that the Committee needed to finalize this
15 document to get this opinion back to the Agency instead
16 of just waiting for more data so that the report would
17 be delayed indefinitely. There'll always be new data
18 coming in, so the idea was just to get this report back
19 and when we get more data, pull that Committee back
20 together.

21 DR. SEWARD: Very good. Thank you.

22 DR. WACHSMUTH: Bill?

23 DR. SPERBER: Yes, thank you. Just a minor
24 grammatical correction. In the answers to both

1 questions, three and four, data is a plural word, so
2 "is" should be "are" and "was" should be "were".

3 DR. WACHSMUTH: Can you give those to Dr.
4 Kvenberg?

5 DR. SPERBER: Yes. Thank you.

6 DR. KVENBERG: On questions three and four.

7 DR. WACHSMUTH: Larry?

8 DR. BEUCHAT: Larry Beuchat. Along that line
9 also, grammatical, on the bottom of page two, last
10 line, "additional data are needed" rather than "is".

11 PARTICIPANT: It's scratched.

12 DR. BEUCHAT: It's scratched? Okay. Page
13 three, under question three, the sentence beginning,
14 "The Committee concluded that there are insufficient
15 data" rather than "is".

16 DR. KVENBERG: Bill has that one already.

17 DR. BEUCHAT: You have that one? Okay, I'll
18 try to get one more here. At the top of page four --
19 "additional data are being presented.

20 DR. KVENBERG: Got it.

21 DR. BEUCHAT: And under point two, under
22 recommendations, are you going to -- are you
23 recommending that more than one species of Salmonella
24 be evaluated, or are you referring to enteric and

1 various serotypes? There's a difference there.

2 DR. KVENBERG: Madam Chair, can I respond?

3 DR. WACHSMUTH: Yes, John.

4 DR. KVENBERG: Perhaps we could clarify it.

5 Would it help just to strike "spp" and just say

6 Salmonella -- it's implicit then that the door is open

7 for various serotypes.

8 DR. WACHSMUTH: Yes, I think Larry's point is

9 there are all -- all of the different serotypes are

10 under Salmonella enterica.

11 DR. BEUCHAT: All the ones of probably any

12 consequence.

13 DR. WACHSMUTH: And you don't want

14 choleraesuis (ph) or other species, you want -- so

15 should we -- how should we do it, Larry?

16 DR. BEUCHAT: I think the answer would be

17 Salmonella. That would include --

18 DR. WACHSMUTH: Just strike --

19 DR. BEUCHAT: Yes, just strike the "spp".

20 DR. KVENBERG: Got it.

21 DR. WACHSMUTH: Alright. We need to move on.

22 ... up again or --

23 PARTICIPANT: Oh, sorry.

24 DR. WACHSMUTH: Alright, thank you all. I

1 think those changes help. And now we have our largest
2 document, our biggest piece of work, the performance
3 standards.

4 DR. TOMPKIN: Excuse me, do we have to
5 formally approve as a Committee, or is it understood.

6 DR. WACHSMUTH: I assumed that when there
7 were no more comments --

8 DR. TOMPKIN: Okay, because that will apply
9 to the next one also.

10 DR. WACHSMUTH: Both are final -- the hot
11 holding and the blade tenderized.

12 DR. TOMPKIN: Okay.

13 DR. WACHSMUTH: And what I'd like to do with
14 the performance standards is let Spencer give us any
15 thoughts he has before we go through it, and then to
16 take it question by question and finalize the
17 Committee's agreement with the approach to each of the
18 questions, so we can at least bring some closure to a
19 couple. If we don't get through the whole document, if
20 we can at least get through question one or question
21 two, we can get that information back to the Agency.
22 If that -- if no one has an objection. Spencer, you
23 want to start us?

24 MR. GARRETT: Thank you, Madam Chair, as we

1 recall, yesterday evening and the afternoon, and late
2 into the night, actually, the full Committee addressed
3 questions one and two. And we took those
4 deliberations, including the public comments, into
5 account and we made modifications to questions one and
6 two. In two instances the modifications are -- could
7 be considered substantial, but there are only two of
8 those instances. So, in actuality, while at first
9 blush they may seem substantial, in fact, they really
10 clarify points and make the document more readable.

11 In question one, the major change was made on
12 page three of the report that you have in front of you
13 dated January 25, 2002, and that would be, under
14 "General Principles", the second full paragraph
15 beginning with "Performance standards define the
16 expected level" et cetera.

17 The only other substantial change then we
18 made, would be on question two, on page seven of that
19 same document, in the middle of the page, under
20 "Salmonella performance standards", it would be then
21 the second full paragraph, where it indicates "The
22 Committee points out that when HACCP systems and other
23 prerequisite programs" and so forth.

24 So with that introduction, Madam Chair, we

1 would be ready to proceed. It very well may be that
2 you may wish to take 20 minutes or 15 minutes for
3 people to read questions one and two. We did not
4 address question three, as you recall, nor have we
5 addressed question four in full Committee. It's not
6 our intent to address question three.

7 DR. WACHSMUTH: Well, let's take a break at
8 this point then, 20 minutes, and if everyone would
9 particularly pay attention to the two places in the
10 document that Spencer has identified, we'll come back
11 and go as far as we can go with the document.

12 (Whereupon, a 23 minute recess off the record
13 was taken.)

14 DR. WACHSMUTH: The Agency does need the
15 advice of this Committee and one of the highest
16 priorities for the Agency, and certainly urgent
17 matters, so we'll do our best today. We will try to
18 end at noon. We'll also save time for public comment.
19 We have one person signed up for public comment.

20 Okay, I don't want to interrupt the progress
21 over here, but -- Spencer, did you want to say anything
22 else before I start leading us through page by page?

23 MR. GARRETT: No, ma'am, I think that -- I
24 think I've introduced it appropriately. There were not

1 really that many changes made except in those two areas
2 that I did indicate they are significant.

3 DR. WACHSMUTH: Okay, page one is essentially
4 the charge from the Agency, so I don't think there's
5 much that this Committee would want to change or should
6 change. Any comments on page two? Okay, that takes us
7 to the findings, to page three. And this, under
8 "General principles", I think, is where we had one of
9 the more significant revisions.

10 MR. GARRETT: Yes, ma'am. It's -- under
11 "General principles", the second full paragraph
12 beginning with "Performance standards define the
13 expected level of control". And this is essentially
14 what we understand was agreed to in full Committee
15 yesterday. We've just merely scribed it.

16 DR. WACHSMUTH: Bill Sperber?

17 DR. SPERBER: Bill Sperber. Under the
18 "Findings", the first sentence, "The subcommittee
19 believes" -- I would propose changing "believes" to
20 "thinks" -- it's a minor point, but since this is a
21 science-based Committee, I would associate thinking
22 with reason, more than belief with reason.

23 MR. GARRETT: I would support that, or "is of
24 the opinion".

1 DR. SWANSON: "Concluded"?

2 DR. SPERBER: Concluded would be --

3 MR. GARRETT: Concluded.

4 DR. WACHSMUTH: Okay, "concluded"?

5 MR. GARRETT: Concluded.

6 DR. WACHSMUTH: Alright, let's move to page
7 four.

8 DR. TOMPKIN: Excuse me.

9 DR. WACHSMUTH: Okay. Oh, Bruce?

10 DR. TOMPKIN: In the middle of the paragraph
11 where it talks about risk assessments and we really --
12 it's confusing the way it's stated, and we had
13 extensive discussion over the difference between a risk
14 assessment and a risk evaluation, and I don't think,
15 Bob, you had a chance to read this part yet, but what I
16 suggest that this be modified. This would be the
17 seventh line, over on the far right, it states "Risk
18 assessments can be quantitative or qualitative in
19 nature". I would delete the next sentence. And then
20 continue with "The decision to undertake a formal
21 quantitative or qualitative risk assessment" and then
22 delete "versus a quantitative or qualitative evaluation
23 of risk".

24 MR. GARRETT: Are you going to talk at all

1 about qualitative or quantitative risk evaluation? The
2 purpose that was put in for was to -- specifically to
3 distinguish between qualitative and quantitative risk
4 assessments, full blown with all of the bells and
5 whistles, and qualitative and quantitative risk
6 evaluations that are less than that, but just as
7 applicable in many cases.

8 DR. TOMPKIN: I think the idea of a risk
9 evaluation was just a generic term that did not -- that
10 included the whole range of quantitative down through a
11 qualitative risk assessment.

12 MR. GARRETT: That's exactly the sentence we
13 wrote last night.

14 DR. TOMPKIN: I understand, but it's -- to me
15 it's not clear. Having that information in there. I
16 don't know if you're ...

17 DR. BUCHANAN: I'd support the change.

18 DR. WACHSMUTH: Bob, you support deleting?

19 DR. BUCHANAN: I would support the changes
20 that Bruce has suggested. I think it is much clearer
21 now with eliminating what he has just indicated.

22 DR. WACHSMUTH: Okay, we'll delete that.

23 DR. TOMPKIN: We do, throughout the text --
24 we have made modification to risk assessment in certain

1 places, and we have inserted risk evaluation. To bring
2 in the broader concept without committing anyone to
3 having to do a formal quantitative risk assessment.
4 Risk evaluation is the terminology that's going to be
5 used in most places throughout the text. This is Bruce
6 Tompkin.

7 DR. WACHSMUTH: I'm going to do something
8 with great trepidation. I don't like to play with
9 subcommittee's or the Committee's work, but I do have a
10 suggestion that I think might help.

11 In the first sentence under "General
12 principles", I believe that the sense I had from
13 listening to the subcommittee's sessions, and knowing
14 the references that are cited here, that "These are
15 general principles for deciding whether to and
16 developing a risk assessment" -- and I believe that
17 would make it more clear right up front that part of
18 this is deciding whether or not to do risk assessment,
19 because I know that's what the subcommittee was
20 discussing the other night.

21 MR. GARRETT: So it would be "deciding to
22 conduct and develop risk assessment"?

23 DR. WACHSMUTH: "Deciding whether to and how
24 to".

1 MR. GARRETT: "Deciding whether to conduct
2 and developing"?

3 DR. WACHSMUTH: Yes, I think that's the sense
4 of the discussion I heard. And I know these references
5 are in reference to risk management documents. Bob?

6 DR. BUCHANAN: Kaye, I'd like to -- being
7 familiar with all three references, the NACMCF
8 reference does not really address deciding, other than
9 to say that it's a risk management decision; likewise,
10 the Codex document does not really address --

11 DR. WACHSMUTH: Yes, it does. This is the
12 Codex risk management expert consultation, which
13 defines risk evaluation.

14 DR. BUCHANAN: The Codex document, I thought,
15 was the framework -- what we were referring to was the
16 framework document.

17 DR. WACHSMUTH: No, the discussion that night
18 -- this is the "Consultation on Risk Management" -- WHO
19 and FAO held three consultations, one was essentially
20 on risk assessment and was called "Risk Analysis". The
21 second was on risk management, and the third was on
22 risk communication. This reference was to risk
23 management which has a definition for risk evaluation
24 before it entered the Codex process.

1 MR. GARRETT: In my mind, it's a WHO/FAO
2 consultation.

3 DR. WACHSMUTH: That's what I meant -- WHO
4 and FAO consultation.

5 DR. BUCHANAN: Yes, and you're going to have
6 to insert those references, because the reference here
7 is for Codex Alimentarius --

8 DR. WACHSMUTH: I see, okay.

9 DR. BUCHANAN: -- is specifically the
10 principles and guidelines for the conduct of a
11 microbiological risk assessment. It is not the one
12 that -- the only one of these three that deals at all -
13 - of the references cited, that deals at all with
14 determining whether or not you should or should not do
15 one is the ICMSF one.

16 DR. WACHSMUTH: Okay.

17 MR. GARRETT: Well, we can certainly add the
18 consultation --

19 DR. BUCHANAN: Yes, you can add them, but I
20 just wanted to point out the references you cited are -
21 -

22 DR. WACHSMUTH: That was the reference that
23 was discussed the other night. Is that okay, Spencer?

24 MR. GARRETT: Yes, we'll add that reference.

1 DR. WACHSMUTH: If people don't want to go
2 there, say so. Okay, any other comments on page three?

3 DR. BERNARD: Could I request --

4 DR. WACHSMUTH: Dane?

5 DR. BERNARD: -- a reread of Bruce's changes,
6 Madam Chair?

7 DR. WACHSMUTH: Bruce asked if we would
8 delete -- let's see -- the sixth line from the bottom
9 of the second paragraph under "General principles".
10 "The decision to undertake a formal quantitative or
11 qualitative risk assessment" -- and the deletion is on
12 the sixth line -- "versus a quantitative or qualitative
13 evaluation of risk".

14 PARTICIPANT: There's also another delete.

15 MR. GARRETT: And then two lines above that
16 was another deletion.

17 DR. BERNARD: So we have two deletions?

18 DR. WACHSMUTH: Yes, sorry. "Risk
19 assessments can be qualitative or quantitative" also.

20 MR. GARRETT: No, and then you -- then you
21 delete the "Risk evaluation can be quantitative or
22 qualitative."

23 DR. WACHSMUTH: Oh, okay. Sorry. Delete the
24 same thing in two places. Anything else, Bruce?

1 DR. TOMPKIN: No.

2 DR. WACHSMUTH: Dr. Habtemariam?

3 DR. HABTEMARIAM: Yes. Thank you, Madam
4 Chairman -- Chairperson, rather. I agree with the
5 points that were made by Dr. Tompkin. I was going to
6 be standing behind and listening this whole time, but I
7 was also getting confused because there are really
8 three words -- risk evaluation, risk assessment, and
9 risk analysis -- that are being used as if they are
10 being used interchangeably, and the publication by Dr.
11 Buchanan ... is very important. I think that's a very
12 useful document for all of us to share at some point.
13 Because the general term "risk analysis" really takes
14 care of risk assessment, risk communication, and risk
15 management. But we seem to be using them
16 interchangeably. That was my concern. And I
17 understand what Spencer was talking about -- risk
18 evaluation in the context from yesterday, but I think
19 it would be very useful to revert to risk assessment,
20 and if we do use risk analysis, which is really quite
21 proper, because I don't see risk evaluation as the more
22 general term, at least to my understanding.

23 Because, like at the last paragraph,

24 "Conducting any risk evaluation must address

1 uncertainty" -- which is really risk assessment in a
2 formal way. So my concern, let's not use them
3 interchangeably. They actually have different meanings
4 and just want to be careful, and I think that
5 clarification helped that Dr. Bruce Tompkin raised.
6 But I think the work that was published is very useful
7 for everybody, I believe.

8 DR. WACHSMUTH: That's -- I think we're all
9 in agreement.

10 MR. GARRETT: Madam Chair, just so there's no
11 mistaking my position, I do agree to take it out.
12 Okay?

13 DR. WACHSMUTH: Yes. Yes. So we've made the
14 deletions. Were you suggesting another change in the
15 text? I think that everyone's in agreement that those
16 are different terms that mean different things.
17 They're not meant to be used interchangeably. Okay, we
18 move to page four? Okay. Page five? Dane.

19 DR. BERNARD: Thank you, Madam Chair. I
20 almost hate to even go there, but on page four, under
21 the heading "Current Applications and Limitations", the
22 second line, we refer to a risk evaluation. If we have
23 taken out the previous introduction of the term, do we
24 leave it here?

1 DR. SWANSON: Yes.

2 DR. WACHSMUTH: I think we do.

3 DR. SWANSON: Yes, we should leave it there.

4 DR. BERNARD: Thanks.

5 DR. WACHSMUTH: Okay, we're on five up to
6 "Data Needs". Okay, we'll go on to "Data Needs" then.
7 I'd like to again compliment the subcommittee who took
8 many suggestions and public comments and incorporated
9 them nicely. Okay, page six, question two. Go through
10 the "General Principles" -- five principles, and
11 "Current Applications and Limitations." Bob?

12 DR. BUCHANAN: In looking under number one of
13 "General Principles", I'm unsure what the role of the
14 second sentence is. It seems to me that that more is
15 directed towards the specific Salmonella performance
16 standard, and I'm not sure it's needed in a "General
17 Principle".

18 MR. GARRETT: Madam Chair, I would support
19 that as a General Principle, I think the first sentence
20 is predominant.

21 DR. WACHSMUTH: You want to delete "It is
22 implied but not explicitly stated that this will result
23 in a decrease in human illness attributable to
24 consumption of these products"?

1 MR. GARRETT: I would say either that, or --
2 or we change it or modify the second sentence slightly,
3 to indicate "Such reductions should lead to" -- "Such
4 decreases in pathogens should lead to --" or "Such
5 reduction".

6 DR. WACHSMUTH: Okay. "It is implied, but
7 not explicitly stated that such decreases in pathogens
8 will lead to --"

9 MR. GARRETT: No, I was actually going to say
10 -- I would get rid of "It is implied, but not
11 explicitly stated", and I would simply say, "Such
12 reductions should lead to a decrease in illnesses
13 attributable to --"

14 DR. WACHSMUTH: Okay, I think decreases can
15 refer back to the other sentence.

16 DR. BUCHANAN: So, just for clarification,
17 the way I have the sentence now is, "Such reductions in
18 pathogens should lead to a decrease in human illness
19 attributable to consumption of these products".

20 MR. GARRETT: They lead to a decrease in
21 human illness as a function of these products.

22 DR. BUCHANAN: Right.

23 DR. TOMPKIN: Could you please clarify where
24 this is?

1 DR. BUCHANAN: This is in question two, right
2 after where it says question two, it says "General
3 Principles", and then number one.

4 DR. TOMPKIN: Okay.

5 DR. BUCHANAN: Okay? And it's the second
6 sentence in that number one.

7 DR. WACHSMUTH: I think what happened is this
8 was in relation to Salmonella, as Bob said,
9 specifically, and now we need to make it more generic.
10 Dane?

11 DR. BERNARD: Thank you. Just one more time
12 with the latest revision.

13 DR. WACHSMUTH: Okay.

14 DR. BERNARD: I was going to move to strike,
15 but I think as revised it's probably okay.

16 DR. WACHSMUTH: Sorry, say that again?

17 DR. BERNARD: Just if I could have the last
18 revision.

19 DR. WACHSMUTH: Okay, what we're doing in the
20 first general principle under question two, the first
21 sentence stays as it is. The second sentence will be
22 changed. We would delete "It is implied but not
23 explicitly stated that". We'll put, "Such reductions
24 in pathogens will lead to a decrease in human illness

1 attributable to consumption of these products."

2 DR. BERNARD: Could we say "are expected to"?

3 DR. BUCHANAN: I think the term that we
4 actually suggested was "should".

5 DR. WACHSMUTH: "Should". Okay. "should
6 lead to a decrease in human illness attributable to
7 consumption of these products." Okay, that stands.
8 Bill, is it to this?

9 DR. SPERBER: Thank you, Madam Chair, this is
10 Bill Sperber. I'm not comfortable with those changes,
11 and I'm not quite sure why this second sentence is in
12 number one under "General principles". But I think
13 this is the crux of the current debate on the
14 Salmonella performance standard. Does it or does it
15 not lead to a reduction in human salmonellosis? So I
16 think the Committee would be prejudging the situation
17 by the altered wording, which pretty much states as a
18 fact that microbiological performance standards as
19 outlined in the first sentence would, in fact, or in
20 fact, should lead to reduction in human illness. We
21 don't know that. We can't make such a claim. That's
22 why we're asking for a risk evaluation.

23 DR. WACHSMUTH: I think some members of the
24 Committee might think that -- Bruce, is it to this?

1 DR. TOMPKIN: Excuse me, no, it's not.

2 DR. WACHSMUTH: Bob?

3 DR. BUCHANAN: I guess I'm reading the
4 sentence in a different framework than Bill in this
5 case. This is, again, the general principle that
6 basically says that a microbiological performance
7 standard is intended to achieve a decrease in the
8 presence of an enteric pathogen, and that decrease in
9 the enteric pathogen should, in order to fulfill the
10 requirement for putting a performance standard into
11 place, lead to a reduction in human disease.

12 DR. WACHSMUTH: I think we've stated that in
13 the -- I can't find the citation right now, but in the
14 first question in relation to meeting public health
15 goals -- goals being reduction in food borne illness.
16 So that's -- that is a part of this document already.
17 Dave?

18 DR. ACHESON: I was going to suggest at the
19 end of that first sentence, and potentially, based on
20 this and deleting the second one, adding the words,
21 "with the goal of improving public health". So it
22 would read, "Microbiological performance standards are
23 intended to effectuate a decrease in the presence of
24 enteric pathogens in raw meat and poultry with the goal

1 of improving public health."

2 DR. SWANSON: Perfect.

3 DR. ACHESON: If we say that, do we need that
4 second sentence in there?

5 DR. WACHSMUTH: Okay, read your end of the
6 sentence again.

7 DR. ACHESON: Just simply adding the words
8 "with the goal of improving public health" at the end
9 of the first sentence, and then I think that covers the
10 debate on the second.

11 DR. WACHSMUTH: Sounds like a fix. Is that
12 okay with everyone? Okay. Alright, so we're back to
13 one sentence now, "Microbiological performance
14 standards are intended to effectuate a decrease in the
15 presence of enteric pathogens in raw meat and poultry
16 with the goal of improving public health." Okay, and
17 that's consistent with the Committee's comments under
18 question one. Alright. Okay, now if we can -- any
19 other comments on the general principles?

20 Okay, we move to page seven, and this is,
21 again, where we had a significant change in the text
22 under the Salmonella performance standards. Spencer.

23 MR. GARRETT: Madam Chair, since this has
24 been printed, it has been recommended that there be a

1 modification in the second line of the second paragraph
2 under "Salmonella performance standards". Second line
3 begins with "beef" -- and toward the end, it says,
4 "reflects the microbial" -- it's requested that a
5 phrase be inserted between the word "reflects" and
6 "the", and that phrase is as follows: "the total
7 process control, particularly" and then goes on
8 "microbial" -- so there's five words and a comma --
9 "the total process control, particularly".

10 DR. WACHSMUTH: Any objections?

11 DR. ACHESON: Could you read that sentence?

12 MR. GARRETT: So the sentence, the whole
13 sentence then would read -- "The Committee points out
14 that when HACCP systems and other prerequisite programs
15 in ground beef operations are adequate and verified,
16 the measurement of Salmonella reflects the total
17 process control, particularly the microbial conditions
18 of raw material."

19 DR. WACHSMUTH: And Spencer just gave us an
20 editorial change -- the "than" with the "that". Okay,
21 any other comments on this paragraph. Bob?

22 DR. BUCHANAN: It's not in this paragraph,
23 but it's on the first paragraph on this page.

24 DR. WACHSMUTH: Uh-huh.

1 DR. BUCHANAN: The next to the last sentence
2 that begins "In this instance the levels of E. coli",
3 I'd like to request that the "or" at the end of that
4 sentence between "contamination" and "duration" be
5 changed to "and the". The two conditions are not
6 exclusive to each other.

7 PARTICIPANT: (inaudible)

8 DR. BUCHANAN: Modify the next to the last
9 line in the first paragraph to read, "In this instance,
10 the levels of E. coli should be a measurement of fecal
11 contamination and the duration ..."

12 DR. BERNARD: So you're changing "would" to
13 "should"?

14 DR. BUCHANAN: No, I'm proposing to delete
15 "or" and replace it with "and the".

16 DR. BERNARD: Okay.

17 DR. WACHSMUTH: And that changes the sentence
18 ... is everyone okay with that? Okay. Dane?

19 DR. BERNARD: Small suggestion.

20 DR. WACHSMUTH: Go ahead.

21 DR. BERNARD: "and/or". No?

22 DR. BUCHANAN: No. You have to have the
23 initial fecal contamination to have the E. coli
24 present, but the levels of the E. coli are dependent,

1 then, in addition to the amount of fecal contamination
2 that occurred, you can also get an increase as a result
3 of growth. So it's -- you have to have both
4 conditions. If the organism's not there, abusing it in
5 terms of temperature will have no impact on the level
6 of E. coli.

7 DR. BERNARD: Okay. Reading the rest of the
8 sentence, when it's linked to the temperatures I would
9 agree. If you don't have storage temperatures -- then
10 it's taken care of, okay.

11 DR. WACHSMUTH: Okay, anything else on page
12 seven? Yes, Mike.

13 DR. JAHNCKE: Mike Jahncke. A question on
14 the bottom, just a point of clarification. As we were
15 discussing earlier today, it's a little confusing,
16 under the section "Indicator Organism in lieu of a
17 Pathogen", when we say "Neither" -- and we're talking
18 about E. coli or Salmonella -- "Neither is being
19 measured in lieu of a pathogen". Salmonella is a
20 pathogen. I don't know if we put a couple of -- it
21 just -- reading it at first blush was -- it didn't
22 follow or make a lot of sense. It's not as clear as it
23 may be or should be.

24 DR. WACHSMUTH: Can you give us a fix?

1 DR. JAHNCKE: "Neither is being measured in
2 lieu of other pathogens" -- in the case of Salmonella.

3 DR. WACHSMUTH: "Neither is being measured in
4 lieu of other pathogens". Is that the suggestion?

5 DR. JAHNCKE: Well, that doesn't fix it
6 either, does it? I think we just have to make the
7 distinction between the use of E. coli in this case, as
8 an indicator, and then Salmonella, which is a pathogen,
9 but we're saying in lieu of another pathogen. We have
10 to make the distinction to say that -- you know,
11 Salmonella -- I'm not sure what the wording is. I know
12 the subcommittee probably struggled with the wording on
13 this paragraph too. Yes.

14 DR. WACHSMUTH: Bob?

15 DR. BUCHANAN: This is where, now that we're
16 down to a specific application, this is where the
17 statement that "It is implied but not explicitly
18 stated" that controlling these two organisms would
19 control other pathogens. That's where that sentence
20 that was in the general principles should be moved to -
21 - and that's --

22 DR. WACHSMUTH: So substitute that for the
23 current sentence?

24 DR. BUCHANAN: Right, it would require some

1 modification, but -- "It is implied, but not explicitly
2 stated that control of these two organisms would lead
3 to control of other enteric pathogens."

4 DR. MADDOX: Kaye?

5 DR. WACHSMUTH: Carol, is it to help with
6 Bob's?

7 DR. MADDOX: I would just like to insert in
8 lieu of just "these two organisms" -- "or other
9 appropriate indicators of enteric contaminations" to
10 again leave us some leeway for future improvements in
11 detection systems.

12 DR. WACHSMUTH: Okay, I'm only half way
13 there. "It is implied, but not explicitly stated that
14 control of these two organisms and other --

15 DR. MADDOX: "or other appropriate indicators
16 of enteric contamination".

17 DR. WACHSMUTH: And would you finish --

18 DR. BUCHANAN: Kaye, I think the issue here
19 is we have to make a decision on whether we're
20 describing the current regulation or we're talking
21 about the future. I might suggest, to avoid confusion,
22 stating that "It is implied but not explicitly stated
23 in the pathogen reduction HACCP regulation that these
24 two organisms -- that control of these two organisms"

1 et cetera.

2 DR. WACHSMUTH: Okay, can you ... that means
3 we'll need to delete that, Carol. So could you read it
4 again, Bob? "It is implied but not explicitly stated
5 in the pathogen reduction HACCP rule that control of
6 these two organisms would lead to --

7 DR. BUCHANAN: "control of other enteric
8 pathogens".

9 DR. WACHSMUTH: Okay. And we've deleted the
10 last sentence? Is that correct? Spencer, you had
11 words?

12 MR. GARRETT: Yes, two requests, Madam Chair.
13 One is I'm presuming that on page six we're still
14 leaving the second sentence as we modified it? Or we
15 just destroyed --

16 DR. WACHSMUTH: No.

17 DR. BUCHANAN: No, we eliminated that.

18 MR. GARRETT: Then secondly, secondly, would
19 you read that again slowly with feeling now?

20 DR. WACHSMUTH: The current one?

21 MR. GARRETT: Yes, as it says, "It is
22 anticipated, but not explicitly" --

23 DR. WACHSMUTH: Okay, "It is implied but not
24 explicitly stated in the pathogen reduction HACCP rule,

1 that control of these two organisms would lead to
2 control of other enteric pathogens."

3 MR. GARRETT: Thank you.

4 DR. WACHSMUTH: There is a statement in the
5 preamble about Salmonella --

6 DR. BUCHANAN: Kaye, as it now stands, this
7 is a statement of fact.

8 DR. WACHSMUTH: Bruce?

9 DR. TOMPKIN: That little section down there
10 at the bottom of page seven, seems to be what's left of
11 a previous section we had, that had to do with using
12 one pathogen for testing for another pathogen. And
13 this is what's left. And if you think about this
14 particular question and the general principles, and
15 then on page seven it's the current applications and
16 limitations, we deal with E. coli and then with
17 Salmonella, it doesn't really answer the question of
18 one pathogen and testing for another. I suggest we
19 delete that whole section. I don't know that it adds
20 more information that's not already covered up above,
21 or in the principles.

22 DR. WACHSMUTH: Katie?

23 DR. SWANSON: I would agree with Bruce's
24 suggestion, or we need to add something more. If you

1 read this section as it stands right now, the question
2 "so what?" comes to mind. It's just a statement of
3 fact, so we either have to say whether this is an
4 appropriate implication, we have to say we agree with
5 it or we don't, or we just delete it and be done with
6 it.

7 DR. WACHSMUTH: I think you're correct. So
8 we have at least -- we have a proposal now, by Bruce,
9 that this particular paragraph doesn't add anything.
10 Does anyone object to that?

11 MR. GARRETT: Yes.

12 DR. WACHSMUTH: Anybody else have anything
13 except Spencer?

14 MR. GARRETT: Well, before I determine if I
15 object or agree, I think Bruce indicated that it's
16 implicit in other places earlier. Bruce, I'd like you
17 to point that out where you think that may be.

18 DR. TOMPKIN: Sorry?

19 MR. GARRETT: You had indicated that the
20 reason to get rid of it is one, it's merely a statement
21 of fact or it's just what's left of an earlier write
22 up, just actually some of that wording's been removed,
23 and so therefore it doesn't answer the question but
24 there are other places in the document that do. I'd

1 just like you to point that out to the Committee if you
2 would so --

3 DR. TOMPKIN: Okay, well, excuse me. Bruce
4 Tompkin. On the bottom of page six, under general
5 principles, number five, it actually does address the
6 issue of "One pathogen can be used as an indicator"
7 that was that original idea. So we do say that "One
8 pathogen can be used as an indicator of the state or
9 condition affecting another" -- so that's present, and
10 then when it comes to the current applications, we have
11 E. coli as an indicator organism and the discussion
12 under it, the Salmonella performance standards, and I
13 think in both they're really addressing the state or
14 conditions of operations. And then it would move into,
15 on page eight, the recommendations that deal with
16 question number two.

17 DR. WACHSMUTH: Okay, Bob?

18 DR. BUCHANAN: Bob Buchanan. I'd like to
19 make an alternate suggestion. I think that if this
20 section is to describe what the current situation is,
21 and we've stated in the general principles that it is
22 possible to use one pathogen as an indicator of
23 another, this provides us with confirmation that in the
24 current regulation they are, in fact, using one

1 pathogen as an indicator for others.

2 Alternatively, what I would suggest is simply
3 to delete the subheading there, "Indicator Organism in
4 lieu of a Pathogen" and just incorporate this as a
5 follow up paragraph under the subheading "Salmonella
6 performance standards".

7 DR. WACHSMUTH: I'm not sure you could do the
8 second thing, Bob.

9 PARTICIPANT: I agree.

10 DR. WACHSMUTH: Spencer?

11 MR. GARRETT: Well, I thought you probably
12 could do the second thing.

13 DR. WACHSMUTH: Well, go further. I mean
14 you're talking about E. coli under Salmonella
15 performance standards, but -- what were you going to
16 say?

17 MR. GARRETT: No, ma'am. What we were going
18 to do was get rid of the subtitle "Indicator organism
19 in lieu of a Pathogen" and then just let the paragraph
20 as modified --

21 DR. WACHSMUTH: Well, it contains E. coli is
22 what I'm saying/

23 MR. GARRETT: Oh.

24 DR. WACHSMUTH: Dave?

1 DR. ACHESON: Excuse me, David Acheson. I
2 was wondering, if we want to keep this, could we move
3 it right up to the front of question two, and put this
4 above "General principles" and after the heading,
5 because it really is a statement of the current
6 statement of facts.

7 DR. WACHSMUTH: Maybe not general principles,
8 but maybe directly under "Current applications" --
9 because we're trying to make "General principles" --

10 DR. ACHESON: Yes, that would also work.
11 Yes.

12 DR. SWANSON: That would work.

13 DR. WACHSMUTH: Okay, so we now have a
14 suggestion to keep Bob's modification and move that
15 current paragraph up directly under -- as sort of a
16 statement of this is what the status is right now with
17 the Agency, under the "Current applications and
18 limitations". Is there any disagreement with that
19 proposal? Disagreement?

20 DR. SEWARD: Not with that one.

21 DR. WACHSMUTH: Okay, then I've got a list of
22 people to go to. Katie?

23 DR. SWANSON: Under "General Principles"
24 point number five says that a "pathogen can be used as

1 an indicator of the state or condition affecting
2 another pathogen if it meets the criteria above." We
3 had substantial discussion in the subcommittee meetings
4 about the fact that Salmonella in lieu of other
5 pathogens don't necessarily meet the conditions that
6 are listed above, and we haven't really discussed that
7 anywhere in this document. Having said that, I do
8 believe that reductions in Salmonella can lead to
9 reductions in other pathogens. I think that is a valid
10 point, but the -- for example, the growth
11 characteristics of Salmonella don't match the growth
12 characteristics of something like --

13 DR. WACHSMUTH: You're going someplace the
14 subcommittee --

15 DR. SWANSON: Doesn't want to go.

16 DR. WACHSMUTH: -- isn't ready to go.

17 DR. SWANSON: Okay.

18 DR. WACHSMUTH: There was some confusion, and
19 I think it raised some problems that were cited
20 yesterday. The subcommittee began this work at a time
21 before the Supreme Beef court decision, at a time when
22 certain questions weren't as pressing as they seem to
23 be now for the Agency. This document was intended to
24 be more of this is where the science is now, and these

1 are the general principles, and then answering the hard
2 questions was the next step. If I'm mistaken, correct
3 me Spencer, but I think that's where we hit some
4 confusion.

5 DR. SWANSON: Never mind.

6 MR. GARRETT: Yes, these are just the warm-
7 ups, so to speak.

8 DR. SWANSON: Okay.

9 DR. WACHSMUTH: But it's the principles and
10 then the specifics of where FSIS is, and I think if you
11 look at it that way, the way David suggested moving
12 that, it's an accurate reflection.

13 DR. SWANSON: Okay.

14 DR. WACHSMUTH: Okay, Bill Sperber?

15 DR. SPERBER: No, my question has been
16 answered, thank you.

17 DR. WACHSMUTH: Dr. Habtemariam?

18 DR. HABTEMARIAM: Yes, I'm okay, thank you.

19 DR. WACHSMUTH: Okay. Okay, any other
20 comments now on -- sorry, Dane.

21 DR. BERNARD: Thank you. Could we have the
22 last fix? We have moved these two sentences up to
23 right under Salmonella performance standards --

24 DR. WACHSMUTH: No, no. Right under "Current

1 applications".

2 DR. BERNARD: Under "Current applications and
3 limitations", okay. The sentence that was added, we're
4 saying that "It's implied..." da, da, da. Is the
5 Agency comfortable with this Committee interpreting the
6 rule? Okay, I just want to make sure, because we're
7 saying as a Committee that the rule implies this. For
8 us to say what the rule implies, I think may be a bit
9 presumptuous.

10 DR. WACHSMUTH: I'll call on Dr. Engeljohn
11 from the policy office to make sure this is okay.

12 DR. ENGELJOHN: I think that -- Engeljohn --
13 I think the statement as revised is accurate and fine.

14 DR. WACHSMUTH: Okay, "Recommendations". Any
15 questions? And I think this gets to your point, Katie,
16 what we need to answer next. Okay, question three.

17 MR. GARRETT: Madam Chair, given the length
18 of the time, we're not -- we have supplied text for
19 question three, but we've not finished the data
20 analysis, and given the lateness of the hour, I would
21 suggest that we move to question four and hold question
22 three in abeyance, and then before we close, I do want
23 to mention one thing about question three.

24 DR. WACHSMUTH: Okay, that would take us then

1 to page 11, question four about quantitative standards.
2 Bob?

3 DR. BUCHANAN: I was asked by our consulting
4 statistician to bring up an issue in the definitions of
5 quantitative variable and qualitative variables, and he
6 recommends that we modify the two examples, because
7 they're units, not variables, and so he suggested that
8 we modify that statement that says, "e.g., levels of a
9 microorganism" and then put "cfu/g" in parentheses as
10 the unit, and then suggested under qualitative that be,
11 "e.g., detection of a microorganism" and put in
12 parentheses (presence or absence), and that would more
13 accurately describe what a quantitative and a
14 qualitative variable -- what quantitative and
15 qualitative variables are.

16 DR. WACHSMUTH: Okay. Thank you. Larry?

17 DR. BEUCHAT: Larry Beuchat. I have problems
18 with the word "level" which isn't quantitative either.
19 Could we use "number" or "population".

20 DR. BUCHANAN: You could use "number", you
21 could use "concentration" -- anything to imply some
22 quantitative measure.

23 DR. BEUCHAT: Thank you.

24 DR. BUCHANAN: So "number" would be fine.

1 DR. WACHSMUTH: Okay, this could be a problem
2 throughout if you don't think "levels" is good. Dane?

3 DR. BERNARD: Just in the use of the word
4 "number", that doesn't make sense when we've got
5 "numerical value". What else would it be but a number?

6 DR. BUCHANAN: That's why we originally
7 suggested "level".

8 DR. WACHSMUTH: What is the main problem with
9 "level"? Larry, is there something that we could
10 discuss or is it -- do you feel strongly about it?

11 DR. BEUCHAT: I don't feel that strongly
12 about it, but I think the word "level" doesn't, to me,
13 imply a specific number.

14 DR. SWANSON: How about "concentration"?

15 DR. WACHSMUTH: Okay, let's try
16 "concentration". We'll have to do a global search,
17 Spencer, for "levels" I guess, at least in the first
18 general principle it looks like that'll be okay. Did
19 you have something else, Larry?

20 DR. BEUCHAT: No. That's it.

21 DR. WACHSMUTH: Okay. "Special
22 Considerations" takes us over into 12. Page 12. And I
23 think much of this text is as you had it initially.
24 Okay, "Scientific considerations".

1 DR. SWANSON: Uhm --

2 DR. WACHSMUTH: Oh, Katie.

3 DR. SWANSON: Number 11, a quick addition --
4 page 11, I'm sorry, number five, the end of it.

5 "laboratory methods for quantification may be more time
6 and resource intensive for certain pathogens."

7 DR. WACHSMUTH: Any objection to that? Okay.

8 Page 12. And down into the scientific considerations
9 when you're considering the use of quantitative
10 baseline data. Okay, try getting to 13, and I think
11 Katie, this -- at the bottom of 13, when you get into
12 "Next steps" if you'll look at that, I think this is
13 important for the Committee to realize and concur with
14 as well, we're saying that as soon as possible the
15 Committee will "address the new questions related to
16 whether the performance standards are working and
17 they're" -- need to respell that -- no, and there are -
18 - I misread this, sorry -- but something about whether
19 there are effective alternatives to the performance
20 standards, which gets to your concerns.

21 DR. SWANSON: Yes.

22 DR. WACHSMUTH: Okay.

23 MR. GARRETT: Madam chair?

24 DR. WACHSMUTH: Spencer?

1 MR. GARRETT: On that particular issue, I had
2 a comment as Chair of the subcommittee and as an
3 individual member --

4 DR. WACHSMUTH: Okay, can we take Katie's
5 question first then, and I'll come right back to you.

6 DR. SWANSON: Well, I had something higher on
7 the page, so as long as we're on the topic.

8 DR. WACHSMUTH: Well, let's finish with this
9 question four and then we'll go to this topic.

10 MR. GARRETT: Yes, and what that is what I
11 would like to inform you that we are so close to
12 finishing question three, including the analysis of the
13 data, and I know that Dr. Rainosek is going to
14 recommend because he has analyzed the 2001 data which
15 consists of over 24,000 samples collected randomly, and
16 it could have the same statistical treatment, and
17 analytical techniques that were used for the baseline
18 survey to begin with, which the baseline survey is
19 serving as the benchmark, that I think we ought to
20 spend the time to finish that, and then move on to the
21 questions because I think we're much, much closer than
22 perhaps we realize, or at least we ought to examine to
23 see if we're that close.

24 DR. WACHSMUTH: I think it would make sense

1 if -- particularly if that analysis would help answer
2 these questions.

3 MR. GARRETT: I'm confident that it would.

4 DR. WACHSMUTH: Okay, we might -- I don't
5 know how we handle that.

6 DR. BUCHANAN: Kaye, as it's written, the
7 paragraph does not imply that you're going to do one
8 before the other, that you're going to do the new
9 considerations before you're going to do the analysis
10 of question three. As currently written it says that
11 we will finish questions one, two and four, and then we
12 will do both of the others, so --

13 DR. WACHSMUTH: Okay, so it's alright, then.

14 DR. BUCHANAN: It's alright as written.

15 DR. WACHSMUTH: Okay.

16 MR. GARRETT: It's not that you don't do both
17 of the others, it's the sequence in which you do them.

18 DR. WACHSMUTH: And perhaps the subcommittee
19 will be doing more than one thing at a time.

20 MR. GARRETT: I'm not so sure of that one.

21 DR. WACHSMUTH: But the data could help, I
22 agree. I think if Bob's correct, the way it's written
23 would allow --

24 MR. GARRETT: No, we looked at that. It's

1 fine.

2 DR. WACHSMUTH: Okay, Katie?

3 DR. SWANSON: Okay, Katie Swanson. The
4 paragraph preceding "Applications of quantitative
5 performance standards", I submit that the issue with
6 the cost of doing studies is related to your trying to
7 enumerate an organism like Salmonella, which requires
8 an MPN right now. I would suggest that this is one
9 section that we don't have a research need, and one
10 research need that would be very useful is a cost
11 effective enumeration system for Salmonella that
12 wouldn't be as intensive as an MPN.

13 DR. WACHSMUTH: I think that's an excellent
14 suggestion, certainly is a research need, but it's
15 broader. I can speak for the Agency, one of the
16 pathogens that actually stimulated this question was
17 Campylobacter.

18 DR. SWANSON: Right, so again, if we have a
19 research need that says we need to spend resources on
20 cost effective quantification methods for pathogens --
21 I think that this would be enhanced.

22 DR. WACHSMUTH: Are you getting a sentence,
23 Spencer?

24 MR. GARRETT: Yes, "Cost effective

1 quantification methods for pathogens which is not as
2 intensive as Salmonella".

3 DR. SWANSON: You don't even need the "not as
4 intensive as" -- as MPNs.

5 MR. GARRETT: As MPNs, I'm sorry.

6 DR. WACHSMUTH: Okay, I think we can trust
7 Spencer to accurately capture that one. David?

8 DR. ACHESON: I wanted to come back to the
9 "Next Steps" but I may not be -- if you still want to
10 finish question four.

11 DR. WACHSMUTH: Any other things --
12 questions, issues with four? Okay.

13 DR. ACHESON: I was a little confused with
14 line two in terms of finalizing our responses to
15 questions one, two and four. I was under the
16 impression that that was what we've just done.

17 DR. WACHSMUTH: We just did.

18 MR. GARRETT: We did.

19 DR. ACHESON: We did, okay.

20 DR. WACHSMUTH: And now it's to see how far
21 we can get on three. And what I'd like to do, since I
22 am not as familiar with the subcommittee's discussion,
23 is to let Spencer take us through question three.

24 Okay, Spencer?

1 MR. GARRETT: Thank you, Madam Chair. In
2 Question three, we still have formatting issues to deal
3 with this, but if you recall, we were requested to make
4 certain that we're using the terms indicator, index
5 organism correctly and so forth, and additionally to
6 make this a little bit more readable.

7 Relative to the first question, we first
8 started out with -- we only have two issues here in
9 terms of "What constitutes scientifically appropriate
10 methods for considering variations that may be due to
11 regionality, seasonality, or other factors when
12 developing performance standards?" We point out that
13 there's two questions when you deal with that issue,
14 one is to acquire the data in a scientifically
15 sufficient manner, and then on the other hand, you have
16 to analyze the data in a sufficiently scientific
17 manner. So that -- we broke the questions down to an A
18 and B.

19 What I would suggest that we do, given the
20 time, would be to go ahead and have the full Committee
21 just spend time reading this, if they have not done so,
22 and I'd be prepared to do it page by page.

23 DR. WACHSMUTH: Well, this went out a week or
24 two weeks before the meeting, so I think --

1 MR. GARRETT: Well, I certainly would be glad
2 to take -- we would like to get the text finalized if
3 we can with the Committee, because if just the data
4 analysis -

5 DR. WACHSMUTH: There's been no changes in
6 this since it went to the committee members --

7 MR. GARRETT: Not as extensive changes in
8 this at all compared to the others. No.

9 DR. WACHSMUTH: If there are objections from
10 any Committee member who would like more time with it,
11 we'll listen to that, otherwise --

12 MR. GARRETT: It begins on page eight. Are
13 there any comments on page eight?

14 DR. WACHSMUTH: Okay, if anyone is
15 uncomfortable just let it be known, otherwise, go
16 ahead.

17 MR. GARRETT: I don't see any discomfort
18 dealing with this. Page nine?

19 DR. SWANSON: Tsegaye.

20 DR. WACHSMUTH: Tsegaye?

21 DR. HABTEMARIAM: I have a couple of
22 problems. First I guess that A and B, the way the
23 sentence reads, "Scientifically appropriate methods for
24 the acquisition of data to considered" -- I mean that

1 could be corrected easily. The two sentences are not
2 quite correct.

3 The issue that I have really is the paragraph
4 that starts "Understanding" -- the last sentence. "The
5 subcommittee considered in its deliberations that this
6 question encompassed two conceptual elements". I look
7 at conceptual as rather big, but they're just two
8 elements as far as I see, one is regional and the other
9 one is seasonal. I didn't think that they were
10 conceptual.

11 DR. WACHSMUTH: I think, if I could help a
12 little bit, I believe what they're talking about there
13 is the two elements of acquisition and evaluation.

14 DR. HABTEMARIAM: Good, well, I just --

15 DR. WACHSMUTH: Not the season --

16 DR. HABTEMARIAM: Okay, either way, the word
17 conceptual is too important a word -- there are two
18 elements, basically, they're not that -- and so the
19 word "conceptual" was out of place for me, anyway.

20 DR. WACHSMUTH: We could strike that.

21 DR. HABTEMARIAM: And the part that I
22 actually have a problem with that, that acquisition and
23 data analysis, they're very important, but I don't see
24 them as separate or distinct. You know, most often we

1 acquire data and don't take enough time to really see
2 what we're going to do with it, and therefore we
3 accumulate all this stuff, we don't know what to do
4 with it, and if we think ahead of time, both for data
5 acquisition and data analysis together, we would be
6 able to really see where we're going ahead of time.
7 But often we fragment these into two distinct areas and
8 then in the process lose what our goal is, and I would
9 have really liked to indicate that it is very important
10 that it incorporates data acquisition followed by data
11 analysis which is the result that we are interested in.
12 That's the point I wanted to make.

13 The other issue is about seasonality and
14 regionality. These are very important issues. These
15 are factors that eventually have to be decomposed --
16 and I look at them as epidemiological issues that
17 require decomposition from these factors to specific
18 variables that have to be studied, not as separate
19 entities, again, but as integrated multi-variable
20 studies because say, seasonality is really a function
21 of so many variables -- example, look at climate, look
22 at temperature, look at humidity, and so on and so
23 forth.

24 That also brings up the issue of regionality,

1 which really is not -- I mean it's foggy by itself, but
2 we have to decompose it to its component parts, and at
3 that time it becomes relevant, and we've got to look at
4 these as integrated activities as opposed to separate
5 activities.

6 So I wanted to make those comments and see
7 how best to do it. Maybe one way is to approach it
8 separately, but we don't want to leave out the issue of
9 integrating and looking at the totality of these issues
10 and other appropriate systems based on this study.

11 DR. WACHSMUTH: Thank you, that was excellent
12 comments. You want to address that, Spencer? Should
13 David comment? David?

14 DR. ACHESON: That's what I was going to try
15 to address, a potential fix to that. And I'm looking
16 at the last sentence in the first paragraph under
17 question three, beginning "The subcommittee" and it
18 would -- remove the word "conceptual", and so, "that
19 this question encompassed two distinct, but integrated,
20 elements which need to be considered" and then strike
21 the word "separately" in the last line. So it would
22 read, "The subcommittee considered in its deliberations
23 that this question encompassed two distinct, but
24 integrated, elements which need to be considered in

1 order to adequately address the question dealing with:"

2 DR. HABTEMARIAM: That sounds good to me.

3 DR. WACHSMUTH: Is that --

4 MR. GARRETT: Yes, that sounds good.

5 DR. BUCHANAN: Could you repeat it again,
6 please?

7 DR. ACHESON: Yes -- read the whole sentence?

8 DR. BUCHANAN: Yes.

9 DR. ACHESON: "The subcommittee considered in
10 its deliberations that this question encompassed two
11 distinct, but integrated, elements which need to be
12 considered in order to adequately address the question
13 dealing with:"

14 DR. WACHSMUTH: I think it was an excellent
15 point. You don't want to consider those separately.
16 If you don't have your consultation with your
17 statistician before you begin to collect, you're in
18 real trouble. Spencer?

19 MR. GARRETT: We certainly understand that.
20 I would just say it's now the Committee -- it's now
21 "The Committee" considering this, so it's just an
22 editorial.

23 DR. WACHSMUTH: Okay, page nine?

24 DR. HABTEMARIAM: Kaye?

1 DR. WACHSMUTH: Oh, yes.

2 DR. HABTEMARIAM: Thank you, Madam
3 Chairperson. The last paragraph of A, you know, "A
4 team of qualified personnel, including but not limited
5 to" and so on, the point is well taken, and I'm sure we
6 ... qualify -- I would suggest we say "A
7 multidisciplinary team of scientists should be formed
8 to design the study." That way we don't have to be
9 specific about microbiologists, statisticians, talk
10 about qualified personnel -- we can't do anything
11 without qualified personnel. I suggest "A
12 multidisciplinary team of scientists".

13 DR. WACHSMUTH: Bill?

14 DR. SPERBER: I'm sorry, I've got a little
15 grammatical fix on page eight. The two elements?

16 DR. WACHSMUTH: Yes.

17 DR. SPERBER: Element A --

18 DR. WACHSMUTH: We'll take Tsegaye's
19 suggestion if there are no objections. Okay. Go
20 ahead.

21 DR. SPERBER: "Methods for the acquisition of
22 data to considered" doesn't make sense. I believe it
23 meant "that considers" as is in the case below?
24 "evaluation of data that considers the referenced

1 variations." So, I think the point is, it should be,
2 "methods for the acquisition of data that consider the
3 referenced variation", so that it would be the same
4 construction as part (B), would be the "evaluation of
5 data that consider" -- and it should be "that
6 consider", not an "s" on the end of "considers".

7 DR. MADDOX: No, "acquisition considers".

8 DR. WACHSMUTH: She's right. Spencer.

9 MR. GARRETT: Yes, ma'am. We picked that up.
10 I wanted to go to Tsegaye's next point. And that
11 would be, I think we agreed, "A qualified
12 multidisciplinary team of scientists should be formed
13 to design the study." I think that's what Tsegaye
14 suggested.

15 DR. HABTEMARIAM: That's right.

16 DR. BUCHANAN: Just as a sensitivity --
17 mathematicians do not consider themselves scientists.

18 MR. GARRETT: I think the operative word is
19 "qualified".

20 DR. WACHSMUTH: Move to page nine? Oh, I'm
21 sorry, Spencer.

22 MR. GARRETT: I would just introduce the
23 reason it is -- the information is captured in this way
24 is because we felt in the acquisition stage that there

1 are about -- when you begin to acquire the data, you
2 need to look at the system in totality, or
3 sequentially, and what's happening in the sequential
4 operation, the distribution -- so it's factors that --
5 so you begin to think about collecting data, the
6 "Factors that may influence the microbiological status
7 of the animals that are presented to the slaughter",
8 going back to the farm and transportation, whatever;
9 the slaughter practices themselves being the
10 contamination prevention; application of intervention
11 strategies that reduce contamination; and then the
12 "Handling and holding of meat and poultry" all the way
13 through to the consumer.

14 So then you'll see that in terms of these
15 four -- these four paradigms for collecting the data,
16 then there are very specific things under each one of
17 those factors that go on within this page and the next
18 page.

19 DR. WACHSMUTH: Okay.

20 DR. BERNARD: Small editorial. I think the
21 word in quotes in the first paragraph should be
22 "upline" instead of "uplink".

23 DR. WACHSMUTH: Okay. That's pretty
24 straightforward. Any other comments?

1 DR. DONNELLY: Under -- Catherine Donnelly.
2 Under three, could you entertain just an amendment:
3 "Applications of interventions that reduce
4 contamination both pre- and post-slaughter"? Because
5 if you read through this section, most of the focus is
6 on post-slaughter interventions, and I think you --
7 there's one sentence in the document that kind of
8 expands it from farm to fork, and I think anything you
9 can do to weave more of the pre-slaughter interventions
10 would be helpful.

11 DR. WACHSMUTH: Give us a place and the exact
12 words again.

13 DR. DONNELLY: Under item three at the top of
14 page nine. Just modify the sentence to say
15 "Applications of interventions that reduce
16 contamination both pre- and post-slaughter".

17 DR. WACHSMUTH: Interventions however don't
18 track that. If you look at the top of page ten, those
19 look like mostly post.

20 DR. DONNELLY: And that's kind of my point is
21 I think there are some on the farm interventions that
22 need to be incorporated.

23 DR. WACHSMUTH: Okay, this -- we've come to
24 the point where if we want to proceed with this

1 document, you know, get this particular question down
2 rather, the rest of the document will go, and then
3 we'll have to pretty much keep it to editorial. If
4 we're not comfortable with it the way it is, if we need
5 to expand sections, we may need to hold on to this
6 question.

7 DR. DONNELLY: Exactly. Bill suggested
8 sticking "competitive exclusion" to that section.

9 DR. ENGELJOHN: Engeljohn. I would just
10 point out that down at the bottom of the page under
11 number one, number 1(c) has "Husbandry practices" so we
12 are in fact, we have included that in the concept in
13 this to capture what you say.

14 DR. WACHSMUTH: Is that enough, Catherine?

15 DR. DONNELLY: That's where I thought it was
16 captured, under Husbandry practices.

17 DR. WACHSMUTH: Or so we don't need to --
18 Dane?

19 DR. BERNARD: I would like to suggest an
20 editorial change. Near the bottom of page nine where
21 we begin the list of the individual factors, the
22 sentence that leads into that should be qualified to
23 say something such as "Some of the factors" -- or it
24 needs to be something so this is not all. It's what we

1 thought of at the moment we drafted it, but there may
2 be others. So I would suggest adding "Some of the
3 factors to be considered are listed below."

4 DR. WACHSMUTH: Bob?

5 DR. BUCHANAN: Just a real quick grammatical
6 one because my eyes just fell on it. The first
7 sentence in the first paragraph on page nine, you need
8 to get the subject and the verb to match in terms of --
9 it's either "analyses are" or "analysis is".

10 DR. SWANSON: Is.

11 DR. WACHSMUTH: Okay, Spencer?

12 MR. GARRETT: And I'm assuming that we're
13 retaining Catherine's -- Cathy's "both pre- and post-
14 slaughter" and then the animal husbandry is one of the
15 things, one of the factors, when it's presented to
16 slaughter, that's all you can get.

17 DR. WACHSMUTH: Okay, all the way to data
18 needs? Dane?

19 DR. BERNARD: We will do a global search for
20 where it says "the subcommittee" and change that to
21 "the Committee".

22 MR. GARRETT: Right.

23 DR. BERNARD: The Committee -- and again, it
24 says believes -- what was our modification to that word

1 before? Thinks? Concludes? Okay. Thanks. I'm
2 speaking, of course, near the top of page nine at the
3 first full paragraph.

4 DR. WACHSMUTH: Okay. Excellent. We'll get
5 this base document back to the Agency and this
6 subcommittee will continue its work -- the
7 subcommittee's done a great job. I really think
8 they've gone the extra yards. I think your fellow
9 members appreciate it. I know the Agency does.

10 With that note, I'd like to open it for
11 public comment. We do have Caroline DeWaal and also
12 anyone else who would like to. Caroline?

13 MS. SMITH-DEWAAL: I feel like I'm wrestling
14 with this thing. Thanks, that's fine. Okay. Thank
15 you. I'm Caroline Smith-DeWaal, Center for Science in
16 the Public Interest. If anyone's missed that earlier
17 in the meeting. I really appreciate the fact that
18 again that the Committee has allowed for public comment
19 at numerous times during the meeting. It allows us to
20 weigh in on what I think has been a very -- a very
21 important product of NACMCF and I think that the
22 Committee has done a very excellent job at producing
23 this paper. It is continually improving, which is, I
24 know, the goal here, and I think today's version is

1 very readable for the lay person, and with some of the
2 edits, it accomplishes what you need also in terms of
3 how it may be presented publicly.

4 This document is going to be very important
5 to, not only the regulators, but I think to members of
6 Congress and other key decision makers in addressing
7 the gap in consumer protection which has occurred
8 because of the Supreme Beef case. So I just wanted to
9 give everyone on the Committee a lot of credit for the
10 work you've done.

11 I did also appreciate the fact that you
12 allowed us to distribute this "Handy Desk Reference".
13 This is the best we can discern about the pathogen
14 commodity connection that I know that the Committee has
15 criticized or challenged the CDC to actually produce
16 records talking about what pathogens are being linked
17 to what foods. Well, CSPI recognized that gap about
18 five years ago and this is our third published report.

19 It gets bigger every year, and my boss keeps
20 threatening to actually make us not publish the list in
21 this form, but just put it up on the internet so people
22 can download it themselves. It's got 1700 outbreaks
23 dating from 1990 to the current -- to 2001, and we try
24 to publish it once a year.

1 As everyone knows, there are problems with
2 using outbreak data exclusively, and yet we haven't
3 been able to find another mechanism to link pathogens
4 with food commodities. The FoodNet data is collected
5 largely based on laboratory sampling information, and
6 there's no effective way that they've been able to
7 track most of those illnesses back to a specific
8 commodity.

9 I know Kaye is very familiar, and knows more
10 than I about the Case Control studies that are being
11 done as part of that, and maybe that will give us more
12 information in the future. But for right now, I will
13 hazard to say that Outbreak Alert is the best available
14 source for the linkage of pathogen and food
15 commodities.

16 We also are able to sort the dataset, so for
17 example, if we want to look at Clostridium perfringens
18 and what foods it's showing up in, I can -- I have a
19 researcher who's done most of the -- much of the work
20 on this who can do that.

21 I did also want to note the person doing the
22 research is Kristina Barlow. She maintains the list
23 and is continually improving it. She is a -- has a
24 Master's degree in food microbiology from Penn State.

1 She was also a student of Dr. Doores. So she has come
2 on board about a year ago and she's doing that.

3 We also have, for those who are interested, a
4 more comprehensive methodology for how we're making
5 decisions about which outbreaks go on the list. We try
6 to sort through all available outbreaks and we're very
7 careful to check for duplications, but if there are two
8 reliable sources an outbreak may, because we can't
9 guarantee that it's not two separate outbreaks. An
10 outbreak may be duplicated, but we're actually in the
11 process of trying to analyze what our error rate may be
12 for the list.

13 The list is quite comprehensive. It includes
14 more than CDC's outbreak data. It includes information
15 from scientific journals and other government reports,
16 and it's amazing to us that even the CDC's lists
17 sometimes don't match. The general list for CDC, in
18 fact, may have E. coli 0157H7 outbreaks which aren't
19 included on the specific E. coli list. So, I mean
20 we've found a lot of gaps and problems with CDC's
21 system, and we're in constant contact with Rob Tauxe to
22 inform him of what we found and encourage them to do a
23 better job.

24 So I just want to alert you, and if anybody

1 wants a more comprehensive methodology, we have one
2 prepared. We're submitting it to the National Academy
3 of Sciences, probably Monday, as part of our response
4 on their consideration of E. coli 0157H7 risk
5 assessment, because we think our list is actually
6 better than the one they've used in that risk
7 assessment.

8 Anyway, thanks so much for letting us
9 participate and for the work of the Committee. Take
10 care.

11 DR. WACHSMUTH: Thank you Caroline. Also, I
12 think -- I'll speak for myself as the Chair, we
13 appreciate the feedback and the input from your
14 perspective and from the public's perspective, because
15 sometimes we do get in the trees, and it's very
16 difficult for us to see how some of our work will be
17 perceived by those outside. And we also have no
18 lawyers on this Committee, and sometimes we don't see
19 how something might be perceived from that angle. So
20 it's valuable input and we do appreciate it.

21 And we are still open for anyone else in the
22 public who might have a comment. If not, I think this
23 Committee has done an excellent job. And my co-chair
24 would like to talk.

1 DR. OLIVER: Yes, I would just like to thank
2 the subcommittee and the Committee also, but what I'd
3 also like to do is take this opportunity to once again
4 express my appreciation to Kaye for her chairing of the
5 Committee, and I think we all should give her a round
6 of applause. She's done an excellent job this time
7 too.

8 (Applause.)

9 DR. WACHSMUTH: And I applaud you. A good
10 week's work and I won't be there, but I think you'll
11 all be meeting again some time around August, and I'll
12 keep an eye on this Committee. Catherine?

13 DR. DONNELLY: Could I entertain a formal
14 motion from this Committee to wish you well in your
15 retirement.

16 DR. WACHSMUTH: Thank you. I'll take that.

17 MR. GARRETT: Second. Here. Here.

18 DR. WACHSMUTH: Dane?

19 DR. BERNARD: Just a closing note. The
20 subcommittee working on the standards has been very
21 collegial piece of work, and I think we have made good
22 progress, but I'd just like to personally thank Spencer
23 for his leadership and -- it just wouldn't have
24 happened this way without Spencer and his staff and

1 their able support, and Dr. Rainosek for all of his
2 advice on the statistics. So I just wanted to get that
3 on the record, what a great job I think they did.

4 DR. WACHSMUTH: How about a hand for Spencer?

5 (Applause.)

6 MR. GARRETT: That's Spencer and staff.

7 DR. BERNARD: Spencer and staff.

8 DR. WACHSMUTH: Okay, that's it for today.

9 MR. GARRETT: Kaye, we'd like to make a xerox
10 copy of your notes in the business center before we
11 depart.

12 DR. WACHSMUTH: Yes, sure.

13 (Whereupon, at 11:46 a.m., the meeting in the
14 above captioned matter was adjourned.)