UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE: National Advisory Committee on Microbiological Criteria for Foods

Open Plenary Session held on the 27th day of August, 2004

at 8:30 a.m.

Hotel Monaco
700 F Street, NW
Washington, DC

TRANSCRIPT OF PROCEEDINGS

8-27-04 NACMCF Meeting Participants

Chair:	Dr. Merle Pierson
Vice-Chair:	Dr. Robert Brackett
NACMCF Members:	Dr. David Acheson Mr. Dane Bernard Dr. Peggy Cook Dr. Catherine Donnelly Dr. Stephanie Doores Dr. Frances Downes Dr. Daniel Engeljohn Mr. Spencer Garrett Dr. Patricia Griffin Dr. Lee-Ann Jaykus Maj. Robin King Dr. John Kvenberg Dr. Anna Lammerding Dr. John Luchansky Dr. Carol Maddox Dr. Eli Perencevich

Ms. Angela Ruple
Ms. Jenny Scott
Dr. Skip Seward
Dr. John Sofos
Dr. Katie Swanson
Dr. R. Bruce Tompkin

NACMCF Executive Committee:

LTC. Bradford Hildabrand
Dr. LeeAnne Jackson, FDA

FSIS Staff: Ms. Gerri Ransom
Ms. Karen Thomas

FDA Staff: Mr. Brett Podoski

NMFS Staff: Ms. Emille Cole
Ms. Barbara Comstock

Outside Participants: Mr. Nick De Pinto,
Avure Technologies
Mr. Tony Corbo, Public Citizen
Mr. Peter Jenkins, Center for
Food Safety

P R O C E E D I N G S

August 27, 2004

8:30 AM: VICE-CHAIRMAN BRACKETT: Good morning, everybody. I guess we'll get started at 8:30 and if you've looked at the agenda and if you've looked at the materials, there is a lot to get through today, so we want to get moving. All right, good morning. I'd like to welcome all of our members and guests to the final Plenary Session of the 2002-2004 National Advisory Committee on Microbiological Criteria for Foods, otherwise affectionately known as NACMCF. I'm active Vice-Chair, Dr. Robert Brackett and the Director of FDA Center for Food Safety and Applied Nutrition and Dr. Merle Pierson is the Chair of the Committee and USDA Deputy Secretary for Food Safety. And unfortunately, Dr. Pierson was not able to be here this morning; he got called away, but he will plan on joining us a little bit later.

As most of you know, the Plenary Session brings us to a close to the current two-year cycle of this Committee that began on September 5, 2002. Before I go any further, let me say that this Committee is performing an invaluable service to supporting federal food safety agencies, those being the USDA Food Safety

and Inspection Service, the HHS Food and Drug Administration and the Centers for Disease Control and Prevention, the Department of Commerce, National Marine Fisheries Service and the Department of Defense Veterinary Service Activity. NACMCF is providing scientific advice to our nation's food safety program. I'd like to thank each of you for your service, your expertise, lively scientific debate, and the valuable time that you have given in support of the activities of this Committee.

At this time I would like to go around the table and have the Committee members introduce themselves and state their affiliations and please remember to use that microphone and in order to use the microphone, you just push the little mike button that says on or off until the light stays on and then you're on. So I think we'll start to my left here.

MS. RANSOM: Okay. Gerri Ransom, Food Safety Inspection Service.

MS. THOMAS: Karen Thomas, Food Safety Inspection Service.

MR. PODOSKI: Brett Podoski, FDA.

DR. SEWARD: Skip Seward, American Meat Institute.

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

DR. DOORES: Stephanie Doores, Department of Food Science, Penn State University.

DR. ENGELJOHN: Dan Engeljohn, Food Safety Inspection Service.

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

DR. LUCHANSKY: John Luchansky, Agricultural Research Service.

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

DR. LAMMERDING: Anna Lammerding, Health Canada.

DR. TOMPKIN: Bruce Tompkin, Independent.

DR. SOFOS: John Sofos, Colorado State University.

DR. MADDOX: Carol Maddox, University of Illinois College of Veterinary Medicine.

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

DR. DONNELLY: Cathy -- do you want me to -- Cathy Donnelly, University of Vermont.

DR. KVENBERG: John Kvenberg, FDA.

MR. GARRETT: Spencer Garrett, National Marine Fisheries Service and I'm joined on my immediate left by Emille Cole, who's also with the National Marine Fisheries Service.

DR. DOWNES: Frances Downes, Michigan Department of Community Health.

MR. BERNARD: Dane Bernard, Keystone Foods.

DR. SWANSON: Katie Swanson, Ecolabs.

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

DR. GRIFFIN: Patricia Griffin, Centers for Disease Control and Prevention.

DR. ACHESON: David Acheson, FDA.

DR. COOK: Peggy Cook, Tyson Foods.

LTC. HILDABRAND: Brad Hildabrand, Department of Defense Veterinary Service.

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

VICE-CHAIRMAN BRACKETT: Thank you all. Our 2002-2004 Committee has been quite active this term and the working subcommittees, during this time, are first of all, the Subcommittee on Criteria for Refrigerated Shelf-Life Based on Safety, and this was chaired by Dr. Don Zink and this morning Dr. David Acheson is

filling in for Don today. Don's unable to be here because he is moving his whole household cross-country to the DC area. And secondly, the Subcommittee on Scientific Criteria for Redefining Pasteurization, chaired by Dr. Kvenberg; and the Subcommittee on Microbiological Performance Standards for Ground Chicken and Ground Turkey, chaired by Spencer Garrett. We will hear from all three of the subcommittees today, as we have a total of four documents being brought forward to the full Committee for consideration of adoption.

The Subcommittee on Criteria for Refrigerated Shelf-Life Based on Safety has been looking at the scientific basis for establishing safety-based "use-by" date labeling for refrigerated ready-to-eat (RTE) foods. They will be presenting their final document to the full Committee for a discussion.

The Subcommittee on Scientific Criteria for Redefining Pasteurization has been aggressively at work on a project in response to the 2002 Farm Bill language amending Section 403(h) of the Food, Drug and Cosmetic Act to include that a food is misbranded if it purports to be pasteurized unless, "Such food has been subjected to a safe process or treatment that is prescribed as pasteurization or has been subjected to a safe process

or treatment that destroys the most resistant microorganisms of public health significance that are likely to occur in the food." The group has reviewed alternative treatments to traditional heat pasteurization and has looked at those that meet the criteria for pasteurization. This group also has a document to bring to the full Committee today.

Our Performance Standards Subcommittee has worked on various raw meat and poultry commodities and evaluated the existing performance standards for *Salmonella* and they've worked to define the general principles and mechanics and requirements for setting up performance standards critical to the design of updated program. The group has both a ground chicken and a ground turkey document up for discussion today.

And now I would like to turn the floor over to Gerri Ransom, our Executive Secretariat, who will provide you with some additional information.

MS. RANSOM: Good morning and welcome again to our members and guests. I want to first say if any members or guests need any assistance, please feel free to come see Karen Thomas or I and we'll see if we can help you out. I wanted to point out to you that the minutes from our last Plenary Session, which took place

in February, are under Tab 5 of your member notebooks. The minutes are also out on the table up front, if anyone would like a copy. Okay.

Now, for anyone wishing to make public comment today, we do ask that you sign up outside at our registration desk and registrants will be given ten minutes each for the public comments. I did want to mention that we are making transcripts of these meetings, so you will be part of the public permanent record, so -- okay. And we do have a table up front that contains all documents that'll be under discussion today, as well as some other documents related to NACMCF and the table is right there by the door, so guests, please feel free to pick up any documents that interest you. If any guests have brought some documents for distribution, there is a table set up outside where you can leave those documents and Sally, at our table, will help you with that. Okay.

Now, on the business end of NACMCF, I wanted to mention a couple of things. We are in the process of re-chartering NACMCF, as the current Committee and charter expire on September 5 of this year. Approvals for a new Committee are in process as we speak. Now, after we receive Committee renewal approval, a Federal

Register notice will go out detailing a call for nominations and this will go out, hopefully sometime in September or October. This will start the nominations process that will lead to new Committee appointments by the Secretary of Agriculture.

Now, as with any cycle of the Committee, a number of members will be rotating off who have served their maximum term, which is three two-year periods and we also have some people that are going to not seek re-nomination, so reconstituting this Committee is going to be a very tough and important job this time around because we are losing so many members. We do need to get the right mix of experience and expertise, so this is going to be quite a job to do this.

Finally, I wanted to mention that we have had some changes to our Executive Committee late this term. LTC. Brad Hildabrand, Deputy Director of the U.S. Army Veterinary Corps, has joined us and he's in the center of the table here. And also Dr. Walt Hill, Director of our Microbiology Division at FSIS has joined the Executive Committee. Walt couldn't be here today, but LTC. Hildabrand and Dr. Hill, we welcome you on behalf of NACMCF and we -- and our sponsoring agencies, and we thank you for your participation and willingness to

serve on the Executive Committee. And with that, I'll turn the floor back over to Dr. Brackett.

VICE-CHAIRMAN BRACKETT: Thank you, Gerri. At this point we'll get started on the business of the day and what I'd like to do first is call upon Dr. David Acheson, who, as I mentioned, is going to be filling in for subcommittee chair, Don Zink, who will be discussing their document covering the criteria for refrigerated shelf-life based on safety. David.

DR. ACHESON: Thank you, Dr. Brackett. What I thought I would do is to first of all, just go over some of the key elements of our deliberations and then take the document, which I hope you all have, page by page. As you all know, a version of this document was sent out a few weeks ago. The subcommittee met yesterday and it made a number of changes -- so we decided to try to distribute this with the track changes so that you could see the changes if you'd read the previous document you can see the differences, which will help people focus on what's changed since the previous version.

So first of all, I just want to summarize what this subcommittee was really discussing and it really begins with the issue that the Committee was asked to provide advice on the requisite scientific parameters for

establishing safety-based "use-by" date labels for refrigerated RTE foods. In order to do this, the Committee reviewed the history and the use of date labels and some of the issues surrounding that and determined that if the concept of a safety-based date label, which I will use the acronym SBDL, which is used throughout the document, was pursed, then *Listeria monocytongenes* was an appropriate target organism for refrigerated RTE foods.

One of the reasons that *Listeria monocytongenes* was considered to be important was really because of the morbidity and the high mortality associated with that organism and its association with refrigerated foods from epidemiology. Based on that, the application of an SBDL for products that support the rapid growth of *Listeria monocytongenes*, which is another important criteria, at the consumer level, certainly was something that the Committee felt was an important area to look at and for example, a "use within X days of opening or purchase" could be a -- have a positive impact on public health.

But that if it was that, it had to be combined with a public education campaign, which would be linked with research to determine consumers' knowledge and aptitudes

and practices regarding SBDLs in order to get this phrased correctly to maximize the public health impact. There was discussion around the application of SBDLs in relation to manufacturers and the consensus of the subcommittee was that at the manufacturers' level of doing this, there were many practical limitations and this is discussed further in the document.

The Committee really focused on four major scientific parameters, as identified as being important and they're listed in the Executive Summary there. First of all, that the pathogen of concern must be able to grow at refrigeration temperatures in the food in question to a level that's likely to cause illness in the host. Secondly, there's got to be scientific evidence that an SBDL will reduce the risk of foodborne illness for that food. Thirdly, there's got to be identification of the safety-based end points for establishing the SBDL and fourthly, a determination of the temperature to use to establish the SBDL.

The Committee considered that many things were important as part of this, including strain differences, the food matrix, competing microflora, the packaging, the production, the distribution, the handling and the consumer susceptibility. The -- I think the bottom line

of all of that is really summarized -- I'm now on page three, for those who are trying to follow, at the end of the Executive Summary -- that the Committee's hazard analysis, when they took all these factors into consideration, concluded that the duration of the refrigerated storage was not a major factor in foodborne illness caused by various organisms that were considered; *Yersinia enterocolitica*, *Bacillus cereus* and psychrotrophic *C. botulinum*. Therefore, the Committee believed that an SBDL, to limit the potential for the growth of *Listeria monocytogenes* would -- could be useful, but not for the other organisms. And as I had mentioned previously, it was important that educational efforts to utilize SBDLs was an integral part of making this successful. So that really summarizes where the subcommittee discussions went to and what their major conclusions were, so if it's okay with the Chair, I will just take it page by page and ask for comment.

VICE-CHAIRMAN BRACKETT: I think that would be fine and just to remind everybody, if you do have comments, please state your name with your comment. Okay, thank you.

DR. ACHESON: We can go back to begin -- I suggest we begin at page one and just looking for

comments on page one? Page two? Yes.

DR. SEWARD: Skip Seward. Skip Seward.

DR. ACHESON: Skip, yeah.

DR. SEWARD: On the fourth paragraph, the two new paragraphs that were added, the very first sentence of the first new paragraph, I wondered if -- when you talked about an appropriate SBDL, I wasn't sure if you were referring to an FSO-based SBDL, as you state in the second new paragraph there or whether you could re-write that to say "believes that the use of an SBDL, developed according to the scientific criteria defined herein could have a beneficial public health impact," and then, to me, in order to believe that it has a beneficial health impact, I thought an additional sentence right after that one could say "Improved epidemiological links between listeriosis and the shelf-life of the implicated food could support this belief" because I didn't see that really emphasized in the document.

DR. ACHESON: Okay. Any comments on that from any members, anybody else?

DR. KVENBERG: Chairman, Dr. Acheson, just a question of convention and procedure. How are we going to track changes on these proposed changes? Is there going to be a recording secretary to do that or is the

Chair -- the working group responsible for -- I have a selfish reason for asking.

DR. ACHESON: Dr. Jackson's going to do that for this one.

DR. KVENBERG: Thank you.

DR. ACHESON: Yeah, in order to that, Skip, we need to -- can I have re-read what it is that you suggested? I haven't anybody have a problem with it, so -- but we want to capture it.

DR. SEWARD: Okay, I just wanted to help clarify what an appropriate SBDL was and so my suggestion was that -- to modify that first sentence to say "The Committee believes" and I'll just read this and then share the information later so you don't have to try to capture it unless you want to, but "believes that the use of an SBDL, developed according to the scientific criteria defined herein, could have a beneficial public health impact." And then I felt that in order to say that we believe that it has a beneficial health impact, we could add a sentence that says "Improved epidemiological links between listeriosis and the shelf-life of the implicated food could support this belief."

DR. ACHESON: So that second sentence would

follow right on from the one that you've just amended?

DR. SEWARD: Correct, correct.

DR. ACHESON: Okay, okay. Yeah, Katie.

DR. SWANSON: When we were discussing this yesterday, we were trying to clarify just the point that you brought up, Skip, and correct me if I'm wrong, other Committee members, we put "appropriate" in there to try to lead somebody toward the "consume within X number of days after opening" type of SBDL and not the "consume by date thus and such" SBDL. Apparently -- am I correct in that assumption?

DR. ACHESON: Yeah.

DR. SWANSON: So I like the words that Skip is inserting, but it kind of opens it up to both kinds of SBDLs instead of that, you know, "consume within X number of days."

DR. ACHESON: Well, I think that if you can live with that --

DR. SWANSON: I can live with it, but I'm just -- I just wanted to clarify the intent of the term "appropriate."

DR. ACHESON: Yeah.

DR. SWANSON: It didn't work, apparently.

DR. ACHESON: Yeah. Thanks, Katie. John?

DR. KVENBERG: John Kvenberg, thank you. I also like the suggestion that Skip put forward. I guess one of the things that Dr. Swanson was putting forward was appropriate and I think underlying that, it depends on the nature of the food. Maybe you could get to the -- something succinctly that would say it is food dependent -- what I'm getting at is some foods, over time, will support the growth up to maximum levels. Some foods, over time, will actually decrease the level, so it has to be looked at as a food mainstream condition, I think, relative to what we're looking -- driving for here is the number of organisms ingested. And some foods which support the rapid and progressive growth, some foods would be static, in some foods it would die off over time; that's my point.

DR. ACHESON: I think Skip's new language captures that, John. Yeah. Spencer?

MR. GARRETT: Thank you. Spencer Garrett. Just a small change, Skip. I think you might want to add the word "further" so it would read "could further support this," because the way it currently reads, it sounds like you don't really have that support.

DR. ACHESON: Any other comments on page two? Okay, page three. Okay, you don't see anything on page

three, so page four. Page five?

DR. SEWARD: Excuse me, I just saw --

DR. ACHESON: Yeah.

DR. SEWARD: Skip Seward. On page five, I wondered if the Committee would consider including in the paragraph that's right above Roman numeral III, History, the first line of that paragraph, "The foods of concern in this document are adulterated refrigerated ready-to-eat foods," since -- if you produce foods today that are refrigerated, ready-to-eat foods, at least I believe all refrigerated ready-to-eat foods must be Listeria-free when they're produced at the manufacturing facility, if they meet the regulatory requirements, so I'd just like to offer that as a consideration for the Committee.

DR. ACHESON: Any comments? Cathy.

DR. CONNELLY: Skip, I think the -- Cathy Donnelly -- the problem with that suggested change is the foods could become contaminated in the consumer's home and the public health impact of the consume-by date label just reduces the time, so not -- so I don't think the term "adulterated" would necessarily apply to the full intent of the SBDL.

DR. ACHESON: So Skip, we leave it as it is?

DR. SEWARD: I withdraw the --

DR. ACHESON: Okay, thank you. Any other comments on page five? Dan?

DR. ENGELJOHN: On the definition of safe harbor that we added, would the Committee consider just adding the word "recognize" before the word "procedure" so that it's a term that is defined as a “recognized procedure” that can be employed?

DR. ACHESON: Any comments on that suggestion? Looks good, Dan. Thank you. Anything else on page five? Okay, page six. Page seven. Okay, page eight. Page nine.

DR. SEWARD: Skip Seward.

DR. ACHESON: Yeah.

DR. SEWARD: On the paragraph before *Yersinia enterocolitica*, in the fourth line down, I would like to recommend that we add "is a significant hazard when present in refrigerated ready-to-eat foods."

DR. ACHESON: Okay, any comments on that suggestion?

DR. SWANSON: Katie Swanson. It also -- that decouples it from the potential for growth in the product. It's an organism that one must consider and look at it in light of the potential for growth or

decline or whatever, so presence doesn't necessarily make it a hazard.

DR. ACHESON: What are you saying?

DR. SWANSON: Well, Skip was suggesting to say that it is a food, you know, when present is a hazard and I can see on one side that means it's not a hazard if it isn't there and that's true, but by the same token, if it's present, it isn't necessarily a hazard if the product doesn't support growth or declines.

DR. ACHESON: Okay. So if you wanted to add "when present," you'd want to put some more language around that? Or otherwise, just don't put it in at all, leave it as it is?

DR. SWANSON: I don't know.

DR. GRIFFIN: Patricia Griffin. I support the -- whoops. Patricia Griffin. I support the suggestion.

DR. ACHESON: To leave it -- to put it in?

DR. GRIFFIN: To put it in.

DR. ACHESON: John?

DR. SOFOS: It may be changed to include that after -- well, is it significant as in refrigerated foods, when present in refrigerated foods that support growth. So that would also indicate that it is present, but the food supports growth.

DR. ACHESON: Well, that's what it says now. I mean, to get to Katie's point, it does say that the food has to support growth -- and be present. Are you okay with that? Yes?

DR. SWANSON: Yes.

DR. ACHESON: Okay. So we'll insert "when present" after hazard, okay. Any other comments on page nine? Okay. Page ten? Jenny.

DR. SCOTT: A couple things. But first, can you clarify for me in the paragraph on Psychrotrophic *Clostridium botulinum*, is that in square brackets or is -- are the brackets removed? I can't tell from this.

DR. ACHESON: Yes. Let me clarify that point. I apologize; I should've talked about that. During the discussion yesterday, there were questions around the language that was used in those square brackets and the decision was taken that we should go back and look at that Hathaway paper to see exactly the language that Hathaway used. If you look in the references, you'll see that actually it's not a paper, it's a memorandum to Mitch Cohen at CDC and it's currently locked in Don Zink's office and we'll have to fix that when he comes back, but what we propose to do is to use the language that Hathaway used.

DR. SCOTT: Okay. And by the way, I'm Jenny Scott from NFPA and I think that is the language he used, yeah.

DR. ACHESON: Okay, then we're stuck with it.

DR. SCOTT: Right.

DR. ACHESON: Or else we take it out.

DR. SCOTT: Yeah. I like it.

DR. ACHESON: That's fine. I -- with the questions around, I think more the grammar as much as anything else, rather than the sentiment of it, Jenny, so it was -- it was reading awkwardly to certain people and it was -- there were questions to try to fix the grammar, but we don't want to do that if that's what he said.

DR. SCOTT: Okay. Then I had another question, or a point under the *Bacillus cereus*; in the middle of the paragraph it says that "There is insufficient information on the potential for toxin production following growth to high numbers that could lead to illness," et cetera. This doesn't take into account that there are two syndromes with *Bacillus cereus*. Both of them require growth to high numbers. In one case, toxin is produced in the foods; in the other situation, high numbers are ingested and toxin is

produced in the gut, so I would suggest that we re-word that sentence to say "There is insufficient information on the potential for toxin production and/or growth to high numbers that could lead to illness."

DR. ACHESON: Any comments on that suggestion? Okay, thanks. We'll put that in there. Any other comments on page 10? Okay, thanks. Page 11? Skip.

DR. SEWARD: Skip Seward. In the first full paragraph, the second-to-the-last line, to be consistent with Example 2, I would suggest that -- I recommend that we add "instances where the SBDL would be better determined and applied elsewhere in the food chain," to be consistent with Example 2 there where --

DR. ACHESON: So the words "determined and"?

DR. SEWARD: Correct.

DR. ACHESON: Okay. Any comments on that suggestion? "Determined and."

DR. SEWARD: Right before -- in the second -- just as -- I just have one other comment, if I may?

DR. ACHESON: Sure.

DR. SEWARD: Or two others. One is in the last paragraph, before number VI, "For" should be -- not be capitalized, I believe and then under --

DR. ACHESON: Hold on, I -- just wait a

minute.

DR. SEWARD: Okay.

DR. ACHESON: Which -- what -- can you just repeat that?

DR. SEWARD: In -- I believe in the last sentence of Example 3, the word "For" should not be capitalized there.

DR. ACHESON: Thank you.

DR. SEWARD: Just as an editorial thing. Under VI, 1, in that first paragraph, in reading that, I would like to recommend that we add "Once the pathogen of concern has been identified (in this case, *L. monocytogenes*) to be a hazard reasonably likely to occur, the following scientific parameters should be considered." I don't know if that changes the meaning significantly, but I think it adds clarification that when you would proceed with a safety-based date label.

DR. ACHESON: Okay. Any comments on that suggestion to add the language after the parens about *mono* to be a hazard reasonably likely to occur? Okay, seems like that -- we'll insert that. Any other comments on page 11? Okay, page 12. Page 13? Oh, is there a comment on page 12?

DR. SWANSON: I do. We should insert point D

at the top of the page, the temperature-related?

DR. ACHESON: Yes, you're right. Thank you.

DR. SWANSON: Or that should probably go right above the A, you know, after the list of strain differences, that's where the D should go. Or -- no, it goes after C. Whatever.

DR. ACHESON: Any other comments on page 12? Okay, page 13. Page 14.

DR. SEWARD: Skip Seward.

DR. ACHESON: Yes.

DR. SEWARD: Just a point of clarification for me in the next-to-the-last paragraph on page 14, one of the new paragraphs, the last sentence where it says, I believe, "Therefore, < 45 degrees F should be used for establishing an SBDL, " et cetera, and I just wondered whether or not the subcommittee meant to say < 45. Does that imply that someone could use 40, as well, or did you mean to just say, "Therefore, 45 degrees F should be used for establishing an SBDL"? I know later in the document you talk about being to parallel the temperature profile of the product, so to state here that just 45 is the right temperature without expanding on it may not be consistent with what you say later in the -- what we say later in the document, so just need

to clarify that.

DR. SWANSON: I believe that should be 45.

DR. ACHESON: It should stay as is?

DR. SWANSON: No. Delete the <, so --

DR. ACHESON: Okay.

DR. SWANSON: -- "Therefore, 45 degrees" should be used.

DR. ACHESON: Okay.

DR. SWANSON: Katie Swanson.

DR. ACHESON: Any other comments around that? Okay, thank you. Anything else on page 14? Page 15. Skip.

DR. SEWARD: Excuse me. Just to point a clarification, for me, under B there's a fairly significant statement in there, line three, "If the food does not permit growth of *L. monocytogenes*, then an SBDL is not warranted." Does the -- did the subcommittee exclude the fact that if *Listeria monocytogenes* is absent, as well as the fact that it did not support growth, would those be -- would that be another criterion for a decision-making or solely if it does not support the growth? Just a point of clarification?

DR. ACHESON: Katie.

DR. SWANSON: Absence doesn't remove the need

for the potential application for an SBDL because the product could become contaminated after opening. And you have to remember that, you know, that it is the type of labeling that the Committee thought would have the biggest impact, so it could be re-introduced on a product after opening and so -- within X days could be applied. Katie Swanson.

DR. ACHESON: Any comments on that, Skip?

DR. SEWARD: No, that's fine. Thank you.

DR. ACHESON: Okay, leave it as it is? Okay. Any other comments on page 15? Okay, page 16.

DR. SEWARD: Sorry. Skip Seward. On the very last sentence there, the addition on the bottom of page 16, the thing that struck me about that sentence is that in the different examples, that was the only place where it seemed to me the Committee would be talking about whose responsibility is to put the label on at what point and I'm not sure that I felt that that really fit into the charge of the Committee on defining a scientific criteria associated with this issue, so I would recommend that that statement be taken out of this document.

DR. ACHESON: So you're suggesting the insert on the bottom of 16, top of 17 be struck at this point?

DR. SEWARD: That's correct.

DR. ACHESON: Okay. Any comments? Katie?

DR. SWANSON: Actually, earlier on, Skip, you identified the examples where that's, in fact, was called out. On page 11, there were some examples where the SBDL would be determined and better applied in the chain, so we do have examples of just that. What we could do is take that and move it up in the examples on page 11, but I think this an important concept that illustrates the need for control throughout the food chain.

DR. ACHESON: Skip?

DR. SEWARD: Well, to me, again, I just believe that here we're -- the Committee is saying who should be responsible for establishing the time frame and who should be responsible for putting on the label and if the subcommittee or the Committee here wants to do that, then it seems to me that for all of these examples that are here for packaging and retail and the one prior, that we had to make a statement as to who's responsible for doing what, rather than just on this one item.

DR. ACHESON: So your point, Skip, is you think this is veering away from the charge of the

Committee?

DR. SEWARD: That's correct.

DR. SWANSON: Frankly, I withdraw my comment, because as I read the examples on page 11, Example 2 talks about taking frozen chicken and they would re-determine -- it would be their responsibility to apply -- determine the amount of time and the retailer would apply the label, so we already have that example elsewhere in the document.

DR. ACHESON: Strike?

DR. SWANSON: Strike. I move to strike.

DR. ACHESON: Okay. I haven't heard anybody else say they want to keep it, so we'll strike that insert on the bottom of page 16 and top of page 17. Any other comments on page 16? Okay. Page 17. Page 18. Okay, page 19. Page 20. Okay, page 21. Page 22. Page 23. Okay, page 24. Okay, page 25. Skip?

DR. SEWARD: Two things. One is I would suggest that we need to put the same language of this new paragraph here that was in the Executive Summary paragraph, since that's the same wording.

DR. ACHESON: So essentially, you'd use the same language that you'd suggested earlier from page two?

DR. SEWARD: That's correct.

DR. ACHESON: Okay.

DR. SEWARD: And then the first full paragraph at the top of that section that begins "The FDA/FSIS risk assessment," I guess -- just help me understand. That's in there -- it seems like that's already been said in the document, but is that in there because it relates to the modeling, the risk assessment modeling? I -- otherwise, I would move that we strike that paragraph. I wasn't quite sure how that related to the modeling.

DR. SWANSON: Katie Swanson, Ecolab. This is a very important paragraph in that the risk assessment demonstrated that the impact of temperature was much more significant than the impact of time. And when you're applying -- talking about application of SBDLs and the educational efforts, those educational efforts should emphasize the need for proper temperature control in addition to time to have the greatest impact on public health.

DR. SEWARD: Okay, thank you for clarifying that. I withdraw my suggestion.

DR. ACHESON: Okay, thank you. Anything else on page 25? Dan?

DR. ENGELJOHN: Sorry, page -- this is Engeljohn. Sorry, I go back to page 24.

DR. ACHESON: Okay.

DR. ENGELJOHN: In the question 5 there's a straight bracket after the word "*monocytogenes*."

DR. ACHESON: Yeah. The -- question 5 was amended slightly by the subcommittee and the decision -- this was discussed yesterday -- and the decision was taken to leave the square brackets in there with a note that those were the changes. We could certainly simply remove that, if that's going to clarify question 5, but we thought it was important to leave it as indicative of the changes that have been made.

DR. SWANSON: Suggested fix. In the note we could say the Committee modified the question or added the phrases within brackets to the question to clarify the intent.

DR. ACHESON: Dan, are you saying it's a straight bracket?

DR. SWANSON: It's not.

DR. ENGELJOHN: I thought it was, but it's not.

DR. SWANSON: It's not.

DR. ENGELJOHN: I see that there's two sets of

brackets in that.

DR. ACHESON: Right.

DR. ENGELJOHN: Okay.

DR. ACHESON: Right.

DR. SWANSON: But this came up yesterday, so if we say that the inserted phrase in brackets were added by the Committee to clarify the question, I think that might take care of it.

DR. ACHESON: Yeah. So we put some language in there to just change that -- the final part that's not bolded to say that the sections in square brackets were inserted by the Committee. Is that okay, Dan? Yeah, okay. Anything else on page 25? Okay. Any comments on the references? I should just point out that we are aware that there are two references missing from the appendix which need to be added. We have those, so they will be added in the final version. Any comments on the references as they stand? Okay. Any comments on the appendix? I'm taking that as all two and a half pages of the appendix. Anybody got any comments anywhere on those two and a half pages?

MR. GARRETT: DR. Chairman.

DR. ACHESON: Yeah.

MR. GARRETT: Spencer Garrett of the National

Marine Fisheries Service. I would merely like the minutes of our deliberations to reflect that the appendix is, in fact, part of the full document. There was some confusion yesterday on that and there's been confusion in Codex, as well, on that, that the appendix is, in fact, part of the document.

DR. ACHESON: Thanks, Spencer. Are there any further comments on the appendix? Okay. Well, thank you very much. I'll pass it back to Dr. Brackett.

VICE-CHAIRMAN BRACKETT: Okay. Thank you very much, David, and thank you for assisting in this and I'd also -- in his absence, would like to acknowledge and thank Dr. Zink for leading this effort. At this point, we will move to adopt this document by vote of the Committee we have here and that is with the understanding that the final document would include the final or the other two references that would be added, also. So at this time, do we have a motion to accept the document as submitted with the edits and references?

MR. BERNARD: I so move. Dane Bernard, Keystone Foods.

DR. TOMPKIN: I second it.

VICE-CHAIRMAN BRACKETT: Second by Tompkin.

Okay, the motion has been made to accept the document. It has been seconded by Bruce Tompkin. At this point, all those in favor of accepting the document as described, signify by saying aye.

COMMITTEE MEMBERS: Aye.

VICE-CHAIRMAN BRACKETT: Opposed?

[No response.]

VICE-CHAIRMAN BRACKETT: Okay, this document is adopted. And this took us less time than we thought it was going to and this is a good thing. So at this time -- actually, in the original schedule, we had thought this was going to take longer. We were going to move to a break, but I would recommend that we continue to charge on. The next particular one will be perhaps a little bit longer and so we want to make sure we get plenty of time for that. And I will notice -- note for those of you who are expecting a break, too. Before the break, we wanted to mention, so we'll do it now, just so you know, that check-out time is at 12:00 noon, but the hotel will hold your luggage so you can, you know, modify your plans accordingly. So at this time, I would like to turn the floor over to Dr. John Kvenberg to discuss redefining pasteurization.

DR. KVENBERG: Thank you, Chairman. I guess,

as this convention, I would like us to begin by thanking the working group members and other contributors -- to the document from the full Committee. This was a complicated issue, to say the least, in that we were faced with many new technologies that are coming on the horizon of food processing that could be alternatives to conventional time temperature pasteurization studies. As was mentioned by the Chair at the initiation of the morning session here, the Plenary Session, what brought us to this was a change in the Food, Drug and Cosmetic Act as amended by the Farm Security and Rural Investment Act of 2002, which broadened the definition for pasteurization. I hope this will be helpful and Brett, do you have the slides ready to put up? I just thought, as a brief overview, it might be useful to go through an overview of the document before we go through a page-by-page convention on the full document, for the benefit of the full Committee.

As we introduced on the beginning of this thing, the scientific criteria or what we focused on in redefining pasteurization and incumbent within that is the need to define pasteurization, because there are many different concepts and thoughts involved in it and I would like to also advise the Committee -- I think

there's a dual thing that became apparent while we were working on this document, not only is there a need to define the term pasteurization, but define in terms of what pasteurized would mean on the labeling of the product, which is where this document led to us to, when it's appropriate to use pasteurized on the product given a definition of pasteurization. Next slide, please.

The establishing of the equivalents of alternative methods to pasteurization, as we will go through this document, included many technologies that had been around, some of them for a great number of years and some of them who are novel and new approaches. But in our consideration, we were guided and we were grateful for the guidance that preceding the establishment of the requirement through passing by Congress, IFT developed a base document that gave us a road map to begin our considerations in reviewing new technologies that have been applied to this quest and so that was very helpful to get us started on the document. Next slide, please.

So these were the base questions that we were charged with to be posed to the subcommittee. What we did, in the base document and we'll be reviewing in the front end of the document, are responses to these

questions that were raised to the Committee for all new technologies. We reiterated the questions in each technology down to the degree, if you'll look through the document, where this was possible. We have discussion at the end of this document about emerging technologies where we did not feel we had enough information yet to go through the full discussion of those newer technologies to actually and adequately address the five questions, so they are just basically discussed in paragraph form. Next slide.

So we've struggled this issue mightily and I think one of the main cruxes and a very important issue to focus on is we are recommending the National Advisory Committee's evaluation of the traditional process of pasteurization and so I think it's very important to focus on the definition that we're putting forward for this work. We'll go through the document itself and here's the definition that we're putting for and posing, and I don't know what level of discussion we have had. It's been changed slightly in last edition. You will note that you have a clean copy of the actual document that we're putting forth for consideration. I do have a changed track document available on the side for those of you who are, you know, have reviewed the previous

document and we'll be happy to point out on the pages what changes have been made or what discussions have happened during this working group session. Next slide, please.

This is a list of the process and technologies that we reviewed within the document, as a basis -- a base document of what we did and the way we broke this out is basically assign champions to each technology, so there are lead discussions and we'll rely, to some degree, for in-depth discussions or any questions that may arise from full Committee on a specific technology to the leads on the specific technology that was reviewed. Next.

These are the technologies that I spoke about that are emerging that didn't have enough information presently to address the full consideration or did not appear to be at a stage which they would have applicability to food pasteurization, so they're also included within the document under discussion.

So we will go through the document in plain language. Basically, what we did was summarize here our recommendations that's explained in the Executive Summary and also at the conclusion of the document. I won't dwell on it now. We did focus and did some

revision relative to a discussion of HACCP systems to make sure that we were compatible and you'll see that in the revised Executive Summary. Next.

In our conclusion, I think it's important to point out research is needed to determine the adequacy of pasteurization, pasteurology for these new technologies. As you -- we'll go through and it's explained in the text of the document, the door's open for label changes for labeling products as pasteurized and -- the importance of this document is to provide a road map for persons wishing to move ahead with the term pasteurization on alternative technologies to products and as a guide to particularly the Food and Drug Administration, at this point in time because our act was modified, but also FSIS will be faced with the same challenge on not only providing guidance, but also internal review processes that would be recommended to go through in order to make a determination for the appropriateness of the term pasteurized on the label.

I believe that's it, is it, Brett? One more? This is -- all right, in addition to traditional thermal processing, we can just go through this, this is in the document, as well, and I won't dwell on it, but this is within the text of the document, as well, of discussing

the alternatives and also, we did consider, as you will note within the document, several technologies being pulled together to retrieve an end result of pasteurization.

Finally, I hope, Brett -- because I haven't reviewed the slides -- importantly -- and I guess we would like to point this out, protection of the product from contamination after processing is required for a product to being considered pasteurized. What we're getting at or driving here is again, the difference between the term of what the process is to apply the term pasteurized as opposed to what process adequately will pasteurize a product, because integrity of the product to avoid recontamination or allow for a hazard to be created is quite an important inclusion in any review of applying the term pasteurized to a product. Thank you.

With that being said, as open remarks, I would like to use the same convention, if that's acceptable to the Committee, to go through page by page of the document? Oh, I'm sorry. There was one more slide. I thought we were done. There is a final one here. Well -- yeah, I think the term -- I think the important point of the -- to bring out at the end of the document is consumer

research and indicated the lack of acceptance. I don't know if this concept falls within or out of the purview of the National Advisory Committee, but I think we should actually bring this out that on many occasions throughout our considerations and through the whole system, there is a recommendation for consideration at the end of our document and a conclusion about talking about consumer research and label perceptions by consumers. So we can certainly have that discussion.

I think that it was consensus of the working group that the main charge that the Committee would be involved with is what does a consumer need to know about the product and the term pasteurization would cue them on how to handle the product in order to part of the safety assurance system of the food that they have purchased. Pasteurized foods are not necessarily shelf stable, but this an overall question we can discuss at the end of the document on consumer perceptions and the application of the term pasteurized I would propose as opposed to pasteurization. Thank you. That is the last slide, I assume. Okay. And there are working group members that participated in this group and again, my great thanks for a lot of very intense review of literature and very strong and good deliberation to get

to the document to the point where it is today. Thank you.

Okay, with that, if we can again go through the document by page. We --

MR. BERNARD: John?

DR. KVENBERG: Yes.

MR. BERNARD: Hi. Dane Bernard, Keystone Foods. First of all, Chairman, my compliments to the subcommittee on their fine work to bring this document to this point. You've done marvelous things in pulling this topic together. It is a rather dense document in terms of the information that is here, to plough through and for those -- the rest of us on the Committee that were not on the subcommittee, I have to confess, personally, I haven't had a chance to read through the entire document, so I feel a bit unprepared to go through the document. We're a bit ahead of schedule. I'm just bringing up a couple of things here. I don't want to say let's not go through it today, I'm just asking for a bit of time. I'm looking at the schedule for the rest of the day and I would certainly yield to Spencer's analysis of the amount of time it's going to take to go through the ground chicken and ground turkey documents, but we may not need the entire afternoon for

those two documents, so it's merely a request, Chairman, for some additional time to give this a good read and make sure that we have identified all of the issues that might need to be further discussed. Thank you, Chairman.

VICE-CHAIRMAN BRACKETT: This is Bob Brackett. I don't really have a problem -- I mean, if the Committee feels that now would be a good time, perhaps, to break and read this in greater detail, I don't know. Again, Spencer Garrett may want to elaborate on how much time he thinks that his will take this afternoon, but we do -- we would like to get this done fairly quickly. Spencer?

MR. GARRETT: Thank you, Mr. Chairman. I think that given the fact that our two documents are essentially re-writes of previous documents that we've done or just modifications, that we may not need the entire time, but you know, it's -- who's to say, but I do think that we were to take half an hour now to go ahead and read this document- that probably should be sufficient. I have one or two questions on the document, myself, that I would like to bring forth, but why don't we go ahead and take a half an hour now to read the document and then go through it?

VICE-CHAIRMAN BRACKETT: Jenny?

DR. SCOTT: Jenny Scott. If we take some time to read this, I'd like to point out that the crux of the document is in the first 13 pages where we have the definition and we respond to the five questions in general. The rest of it concentrates on specific technologies and I think is less important to the overall thrust of the document.

VICE-CHAIRMAN BRACKETT: Okay. Well, okay, it's now 9:35. Why don't we take actually maybe a 45-minute break now. It'll give people time to do some other things and come back here at 10:15 and then we'll initiate that and that'll give people, hopefully, time to review the document and do anything else that they need to do during this time. So we'll have a break --

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[Off the record]

[On the record]

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CHAIRMAN PIERSON: -- and again welcome to the members of the National Advisory Committee on Microbiological Criteria for Foods, as well as the guests. Sorry I had to show up a bit late. It wasn't because I was, you know, out partying late last night,

although I did go out with a group from here last night, carrying on the tradition of, you know, social events following all-day-long meetings. So it was enjoyable to talk to everyone last evening and kind of catch up on things. Wish I could've been here for the earlier discussion but I had to be in some other discussions this morning.

I want to commend you for your -- the progress that has been made and actually, it's very, very good timing, too, because these -- hopefully, we'll all be wrapped up today, right, John? Okay, good. It's -- you know, when you -- when the Committee is to be re-chartered and turn over its -- it becomes a little bit of a challenge if you have the continuing work and lots of new Committee members coming back on, so believe me, we covet and value your input on all this and especially so we can complete all this work that's on the docket. It's perfect timing.

You know, there's been obviously a lot of hard work that is going on and, we very much appreciate that and the work that you are doing, again, has a tremendous amount of importance to serving as a reference in -- as a scientific analysis of various critical areas on food safety and it's the safety shelf-life work, the

redefining pasteurization, the performance standards, the works are all very, very important scientific analyses that we look at when we consider policy for our respective agencies. So I thank you very much for your contributions in that regard.

You know, there's a number of accomplishments that have been made during your tenure here on the Committee. You've responded to the questions posed by FSIS regarding performance standards in reference to young chickens, the response to USDA/FSIS's request for guidance on baseline study design and evaluation of raw ground beef. And as I say, there are reports that will be finished up here today for adoption. You know, the requisite scientific parameters for establishing equivalence of alternative methods of pasteurization, considerations of establishing safety-based consume-by date labels for refrigerated ready-to-eat foods, and performance standards for ground chicken and performance standards for ground turkey.

We again very much appreciate this work and the outcome of all the work. What I might interject here, too, is that in the past I know we've published these documents in journals and when I look at these materials, I'm going to encourage Gerri to work with the

chairs of these subcommittees to publish these works in our scientific journals. It's very important. I mean, we post it on the web site but -- as especially you academics know, it's really not out there until it's in a journal, so we need to drive towards that and I -- for example, your pasteurization document is -- it's just an excellent overall analysis and review and I hope that we'll be able to do that sort of thing.

Of course, in that regard, too, there's a procedural matter that I'll be talking to Gerri about further and that is we need to look at maybe more standardizing the format that we put these into so we have consistency, so we probably should develop some guidelines as to what should the cover page be and the format for the outline because believe it or not, we have some wild things when we get these in. Some people get uptight within various areas of government about the spacing and big letters and little letters and all that sort of thing, so if we could establish a consistent format, then we can say well, this how it is, here. You know, the literature citations, et cetera, and that might help you out, too. So I thought I'd interject that and I'm surprising Gerri by all this because she didn't expect that. But, you know, last night during

some of our discussions some of you folks brought that issue up and so I was listening about that.

So with that, we'll move on to John Kvenberg's subcommittee meeting and I'm sure we're going to be able to get through this in a very expeditious manner. John?

DR. KVENBERG: Thank you, Chairman. Just prior to the break for information of the chairs, we'd introduced the subject and I had proposed to, at this point, after -- ability for members to re-read and re-review because it is a complicated document, to propose we go ahead as we did with the previous document this morning, page by page. I assume that's going to be an acceptable procedure to follow. And in addition, if it will be helpful, I have the track changes document that -- we have a copy and I can use that as a guidance if there are questions on language changes of the document received before the meeting and the changes that were made yesterday because the last two days we were meeting in session, so I'd be happy to go through and revise what's new at the point we go through the page changes.

Okay, with that, if it's acceptable, I'll start rolling through the document itself. The current document, pages one and two, I believe are correctly

marked with page numbers that guide you through the document and these are the sections. Any comments on one and two? Okay. Page three begins the Executive Summary and I will note for the full Committee that over the last two days we have redrafted the Executive Summary and got input from Bruce Tompkin to our group and so I think it's an improved Executive Summary and it flowed through the document from the changes that were made here. Any comments on page three? Four?

DR. JAYKUS: John? Lee-Ann Jaykus. To be consistent with our conversations in subcommittee yesterday, I would suggest on the paragraph of "Research needed," we add the term "predictive modeling" rather than simply "modeling."

DR. KVENBERG: On page four? Where's that exact wording?

DR. JAYKUS: It's the full paragraph, the first full paragraph and it's the very --

DR. KVENBERG: Very last word --

DR. JAYKUS: Right.

DR. KVENBERG: -- "and/or predictive modeling."

DR. JAYKUS: Correct.

MR. BERNARD: Chairman? Dane Bernard,

Keystone Foods. That paragraph that we were just discussing, on page four, since we've opened to page four already in the discussions; the second sentence in that paragraph, I would like to suggest some rewording. Right now it reads as, as an all-inclusive list, that each of those should be done, at least in my reading of it. I would suggest that we change as follows: "All pasteurization processes need to be validated. This can be accomplished through the use of one or more of the following: process authorities, challenge studies, predictive modeling and/or use of recognized “safe harbors.” Thank you.

DR. JAYKUS: Lee-Ann Jaykus. To that question, if you refer to page 45, we actually did come up with a statement very similar to that, so I'm in favor with what Dane says.

DR. GRIFFIN: Chairman? Patricia Griffin, CDC. I was still back on page three. In the last paragraph, that first long sentence with the list of factors, one factor that's not listed there is the normal conditions of distribution and storage, which is a phrase that's used in the indented paragraph near the top defining pasteurization and I find that phrase more understandable than the very last phrase, the intended

use of the food. Is that what is meant by "the intended use of the food"?

DR. KVENBERG: I guess I'll defer to comments from the Committee. Those are separate thoughts. Or if this would be a better replacement phrase for that. Almost seems to me, speaking for the group, that's a -- it's not the same issue. It could be an additional issue, but I don't think it's an either/or. So we could add it as an additional point since it's in the text, correct? It's in the text, so your point to put it in the Executive Summary and I guess we'll have to keep an eye on the document itself to make sure that that is amended accordingly, too, if the group agrees this is a useful thing to put here. Everybody seems to be raising their head that we would use the phrase. Do you have a problem with the other phrase that's --

DR. GRIFFIN: No, I don't.

DR. KVENBERG: Okay. So I guess, then, we could -- would you say it again so we clearly have the --

DR. GRIFFIN: Right, it's just quoting that same phrase that's the very last phrase in the definition of pasteurization.

DR. KVENBERG: Um-hum.

DR. GRIFFIN: So it would be "the normal conditions of distribution and storage."

DR. KVENBERG: Well, okay, only one thought from style relative to this -- these are all -- these bullets starting off with an action, either conduct, determine -- is this defined?

DR. GRIFFIN: Well, no -- no.

DR. KVENBERG: Where are you talking about?

DR. GRIFFIN: I'm talking about the sentence that starts that paragraph.

DR. KVENBERG: Oh.

DR. GRIFFIN: "One must consider numerous factors" --

DR. KVENBERG: Okay.

DR. GRIFFIN: -- and I would put this factor right in front of the last factor. So --

DR. KVENBERG: Oh, I'm sorry. It's in the text.

DR. GRIFFIN: Right.

DR. KVENBERG: I see it. Just an insertion of --

DR. GRIFFIN: Following "matrix characteristics," then put this phrase.

DR. KVENBERG: Got it, got it. Right after

the "and." Okay. That would be the last one or after -- "intended use" would be last, so it should be a comma, then "and" and then the last one will remain in its place?

DR. GRIFFIN: Yes.

DR. KVENBERG: Okay.

DR. JACKSON: LeeAnne Jackson, FDA. Can you please state exactly, for the record, what it is that you want inserted so that we make sure we get it exactly correct in the document, please?

DR. GRIFFIN: Yes. I would like the fourth line of that last paragraph to read "matrix characteristics, the normal conditions of distribution and storage, and the intended use of the food."

DR. KVENBERG: Well, Chair, I think -- I believe we have consensus on the insertion. Okay, thank you. We're on page five, I believe. Are there any more comments on four?

DR. LAMMERDING: Can we just clarify exactly what the intervention is and what words we're going to use, specifically? Because the wording on page 45 is somewhat different and I'm not sure that the -- that we agree that “safe harbors” is something to insert here. I mean, safe harbors is something that is not part of

the validation process. They are processes that are validated.

DR. KVENBERG: Could I -- I noticed Jenny Scott had her flag up. Maybe she can speak to the point.

DR. SCOTT: We went through several iterations in trying to clarify that we did not intend any one of these, nor all of these necessarily be validations, so I like Dane's change and I would agree that recognized safe harbors is an approach that is used for validation in lieu of doing challenge studies and I like that addition, so I support --

DR. KVENBERG: Can I go back to Anna's point is -- her comment was not exactly consistent for Dr. Griffin's proposed addition to the other paragraph. Hers is fine. You're just talking about speaking in favor of Dane's, okay. I would like to close, if I could, just for clarification with you, Anna, is that we revisit later and accept this and move on or we look at it again on page 45, would that work?

DR. LAMMERDING: I'm fine with that.

DR. KVENBERG: Okay.

MR. BERNARD: Chairman? Dane Bernard, Keystone. I also recognize that we need to remember

this intervention as we get to page 45, because we need to be consistent and right now it's not, so thank you.

DR. KVENBERG: Thank you. I'll dog-ear 45 for us. Any additional comments on page five, I guess is where we're at now. This is basically the charge and the -- I think we have it correct now. Page six. Again, it's informational and -- until we get to Roman numeral II. Any comments on page six? I see none. Page seven?

MR. BERNARD: Chairman? Dane Bernard, Keystone Foods. At the top of page seven, after the indented paragraph, the sentence has reference to potential for recontamination and having read through that a couple of times, I'm still not exactly sure what the Committee is trying to say there. Could I have some explanation on that relative to the definition of pasteurization? Thank you.

DR. KVENBERG: Thank you. Perhaps we could Wordsmith -- it's just my interpretation. Let the working group of other Committee members go to intent. Perhaps it does need a little clarification. My reading of this is, at least my major concern -- and maybe we should be more clear in elucidation of the statement is after the pasteurization process is applied to the

product and immediately before it's packaged, there is an opportunity for introduction through cross-contamination. So maybe we could use some clarification. I'll defer to the rest of the working group or anyone on the Committee that would take exception to clarification of that term, but the potential for re-contamination, in my mind, is between the application of the kill step of the process and making assurance there are good manufacturing HACCP procedures to assure that you don't reintroduce what you've just gotten rid of. I don't know what the words would be, but I think that's the intent.

DR. DONNELLY: Cathy Donnelly. Or even a different pathogen. In the example we were using in the working group was if a consumer's purchasing pasteurized milk, that term "pasteurized" has a connotation of "safe to consume," so even though *Coxiella burnetii* is your target for an activation, the product after pasteurization is still susceptible to environmental contamination by things like *Listeria*, so that to have that term "pasteurized" on your product label for sale means that you've taken care not only of your pasteurization target but other things that potentially could cause a public health concern in that product.

DR. KVENBERG: Thank you. I guess to add to that is we were using as a model current application of pasteurization processes, so would it work to say, for clarification purposes, where I think you were driving, "the potential for recontamination either immediately prior or prior to packaging," because I think that was our intent. Any words would be welcome here, but that was, believe it or not, under consideration.

DR. TOMPKIN: Bruce Tompkin. It could say "for recontamination prior to final packaging." Or if you wish, "between pasteurization and final packaging."

MR. BERNARD: Chairman, Dane Bernard, Keystone Foods. I'm still not sure that we have completely captured this. Using the *Listeria* and pasteurized or heat-treated milk example, can I label my milk pasteurized if there is still a potential for recontamination even though I have a program in place that addresses that, I don't think there's any program that will ever be able to say, unless it is an aseptic process, that we can absolutely preclude the possibility of recontamination.

DR. KVENBERG: Could I offer the following? It just popped into my head. "Are not reasonably likely to occur." Would that help? Because I think what we're

just basically, Dane, is normal prudent safeguards need to be applied in order to not negate the process. I don't know what the fix is, but that was the intent. Again, this is the difference between applying the process of pasteurization and what pasteurized on the label means, but due diligence is somehow required, so any help here would be useful. I'm trying to be transparent and clear what our thought was and see if it will hold up through the document.

MR. BERNARD: I'll go with the wishes of the Committee, it just -- this is a tough one because you're linking the fidelity or the success of a post-pasteurization program, which is absolutely essential, to being able to label a product as pasteurized or not, which personally, I view as what we did to the product, itself. No doubt in public health protection terms, we have got to guard against recontamination, I just have difficulty in linking them as to how we're going to define a label for a product. Thank you.

DR. KVENBERG: I have two flags up, if I could, Chair. I think Jenny was -- Jenny Scott was first and John wanted to make a comment.

DR. SCOTT: Jenny Scott, NFPA. It seems to me that Bruce's fix to adding "the potential for

recontamination between pasteurization and final packaging" really best gets at our concern and we're not necessarily saying you could not label it as pasteurized if you could have some contamination, you just have to consider this whole issue and how it affects the safety of the product in assessing whether or not the product would be labeled pasteurized.

DR. KVENBERG: If I have this clearly then, Bruce, intervention we must consider was, I think, a key phrase I heard you say might be helpful here. I'm trying to get this sentence correct. John, did you have additional thoughts?

DR. LUCHANSKY: I was -- John Luchansky, ARS. I was going to echo what Jenny had said, but also, John, your statement about the difference between pasteurization, as a process, and pasteurized, as a label, should come stronger and more clear earlier on in the document and that might be a good place to introduce it, right after the definition and then have the paragraph with Bruce's suggested fix and Jenny's comments introduced there, because even having served on the Committee, that's one that I don't think is adequately articulated in this document. So I would make that suggestion. And the way you said it, John, I

liked.

DR. KVENBERG: With the intervention of must consider?

DR. LUCHANSKY: Well, the concept of we define pasteurization --

DR. KVENBERG: Um-hum.

DR. LUCHANSKY: -- but maybe that paragraph that begins "However, application," a sentence prior to that differentiating between pasteurization and labeling something as pasteurized would clarify or at least begin to clarify some of the concerns that Dane had. Well, we don't have that captured in here.

DR. KVENBERG: Okay. And I guess we should take an opportunity to try to craft that sentence and then get on to the addition that Bruce put into the paragraph.

CHAIRMAN PIERSON: John, I might comment. I think this discussion's a very good discussion, an important discussion. It's also important to look at the charge and see what specifically the charge was asking about of the pasteurization process and these are very important considerations and make for good discussion as to all the post events, et cetera, is to whether or not, though, that that falls within the scope

of the charge here.

DR. KVENBERG: Okay. Just to get guidance on this, are you suggesting the paragraph should be deleted or modified as Bruce has said? We do -- with the intervention, it would read "but also should consider the potential for recontamination between the application of the process and packaging". Is the thought that we should strike the paragraph or take the addition -- I just don't understand where we should go.

VICE-CHAIRMAN BRACKETT: This is Brackett. My reading of the original charge that we got from the Act was actually to the definition of the process, itself. There are a lot of other implications of that, but I would say that that's not necessarily the goal, is to address those, although they will have to be at some point, but not for this particular case.

DR. DONNELLY: Cathy Donnelly. I think we read the charge more broadly than you're interpreting it under part three, the statement about "is effective for a period that is at least as long as the shelf-life of the food when stored under normal and moderate abuse conditions," and so, to the Committee, we looked at not only that inactivation treatment, but also protection of the food for public health throughout its shelf-life.

DR. KVENBERG: DR. Chairman, I've got several flags up. I think Katherine Swanson was up first.

DR. SWANSON: Katie Swanson, Ecolab. I would move to strike the paragraph because as I'm reading it, I do think it is important to consider protection of the product after pasteurization, but one of the things that we did not address in committee was non-consumer type pasteurizations that might go through, for example, tank trucks of dairy, et cetera, which would also have to be considered and it gets very complicated if you throw that aspect in it, as well. Removing this paragraph kind of gets us out of that realm and focuses on the process.

DR. KVENBERG: Jenny Scott had her flag up, I guess.

DR. SCOTT: Jenny Scott, NFPA. I can agree with Katie's comment there. I have a reworded sentence if we wanted to keep this in, but I think that the easiest fix is to simply delete the paragraph.

DR. GRIFFIN: Patricia Griffin, CDC. I'm still trying to grasp the document, but I like having the paragraph in because when we look at illnesses, the vast majority of illnesses from pasteurized product are from post-pasteurized contamination and I would like to

think that this paragraph is true, that the regulatory agencies would assure that a plant that's producing pasteurized product doesn't have the ability to apply the label unless they have a process that assures that there's not post-pasteurization contamination. So I think it's very good to have that paragraph in there, to show that pasteurization is by far not the only control measure.

DR. KVENBERG: Chairman, if you allow, there's still flags that would like to comment. Should we do that? I'm watching flags going up and I think Dr. Swanson was up first.

DR. SWANSON: Katie Swanson, Ecolab. I'm just wondering if we can't get to the point that Dr. Griffin made under the section of when we -- the definition normal use, normal conditions of distribution in storage, we could potentially put a bullet in there that would address the need for protecting the product as it is used throughout the chain instead of having it hanging out there alone as a paragraph, because to me, that's kind of where it fits.

DR. KVENBERG: I saw Jenny Scott's flag up.

DR. SCOTT: I just thought I would offer the reworded sentence, in case we decide to keep it, but I

think we could work it as Katie suggested, too. In order to couple what we're saying here about the label with the process, I would reword the paragraph to say well, we have defined pasteurization as a process. Application of the term "pasteurized" on a label requires consideration of whether recontamination can occur between application of the process and final package in order to ensure, et cetera, et cetera.

DR. KVENBERG: Thank you. I think, Frances Downes, I missed you. I'm sorry.

DR. DOWNES: That's okay. Thank you. I just wanted to point out to the Committee that under -- on page eight, under the "...[population] that is not likely to present a public health risk," there is a statement that says "Pasteurization does not protect public health when product is subsequently recontaminated during manufacture or after the container is opened." So as Katie suggested, it is in the -- broken out in a definition not exactly where she suggests, but it's there and I'd like to support Jenny's amendment to that paragraph.

DR. KVENBERG: Angela, do you have a comment?

MS. RUPLE: Angela Ruple. I'd also like to support Jenny's changes, as well as Katie's suggestion

to move the paragraph perhaps under the title "normal conditions of distribution and storage." I think it's important that we keep that paragraph in the document, but I'm not opposed to moving it to another location.

DR. KVENBERG: Okay. DR. Chairman, I guess we have another comment from Dr. Griffin.

DR. GRIFFIN: Yeah, Griffin, CDC. I don't think that the term -- I think my reading of the term "normal conditions of distribution and storage" refers to after a product is packaged, then it is distributed and then it is stored and I think what we're talking about here is after pasteurization and before distribution and storage. Maybe I'm reading it incorrectly.

DR. KVENBERG: Dr. Jaykus?

DR. JAYKUS: Lee-Ann Jaykus. No, actually, the subcommittee was considering the entire life of the product, not just that period between.

DR. KVENBERG: DR. Chairman, I have a, I think a proposed fix, and I'm not sure to move the paragraph to that section as reworded and I guess I would defer back to the last commenter of the exact wording -- of location and wording. Jenny, will

you be able to guide us through that? We're talking about taking the paragraph that we will amend and moving it to where?

DR. GRIFFIN: Chairman, before we do that, I have another -- a different comment on that same paragraph that may affect -- and it's just a question. Could I do that?

CHAIRMAN PIERSON: Sure.

DR. GRIFFIN: Okay. This phrase, at the top of page seven, "under normal conditions of distribution and storage," I'm a bit confused by that, because when I look at page five, the very bottom, there's a definition in that language that, at the very bottom says "when stored under normal and moderate abuse conditions," and it seems that that's language in the bill that was not put into the phrase at the top of page seven. And so I'm wondering how that intent will be incorporated.

DR. KVENBERG: Well, I think that's a different issue than the one we're discussing now, but it's an important one. From the standpoint of how the -- this was an area I think you correctly keyed in on where two documents are linked. We just passed the prior document on "use-by dates"

and they delved in deeply the term of abuse. I'm not proposing we table that discussion, but it might be more useful when we get in -- we may have to track back to discuss our proposed fix because we were not coming to terms on moderate abuse conditions.

DR. GRIFFIN: Chairman, is -- the reason why it confuses me with respect to my earlier question is that I -- the assumption that moderate abuse is talking generally about abuse at the consumer level and so when I read that phrase on page seven, "normal conditions of distribution and storage," I did not think that the intent would be that there could be moderate abuse at the plant level or in truck distribution, that sort of thing. I thought that the moderate abuse was intended to be able to occur at the consumer level.

DR. KVENBERG: Well, just so I'm clear on your point, I think our considerations to the term abuse dealt with temperature, not reintroduction by GMP violations or reintroduction by the consumer of a pathogen that didn't see the process, so our reading of abuse dealt strictly with time and temperature, not with reintroduction. Maybe that's

not clear, but that was the language that we were working off of and our interpretation of the Act -- if we're talking about abuse conditions, it was time and temperature.

DR. SWANSON: However, it was -- Katie Swanson. It was not restricted to consumer abuse. It can happen at retail, it can --

DR. KVENBERG: Right.

DR. SWANSON: -- happen during distribution, you know, any number of places along the food chain, you need to consider that when you're designing processes and products.

DR. KVENBERG: Well, what I'm working with at the moment is the potential for recontamination, which is a separate issue from time/temperature abuse, so I'm just trying to find a home for this orphan paragraph for discussion relative to the key word here being recontamination. And abuse, time/temperature, it should be addressed, perhaps, but I don't know if it's germane to this paragraph.

MR. BERNARD: Chairman, Dane Bernard. Could we go back to the Chair and their earlier --

DR. KVENBERG: Um-hum.

MR. BERNARD: -- statement about -- their interpretation of the original --

DR. KVENBERG: Right.

MR. BERNARD: -- charge to the Committee? I'd like to get a clarification, because if -- we're spending a bunch of time on something that --

DR. KVENBERG: We may strike.

MR. BERNARD: -- I heard earlier was not part of our remit in the first place, so --

DR. KVENBERG: Right. Let me go back -- can I go back and defer to the Chair for guidance. Are we wasting our time? Should we strike it? Or should we continue? If we're outside the charge, perhaps we should strike and move on.

CHAIRMAN PIERSON: In Bob and my discussions, I think we're coming to the conclusion it's a -- you know, the narrower charge and the zeroing in on the process of pasteurization, itself, and there's made reference to, for instance, on page five, three -- it would be H [ph] three -- three, even that one, I think, makes reference back to that process of pasteurization. You know, it's not addressing post-processing contamination or other issues, et cetera; it's a

narrower aspect of the definition of pasteurization, per se. Again, certainly these other steps are important, but --

DR. KVENBERG: Well, with that as guidance, it sounds like what we should do is strike the paragraph. John?

DR. LUCHANSKY: Can I just ask a question, though? Obviously, you've touched on something that the group spent a lot of time deliberating on, that portion of the Farm Bill and in different iterations of our definition of pasteurization, we did and did not have the last phrase which is included in there now. I think it would be critical for the rest of the deliberation and for how the document was drafted if we got some clarification as to whether that phrase "under normal conditions of distribution and storage" should be part and parcel of the definition. It also takes up what Dr. Griffin brought up relevant to recontamination and the issues of what constitutes moderate and gross abuse, so can we get some clarification on the inclusion of that phrase?

DR. KVENBERG: Actually, if I could -- Dan, do you have any interpretation -- further

interpretation of this?

DR. ENGELJOHN: This is Engeljohn. I don't see how we cannot address the issue if the section of the -- that we're working from, from page five, talks about under normal and moderate abuse. I mean, we spent an enormous amount of time in the committee to address that issue, which I think does impact how you set the standard.

DR. KVENBERG: Correct. I mean, it's -- I agree, in that sense, that it has to be under normal storage and moderate abuse/storage conditions, but -- does that pasteurization process hold under those conditions? I agree with that, yes.

DR. ENGELJOHN: Yeah. And specifically, referring on page five, the very last line which says --

DR. KVENBERG: Right.

DR. ENGELJOHN: -- under number three, which is "of the food when stored under normal and moderate abuse conditions." That's as of the shelf-life, so I don't see how we can not keep that --

DR. KVENBERG: Oh no, I agree. You

address that as -- Jenny Scott.

DR. SCOTT: There are some issues going on here -- Jenny Scott, NFPA -- it's hard to know where to start, but first of all, with respect to the normal and moderate abuse, we did take that into consideration is our belief that normal conditions of distribution and storage do involve some abuse and so that captures it. So we did not use the specific words "with moderate abuse" in part because it became almost impossible to define what we meant by moderate abuse.

Secondly, one concern about just dropping this whole issue with respect to the term pasteurized on the label as opposed to pasteurization as a process, leaves us with a definition that if I apply that definition literally, I could high-pressure treat a product, not in a package, and by this definition call it pasteurized and then I could put it in a package and I don't think that's anyone's intent here. So we were trying to get at the concept that once you apply this process, you then have to protect the product from contamination in order to be able to label it as a pasteurized product.

And that's not to say that it has to be -- the process needs to be delivered to the product in the package, itself -- that doesn't happen to milk, itself, but there is some consideration for protecting that product to ensure that it doesn't become recontaminated. And this is what we were trying to get at with this whole paragraph. We know that we didn't need to address all the labeling issues with respect to pasteurization. That's just our thinking here.

DR. DONNELLY: Cathy Donnelly. We spent a lot of time in our deliberations going back to the Pasteurized Milk Ordinance as a model example. Just the heat treatment of milk, in and of itself, is not protective of public health. The public health protection comes by embracing all of the concepts associated with the Pasteurized Milk Ordinance that looks at incoming quality of raw milk, potential for recontamination afterwards -- Schwann's Ice Cream is a good example of how an initial treatment in and of itself, if you don't look at what happens to the product down the chain, it could do more adverse -- it could have more of an adverse impact on public health and benefits,

just that treatment, itself. So I think that's where the Committee's coming from.

I think Jenny actually offered a nice fix to where we are and leaving that paragraph as it is, where it is, with Jenny's modifications addresses Dr. Griffin's concerns because following the definition that's stated, the very last line of the existing paragraph deals with the normal and moderate abuse conditions and so linking those two just clarifies our intent. I think Jenny offered a great amendment that clarifies the language.

DR. KVENBERG: Thank you, DR. Chairman. Merely to point out that as the paragraph has been modified either by Jenny or Bruce Tompkin, where it would say, essentially, "must contain" -- "but also must consider the potential for recontamination between pasteurization and final packaging" or whatever Jenny's was. The -- I want to point out that it says "throughout the shelf-life in an unopened container when stored under normal and moderate abuse conditions." That's what currently occurs. Does that not occur?

UNIDENTIFIED SPEAKER: Not in commercial settings.

DR. KVENBERG: Not in commercial settings? Then I would take Jenny's modification and put it under "as has been recommended" under the section that says "...[population] that is not likely to present a public health risk." I think we're -- I think maybe we're overcooking it a little bit and I think we all agree that you have to -- when you pasteurize products, you have to take recontamination into consideration. I think under commercial conditions, you certainly do. And I think even a prudent manufacturer even takes under commercial conditions what the normal and usual distribution patterns are, including moderate abuse; moderate abuse, however that's defined.

So I think maybe we could take the wording that's been offered and merely put it under how you've broken down the definition as a bulleted item and I think you could probably get beyond this and that would be separate from the labeling issue. The labeling issue, to me, is a totally different issue. I don't know if that's helpful or not, but at least that's my opinion. Dane was up.

MR. BERNARD: Thank you, Chairman. It seems that there is a lot of -- I don't think

anybody here is disagreeing that addressing the potential for post-processing contamination is essential, but it seems that there is a faction that would like the pasteurized label to mean that this product is safe to consume and I think Cathy Donnelly very well mentioned the example with milk, that there's a lot more than just the delivery of the process and prevention of recontamination that would go into that.

And once you open that avenue in terms of applying a label, I don't know where you cut it off, so I'm still concerned, not about the intent, because I think we're in agreement that this is essential for public health protection, but tying it in this paragraph to the application of a label sets up a system where somebody's going to have to judge each of these things. Not that there aren't programs in existence, but somebody's going to have to judge the adequacy of those programs in every instance and maybe that's what you want to do, maybe that's what we want to recommend as a Committee, but that's a big job.

Think of -- you know, as far as I know, pasteurization of milk and shipping it by tankers

is still a legal practice; pasteurization of eggs and shipping them by tanker is still a legal practice; there's a lot of things that one must consider if you're going to link the two in this paragraph. Thanks.

DR. KVENBERG: Spencer? Comment?

MR. GARRETT: I forgot to take it down.

DR. SOFOS: I support removing the paragraph, because it states on page eight, seven lines from the bottom, they show recontamination is adequately addressed, in my opinion. And also, we shouldn't forget that there are products that are labeled as fully cooked and they may be exposed to recontamination after -- and cause illness and we still label them fully cooked.

VICE-CHAIRMAN BRACKETT: Jenny, did you have a comment? No. Well, let me also say, just in background, some of the -- the sort of debates that we're getting into really fall more into the realm of legal sort of interpretations and so I would really like to get beyond that part. Would I be restating the feeling here is that the technology involved is the primary part, but you cannot take that all by itself, that you have to

consider the whole picture, as is done in the case of milk. If that is the intent, and I think that is the intent and I would agree, finding some way to include that sentiment in the document, I think, is appropriate, but not necessarily including that as the definition of pasteurization. Anna?

DR. LAMMERDING: Anna Lammerding. I think that is a very good suggestion and I just wonder if somewhere we can insert words to the effect of that the Committee recognizes that, et cetera, but this document addresses the process. We're more explicit about we're talking about, but putting some emphasis on the fact that we do recognize there are bigger issues or further issues.

DR. KVENBERG: DR. Chairman, in the essence of time and moving on, I think the most expeditious thing is to strike the paragraph from where it is, mark it and review to where Dr. Lammerding is proposing to maybe perhaps put this in a discussion section and get on with this, so it doesn't encumber the definition. That would be a way to proceed.

CHAIRMAN PIERSON: I think that's a good

suggestion, assuming that the rest of the subcommittee and the full Committee agree with that suggestion. Keep in mind, too, that this is not going to be the legal definition of pasteurization, which is, I think, what some people are wrestling with. It is the basis upon which the Agency will actually propose a regulation to do that.

DR. KVENBERG: Patty Griffin has her flag up.

DR. GRIFFIN: My question is about the definition, not about that paragraph, but I'm not sure you're ready to move on to that.

DR. KVENBERG: Well, I just wanted to get a disposition so we can move down the document. Cathy Donnelly had a suggestion about where the wording would go, if it would remain here or not, but additional wording that would be useful, perhaps, if we're going to put this paragraph or this thought somewhere within the document here or elsewhere.

DR. GRIFFIN: Yeah, I think -- Cathy Donnelly -- in attempt to bury this issue, not that -- it's critically important, but I think Anna offered a good suggestion; if we just take

that paragraph, modify it to say the Committee recognizes that application of the term, blah, blah, blah and then at the end, this is best done by the appropriate federal agencies with regulatory jurisdiction and leave it at that.

CHAIRMAN PIERSON: I think that's an excellent suggestion and if the -- if we could get a consensus on that at this point in time, we'll move forward. Is there --

DR. KVENBERG: It's a procedural thing, then. If I understand it correctly, with her injection, perhaps the paragraph can stay where it is and then we can state it and then if you want to move it later, you can, if this is out of context of where it should appear, but I'd like to get a reading of what the paragraph now says, regardless if we move it, but it doesn't look like it's going to die, let's --

CHAIRMAN PIERSON: Right. It's still -- it's --

DR. KVENBERG: Okay.

CHAIRMAN PIERSON: -- alive and well.

DR. KVENBERG: Could we get a clear wording of exactly what the --

CHAIRMAN PIERSON: Yeah, if we could have the wording on that paragraph.

DR. KVENBERG: All right. For LeeAnne's benefit. Dr. Donnelly?

DR. DONNELLY: My suggestion was to begin on page seven, paragraph two, with "The Committee recognizes that application of the term pasteurized on a label requires not only an assessment of the reduction process, but also the potential for recontamination between treatment and final packaging to ensure the safety of the product throughout the shelf-life in an unopened container when stored under normal and moderate abuse conditions. This is best done by the appropriate federal agencies with regulatory jurisdiction."

DR. KVENBERG: You want to do it? Are we okay with that? Two flags up. I guess Dr. Swanson was up first.

DR. SWANSON: I would suggest doing a full stop after safety of the product and deleting the bit about the shelf-life and the unopened container under normal and moderate abuse.

VICE-CHAIRMAN BRACKETT: Just for clarification, you want the first words that --

DR. SWANSON: The first words could stay and so it essentially would convey the thought that you have to assess the process and the potential of -- for contamination after -- to ensure the safety of the product and this is best done by somebody else.

DR. KVENBERG: Well, just to reword what I think this is now saying is the paragraph remains where it is; it begins, "The Committee recognizes that application of the term pasteurization on a label requires not only an assessment of the reduction process, but also must consider the potential for recontamination between treatment and final packaging to ensure the safety of the product," full stop.

DR. SWANSON: That would be -- between process and packaging -- that makes it broader. It covers all scenarios, it doesn't exclude anything. It's more inclusive.

DR. KVENBERG: DR. Chairman, can I just reiterate that before we move on one more time so -- I think we're trying to get clear language here. "The Committee recognizes that application of the term pasteurization on the label requires not

only" --

VICE-CHAIRMAN BRACKETT: John?

DR. KVENBERG: Yes?

VICE-CHAIRMAN BRACKETT: In my version, it's pasteurized.

DR. KVENBERG: "Pasteurized on the label requires not only an assessment of the reduction process, but also must consider the potential for recontamination to ensure the safety of the product." End of sentence. That's what I think where it stands right now. I'm just trying to -- that's, I think, the language before the Committee.

VICE-CHAIRMAN BRACKETT: Okay, where's the language -- to still keep it -- this is best done by appropriate regulatory agency?

DR. KVENBERG: It was -- oh, I'm sorry. That was not struck. My misunderstanding. "This is best done by the appropriate federal agency with regulatory jurisdiction," was the final word to the that phrase. That's what we have in front of us and I think Dr. Griffin had her flag up.

DR. GRIFFIN: Griffin, CDC. Are there some products that are not shipped intrastate for which the regulator may be state-based and so

should the term federal be used?

DR. KVENBERG: I think that's a good point. There might be intra-state distribution; if the word "federal" was struck, it would -- I don't know. I mean, we're getting into the weeds in the legal issue yet again. But perhaps that's an okay fix if we -- it actually softens it, the appropriate jurisdiction, perhaps. Is done by the appropriate jurisdiction, I don't know. We're getting now -- we're getting into the regulatory process instead of the science process --

VICE-CHAIRMAN BRACKETT: That's right.

DR. KVENBERG: -- we might be cleaner by dumping that last part of the sentence in totality and let that fall -- if we had it as I first proposed, without that last interjection about the appropriate agency and then just to go full stop at the end of safety of the product, we're out. Is that a fix for everyone? Strike that last -- I think we're out of the process. I think I have it, sir. It stays where it is and it's been duly modified with consensus, so -- okay, very good. We're at page seven and we're what? Half --

CHAIRMAN PIERSON: Well, it's important.

MR. BERNARD: I just want to get it clear where we are. The words "application" and the term "pasteurized," that means labeling, on a label? We have put as equal, in that equation to apply a label, adequacy of the process and control of post-processing contamination, one of which is something that's relatively quantifiable, the other is rather nebulous and in the eyes of the beholder?

DR. KVENBERG: I think with the injection of the words, Dane, "must consider" basically goes to the ruggedness of the -- I don't know. You're basically -- I just want to get a clear statement. You're proposing striking the whole paragraph yet again?

MR. BERNARD: Yes.

DR. KVENBERG: As -- okay. It's as modified or we have one objection to retaining the modified paragraph and saying strike. That's where I think we are.

CHAIRMAN PIERSON: Jenny Scott was up first.

DR. KVENBERG: I would hope to keep it, Dane, if -- particularly if we had not removed the phrase from the working definition "under normal

conditions of distribution and storage." If that remains, I would move to keep the modified paragraph in. Jenny?

DR. SCOTT: I do not like the modified paragraph. I agree with Dane. It is more problematic in its modified form and I don't think it gets at the intent of what we were doing with this paragraph, so I would rather see it out than have it as currently modified.

DR. KVENBERG: I guess -- I don't know. I don't know if we're going to resolve this issue other than to strike.

CHAIRMAN PIERSON: Well, what -- I think what we can do is we have all the discussion on this, you know, we know what the modification is and when we go to adopt this, we'll go through on a vote and we'll just simply take that up as to whether or not, you know, we have a majority vote to have that. If there are dissenting opinions, be it -- that dissent is, you know, minority is to keep or reject. Then we could have the minority --

DR. KVENBERG: Can -- just so I understand this for clarification purposes, then you're saying the paragraph remains as modified in

the text for a vote?

CHAIRMAN PIERSON: Yeah. We'll just vote on it when we take up the whole document.

DR. KVENBERG: Right. Can I move on?

CHAIRMAN PIERSON: Yeah.

UNIDENTIFIED SPEAKER: Clarification, Chairman, on that? When it comes up for vote are we going to accept the document or reject the document as a whole, depending on how we feel about this paragraph, or are we going to vote on the paragraph?

CHAIRMAN PIERSON: I think we should just -- you know, we'll take up that paragraph, since it is a special consideration and we can raise that issue when we vote on the document.

UNIDENTIFIED SPEAKER: Thank you.

CHAIRMAN PIERSON: Okay.

DR. KVENBERG: Can we move on, Chairman, with your permission to any additional comments on page seven? Jenny.

DR. SCOTT: Jenny Scott, NFPA. It's been a long week, DR. Chairman, and we were working hard and furiously and there were some things that we threw in that we said oh, we'll come back and fix

that sentence and I found one that we didn't come back and fix. That's at the bottom of the page under the section "...that is applied to food to reduce..." in the third bullet, where we're talking about the in principle we can't totally eliminate all microorganisms from a product, there's a statistical probability of survival.

And we tried to clarify that nevertheless, in spite of having this statistical probability that there will be survival, the product would be safe and the sentence that is there we didn't come back and fix and I think we are to strike that sentence and insert the following words "however, if the level of pathogen reduction is such that product does not present a risk to the consumer." That is the concept we got -- we were getting at there, the point being that in the law, the term elimination of microorganism of public health significance appears and we recognize, as microbiologists, that total elimination is essentially not do-able statistically, so --

VICE-CHAIRMAN BRACKETT: Jenny, would you please say that again, slowly?

DR. SCOTT: I would like to revise the

third bullet under "...that is applied to food to reduce..." to say "In principle, total destruction or elimination cannot be achieved because there is a statistical probability that an organism will survive in a fraction of products (e.g., 1 in 1,000,000 packages)."

DR. KVENBERG: Strike the rest?

DR. SCOTT: Strike the rest and then say, "However, the level of pathogen reduction is such the product does not present a risk to the consumer." I don't want to convey the fact that we can't eliminate all these pathogens so there is a risk there, but practically speaking, we're saying that that's not, so --

UNIDENTIFIED SPEAKER: Read that again.

DR. SCOTT: The addition, the replacement for the second sentence is, "However, the level of pathogen reduction is such the product does not present a risk to the consumer."

DR. DOWNES: I have a question for Jenny.

DR. KVENBERG: I don't know how to proceed. I think Dr. Griffin was up first and then Frances.

DR. GRIFFIN: Right. Mine is another

topic on this page, so --

DR. KVENBERG: Okay.

DR. GRIFFIN: -- Frances, you just --

DR. DOWNES: My question -- the way you have that phrased then, Jenny, what about that one in a million consumers who consumes that product? So they're not -- it's not risk-free, it's just that we've minimized the risk as much is possible and that's what we're trying to convey here?

DR. KVENBERG: Right.

DR. GRIFFIN: Right. Yeah.

DR. DOWNES: But I don't think that you're phrasing to say that the consumer is not at risk conveys that. The consumer's risk has been reduced as far as conceivable -- as possible, giving the existing technology, that the consumer is not risk-free as long as there's that probability that one in a million does consume a contaminated product.

DR. GRIFFIN: So would you prefer something like the product presents a negligible risk or the product presents a reasonable certainty of no harm, to use the federal phrase that we use to define safety?

DR. DOWNES: Either one of those would be acceptable, but -- I mean, no risk is just what I want to avoid.

DR. KVENBERG: Well, I think the latter is probably pretty good. If you -- if the Committee would accept a reasonable certainty of no harm is something that's widely understood in risk assessment.

CHAIRMAN PIERSON: That would fix it for you?

DR. KVENBERG: Not a risk to, then it would be a reasonable certainty of no harm to the consumer.

CHAIRMAN PIERSON: Acceptable?

DR. KVENBERG: I think that's acceptable, Chair.

CHAIRMAN PIERSON: Thank you.

DR. KVENBERG: I think Dr. Griffin had another comment on this page.

DR. GRIFFIN: Yes, it was the same comment I made before; maybe I need to clarify it. And it's a question about the definition, which may only be a definition for this document, but it still is an important document that gives a

definition of pasteurization. In the third line at the top, it uses the term "under normal conditions of distribution and storage," and I think when I asked about that I was told that normal conditions is supposed to incorporate moderate abuse, but that confuses me a bit in terms of how the Committee thought about -- the subcommittee thought about normal conditions, because when I look at that paragraph, that may or may not be eliminated.

The very last phrase in that paragraph says "normal and moderate abuse conditions," which makes me think that the intent of the subcommittee is that there's a difference between normal and moderate abuse, and also when I look at page nine, the top, the third line, it also says, "Determination of normal and moderate abuse conditions," which would indicate to me that the subcommittee thinks that moderate abuse is something different from normal conditions and also, in -- at the very bottom of page five, the language in the Farm Act says normal and moderate abuse conditions, so unless normal is defined someplace, and including moderate abuse and that's not the way I would interpret it when I read this.

DR. KVENBERG: Chair, with your permission, and Dr. Griffin, I think I would like to defer to Jenny on the issue, but simply state, also, that this part of our document has to be keyed into the one that was just adopted by the Committee this morning, because the shelf-life issue and the question of what constitutes moderate temperature abuse was discussed and passed, so we have -- I think there's a need for consistency between what we're recommending here. Jenny, can you help us out here on this?

DR. SCOTT: Well -- Jenny Scott. It seems that part of the problem is we did not have time to go back to this document and do a search for moderate abuse and address this. Clearly, it was our determination that normal conditions of distribution and storage do involve some moderate abuse. We were unable to come to agreement on what normal storage is or what abuse storage is and we tried to work around that.

I would agree with Patty, though, that we should at least have some statement in here that indicates that normal conditions of distribution and storage will involve some consideration for

time and -- or will involve time and temperature abuse to a certain extent, or moderate abuse or something along those line. The problem we get is that what does that mean and neither committee was willing to define what moderate abuse was. So the best fix, I would say, would be to say delete moderate abuse from the document. When we talk about normal distribution and storage, we consider that it involves some time and temperature abuse and we so state that somewhere in this document.

DR. KVENBERG: Just to reiterate, that -- I think that's worth underscoring, the normal distribution system assumes some temperature variations and we were just unable to, nor was the other working group within the committee able to define moderate abuse.

CHAIRMAN PIERSON: Dr. Swanson, do you have a --

DR. SWANSON: Yes, we're not to page nine yet, but the -- it is being discussed. The phrase in the first bullet on the top of page nine, "Determination of normal and moderate abuse" needs to stricken from the document, because it isn't in the report that we just adopted.

DR. KVENBERG: Okay. So with that being said, trying to work through, I think the appropriate concerns of Dr. Griffin here, if we use the term "normal" with opportunity to revisit and strike out "moderate abuse" in this section, Jenny? Is that where we're looking? To get on with doing an explanation for what normal distribution systems may incorporate some moderate temperature variation abuse, fixing it later? Would that work?

DR. SCOTT: Yes. And I think --

DR. GRIFFIN: I still have some -- Griffin, CDC. I still have some concerns about that, partly because it seemed to me that the mandate in the Farm Act was to include in the definition -- as long as the shelf-life of the food, when stored under normal and moderate abuse conditions, and so if we're not going to take account of that, then we're not doing what the Farm Act has stated and I certainly think normal and moderate abuse are two different things unless it's clearly defined. So I still have concerns about the definition.

DR. KVENBERG: Well --

DR. GRIFFIN: It seems to me that normal

could do what the median 50 percent of the population does and it seems to me that there's a 20 percent out there that keep their refrigerators too warm and we don't want those millions of people in the population to be at risk.

DR. KVENBERG: Well, to get around the issue, basically, because of the Committee's language, I think I'm still going to back to consistency with the document we just published. Maybe I could get some assistance on that front, I don't know. What's the language? I'm not that versed in what we just passed relative to -- it's appropriate to do this, go back to the document we just adopted on -- safety-based shelf-life date labels, what was the language for consistency that we might draw from this? Are Committee members able to help us, perhaps in that regard? What did we say in the document we just approved? Is it in there?

DR. SWANSON: The term moderate abuse is not in the -- Swanson, Ecolab. It's not in the document we just adopted. There is a section in here where we discuss selection of 45 degrees --

UNIDENTIFIED SPEAKER: What page is that?

DR. SWANSON: Page seven. At the bottom of page seven.

DR. KVENBERG: That paragraph --

DR. SWANSON: John, you found it?

DR. KVENBERG: Yeah. "This section imposes a commercial requirement of a maximum of seven" -- is that the one? It starts out --

DR. SWANSON: No.

DR. KVENBERG: -- "While most date labeling?" Is that the paragraph?

DR. SWANSON: That's not it. Page 14.

DR. KVENBERG: Where on 14?

DR. SWANSON: Okay, page 14, the addition at the very bottom of the page. "The Committee agrees with the 2001 Food Code that < 41°F is optimal. However, the Committee recognizes that many consumer refrigerators are < 45°F. Therefore," and we struck the less than in the next sentence -- "45° should be used" to establish "an SBDL for" the "period of time that would reflect consumer handling." So we did not address moderate abuse. Or define it.

DR. KVENBERG: No help there.

DR. JAYKUS: John?

DR. KVENBERG: Lee-Ann Jaykus. The other issue, too, is that this really addresses consumers and not what happens at retail or during distribution.

DR. KVENBERG: Jenny, did you have a comment or is your flag --

DR. SCOTT: It seems to me -- Jenny Scott -- in our description of "under normal conditions of distribution and storage," we can handle the whole issue of moderate abuse. The question is whether people are comfortable with us not specifically defining what moderate abuse is and just describing conditions such as we have here.

We've got optimum storage temperature, we've said that temperatures above 50 for the shelf-life of the product would be gross abuse, we could even -- at one time we had other language in there with respect to describing moderate abuse, but the problem is, it is time, temperature and product specific, and that's where we ran into difficulty in specifically defining moderate abuse. We can also go back to the definition, include moderate abuse in there, if necessary. However, I don't think that we have to take all the wording from the

Farm Bill and put it in our definition. If that was the case, we wouldn't have been charged with having to define pasteurization because it's all there.

DR. KVENBERG: Okay, so I guess I'll go back to the Chair yet again and try to resolve the question now. Is moderate abuse -- it remains undefined, it couldn't -- it was considered by virtually the full Committee by working group members and we have failed to come to terms with that requirement.

CHAIRMAN PIERSON: I think that the suggestion about the Committee recognizing that importance, but -- and for the discussions here, the challenge you get into is, you know, in the charge to the Committee in the first paragraph would be the charge, but on that page five, that second part is as the Farm Bill reads, you know, that's -- it's not -- that's how the Farm Bill reads. When you read that paragraph, quite frankly, we would need a very thorough legal interpretation about that reading.

When you look even at that very last sentence on that page, you have to look at it in context of

what everything else was said before that, so you have to be very careful about that interpretation of what it says. I don't think that this Committee -- we're in a position to make that legal interpretation of the language.

What I strongly recommend is we stick with the questions that are asked on -- well, it's actually on page six and we stick with those questions, because I think what's happening here is we're trying to get into something that is an extension or more of a legal interpretation and the Committee can recognize that importance, but let's be careful -- we're kind of getting bogged down in some things that again, really would be subject to let's say, legal interpretations.

DR. KVENBERG: Okay, for clarification of where we are in the document, then, we're on Dr. Griffin's comment and --

DR. GRIFFIN: Yes, so if we're going to put it to a semantic problem, then I would propose the following, that either that definition at the top of page seven says "under normal and moderate abuse conditions of distribution and storage," or looking at page nine, at the top, we say something

like normal conditions of distribution and storage are meant to include moderate abuse. So that would be my suggestion. Otherwise, the term normal excludes the term moderate abuse, the way it's written now.

DR. KVENBERG: Say normal -- what was the last -- just say -- say it again, please.

DR. GRIFFIN: Say my suggestion?

DR. KVENBERG: Yes. The term normal conditions of distribution and storage -- that the Committee intends the term normal conditions of distribution and storage to include moderate abuse conditions.

DR. KVENBERG: Within the definition?

COMMITTEE MEMBERS: No.

DR. GRIFFIN: No.

UNIDENTIFIED SPEAKER: Below, explaining in the bullet below.

DR. GRIFFIN: This is at the top of page nine.

DR. KVENBERG: Oh, I've got it. We moved. Okay.

DR. KVENBERG: That sounds like it works.

CHAIRMAN PIERSON: Jenny Scott.

DR. SCOTT: Jenny Scott, NFPA. I had a similar fix, slightly different wording. The second bullet on page nine would be that normal conditions of distribution and storage include a range of temperature conditions. In many instances this will include conditions considered abusive with respect to the product.

DR. KVENBERG: Is that close enough? I know we have two -- we've got two proposals for wording on page nine, that's where we've jumped to; second bullet, correct?

DR. GRIFFIN: Griffin, CDC. Could you just say that again?

DR. KVENBERG: And Jenny, if you could, exactly where it's supposed to be?

DR. SCOTT: Yeah. Jenny Scott, NFPA. Page nine, second -- would be a new second bullet. It would follow "Pasteurization is not intended to prevent growth of microorganisms under all time and temperature conditions. The manufacturer should specify how the product would be safely handled and stored. Adequate or proper refrigeration temperatures vary depending on the specifics of the food product."

New bullet: "Normal conditions of distribution and storage include a range of temperature conditions. In many instances, this will include conditions considered abusive with respect to the product."

"Normal conditions of distribution and storage include a range of temperature conditions. In many instances, this will include conditions considered abusive with respect to the product."

DR. GRIFFIN: Griffin, CDC. Could you say in many conditions this would include conditions considered to be moderate abuse?

DR. SCOTT: I was just trying to get away from the word moderate abuse, but if the Committee can accept that we use the term moderate abuse without defining it, then I think we're home free.

DR. KVENBERG: Before we move on, can -- it sounds like at least there's agreement for the rewording of the language of this inserted bullet on page nine and do you have it? Was it -- Chair, do we have that?

CHAIRMAN PIERSON: I think that's -- Jenny, if you could, when you get the exact writing, pass it over to us, please.

DR. KVENBERG: You can read it back -- okay. It sounds like we've maneuvered that. Okay. Any other additional comments on page seven? Okay. We're moving slow, but we're moving. Page eight.

I would point out on page eight that within the definition you'll see on the second bold, there's a term, [population] that still remains in brackets. Just as a word of explanation, it was brought up in the subcommittee the population that is being defined is the microbial population. We dealt with and in various places in the document used levels, numbers, et cetera, so I -- we're open to a final decision. We put it in brackets for a consideration of what the word should be. There was some -- I believe Dr. Brackett, who's not -- or Dr. Beuchat, who's not here, basically put forth the conventional population and that seemed to be somewhat problematic, so we're seeking guidance, I think, on the square-bracketed word on page eight. Any comments on page eight? I'd like to discuss that square bracket.

DR. GRIFFIN: I would recommend we change it to “level.”

DR. KVENBERG: Well, that's the

recommended change. If we could strike the word population and insert level, it would be, I think, smooth sailing. Agreed?

UNIDENTIFIED SPEAKER 1: Level of contamination, maybe?

DR. KVENBERG: Level of contamination would be fine with me.

UNIDENTIFIED SPEAKER 2: Then you have to change the definition.

DR. KVENBERG: Level would work, okay. We'll just use that one-word change for the square bracket, striking population and use the word level on page eight. That would get us past our concern. No additional comments on eight? Oop, sorry. I've got to keep looking over here.

DR. DOWNES: Under public health risk, the first bullet point, I'd like to suggest that we put an additional sentence in there that some populations, like immuno-compromised people, the elderly or pregnant women require special consideration. You have stated that the susceptibility of the host is a factor, but I think that there's some populations that -- I mean, we're talking about population susceptibility, I think we

also need to point out that there are some sub-populations that require special consideration.

DR. KVENBERG: Where is she? An additional sentence or -- do you have the exact sentence again so we can --

DR. DOWNES: It's more or less -- I have it. Some sub-populations like immuno-compromised people, pregnant women or the elderly require special consideration.

DR. KVENBERG: Start out immuno-compromised and then elderly -- I just -- what was the order? Such as --

DR. DOWNES: It's insignificant, the order --

DR. KVENBERG: I'm just trying to get it.

DR. DOWNES: I have it. Immuno-compromised people, pregnant women and the elderly.

DR. KVENBERG: Yeah, Dr. Swanson, you had --

DR. SWANSON: Katie Swanson, Ecolab. We have to remember that this is a pasteurization document that deals with a wide variety of different potential pathogens and the host susceptibility can vary tremendously depending upon

just which organism you're talking about. If we're thinking 0157, then you'd have to talk about young children and so I don't like the inclusion of those because those are kind of the classic *Listeria* susceptibilities. I think that the susceptibility of the host here, because we're talking about this broad term, that includes so many different things, you know, people with high iron, people with low iron, depending upon the pathogen; we need to keep it clean.

DR. DOWNES: I will disagree with that, Katie, because are the same populations that are also at risk for *Salmonella* and the -- forms of Hepatitis A and on and on. I mean, they are the people that are at risk for all -- most at risk for all food-borne illnesses and I think if you want to say for example --

DR. KVENBERG: Yes.

DR. DOWNES: -- that may exclude the children in the 0157 but you're -- you know, we're going to get into a whole deal here of well, it's not that kids are more susceptible, it's that they're more susceptible to the worst outcome, so I would say that if we -- I would propose we keep it,

but input -- include "including" in there or "for example" to indicate that this isn't an exhaustive list of sub-populations, but just examples.

DR. KVENBERG: Could I reiterate what the proposal, I think, is then? If we had an e.g., for example, and listed specifically -- I'm checking this myself -- *Listeria* as the example for sub-populations; it's well-known. I don't know if that's a fix or not, but that's what I think you're now saying, so obviously Katie would like to leave it clean and not have the interjection and Frances would like to propose the interjection, so -- okay?

DR. SCOTT: I agree with Katie. I'd prefer to leave this clean. I mean, we've pretty much defined that pasteurization has to protect the consumer, in general, and that's got to be taken into consideration.

DR. KVENBERG: What's the consensus of the group? I guess they'd like to --

DR. DOWNES: Well, we didn't vote on anything else and we deferred until the end to vote, so I don't -- and I want to -- this isn't just a document for -- I mean, this would be used in making recommendations to people as to what is a

process that's suitable to their particular health needs and so if we're, you know, looking at levels of kill, there might be some processes that are more appropriate for people who are on chemotherapy, for example, than other processes. I mean, for example, you might have ultra-high temperature pasteurization products recommended for people on chemotherapy as opposed to typical heat pasteurization. I'm just throwing that out as an example and I think that some of the recommendations for these populations are not adequate to -- they're not realistic in terms of health protection.

DR. KVENBERG: Well, if I could for -- with -- I think -- I'll try to speak for the working group at this point, just some clarification for the Chair and Vice-Chair, we're using as our base model our prior experience. The term pasteurization has -- it was applied in the use of pasteurized as it appears on the label.

One of the biggest paradigms, I guess, we would put forward is pasteurized milk. Pasteurized milk may, unlikely as it is because we've done a risk assessment, contain a pathogen that could, at

very low levels, present a problem, but pasteurized is, I think, an understood basis. People who are severely compromised may have to avoid all foods except those that are thoroughly sterile in order to -- they don't have an immune system, so -- I guess that's where I'd leave it. I don't know how special consideration here fits. My opinion on this is that leaving it clean and stopping with host is probably appropriate. That's my view, along with several colleagues on the working group. Chair, Vice-Chair?

VICE-CHAIRMAN BRACKETT: Yeah, John. It goes back, again, to the charge -- the purpose of this document is to advise the Agency on how to define pasteurization. It is not meant to provide recommendations to consumers, nor is it meant to apply to medical foods or specialty foods.

DR. KVENBERG: Well -- okay, so I guess where that leaves us is the recommendation of the working group and I don't know if we have consensus or what your view is on this, that not to modify the sentence beyond the language -- but, I mean, I'll defer to how you want to -- this is where I think we are. Where I am, at least.

VICE-CHAIRMAN BRACKETT: Okay. Brackett. The other possibility's for issues such as this, things that are important but not necessarily germane to the purpose, I think it's appropriate to put an addendum to the end, so that that is part of the record, it's recognized but it does still not bog us down into important but not necessarily parts of the charge.

DR. KVENBERG: Will that be acceptable? We'll look at it as an addendum to the document in saying we have to make a consideration for special populations. Please keep us on this when we get to a section where that would fit. Any additional comments on page eight?

DR. SOFOS: The last line of page eight should be bolded, I think.

DR. KVENBERG: Editorial. Thank you for the catch on that. That's correct. Bolded. Nine? Nine, we -- I'm sorry, Dane. I apologize. I wasn't looking --

MR. BERNARD: No, you went on to page nine, correct? You are on nine?

DR. KVENBERG: Yes, sir. Nine.

MR. BERNARD: Thank you. Dane Bernard,

Keystone Foods. The second-to-last paragraph on that page; it's actually a sentence paragraph. I call your attention to the paragraph just above, which ends with "appropriate level of public health protection," which, I think, is very good and I would propose that we insert that phrase in the first line of the next paragraph, "NACMCF recommends establishing an FSO and/or a performance standard" designed to achieve an acceptable level -- appropriate level of health protection or “ALP” if you prefer, "for food/pathogen combinations," yada, yada. Thank you.

DR. KVENBERG: I consider that editorial, but positive. If everybody agrees, we'll just insert. Not controversial, it's just clarification. It's a true statement. Do you have it? Chair has it, I believe. I think they got it. They're not saying no. Page 10?

DR. GRIFFIN: Chairman?

DR. KVENBERG: I'm sorry. All right. I didn't realize you have a --

DR. GRIFFIN: That's okay. Griffin, CDC. Well, you might wish you had gone on because I'm on the third bullet on page nine, "Pasteurization

should not be expected to provide protection under time/temperature abuse conditions." I thought -- yeah. Thank you.

DR. KVENBERG: Where are we -- just so I understand where we are?

DR. GRIFFIN: "Pasteurization should not be expected to provide protection under" insert the word gross --

DR. KVENBERG: Gross.

DR. GRIFFIN: -- "time/temperature abuse conditions."

DR. KVENBERG: Thank you. Go ahead.

DR. LUCHANSKY: Luchansky, ARS. Maybe an editorial thing; the group could help me with it. But in the paragraph under number one, in the middle of the paragraph when it talks about *Salmonella* in eggs, a semicolon or a comma, whereas. Aren't the egg ones linked and -- linked to that Appendix C?

DR. KVENBERG: I have trouble finding -- here? Liquid eggs?

DR. LUCHANSKY: So it says -- Appendix C. So maybe rather than a semicolon after the first phrase, a comma, whereas "in-shell pasteurization

targets" --

DR. KVENBERG: Okay, they have it. I'm not even going to mark it.

DR. GRIFFIN: Chairman? Another comment.

DR. KVENBERG: Yes. I just wanted to make sure the Chair had it and it looks like they do. Thank you. Another comment?

DR. GRIFFIN: This is simply a comment. Things don't need to be changed, but it just may be some lack of understanding on my part. In the first paragraph under number one, the fourth-to-the-bottom line of that paragraph says "juice pasteurization is based on a 5-log reduction of the most resistant microorganism of public health significance," on, on, on, on, on and then the last line is "all afford an appropriate level of public health protection."

I may be mistaken, but I think we had an outbreak by a company who was using that 5-log process and that we at CDC have some concerns about how that 5-log process is performed and if they were using that 5-log process then it did not afford an appropriate level of public health protection, so I'm not sure that appropriate --

that -- I think we still need more information to know whether we at CDC are happy that that process will protect the public health.

DR. KVENBERG: There are going to be comments -- just to clue me in as the working group chair, can you give me a little specifics about the instance because it may be a GMP failure and not a failure of the standard. So what was the -- what kind of issue was it, to help clue us in that you're referring to in this outbreak? What was it?

DR. GRIFFIN: Yeah, it was the fresh juice, it was the orange juice. It was that one -- the company in Arizona that was washing the outside of the fruit --

DR. KVENBERG: All right, can I -- let me just address it and then others may have a comment on it. It basically was, under that particular scenario, a proposed process which was deviated from, so we're talking about not a failure of --

DR. GRIFFIN: Um-hum.

DR. KVENBERG: -- the performance standard to adequately protect, we're talking about a failure of execution. I don't think it -- if I have my facts straight, others have --

DR. JACKSON: I have a fix.

DR. KVENBERG: Well, I guess Dr. Jackson -- for clarification.

DR. JACKSON: LeeAnne Jackson, FDA. Did the outbreak occur before or after FDA published their juice HACCP regulation in 2001? That's my question, because I think that outbreak may have occurred before the regulation was actually published.

DR. GRIFFIN: I don't recall exactly when the regulation was published. My recollection, which could be wrong -- I'm not at all convinced that I recall correctly -- was that they were trying to follow that new either proposed or enacted ruling and I'm not sure that I ever understood where the break in the process has been. I don't know if that was determined and I don't think that I ever understood whether the process had been applied correctly and did not succeed, or whether there was a problem with the process.

DR. KVENBERG: Well --

DR. GRIFFIN: And I understand that this is off the topic of the charge of this committee. This is merely background information, so I just

needed to say that as a comment.

DR. KVENBERG: Okay, I understand your comment and I think I understand the situation. We can leave it behind. Dr. Jackson, I think is correct. Number one, we didn't have an enabling regulation, which -- and number two, this is a processing question on execution, not challenging the pasteurization performance standard. And the whole issue of this was fresh, not pasteurization, so I think it's off the mark. This was marketing of fresh juice, not pasteurized. So it's outside the realm of this discussion.

DR. GRIFFIN: I thought the juice was labeled pasteurized. Well, maybe not.

DR. KVENBERG: I don't think so.

DR. GRIFFIN: Okay.

DR. KVENBERG: Not in Arizona. Additional comments? Okay.

DR. SWANSON: We could add when properly applied at the end of the sentence if we wanted to clarify that. Or we can leave it alone. Swanson, Ecolab.

DR. KVENBERG: I'd soon leave it alone because, I mean, that's implied and that really

gets us down into issues the Chair's already guided us away from. Additional comments on nine?

CHAIRMAN PIERSON: Yes. If I may?

DR. KVENBERG: Yes, sir.

CHAIRMAN PIERSON: On this next to the last paragraph where it says National Advisory Committee "recommends establishing," so on and so forth, you know, FSO, et cetera, "by regulatory agencies"; one of the things we have to be careful on is recommendations relative to policy and actually, we're very sensitive about that in dealing with rechartering the Committee, because it's scientific advice. What I suggest there is rather than saying you recommend that regulatory agencies do the following, you just simply strike "NACMCF recommends establishing," but rather, you just could say if FSO and/or performance standards for food/pathogen combinations could serve as the basis for judging equivalency, so on and so forth.

DR. KVENBERG: Oh, good call. Right. It keeps us clean. We're not a policy recommending --

CHAIRMAN PIERSON: Correct.

DR. KVENBERG: We're still in the science realm if we state it that way. Could serve as.

CHAIRMAN PIERSON: It could serve as.

DR. KVENBERG: Thank you. The basis for judging.

CHAIRMAN PIERSON: Right.

DR. KVENBERG: Thank you. Page 10, if I can pass it. No, I can't get past it. Nine --

DR. DOORES: John, you -- Stephanie Doores. You might just want to, right after FSO, reference Appendix E, since there is a discussion of FSOs there.

DR. KVENBERG: Put in brackets Appendix E?

DR. DOORES: Yeah. After performance standard, put Appendix E.

UNIDENTIFIED SPEAKER: E?

DR. DOORES: E as in Edward.

DR. KVENBERG: Okay. This is a point of clarification because you're the expert on this, Stephanie. We don't go into regulatory agency language in the appendix, do we? We should review that, I guess. Okay. Page 10, if we may move? Comments?

MR. BERNARD: Chairman? Dane Bernard, Keystone. The one, two, three, fourth bullet,

which now reads "Assess the impact of the food matrix," would the Committee consider "consider", instead of "assess" --

DR. KVENBERG: The one we'll change?

MR. BERNARD: It's the fourth bullet on page 10.

DR. KVENBERG: Yeah.

MR. BERNARD: At the top.

DR. KVENBERG: "Consider the impact " as opposed to "assess"? It's a one-word change proposal?

MR. BERNARD: Correct.

DR. KVENBERG: Any comments on that point? Jenny, is that -- Dr. Scott was the first --

DR. SCOTT: I think we can agree to the change. There are consequential changes to that on page four and I think later in the document, as well, that we'll have to pick up.

DR. KVENBERG: You modify one thing and another spring pops out somewhere else. Yes. I guess we're agreeing saying "consider," but we'll have to add it to the document to make it consistent, if we do this. If -- just for

clarification for me, "considering an assessment" sounds like it's mandatory and "consider" means you should take it under consideration, that was your point?

MR. BERNARD: That was the point and it will depend on the agency and the product that you're talking about.

DR. KVENBERG: Just wanted clarification on the reason for the change.

MR. BERNARD: Correct, thank you.

DR. KVENBERG: Okay. I mean, I'm okay with this. We can go -- we'll have to go back and we will edit. Any additional comments on 10? Dr. Doores?

DR. DOORES: Stephanie Doores. The first bullet under number two, I would suggest a change from "surrogates" to "surrogate organisms."

DR. KVENBERG: Thank you. Page 11, if we may move on? Comments from the Chair?

VICE-CHAIRMAN BRACKETT: Yeah, I just had a question on Dr. Doores' statement about organisms. Would that preclude the use of any chemical indicators as a surrogate?

DR. DOORES: I guess I used the term

organism, because that's what we were talking about, like cold -- something like that, as opposed to -- sometimes I think of surrogates as pregnant women, so I just wanted to make sure, in the same vein that we had before when we were mixing population, whether that was human or microorganism. That was my intent. So if you can think of an appropriate term. Surrogates for organisms? Would that -- that would be fine.

VICE-CHAIRMAN BRACKETT: That would include chemicals, as well.

DR. KVENBERG: Surrogates for organisms? We have it. Thank you. John?

DR. LUCHANSKY: I just have editorial, John. With the bullets on the bottom of page 11, we --

DR. KVENBERG: Eleven?

DR. LUCHANSKY: I thought we were on 11.

DR. KVENBERG: Thank you. I'm ready to go to 11.

DR. LUCHANSKY: Trying to be consistent. Consider -- rather, the first bullet is "consider" and the next one's "consideration," if there's a way to be consistent with the syntax?

DR. KVENBERG: Right. Yeah, second bullet, bottom of page 11.

DR. LUCHANSKY: And throughout those bullet points.

DR. KVENBERG: Yeah. Those were editorial. It should've been considered, okay, using -- vary -- yeah, thank you. Predict -- on the next page. No other comments on page 11?

MR. BERNARD: Chairman? Dane Bernard, Keystone. I know it's tough --

DR. KVENBERG: There's so many flags.

MR. BERNARD: It's tough looking over here. Confessing that I'm a slow reader, I did not get a chance to tinker with this as I would like, but somewhere within this validation construct, I think needs to be some tip-of-the-brim to recognize safe harbors as being -- and we've got quite a list of things here that may not necessarily apply if there is a recognized safe harbor or a traditional process that is well-studied and well-known and just make a comment and if somebody else wants to assist in putting something in or if we've got something we can lift from somewhere else, I would appreciate that. Thanks.

DR. KVENBERG: I understand the point and I don't think it would take much for one sentence and I guess my thought is maybe leading off after the first sentence, if you want to insert something about -- I understand the concept of safe harbor. I would be in favor of lifting, so we don't get into wordsmithing. I understand the concept, that basically, if it's -- if there's been prior guidance out there or a safe harbor that they can use, so we just acknowledge that second sentence so that might make sense. I'll go to people's pleasure on -- is there some words we can lift that are not controversial we can insert? MR. GARRETT?

MR. GARRETT: I don't know. I got -- thank you. Spencer Garrett. I've got just the final bullet -- it would be very easy to just say utilization of previously validated safe harbor approaches.

DR. KVENBERG: Where's this? Do I have -- I just don't know where you propose to put it.

MR. GARRETT: I'm just adding a new bullet, that's all.

DR. KVENBERG: New bullet, bottom of page 11 or wherever it fits.

MR. GARRETT: Right.

DR. KVENBERG: Okay?

MR. GARRETT: Utilization -- John?

UNIDENTIFIED SPEAKER: Use of --

DR. KVENBERG: Use of something.

MR. GARRETT: Of previously validated safe harborage approaches. Well, I think the Vice-Chair has a comment.

VICE-CHAIRMAN BRACKETT: Yes. I would stay away from the words safe harbor. That is jargon and it may not be understood by everybody.

DR. KVENBERG: It's fine with me, I think --

VICE-CHAIRMAN BRACKETT: In the shelf-life documents, it's fine, but if this is to stand alone, it'll either have to be redefined again or use something for what it means and --

DR. KVENBERG: Yeah, but without safe harbor, Dr. Brackett, I think we can still pull it out. Would you state it one more time? With the -- without that phrase?

MR. GARRETT: Utilization of previously validated approaches.

DR. KVENBERG: Would that serve our

purpose? Thank you. And that basically sneakily got us over to page 12, after the bullet. And no flags. Any comments on page 12?

UNIDENTIFIED SPEAKER: Two flags.

DR. KVENBERG: Two flags. I guess you were first.

DR. SCOTT: Did you take safe harbor out of --

DR. KVENBERG: Yes, we did.

DR. SCOTT: -- the -- I don't think that that conveys what Spencer was trying to convey.

DR. KVENBERG: Could we go back to Spencer? He revised it.

DR. SCOTT: So -- I like the safe harbor approach. I like getting the words in there. We did use them earlier in the document. Dane put them in on, yeah, page four and if we need to bring over the safe harbor definition from the safety-based shelf-life dating, let's do it. But that's certainly an acceptable validation procedure -- most of the time here, we were thinking about new technologies and understanding that they would need to be validated, maybe previous validation didn't exist, but certainly there are times and

temperatures that have been validated and if you can achieve that with your new process, then there's no need --

DR. KVENBERG: Well, in order to attempt to eliminate jargon in this document and I think I understand the Vice-Chair's concern about this document, because it's going to be widely used and adapted. Could we avoid the term itself and be more illustrative by saying previously validated or somehow approved? I understand where you're going. It's some sort of recognition of the validation, I think, is what safe harbor intends, isn't that right? Yeah, I mean -- I want to be clear that we -- the thought gets through transparently.

I understand your concern and I also understand the concern of not using safe harbor jargon in this document, so I'm just trying to follow both tracks to clearly understand what we're saying here. It's previously validated -- it's a recognition of the previous validation, somehow, is that correct? I'm sorry. Who's got a comment? I don't have the words other than what we have in front of us for the bullet. Use of previously validated approaches is where we are in the

wording.

DR. ACHESON: Could we just bring the definition over from safety-based date labeling document?

DR. KVENBERG: Yeah, but not from the Vice-Chair -- what is it? Dr. Acheson will note --

DR. ACHESON: Yeah, John, we could just say use of recognized procedures that can be employed without further validation studies. That's the language that was in --

DR. KVENBERG: State it again, please, so LeeAnne has it.

DR. ACHESON: Use of recognized procedures that can be employed without further validation studies.

DR. KVENBERG: Does that get us past our quandary, everyone? And it's consistent with the other document?

DR. ACHESON: It is, yeah.

DR. ENGELJOHN: You know, John, we need to make that same change, then, on page four of this document. Of this document.

DR. KVENBERG: On page --

DR. ENGELJOHN: Because we used the term

safe harbor on page four.

DR. KVENBERG: Can we go -- just make that editorial note, page four, same change? Without revisiting page four? Dan can point it out. I just want to make sure you had it as an editorial.

VICE-CHAIRMAN BRACKETT: Could you just bring the definition over by itself? Leave the words in the document the way it is and just define it.

DR. KVENBERG: I'm not quite understanding the definition of --

VICE-CHAIRMAN BRACKETT: Define safe harbor in the document.

DR. KVENBERG: Oh.

VICE-CHAIRMAN BRACKETT: Use the word safe harbor. The concern is that a reader will know what safe harbor is unless they go look at the other document, unless it is defined in this document.

DR. KVENBERG: Okay. Exactly how should we proceed? Where do I put it? Dr. Tompkin?

DR. TOMPKIN: On page -- this is Tompkin. On page four, where we had inserted that phrase

and/or use of safe harbors. Why don't we just put a parenthesis around that and say the use of a recognized procedure? Slip those words in there?

DR. KVENBERG: Works for me. Can we do that? Dr. Jackson's trying to keep notes here.

DR. JACKSON: LeeAnne Jackson. It's going to look odd, because you're including the parenthetical within the Executive Summary. You need to include the definition someplace else in the document.

DR. KVENBERG: Than in page four, which is a summary of the document?

DR. JACKSON: Yes.

DR. KVENBERG: So wherever the first place it would appear in the actual document is where we are, is that correct? So let's do it on page -- where am I?

UNIDENTIFIED SPEAKER: Twelve.

DR. KVENBERG: Twelve. Let's put the definition on 12 and then we don't have to fix nine as has been pointed out. That's an Executive Summary; if we define it in the text. Is that fair? Let's define it right here, then, and insert it on page 12. What are we marking? Was that on

12? I'm sorry. It was on the -- well, you take your pick. It's on the bottom of 11 or the top of 12, but it's a bullet. Dr. Swanson?

DR. SWANSON: Swanson, Ecolab. I'm not sure that it should be a bullet. These bullets are supposed to be considerations for conducting challenged studies. That's not one. I think it would be better to have it as the first sentence after the bullet that says -- so the bullets would say these are considerations when you're going to conduct a study, but you don't always have to do a study if you're using a safe harbor.

DR. KVENBERG: We could discuss safe harbor at the top of the following paragraph on --

DR. SWANSON: Right.

DR. KVENBERG: -- page 12?

DR. SWANSON: Right. That would be a better fix.

DR. KVENBERG: Okay. So we'll take it verbatim and define and put the -- what would the language be, then? How do we craft the sentence to introduce the paragraph? We're starting with a definition. I need -- we just need some brief words in there to basically start that paragraph,

then.

DR. SWANSON: It is important to note that -- whatever the sentence was -- would be the conclusion of the paragraph that had the bullets in it.

DR. KVENBERG: As a separate stand-alone before we go to the next paragraph?

DR. SWANSON: Right.

DR. KVENBERG: It is important to note that and then follow on with the previous definition as crafted --

DR. SWANSON: Right.

DR. KVENBERG: -- that Dr. Acheson gave us with defining safe harbor, correct?

DR. SWANSON: Well, the comment that Spencer had saying utilization, ta-da, ta-da, ta-da.

DR. KVENBERG: Right.

DR. SWANSON: Whatever that wording is and then define safe harbor and --

DR. KVENBERG: I guess -- can I defer to have a final read-back on this one and move on? We will get a fix for the exact wording of that closing sentence of the paragraph after the bullets

on 12, revisited when we have the language? Who can I charge with doing this? Spencer, will you take it? Okay, just in the essence of time, Spencer will revisit the proposed sentence on 12. If we can move on now, we can come back to include that insertion. Thank you.

MR. BERNARD: Chairman, one quick consideration. I think the sentence would be better as a second sentence under *Validation*. And then you have a break and then you go on to say --

DR. KVENBERG: As a suggestion -- this is a procedural suggestion. Why don't we get the sentence and then we can decide its best location, if you'll accept that, Dane. Is that okay? First we get the sentence, then we'll see where it would fit and we'll defer to Spencer having it drafted. Is that okay? Okay. Any additional comments on 12?

CHAIRMAN PIERSON: One, John. Again, just editorial. The first paragraph, first sentence should say "processes" or "of a pasteurization process."

DR. KVENBERG: Where are you?

CHAIRMAN PIERSON: I'm on page 12, right?

DR. KVENBERG: Right.

CHAIRMAN PIERSON: First paragraph, first sentence.

DR. KVENBERG: What it -- should it read "in the design of a pasteurization process" or "design pasteurization processes"? Oh, I think it's just processes. Or take your pick. I don't care.

CHAIRMAN PIERSON: A pasteurization process.

DR. KVENBERG: All right. Insert "a" in front of pasteurization. And also, I guess that in the second paragraph, in the middle of it, that parentheses (NACMCF, 2004), that was presuming adoption of the -- I guess that asterisk will -- has disappeared because we have taken a vote, so strike the asterisk that was -- asterisk was there to denote subject to approval of the other document. Now that's been approved this morning, remove the asterisk. Dr. Griffin?

DR. GRIFFIN: Yes, Griffin, CDC. I have a question about this section, *Validation*, which seems to be talking only about microbiologic validation of a technology that -- but we sometimes

find that there are technologies that appear to be validated and then we find disease associated and it turns out that modifications need to be made and so I was wondering if we want to include in the discussion that feed-back of if illnesses are found, then there would also be reconsideration of the technology and that would seem to fit in with the third full paragraph on page 12, which is "The hazard analysis may change as research provides new data on pathogens and/or efficacy of technologies." It may be that the hazard analysis may change (if)epidemiologic data demonstrate an association between the illness and consumption of a product to which the technology was applied.

DR. KVENBERG: That sounds reasonable. The last -- well, the last full paragraph, a second sentence of that paragraph would be that insertion?

DR. GRIFFIN: Yeah, it's the next-to-the-last full paragraph. The paragraph that begins "The hazard analysis."

DR. KVENBERG: Yeah, I'm sorry.

DR. GRIFFIN: Um-hum.

DR. KVENBERG: Right. That's where I intended to say after the first sentence, you're

inserting a second sentence?

DR. GRIFFIN: Yes.

DR. KVENBERG: It sounded rational to me. Dr. Jenny Scott? Want to hear it again?

DR. SCOTT: Patty, is this not addressed by the last paragraph on "The need to revalidate should be assessed when new hazards are identified or changes are made to the process or product"? Or some modification of that to further capture what your issue is?

DR. KVENBERG: Well, if I could interject, Dr. Griffin, I think what she's thrown in here as new as to the specific wrinkle that it be proven by epidemiological evidence if there was a problem that may -- if it goes back to the process, epidemiology-founded. I thought it was a new thought. I don't know.

DR. GRIFFIN: Yeah, it is -- Dr. Kvenberg's right. It does not simply involve a new hazard.

DR. SCOTT: But I'm suggesting that the place to make the change is in this sentence, not somewhere else.

DR. GRIFFIN: I see.

DR. KVENBERG: I see what you're saying. Okay.

MR. BERNARD: Actually, I could go either way, but as a proposal where Dr. Griffin was talking about "The hazard analysis may change as research provides new data or new epidemiological data is available on pathogens or [sic] efficacy of technology.

DR. KVENBERG: Oh, that's kind of neat. Would that do it? Right there. Just modify the first sentence. Does that work?

DR. GRIFFIN: Yes.

DR. KVENBERG: One more time. Slowly, please.

MR. BERNARD: With feeling?

DR. KVENBERG: Only with feeling after new data.

MR. BERNARD: You know, tradition is you've got to have that at least once in a meeting. "The hazard analysis may change as research provides new data or new epidemiological data is available on pathogens and/or efficacy of technologies."

DR. KVENBERG: It was just lunch time,

but I thought that was brilliant. Consensus? Agreed?

UNIDENTIFIED SPEAKER: Yes.

DR. KVENBERG: Thirteen? I really want to get to the bottom of 13. This is critical. I don't see any flags on 13. Can I assume that question five is okay? I assume that -- now, where we are is at now we've moved past -- this was the initial wash of the overarching document, which was very important to get done from the bottom -- beginning on page 14 is introduced by the last word there, processing technologies. We're now at the point where we're going into specific technologies as subsets, so Chair, I guess whatever you suggest we do at this point.

CHAIRMAN PIERSON: Yeah, we have some options here. Of course, you know, according to the schedule, you were to finish by now and we were to have had public comment.

DR. KVENBERG: But those were very important 13 pages. That was -- I think -- I'd cross the Rubicon, basically, if we got consensus on the overarching consideration up through page 13. That was the crux of this whole paper.

CHAIRMAN PIERSON: Absolutely, and so -- what's clear, though, is we enter for, John, or I'd suggest that we could reconvene at one o'clock, just to keep on schedule. Forty-five minutes would be enough, if you'd like to do that now? 1:15? She wants an hour. And you know, we do infringe upon Spencer's time. Spencer, would you yield some of your time this afternoon to continue on with this?

MR. GARRETT: Well, we're known as team players, of course, but just all you want to do -- but I do have a definition for safe harbor here, if you want to -- I don't know where it goes, but I know what it is.

CHAIRMAN PIERSON: Okay. Well, what we'll do is make a decision here, so -- we'll reconvene, then, at 1:15 and this will -- we'll start our break, then, as soon as Spencer finishes his fix. Go ahead, Spencer.

MR. GARRETT: Emille's rewriting it so I can read my own writing. This goes someplace, okay, but the introductory sentence is, "It is important to note that validation studies are not always necessary when the safe harbor approach is

used." Then in parentheses after that "(For the purposes of this document, a safe harbor is defined as a recognized procedure that can be employed without further validations studies)." And that's taken straight out of the previous document.

[Off the record]

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[Whereupon, at 12:20 p.m., a lunch recess was taken]

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[On the record]

A F T E R N O O N S E S S I O N

(1:15 p.m.)

CHAIRMAN PIERSON: Started on -- continue on, not start, but we'll continue the pasteurization document. The management decision here on this document is we've gone through the first 13 pages, which is the bulk of -- or it is the response to the questions and then you also have a -- what page is that on, the summary? Conclusions? On page 45. Now, for the rest of these -- the material describes, of course, processes and it answers questions relative to those processes.

The question is, is I don't know to which extent we're going to have extensive discussion on the rest of this material. We have some options here. One option is, is that we could take the document and split it, and that is the first 13 pages plus the conclusions and adopt that. And then the second part, it could then come up to this Committee again in the future for adoption. The logistical difficulty of that is then we have new members and then you end up in -- well, there's all sorts of difficulties with that, but it's one way of handling it, but adopting the first part of this document would get us through, you know, these broad questions. So I don't -- can we get some sort of sense on the extent of discussion that we might need relative to these pages after page 13? Yes?

DR. DONNELLY: Cathy Donnelly. Either yesterday or the day before when we were in the subcommittee working on this document --

CHAIRMAN PIERSON: Um-hum.

DR. DONNELLY: -- a suggestion was made to put the technologies in an appendix section --

CHAIRMAN PIERSON: Um-hum.

DR. DONNELLY: -- and it was pointed out in order to answer question three, we had to go through each of the technologies.

CHAIRMAN PIERSON: You had to go through them, okay. A difficulty I don't want to get into is not being able to adopt or -- is for this document having to carry over to the next session. That would become very difficult for John, recycling, so -- do we have -- is there some sense as to the extent of comments that we have on these sections -- folks that have general extensive comments? It looks like you want to say something, Jenny.

DR. SCOTT: Jenny Scott, NFPA. I would not expect to be there'd be a lot of discussion on the technologies, per se. I may be wrong there, but --

CHAIRMAN PIERSON: Well --

DR. SCOTT: -- I was on the subcommittee, so maybe there's people that aren't on the committee that you should ask.

CHAIRMAN PIERSON: Okay.

DR. MADDOX: Carol Maddox. It's my interpretation that this is mostly supportive

material in the form a literature review. I don't believe it would create a lot of controversy and I would hate to see it split from the rest of the document because I think some of our decisions in the first part of the document were based on --

CHAIRMAN PIERSON: Okay.

DR. MADDOX: -- the evidence in the literature review and I'd like to see it go forward as an entire document. I don't think there'd be terrible much discussion about the technologies.

CHAIRMAN PIERSON: Well then, let's forge forward on this and if we start getting bogged down, then we're -- we may have to consider something. Okay? So John, carry --

DR. KVENBERG: Thank you, Chairman. I guess one of the critical things that we'll have to consider at some point -- we'll see when we're there -- is we will have to visit Roman numeral V. Conclusion, because that's critical to the whole report regardless of where we're going, so keep me honest with that. We also have two housekeeping matters that we have to revisit on this document on critical phrasing of sentences and words that we've got to go back to the earlier section, I'm aware.

So those are the two issues. That being said, I'm looking at forging ahead with Section IV, Processes and Technologies and other than the introductory paragraph, the first item is cooking on page 14. I don't see any comments. Fifteen.

DR. GRIFFIN: Wait.

DR. KVENBERG: Fourteen.

DR. GRIFFIN: Griffin, CDC. The last two lines under Cooking, it says "pasteurization is performed on products in a hermetically sealed container." I just don't understand. I thought pasteurization is usually performed on milk and that afterwards, milk was packaged.

DR. KVENBERG: In the context of cooking, and I'll defer, I think, to Jenny here, but we're talking about processes where you're cooking in a bag, so it would be one example of this where the process was delivered within the final package, in this context. Jenny, can you help?

DR. SCOTT: You need to read the whole paragraph in context. It comes directly out of the Fish and Fisheries Products Hazards and Controls Guide with respect to seafood and it just describes what FDA has put in there with respect to their

interpretation of cooking versus pasteurization.

DR. GRIFFIN: I think I understand that and I was reading that entire paragraph, but I saw that as an example of pasteurization, but I would think that the document might say that whereas pasteurization of these types of products is usually performed. Because it's not clear in that last sentence that -- what products you're talking about and I think if we'd think about pasteurization in this country, most people think about milk.

DR. KVENBERG: A fix? What's the fix? A word fix?

UNIDENTIFIED SPEAKER: Of these types of products.

DR. KVENBERG: Of these types of products would fix it?

UNIDENTIFIED SPEAKER: Insert "of these types of products" after pasteurization, the last line right above question one.

DR. GRIFFIN: And what am I to understand these -- does it refer to fish products but also to the products above?

DR. KVENBERG: No.

DR. SCOTT: Pasteurization of fish products is --

DR. KVENBERG: Of fish --

DR. SCOTT: -- typically performed.

DR. GRIFFIN: So could we say that?

DR. KVENBERG: Yes. You might want to say fishery, to be technically correct. Fishery products. Accept it? Any additional comments on 14? Fifteen, additional questions before we get to Microwave? Sixteen?

DR. GRIFFIN: Just a question. Sixteen, at the top, mentions bacteria and parasites. Is there a reason that viruses were not mentioned in the discussion? Page 16, at the top.

DR. KVENBERG: Microwave. We're now in Microwave Processing.

DR. JAYKUS: I can address that. Lee-Ann Jaykus, NC State. There's no -- to my knowledge, there's no data on microwave processing with respect to an activation of viruses. At least in the published literature.

DR. GRIFFIN: And what would you think about putting that sentence in the document?

DR. KVENBERG: Yeah. Sounds reasonable.

No published information could be found relative to destruction of parasites by microwave.

COMMITTEE MEMBERS: Viruses.

DR. KVENBERG: Viruses, I mean. Excuse me. Now we got -- viruses. Would that sentence work for you?

DR. GRIFFIN: Yes, thank you.

DR. SWANSON: I'd like to suggest an addition to that. However, as heat is the mode of action in microwave cooking, achieving temperatures that would be achieved in normal cooking processes would likely handle the viruses?

DR. JAYKUS: Lee-Ann Jaykus again. Yeah, I think -- I'm trying to think how you would say it. You could say something to the effect of as heat is the mechanism of an activation, one would expect --

DR. KVENBERG: Viruses to be inactivated.

DR. JAYKUS: -- viruses to be inactivated, similar to as they are by heat or something like that.

DR. KVENBERG: So the sentence would read as an insertion, basically, no literature did not -- I'm just -- I'm trying to get LeeAnne a sentence

here.

DR. JAYKUS: The sentence should read to date, there is no literature available on -- specifically on microwave inactivation of viruses, of enteric viruses, to be more accurate. However, because the mechanism of inactivation of microwave is heat, it could be anticipated that viruses would -- that virus inactivation by microwave would be similar to traditional thermal inactivation.

DR. KVENBERG: Well, as a matter of moving on, she doesn't have it, so --

DR. JAYKUS: Do you want me -- I'll write it out.

DR. KVENBERG: Yeah, will you just write a sentence so --

DR. JAYKUS: I'll write it out and give it to you.

DR. KVENBERG: -- we can get a sentence on that so we can get that in there. Okay, that was why we're silent on virus on page 16. Seventeen? Yes?

DR. JACKSON: LeeAnne Jackson, FDA. On the sentence that you're proposing, if you don't have any data on the application of micro waving to

viruses, then why would you want to try and tack something onto the end?

DR. KVENBERG: It's an opinion.

DR. JAYKUS: Right, but you know, micro waving doesn't always reach, you know, uniform temperatures throughout the entire product, so how are you going to ensure that you would indeed have destruction of viruses in a cold spot of a --

UNIDENTIFIED SPEAKER: That applies to everything else.

DR. KVENBERG: That applies to the whole process of every kind of pathogen you're going to attack and I thought it was discussed in the document.

DR. JACKSON: It is discussed in the document.

DR. KVENBERG: So that's not a germane issue on viruses. Viruses are not unique.

DR. JACKSON: Right, and in a point of fact, if we belabor this point, we're going to have this happen in many, many of the processes because there's a lot of processes --

DR. KVENBERG: It'll happen again and again.

DR. JACKSON: -- that don't do viruses or don't do parasites, et cetera and so on.

DR. KVENBERG: We could put the fix in here at least to say there was a lack of literature, if that's -- if we want to end it there. I just want to move on.

DR. JACKSON: I think that's the most logical fix, is the single sentence.

MR. BERNARD: I'm okay with moving on, but maybe you just want to take the whole section out because it doesn't make any difference. Heat's the activation mechanism, heat will take care of parasites, viruses and bacteria if it's uniformly applied and it's taken care of in validation, so why do we have it in the first place?

DR. KVENBERG: How much do you want to cut?

DR. JACKSON: No, leave it.

DR. KVENBERG: Just leave it and put it in there. I mean, if we start chopping and editing now, we're in trouble.

DR. JACKSON: Right.

DR. KVENBERG: If we would put the insertion there's no literature on viruses, it's

the cleanest thing I can imagine to do, if you're willing to accept that. Seventeen? Comments, 17. Stephanie.

DR. DOORES: Stephanie Doores. On number three, at the end of that heading line, would you just put microwave heating?

DR. KVENBERG: Oh, heating in the bold --

DR. DOORES: Yes, um-hum.

DR. KVENBERG: -- after microwave?

DR. DOORES: Thank you.

DR. KVENBERG: Editorial. Thank you. Additional comments? Eighteen? Eighteen is a table with complete references, primarily. Comments? Stephanie.

DR. DOORES: Stephanie Doores. Also, under number five, not the bolded line, but the one underneath that says "Microwave," would you just put "Microwave heating"?

DR. KVENBERG: Heating again.

DR. DOORES: Thank you.

DR. DOWNES: And to that point, the header says microwave processing, so do we want to change it, everything?

DR. DOORES: You can use either, but

probably microwave heating would be a preferred term, I think.

DR. KVENBERG: Great. Then the header should say heating, as well, correct?

DR. DOORES: Yes. You can use either term, just be consistent.

DR. KVENBERG: All right. I'm trying to give LeeAnne a break here.

DR. DOORES: You could put processing in number three and then also processing under five, also. That would make it consistent.

DR. KVENBERG: All right. Got questions down here.

DR. DOWNES: Comment on Table A. The first two rows under microorganism, those aren't microorganisms, those are methods, so I'm wondering -- of course, the people who have reviewed those methods, if they'd like to insert the -- is that appropriate to be in the table, since it's not microorganisms, or how do you want to --

DR. LUCHANSKY: Could it be type of microorganism?

DR. DOWNES: No, colony count is still not a type of organism. Anaerobic organism or

microorganisms.

DR. KVENBERG: You say the word count [ph] organisms, is that what you want to do?

DR. JACKSON: Would that fix it so we're consistent? Anaerobic colony --

DR. DOWNES: No, no. Not colony count, just aerobes.

DR. KVENBERG: If you change the header, Frances, to type, microorganism type and you said aerobes, coliforms, psychrotrophs?

DR. DOWNES: That would be fine.

DR. KVENBERG: Okay, aerobes, coliforms, psychrotrophs and then the header, LeeAnne. And the rest of the second cell would have to be similarly modified, right?

DR. DOWNES: Aerobes and coliforms.

DR. KVENBERG: Coliforms. Thank you. Nineteen? This introduces ohmic heating. Twenty. If you guys would put your placards down if you don't have a comment, it would be easier for me. Twenty-one. Twenty-two. Twenty-three.

DR. GRIFFIN: Yes.

DR. KVENBERG: Twenty-three, comment.

DR. GRIFFIN: Just editorial. First --

second paragraph, begins "Bacterial spores." "Bacterial spores are more resistant to steam and hot water" than to what?

UNIDENTIFIED SPEAKER: Than are vegetative cells.

DR. KVENBERG: Thank you. "Mature spores are more resistant to steam or hot water than are vegetative cells? That's the fix. We missed that. A good call. Thank you. Additional comments, 23? Twenty-four, high pressure. No pressure here. Twenty-five. Go ahead.

DR. MADDOX: Norwalk virus. Carol Maddox. On page 24, we had deleted something that had the explanation for NoV, which is Norwalk virus or Norovirus.

DR. KVENBERG: Where?

DR. MADDOX: The third paragraph, second from the last line, following feline calicivirus.

DR. KVENBERG: It's the -- it starts out the word calicivirus and then it's NoV. It should be Norwalk virus.

DR. MADDOX: Norovirus.

DR. KVENBERG: Norovirus. That's editorial. Norovirus surrogate. Okay. Comment?

DR. GRIFFIN: Comment, sir. I just -- I'm not sure if surrogate is the correct term. I think Norovirus is a type of calicivirus.

DR. JAYKUS: Lee-Ann Jaykus, NC State. Feline caliciviruses are used as a surrogate for Noroviruses in inactivation studies.

DR. KVENBERG: The key word is feline in front of --

DR. GRIFFIN: Okay, all right. I didn't see that, sir.

DR. KVENBERG: Got it. Twenty-five? Comment, John?

DR. LUCHANSKY: Just editorial. Why is there an underline in the third paragraph there? Is that a placeholder for discussion?

DR. KVENBERG: No, I think it's just a delete. Thank you. Okay, 26. I see no comments. Twenty-seven. Comments?

DR. DOORES: An issue on the table.

DR. KVENBERG: On 27?

DR. DOORES: On 27, second row down. "Biphasic inactivation of *E. coli*."

DR. KVENBERG: Yes, first column, microorganism. I see it.

DR. DOORES: Just want to put *E. coli* there?

DR. KVENBERG: That refers to Lee and et al's citation. I think that's correct. Is that right? Biphasic -- that's referring to a published article. That's a reference.

DR. DOORES: Right, and microorganism being just --

DR. KVENBERG: Okay, but how are we going to do it? Just the biphasic and the inactivation of and just say *E. coli* is a single thing in a cell. Got it. So *E. coli* is all that remains in the first cell. Thank you. Additional comments, Stephanie, on 27?

DR. DOORES: At the -- Stephanie Doores. At the page -- top of the page 27 under the comments, the very first row, it should be "Generally, Gram negative bacteria are more sensitive to HPP."

DR. KVENBERG: Bacteria after negative. Twenty-eight. Twenty-nine. Thirty. Thirty-one.

UNIDENTIFIED SPEAKER: I'm going to yell Bingo.

DR. KVENBERG: Stephanie?

DR. DOORES: On the top of page 31, the second line, beginning of the sentence, "They determined that doses of," not does.

DR. KVENBERG: Doses, D-O-S-E-S. Typo. Carol Maddox.

DR. MADDOX: Maddox. Page 31, last paragraph, fourth line "equivalent to that" either of or for pasteurization.

DR. KVENBERG: Last paragraph, which line?

COMMITTEE MEMBERS: Four.

DR. KVENBERG: Fourth line. "To that of" -- okay. Of. Thirty-two. Thirty-three. Comments, anyone?

DR. SWANSON: Back on 31, second --

DR. KVENBERG: For transcribing, would you identify yourself?

DR. SWANSON: Oh, I'm sorry. Swanson, Ecolab. The second line on the top of page 31, is that supposed to be micro-joules per centimeter squared? I don't know, but we might need to check that. It's micro-joules? Okay.

DR. KVENBERG: Thirty-two. Thirty-three. Thirty-four. Thirty-five. Thirty-five, comment.

DR. DOORES: Stephanie Doores. Bottom of page 35, the fourth line up. The sentence that begins with "Incubated at," I'm not sure whether it's supposed to be incubation at or whether that's supposed to be part of the previous sentence.

DR. KVENBERG: Is it a complete sentence if you say incubation?

DR. DOORES: I think so. I'm not sure if it conveys the meaning that you want. That's correct. It should be incubation.

DR. KVENBERG: Incubation the word is. Okay. Editorial change. Thirty-six. Thirty-seven. Thirty-eight. Thirty-nine. Forty. Forty-one. Forty-two. Forty-three. Forty-four. Forty-five. Forty-five?

DR. LUCHANSKY: Could it be a --

DR. KVENBERG: Identify, please.

DR. LUCHANSKY: John Luchansky, ARS. The paragraph underneath the bullets, would it be appropriate to delete the phrase at the end of that line, "for new technologies" and just state that research is needed, is technology-dependent, whether it's new technology, other technology or old technology, does that -- new technology,

because these technologies, many of which are not new, are just other technologies.

DR. KVENBERG: Okay, how would you like to word it?

DR. LUCHANSKY: I make a motion to strike the words "for new technologies" at the end of that line.

DR. KVENBERG: Okay. Acceptable, everyone? You have it, LeeAnne? We're on page 45? Maybe I'm off.

UNIDENTIFIED SPEAKER: Doesn't make sense.

DR. JACKSON: It doesn't make sense, then. Yeah, it's --

DR. KVENBERG: I'm sure -- I was questioning the word new technology is what I was questioning. I was trying to read quick, but if you strike -- if you just say pasteurization processes technology-dependent. Is that your --

DR. LUCHANSKY: That's what I was getting at.

DR. KVENBERG: Okay, that's the proposal. Dr. Lammerding, you have a comment? No. Yes.

DR. LAMMERDING: The intent of the

sentence is that we have the research that is needed, is technology dependent, so we have to consider them individually, but the sentence has an extra "is" in there that that shouldn't be there. So it should read "Research is needed to" --

DR. SWANSON: No, "Research needed." Delete the "is."

DR. LAMMERDING: Right, right.

DR. KVENBERG: "Research needed to determine" -- the question that John brought up is do we strike "for new technologies" or do we leave it?

UNIDENTIFIED SPEAKER: No.

DR. KVENBERG: What does no mean?

DR. SWANSON: If you delete the "is" -- Swanson, Ecolab. "Research needed to determine the adequacy of pasteurization processes for new technologies is technology dependent." We could strike it.

DR. KVENBERG: Could strike it. Spencer.

MR. GARRETT: No, I think --

DR. KVENBERG: Spencer Garrett.

MR. GARRETT: Thank you. I think if you're going back to your safe harborage defense,

folks, that I think research is sometimes needed because pasteurization dependent. We do need some research, but we don't need it for all technologies.

DR. KVENBERG: All right, just --

MR. GARRETT: Research is sometimes needed.

DR. KVENBERG: Just could I insert this -- I don't disagree with that. Here's the sentence: "Research needed to determine the adequacy of pasteurization processes," strike new technologies. "is technology dependent." So is that inconsistent with your statement? It's a true statement now.

DR. JAYKUS: John?

DR. KVENBERG: Yes.

DR. JAYKUS: Lee-Ann Jaykus. I actually think what we intended to say is to put an "and" there; "Research is needed to determine the adequacy of pasteurization processes for new technologies and is technology dependent."

DR. KVENBERG: So --

DR. JAYKUS: That's what I remember from the subcommittee.

DR. KVENBERG: -- our intent was to keep new technologies and -- that's the complete thought.

DR. JAYKUS: "And is technology dependent."

DR. KVENBERG: Cathy.

DR. DONNELLY: Cathy Donnelly. I think the point John is trying to make is that many of the technologies that we've reviewed were introduced back in 1940 and so they're not new technologies, they're being newly considered for adoption as pasteurization procedures, but they're not really new.

DR. KVENBERG: Okay, so where does this leave us? Can I go to -- I guess, Jenny Scott.

DR. SCOTT: Jenny Scott, NFPA. If we go back to our charge, we're looking at alternative methods of pasteurization and if we could word it in those terms, I think we get out of it. We just kind of equated new technologies as being these alternative methods of pasteurization, so --

DR. KVENBERG: Just so I understand, a possible rewording is "Research needed to determine the adequacy process for" --

DR. SCOTT: Alternative.

DR. KVENBERG: Technologies?

UNIDENTIFIED SPEAKER 1: Processes.

DR. KVENBERG: Alternative processes?

DR. SCOTT: And is technology.

DR. KVENBERG: Does that fix it up?

UNIDENTIFIED SPEAKER 1: Try it one more time. With the microphone.

DR. KVENBERG: Okay --

UNIDENTIFIED SPEAKER 2: Microphone.

DR. KVENBERG: Oh, I'm sorry. I didn't realize the mike went off. Okay. Strike "is", the first "is," then go on "adequacy of pasteurization processes, alternative processes," right? Is that the interjection? "For alternative processes and is technology dependent." Try it again.

MR. GARRETT: I think you're trying to take the first "is" out, "Research is," delete that first "is." So then it would read "Research needed to determine the adequacy of pasteurization processes for alternative treatments or technologies or processes," whatever word you want to use.

DR. KVENBERG: Processes, I think.

MR. GARRETT: "Is technology dependent."

DR. KVENBERG: Strike the "and" that was in there confusing my -- one more time.

Jenny Scott.

DR. SCOTT: How about "Research needed to determine the adequacy of pasteurization for alternative processes is technology dependent"?

DR. JACKSON: Thank you.

DR. KVENBERG: Thank you. LeeAnne, do you have that? Read it back? Do you -- did we get it? Yes, we did. Thank you. I think we've got 45 -- now the conclusions on page -- oh, I'm sorry, 45 still? Yes? Forty-five, Dane Bernard.

MR. BERNARD: I have a number of things on this page. Dane Bernard, Keystone Foods. I think the discussion we had earlier about safe harbors needs to be here somewhere. If you want to add another bullet or something of that nature, or how we resolve it, I suggest --

DR. KVENBERG: Well, if I could, I -- I personally would agree with that. I know what the consensus of the Committee is. We were going to go back and Spencer was going to finally give us the language, or do we have it already? Already? Can

we go back and insert that here under Conclusions verbatim? Would that work?

MR. BERNARD: I think we need to revisit it, but yes, I think that's a thought that works for me.

DR. KVENBERG: All right. And maybe, just at the end, because we had some other editorial clean-ups, let's consider that as a mark and as a separate item on Conclusions.

MR. BERNARD: Okay. Second intervention here. The paragraph we were just working on, the second sentence there needs to now agree with what we did up on page four --

DR. KVENBERG: "All pasteurization" -- John Kvenberg. "All pasteurization processes need to be validated through the combined use of process authorities"? Oh, and this deals again with safe harbor.

MR. BERNARD: Exactly. Can we just borrow whatever we did on page four and put it in there?

DR. KVENBERG: Well, maybe we can put the two things together in that paragraph, then.

MR. BERNARD: And -- fine. And lastly,

on that paragraph, I would move to strike the last sentence. Not that I disagree with verification, but it goes beyond what you -- how you define pasteurization. It gets into process control of regulatory expectations.

DR. KVENBERG: Might be outside the -- it's a good point, but it may be outside the charge. It's in the charge? Jenny Scott.

DR. SCOTT: Jenny Scott. Question number four, "What data needs to be acquired to scientifically validate and verify the adequacy of a proposed technology?"

DR. KVENBERG: Got you, Jenny.

DR. SCOTT: Not quite, sir. Not so fast.

DR. KVENBERG: Okay.

MR. BERNARD: No, I don't disagree with the charge, but verification is an ongoing function. Maybe the charge was misstated because we're confusing again verification and validation. Verification is an ongoing function, where validation is what you do to set up a process. I'm only bringing that up. If you want to leave it, I think it's out of bounds.

DR. KVENBERG: Okay. This is --

verification is a continuing process. Would the fix be all pasteurization must be what? Continually verified or repeatedly verified? If it stays, that's -- what's the point?

MR. BERNARD: Okay, well -- okay. Never mind.

DR. KVENBERG: It's okay? All right.

MR. BERNARD: But you didn't tell us what kind of data it takes to verify. You didn't answer the question, if that's what you're --

DR. KVENBERG: I believe it's technology dependent, but I'm not sure.

MR. BERNARD: Never mind.

DR. KVENBERG: Thank you. Okay, I'm going to slow us down on the next page, 46.

DR. SWANSON: John?

DR. KVENBERG: Yes.

DR. SWANSON: Swanson, Ecolab. The one, two, three, fourth bullet. It should say "Consider" instead of "Assess the impact," to be consistent.

DR. KVENBERG: Oh, good call. Thank you. The fourth bullet on page 45. We changed it before, correct?

DR. JACKSON: Correct.

DR. KVENBERG: So we're bringing forth the -- what was the words, now?

DR. SWANSON: Consider instead of assess. Fourth bullet.

DR. KVENBERG: Which bullet?

DR. JACKSON: Fourth.

DR. KVENBERG: "Consider the impact." Thank you. Good call. We did that before. Now, can we go to the next page? No, one more. Yes, sir. Spencer Garrett.

MR. GARRETT: Thank you. Spencer Garrett, National Marine Fisheries Service. Just to make sure, I had a note to make consistent with whatever we have on page two. We've discussed some things on page two, but I just think the Secretariat just needs to go through page two in totality and make sure these conclusions are consistent. It's just in general. Or page four. Page four, okay?

DR. KVENBERG: Make a note to revisit page four. Okay. If we can go to 46, I have a comment. Anybody else want to go first? I guess my comment goes to a question of the charge. At

the end of our modifications of discussion in the working group last time, we made the statement in the final paragraph.

Here's my quandary; from the standpoint of -- number one, staying within our charge and number two, staying within the Charter of the National Advisory Committee, I think that when it comes to issues relative to proposing research on responding to labeling statements, I think in our terms are limited to how the consumer is part of the food safety chain. My mind goes to using the term pasteurization on a product as opposed to a shelf-stable product, where you could get something like a Bot toxin if you didn't know you needed to refrigerate it because it's pasteurized but not shelf-stable. This comment goes beyond that.

This comment was considered in the working group and I just throw it up for clarification; is this final conclusion appropriate or not? I need clarification from being in or out of the chair. Because this calls for consumer research on the lack of acceptance of the term pasteurization for irradiated foods and I don't think it deals with the charge of the Committee. Not that it's not a

germane issue that the agencies need to consider, but I'm wondering if it fits here. If we assist -- okay, comment that I was just provided -- Cathy Donnelly -- as we ended the final conclusion at the end of the first sentence. It doesn't lose -- I think we're within mission statement of the Committee and within the charge.

DR. DONNELLY: Cathy Donnelly. I think there were two issues. One is the need for proper consumer research to look at how people interpret the labeling statement "pasteurized" because of incidents where individuals have thought that refrigerated ready-to-eat soups were shelf-stable and they put them in their cupboards and so that's the first thought. The second thought was derived from public comment on numerous occasions and data shared with the Committee that points out that there are consumer data, scientific data out there to indicate this fact and so I think it was the desire of the Committee to capture that.

DR. KVENBERG: So I guess I'd like to have clarification, in or out on the second sentence? The final statement within the conclusions.

CHAIRMAN PIERSON: Is there scientific data available for the other technologies, as well? I mean, I don't -- you're singling out a particular hot-button technology, quite frankly, and I think there's scientific evidence out there on how consumers view other types of technologies, repasteurization, as well. Particularly for fishery products, so I would suggest that you do as the subcommittee leaders suggested. Just leave the period after "terms" and go on.

DR. KVENBERG: Well, I think the final paragraph might be -- "More research is needed to develop label statements that are understood by consumers," again, certainly --

UNIDENTIFIED SPEAKER 1: That's what I meant by --

UNIDENTIFIED SPEAKER 2: That's fine.

DR. KVENBERG: Well, consensus to delete the second sentence in the final conclusion with a view toward comments from the Committee that we're certainly sensitized to it, it's just outside our charge on this one and it's outside the scope of the Committee. All right, certainly now we are into an appendix. Comments?

MR. BERNARD: Another comment on 46.

DR. KVENBERG: Yes, sir.

MR. BERNARD: A one-sentence paragraph just -- Dane Bernard, Keystone Food -- just about what you were just debating --

DR. KVENBERG: Yes, sir.

MR. BERNARD: -- is a shortened version of what we debated long this morning. "Importantly, protection of the product from contamination after processing would be required for a product to be considered "pasteurized."" I'm just going to open it up and say whatever fix we decided earlier in the document should also be applied here.

DR. KVENBERG: Okay. I believe if we mark that and be faithful to this and the earlier fix that we must revisit, we're okay. Thank you.

Now, I guess the question is we are certainly in the next group, in appendices, and I'm willing to take comments, Chair, if we have time. I see it's about five after 2:00. Can we keep going? Cut us off when we need to be cut off. Okay.

Bearing in mind this is a historical review and doesn't really have bearing on recommendations,

this is the history of milk pasteurization, not quite going back to the earliest civilization, but pretty far. And we did learn a lot and it bears reading, but I'm not sure -- on pasteurized milk, there's -- comment? All right. And we also visited the history on crab pasteurization. These are the ground -- background, if you will, information that we used in consideration of the term pasteurization. But they're historical. I'm just going through the appendices by -- any comments on C or D or E? No comments. And again, Appendix C goes into food safety objectives.

I don't know if I'm in unsound ground or there are modification -- there was some discussion of FSOs. I don't know if we need to do any editorializing here. I don't think so. Kathy Swanson's got her flag up.

DR. SWANSON: Swanson, Ecolab. We need to bold "Microbiological Criterion."

DR. KVENBERG: That's a bold. Spencer Garrett's up.

MR. GARRETT: Thank you, Chairman. Spencer Garrett, NOAA [ph] Fisheries. Notice I changed my organization. I suggest you -- I

presume these are the same ones we had in the earlier document for shelf life?

DR. KVENBERG: I believe that -- yes. We pulled these and copied your work, or their work.

MR. GARRETT: Okay. I would harmonize them because they may not be -- there may be a slight nuance or difference.

DR. KVENBERG: Can we -- I'm sorry. Oh, page number 52. Page number is 52. Can we go to secretarial editing to make sure this is consistent with the revised language of -- that was the report on shelf-life? Can we just make a note to make sure that our intention here was not to reinvent stuff but to reiterate the same exact language, language of the shelf-life document, on this point? Okay. I'm sorry, I heard -- Carol, did you have the reference date, or page?

DR. MADDOX: Page five.

DR. KVENBERG: Page five. This needs to be consistent with page five of the shelf-life document we've adopted. Fifty-three. These are all -- and we have laboriously gone through -- Jenny Scott.

DR. SCOTT: Jenny Scott. At the -- NFPA.

At the risk of taking us back, the definition of microbiological criterion -- I pulled out the green book this morning and copied some stuff on micro criterion. It's -- there is not a well-defined definition there. On the other hand, Codex Alimentarius has a well-defined definition. It's the acceptability of a product or a food lot based on the absence or presence or number of microorganisms, including parasites and/or quantity of their toxins/metabolites per unit of mass volume area or lot. This encompasses what the green book does in several pages and I would recommend that we use the Codex definition here to reference that.

DR. KVENBERG: If it's agreeable to the Committee, we'll reference the Codex document. That's a final document we've quoted from that's been adopted?

DR. SCOTT: Yes, it is.

DR. KVENBERG: So it's definitely a legitimate reference. Accepted, I guess. No comments. And that'll go to the Secretariat for a copy. Thank you. We were struggling with how to identify it. Thank you very much. I was on 53 or -- going to 54. By golly, we got that formula

right. I just want to pause for one moment and say that formula on top of page 54 was really done by Einstein and we got it right. That's H-Oism [ph], that's a minus, by golly, not a plus. We worked on that. Don't mess with the formula. That was tough work.

Fifty-five is just a continuation of the table on irradiation, which has been largely truncated and continuation of that table on 56.

I'll draw your attention to our references. I think we're going to get them cleaned up. The ones in bold have been totally -- have been -- we've all cross-referenced what's in the document and nothing has been deleted through this morning's discussion. We have done probably further work. The ones that are not bolded, we're doing a final editorial check and that's why you see bold and unbolded comments in this code. Those are just references. Any -- if there are no comments on the references, per se, I doubt that, I would like to say look at the last page on 67 and again, from my subcommittee chair thing is a thank you to everyone on the Committee and on the working group and those that supported that working group that are mentioned here. It was

a very important piece of work.

Now, I guess we've got to go back, DR. Chairman, and start from the top for the orphans we need to fix and I need some help -- we're going to revisit page four, was that our first point? Or am I wrong? Where was our first fix needed? Four? Seven is our first fix? Yeah. Well, I was going to do it by page. I think four is it, right? Somebody please -- Spencer. And I don't know where, but you have the what?

MR. GARRETT: I think LeeAnne has it. I may have it here. "It is important to note that validation studies are not always necessary when the safe harborage approach is used." Then in parentheses, (For the purpose of this document, a safe harbor is defined as a recognized procedure that can be employed without further validation studies). Is that where this goes?

DR. JACKSON: LeeAnne Jackson, FDA. I thought we had already decided to put that someplace else in the document, it wasn't going to be in the Executive Summary. We've already placed it --

DR. KVENBERG: Okay.

DR. JACKSON: -- elsewhere in the document.

DR. KVENBERG: All right. So four is a pass and I believe we go to seven for our next location?

DR. JACKSON: Yes.

DR. KVENBERG: Thank you. And we had the trouble of the -- now, that one I have marked is that paragraph that starts as "However," and we were going to come to closure on that definition or move it or strike it or whatever we're going to do and then -- safe harbor still comes later, correct. Okay. So I draw attention to what I had flagged, it's on the discussion we had earlier for either fixing or totally striking the term and the argument was to keep it, right, but to modify it? John Luchansky.

DR. LUCHANSKY: I'm -- just for clarification, are we in the definition, the last phrase of the definition on page seven?

DR. KVENBERG: Page seven and we are under the paragraph that says "However."

DR. LUCHANSKY: I was still asking for clarification -- are we keeping the phrase "under

normal conditions of distribution and storage" with -- somebody made a modification to that.

UNIDENTIFIED SPEAKER: I think we resolved that.

DR. KVENBERG: Is it as written?

COMMITTEE MEMBERS: Yes, yes.

DR. KVENBERG: Thank you. Okay, so that takes us to the "However" language. Now, I know -- can I go back to the Secretariat -- LeeAnne, do you have revised language? You do not? Okay, Dr. Lammerding?

DR. LAMMERDING: Lammerding. Just a rewording to capture what the intent is here because we did want to recognize we're not giving our blessings to just pasteurization as a process. So "Committee recognizes that" -- and I have it written down, LeeAnne -- "recognizes that while an effective pasteurization process will deliver a safe food product, public health protection cannot be assured without steps to minimize the potential for recontamination."

DR. KVENBERG: That would be the total of the replacement suggestion for this paragraph?

UNIDENTIFIED SPEAKER: One more time?

DR. KVENBERG: One more time, please. They'd like to hear it one more time.

DR. LAMMERDING: "The Committee recognizes that while an effective pasteurization process will deliver a safe food product, public health protection cannot be assured without steps to minimize the potential for recontamination."

DR. KVENBERG: Concurrence? I assume that I have concurrence, no comments. If we could give that to LeeAnne, then we've got a replacement for the current -- strike the current language in there and that's the replacement.

DR. LAMMERDING: And then do we want to add something like this to page 46 where Dane was -- okay.

DR. KVENBERG: Can we do that at one time for the Secretariat to insert that language here and in the conclusion? John?

DR. LUCHANSKY: Luchansky. I think that sounds good. My question is, that I keep struggling with, is in the original "However" paragraph, we thought it was important to talk about not only recontamination, but temperature abuse and we lose that aspect of it.

DR. KVENBERG: Yes, we did. We've been there, we've done that, we've lost it. I mean, unless you want to go back and open the door, I don't see -- we readdress it, we're hung again. It took a long time. John, I acknowledge --

CHAIRMAN PIERSON: I think we've been -- been through that part of it.

DR. KVENBERG: Yes.

CHAIRMAN PIERSON: We're just fine tuning this now. What we'll do is during our, you know, when we vote on this --

DR. KVENBERG: Yes.

CHAIRMAN PIERSON: -- if you have a dissenting opinion, then you could approve the document with the following caveat.

DR. KVENBERG: Okay, that --

CHAIRMAN PIERSON: That would be added as --

DR. KVENBERG: That being said, just so I understand where we are in the process; so the insertion of the revised language goes on page seven and in the conclusions at this point, just verbatim repeated in the conclusion section, correct? What Anna just read goes in here, I

believe at the point where it says "However," the revised language will go and also in the conclusions on page 46, I believe. I just want to make it clear. Additional comments?

DR. SOFOS: Sofos. On page 46, we'll replace those two lines in there or in addition to it?

DR. KVENBERG: Let's do it now and find out, Dr. Sofos. On page 46, this is the one that was -- where we had marked "Importantly, protection." That sentence, yeah. If we strike that one and insert this language verbatim, would that be the fix? Okay. So LeeAnne, if you have that, the language you were provided for insertion on page seven that begins in "However," first full paragraph there, also applies to the second paragraph on page 46. We will strike the current sentence/paragraph that says "Importantly" with that same exact language. Correct? Correct. Do we still have to find a home for Safe harbor, do we? We have it. Okay, and where does that fit so I can interject it? Remember, I said I didn't know where it -- well, I don't know where it goes, either. That's my -- this is my last point.

UNIDENTIFIED SPEAKER 1: *Validation*, bullet four.

DR. KVENBERG: *Validation* point four? Where is that in the physical document?

UNIDENTIFIED SPEAKER 1: Eleven.

DR. KVENBERG: Page 11. So this document will go to page 11, Spencer's revised Safe harbor will go as a bullet on page 11. In the -- below the question in the text above the bullets?

UNIDENTIFIED SPEAKER 2: Um-hum. Right after that.

MR. BERNARD: Chairman? Chairman, Dane Bernard, Keystone. I would suggest, as I've heard from across the table, that that would be basically the second sentence. And you have a break and then you start talking about how to go about new validations.

DR. KVENBERG: It's been proposed and I've heard other talk to, from Dane Bernard, that the proposed change on Safe harbor becomes the second sentence of *Validation*, immediately following "hazard(s)" in the first sentence, right? Before you go to the next sentence, it says "For validation" insert Safe harbor there. All right.

With that, DR. Chairman, I think I've gone through the edits on this document and have no further things to say.

CHAIRMAN PIERSON: Thank you, John. Appreciate it. What I will do is -- we thought a little bit of this procedurally, but what I will do is ask for a motion to adopt this document; somebody makes that motion, ask for a second and then I'll ask if you're all in favor. If you're in favor -- if you're not and if you're not in favor and you have a dissenting opinion, then I'll let you express that, okay? Are we all right on that -- oh, here comes Jenny. She has a --

DR. SCOTT: I was just going to make a motion.

CHAIRMAN PIERSON: Oh, good. She's ready to move on here.

DR. SCOTT: Jenny Scott, NFPA. I make a motion to adopt the document on "Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization" as modified.

DR. DOORES: I second it.

CHAIRMAN PIERSON: We have a second?

Who --

UNIDENTIFIED SPEAKER: Who is the second?

DR. DOORES: Stephanie Doores.

CHAIRMAN PIERSON: Stephanie Doores, okay. Oh, here comes Spencer for discussion.

MR. GARRETT: Thank you, DR. Chairman. So I understand the procedure, I think the superior way may be to -- a person could adopt a document with a specific reservation, like it may one sentence or something like that, as opposed to not adopting the document because they disagree with a couple sentences in it, so I'd kind of like the Codex procedure, you know, you accept with a reservation that --

CHAIRMAN PIERSON: Okay, so we're --

MR. GARRETT: It's just a suggestion, not --

CHAIRMAN PIERSON: Yeah, sure, we can have -- you're suggesting a three-tier process.

MR. GARRETT: Yeah, exactly.

CHAIRMAN PIERSON: Fully adopt the document, adopt it --

MR. GARRETT: Exactly.

CHAIRMAN PIERSON: -- with -- upon

reservation

or --

MR. GARRETT: Or you don't.

CHAIRMAN PIERSON: Again.

MR. GARRETT: Yeah.

CHAIRMAN PIERSON: Okay. So given that, we can do that, so all in -- okay, we called for the motion, all -- okay. I call for a vote for all in favor without reservation.

COMMITTEE MEMBERS: Aye.

CHAIRMAN PIERSON: All right. Okay. In favor with a reservation.

[No response.]

CHAIRMAN PIERSON: Against?

[No response.]

CHAIRMAN PIERSON: Okay, we're unanimous in adopting this document. Great. Well, thank you, John. Yeah, great. Okay. Excellent. Okay, with that, we'll move on to two documents that Spencer has on performance standards, so Spencer, if you'd lead us in those.

MR. GARRETT: Thank you, DR. Chairman. Having gone through -- rapidly through all kinds of pasteurization and new technologies and concerns

and so forth, I want to bring us back to the reality of ground chicken. The document before you -- we're going to have two documents; one is ground chicken and one is ground turkey.

What our subcommittee has done is essentially, we've been moving through a series of documents for performance standards, as you know; ground beef, ground raw products and this document fairly well parallels that, but it's changed to reflect the particular processing nuances or in fact, the public health nuances of chicken versus ground beef and so forth. What I would propose to do, and I would hope that you've had the opportunity to read the document. The -- what I would propose to do is take us through page by page, perhaps not quite as fast as we went -- but not much different, either. Are there any comments on page one? Did we --

UNIDENTIFIED SPEAKER: Which document --

MR. GARRETT: The ground chicken first. Did we at least get the title right? Page two, which again lists the questions that were asked us. Page three, which we kind of reordered the questions to address it in a logical fashion. Page

four, relative to our findings, vis-à-vis the questions. Page five, giving the general principles for conducting a risk assessment. And again, this is very, very consistent with our other documents dealing with ground product. Page six. Pointing out while there is, in fact, a risk assessment available for broilers, there's not currently one for ground chicken. I'm sorry. Anna?

DR. LAMMERDING: I apologize. Just back on page five, in the second paragraph, fourth line down, is there a foot note reference missing from ICMSF? It's just a formatting thing.

MR. GARRETT: Is that page four instead of page five?

UNIDENTIFIED SPEAKER: It's on page four.

MR. GARRETT: Page five.

DR. LAMMERDING: Page five.

MR. GARRETT: Page five.

DR. LAMMERDING: First paragraph, fourth line down.

MR. GARRETT: Oh, there's no superscript under ICMSF.

DR. LAMMERDING: Right.

MR. GARRETT: The footnote was moved to page four. It should be on page five, apparently. It's the formatting. We'll make it correct, okay.

DR. LAMMERDING: It may be formatting, but there's a reference to ICMSF on page four and there's also one on page five. Which one is it?

UNIDENTIFIED SPEAKER 1: Page five doesn't have a superscript on it.

DR. LAMMERDING: Right.

UNIDENTIFIED SPEAKER 2: It doesn't need one.

UNIDENTIFIED SPEAKER 1: It doesn't need one --

MR. GARRETT: Time out, folks. Jenny?

DR. SCOTT: The reference on page five -- Jenny Scott -- to ICMSF is the same reference as that is on page four.

DR. LAMMERDING: No, it's not.

DR. SCOTT: It isn't? And in the sixth -- the one that's number six has a different ICMSF reference.

DR. LAMMERDING: Oh, okay.

DR. SCOTT: So in the first paragraph, where ICMSF appears on page five with no foot note

is because it is the one previously referred to. If you want to put it back again, then you've got either a new number with the same reference, or you put reference two, foot note two; it just didn't seem needed. But there are two ICMSF references and one first appears on page four and the other first appears at the bottom of page five.

MR. GARRETT: With that explanation, would you like for us just to reference it again or just go on? Okay, we'll just put a two there. Yeah. Page seven.

DR. JAYKUS: Question. Lee-Ann Jaykus, NC State. Could the subcommittee clarify what you mean by individual susceptibilities? I generally think of individual susceptibilities as being individual people. I would actually, perhaps, suggest changing that to something like "including stratification for specific at-risk populations."

MR. GARRETT: Are you in one of the bullets here?

DR. JAYKUS: Yes, I'm sorry. Second --

MR. GARRETT: Don't assume I know what I'm doing.

DR. JAYKUS: Second bullet down.

MR. GARRETT: Thank you. Yes, I think exactly what you're saying is different populations at risk or individual susceptibilities.

DR. JAYKUS: Okay, so I would actually suggest changing that to "including stratification for specific at-risk populations."

MR. GARRETT: Any --

DR. GRIFFIN: DR. Chairman?

MR. GARRETT: Who's speaking? Oh, there you are.

DR. GRIFFIN: Griffin, CDC. I just don't think that -- I don't think that it's likely that we can obtain that sort of stratification. I think it can only -- we can only obtain a quality of data. The term stratification sounds to me as though that you can apply a number to different subgroups of the population and I just don't think that's possible with the sort of data that we have.

MR. GARRETT: It may -- stratification may mean different things to different people relative to their profession. To me, it doesn't. Just means -- or how about a categorization of different populations at risk?

DR. JAYKUS: I would state that if --

well, if you can't stratify, you're also not going to be able to get individual susceptibilities.

MR. GARRETT: I think the difference is stratification used in an epidemiological sense as opposed to stratification perhaps used in a more qualitative sense. What we're really going after are the different -- not differing, but different populations at risk. Isn't that what we were looking for? So could we just say "including a categorization of the different populations" at risk and let it go at that?

DR. JAYKUS: That would be fine with me.

MR. GARRETT: Does that sound okay to CDC?

DR. GRIFFIN: I can accept it either way. I just don't think that -- it's one of those sorts of data that's -- it's nice to get, but I don't think we'll get it.

MR. GARRETT: Understand you're talking to a mercury and fish man, you know? Page eight. Page nine. Page 10. Oop, excuse me. I'm sorry. Frances.

DR. DOWNES: Downes. I would suggest under recommendation, the first bullet point on

page eight -- oh, it's on old page eight. It's on nine, sorry. It's the old page eight. Go ahead. That the phrase "if they would include cell numbers in the implicated products." I'm not sure that that, per se, is epidemiological data and was the subcommittee looking for a dose response relationship? I'm not -- I mean, epidemiological data relates to the person, the disease and the person, not to a food criteria.

MR. GARRETT: And I think the committee, from where the committee was coming was -- it would be very nice on those instances where you may or you can, is to look at the epi data and also the product data, including the cell numbers, if you would and see if there's some sort of marriage you can make, is that not correct?

MR. BERNARD: I think it's outbreak investigation information rather than pure epi data, but use that --

MR. GARRETT: Yeah, it's one of them. I don't have a lot to say about this, but when you go into epidemiological investigations, I think this is a thorny issue because once epidemiologically identified a food particular -- if you're going to

consumers, it's going to be well after the facts, so your numbers are likely to change if there is, indeed, any reserve left and if you're going to implicated food lot information, you may or may not get good information.

Dare I go to a hot dog situation where we had -- looking for *Listeria monocytogenes*. We found it at very low levels and that may not have been the situation -- I just think it's difficult to take an epidemiological investigation and include cell numbers in an implicated product through an epi investigation because time's gone by.

DR. DOWNES: And conversely, to rule out an association based on what the product looks like today as opposed to what the consumer ate.

MR. GARRETT: If we were to change, in the second sentence, the word "would" to "could" so it would read "The epidemiological" or you could say outbreak data, if you want -- "could provide" -- Anna?

DR. LAMMERDING: Lammerding. With respect that this is an issue, we are just saying it would provide us with the maximum benefit. We've got tremendous amounts of information from

epidemiological outbreak investigations in other countries where the opportunity has been afforded to collect the information and clearly, that's what we do need for dose response relationships. I don't think we should omit that from this document. We're saying it's going to provide us with the most benefit, we're not just saying, you know, we reject it if we don't do counts. And just to identify that as an issue.

MR. GARRETT: Thank you. Let me go to John, then Jenny, then Dane and then Frances, back to you.

DR. SOFOS: We could modify to say epidemiological in a -- then laboratory data of foodborne illness investigations would provide and so on. "Epidemiological and laboratory data of foodborne illness investigations would provide."

MR. GARRETT: Jenny, does that work for you? Dane, does that work for you?

MR. BERNARD: Similar intervention may be a little simpler. Just start the sentence; strike "The epidemiological" and substitute "Outbreak investigation data." That way we're not confusing the two. Epidemiology is -- doesn't necessarily

include the -- all the data necessary to investigate the outbreak.

MR. GARRETT: Frances.

DR. DOWNES: I defer to John's suggestion.

DR. GRIFFIN: All right, I have a similar fix. "The epidemiological data would provide the most benefit if it were coupled to data on cell numbers in implicated products."

MR. GARRETT: Could we go with what we've got? In the interest of moving on.

MR. BERNARD: I like John's suggestion.

DR. DOWNES: Yeah, I like John's.

MR. GARRETT: What I'll put here is, I'll put the two of yours together, outbreak investigation and laboratory data on foodborne illnesses data then go on. Any more on page nine?

DR. GRIFFIN: Yeah, I -- I would favor John's approach, where he did not use the word outbreak, he used epidemiological and laboratory. It's a broader statement.

DR. SOFOS: Yeah, I agree because not everything is an outbreak.

MR. GARRETT: So we're back to

epidemiological and laboratory data? Going once, twice. Any more on page nine? Page 10? Oops, page 10. Page 11.

DR. JAYKUS: Lee-Ann Jaykus. Your bullet point number three, "One pathogen can be used as an indicator of the state or condition affecting another pathogen if it meets certain criteria." My understanding is that most indicators aren't pathogens. I would be inclined to say "One microorganism and/or metabolic product can be used as an indicator for the state or condition" yada, yada, yada. Number three.

MR. GARRETT: I would be advised by some of my committee members. This actually is wording taken from previous documents that this subcommittee has done and I'm a little hesitant to change it and as you indicated, it's like most are not but some are pathogens, in fact. Jenny, you have a --

DR. SCOTT: Jenny Scott. I guess we were just looking at this in the context of *Salmonella*, so it would be less of an indicator for *Campylobacter* or other pathogens and direct pathogens.

DR. JAYKUS: Okay. Yeah, that's fine.

MR. GARRETT: Page 12. Page 13. Page 14. Page 15. Page 16. Oh, I'm sorry. Dane? Oh, Frances. I'm sorry. Which page?

DR. DOWNES: Fifteen, first paragraph, B. Under B. We had this discussion on a previous document about regional and seasonal variations, especially regional variations and that if they're acknowledged and the evaluations of -- are based -- the recommendations are based on regional differences, then would people consuming food in one part of the country be at higher risk than others consuming the same food in a different part of the country.

MR. GARRETT: If, in fact, that were a practical outcome was the results of a risk management decision that's made by a regulatory agency. All we're indicating is that if you're going to go about doing it, this is what you have to consider when you go about doing these things. We're not recommending that there be regional standards.

DR. DOWNES: Okay, so what you're recommending is that the performance standards

would take these --

MR. GARRETT: No, no. Remember, we're asking a very specific question. It says, you know, how would you relate to these regional, you know, what would you do -- let me read the question specifically. "What constitutes scientifically appropriate methods for incorporating regional variations when developing performance standards? Seasonal variations?" Two question marks. We're merely responding to the question. We're not advocating. Can we move on, then? Page 16. Page 17.

DR. JAYKUS: I have a question.

MR. GARRETT: Yes.

DR. JAYKUS: Lee-Ann Jaykus.

MR. GARRETT: Um-hum.

DR. JAYKUS: On the very bottom of page 17, would it be possible to change the wording? Again, this may have been a previous document. In that last sentence "Moreover, reliable estimates of cell numbers may be difficult to obtain, particularly if the concentration is low and the organism distribution is non-uniform."

MR. GARRETT: Any exception? Why do you

feel prevalence --

DR. JAYKUS: Because prevalence really isn't a distribution --

MR. GARRETT: Okay. So say that slowly and the organism distribution is non-uniform?

DR. JAYKUS: And the organism distribution is non-uniform.

MR. GARRETT: Thank you. Any others? Page 18. Page 19. Page 20. Lee-Ann?

DR. JAYKUS: I've another one. The first full paragraph "Analyses of microorganisms," the last sentence; "It is also important to note that the uncertainty (i.e., error)," in my mind, error equates with variability. I would suggest saying "the uncertainty and variability associated with microbiological analyses."

MR. GARRETT: Without exception? Change will be made, "and variability." Twenty-one. Twenty-two. Twenty-three. Twenty-four. I do want to point out, on page 24, that you'll see a square bracket around Question 6 on *Salmonella* in that the subcommittee -- that's a printing notation, if you would, because we considered the -- answering the question specifically as it relates to the

Salmonella performance standard, which is the current performance standard. Twenty-five. Twenty-six. Everybody's names right?

And let me say this, as John said earlier on his, that this subcommittee has worked very, very hard and very diligently and is truly to be congratulated, DR. Chairman, and I would recommend that we accept this report as modified and give the committee a hand. We've got a ground turkey that mirrors this. The only difference is for the few nuances where there are differences, those differences are noted. But we can rapidly go through the ground turkey document, as well.

CHAIRMAN PIERSON: Why don't we just go ahead and we could have a motion to adopt this particular report and then we'll do the next one, so -- I'd like to adopt this one first and then we could do the second one. And then you can go through the second one. Do we have a motion? John?

DR. SOFOS: Yeah.

DR. SCOTT: Second.

CHAIRMAN PIERSON: We have a second, Jenny Scott. Discussion? Okay. All in favor

without objection.

COMMITTEE MEMBERS: Aye.

CHAIRMAN PIERSON: Now do we have any in favor with a comment?

[No response.]

CHAIRMAN PIERSON: No. And any opposed?

[No response.]

CHAIRMAN PIERSON: If not, this document's adopted.

MR. GARRETT: Moving rapidly on to the ground turkey document. As I've indicated, before we move rapidly on, Jenny?

DR. SCOTT: Jenny Scott, NFPA. Can I make a motion that we make all of the changes from the chicken document that apply to the turkey document without going through those individually and reiterating them?

UNIDENTIFIED SPEAKER: Second.

MR. GARRETT: Without exception, so noted. I kind of operate on Jefferson Rules of Order, like a legislature does, as opposed to Robert's Rules of Order. Some of you know that. Okay. So noted.

CHAIRMAN PIERSON: So are you turning it

back to me now, Spencer?

MR. GARRETT: Yes, sir.

CHAIRMAN PIERSON: Okay. Do we have a motion to adopt the document on ground turkey? Jenny?

DR. COOK: Second.

CHAIRMAN PIERSON: Do you second? Peggy Cook seconds. Okay. Discussion? No. All in favor without objection?

COMMITTEE MEMBERS: Aye.

CHAIRMAN PIERSON: In favor with a comment or two? If there's such a thing.

[No response.]

CHAIRMAN PIERSON: Opposed?

[No response.]

CHAIRMAN PIERSON: So the Committee hereby adopts the ground turkey report. Thank you very much, Spencer. Excellent job.

MR. GARRETT: Well, remember, I'm just the leader of the band. You got to thank the subcommittee.

CHAIRMAN PIERSON: Certainly. With that, we've taken under consideration, then, all the documents that the Committee is -- has in

discussion and you know, completed that -- this work. We have a time now that we will have public comment. Each individual has 10 minutes, or up to 10 minutes for comment. We have three individuals listed to provide public comment and we'll take them in order. At least, I received them on this list. I'll give the name and then if you could identify yourself as to your association and provide your comment and I guess you could use the microphone there. First is Nick De Pinto. Is he here?

MR. DE PINTO: It's actually Nick De Pinto, and Avure Technologies. I wanted to make a statement in relation to the -- discussed the scientific parameters for establishing the equivalence of alternative methods of pasteurization and it really elaborates on the last paragraph on page 46 of the document which ends with the sentence "More research is needed to develop label statements that are understood by consumers." To that, our experience at Avure Technologies and my own personal experience with background in food irradiation, tells us that consumers do desire a full disclosure if --

especially on non-conventional processing methods.

If the label pasteurization is to be used for non-thermal processes, then that label should be conditioned by a modifier such as pasteurized with high pressure or alternative technologies. In addition, the definition of pasteurization should not exclude the fresh descriptor, just like the label pasteurization being a useful descriptor for enhanced food safety, fresh can be effectively used to communicate a higher level of quality that is noticeably better than traditional processing. For example, fresh apple juice pasteurized with high pressure. Thank you.

CHAIRMAN PIERSON: Thank you. Next is Tony Corbo.

MR. CORBO: Hi, my name is Tony Corbo and I'm with the consumer group Public Citizen. I want to commend the subcommittee that dealt with the pasteurization redefinition topic. I attended every single one of the public sessions that they conducted.

Yesterday in the hallway, Dr. Tompkin asked me whether I enjoyed watching grass grow. I like watching paint dry and I absolutely love watching

microbiologists take something that Congress has passed that had no guidance at all and tried to fashion it into a workable definition. I want to commend Dr. Kvenberg for extending me all the courtesies in the world in terms of participating in the process, even allowing me to participate while the committee was deliberating, not waiting for any public comment, period.

That being said, we did bring to the subcommittee a couple of focus groups that FDA and USDA did on the issue of irradiation and its equivalence to pasteurization. And taking the comment that Dr. Brackett made earlier today that the Agency is going to entertain a rule-making process, we hope to revisit that issue because as even DR. De Pinto just indicated, there's going to have to be an awful lot of consumer research to gain acceptance by the consumer of some of these alternative technologies and defining them as pasteurization and irradiation is, as MR. GARRETT pointed out, is a hot-button issue and it's going to take a lot of doing. So with that being said, I -- we hope to revisit the issue of consumer research as the rule-making goes on and again,

thank you very much for extending me all the courtesies in your deliberations.

CHAIRMAN PIERSON: Thank you, Tony. I'm sitting here thinking, you know, maybe we should give you an honorary award for enduring this process.

DR. CORBO: I was on the motorcycle and I was in the sidecar. I got all the bumps and bruises as they did, so --

CHAIRMAN PIERSON: Well, you can -- one of the things is you can fall asleep while you're in the sidecar, right? Okay. Not that he'd fall asleep in one of your meetings, John, but anyway. Next is Peter Jenkins.

DR. JENKINS: Wrap things up here again by saying thanks and I'm an attorney and a policy analyst, my name's Peter Jenkins with the Center for Food Safety, which is a non-profit group that's worked on food irradiation quite a bit and is concerned about this issue about describing irradiated foods as pasteurized. And generally, we have endorsed the comments that Tony and Public Citizen have put in on this issue. I might clarify one distinction from what Tony just said in a

minute, but you've had a difficult task and it was one that Congress asked you to do and we fought that bill in Congress and we're going to keep fighting this issue for a long time.

We think, maybe in your future professional lives you were hoping that you may weigh in on the pros and cons of using the term pasteurized for these alternative processes, despite the fact that you've weighed in on the scientific issues, we think there are some real public policy issues that go along with it and I'll talk about those in a minute. Tony said that he thinks that this issue of consumer research really needs more work, we need more consumer research. I disagree.

There have been plenty of surveys, lots of consumer focus groups on this particular issue run by FDA and private contractors and others. We've got polls all over the place saying that consumers don't want the word pasteurized to be watered down or somehow changed in the way that it's used on products that they purchase so that they can't trust the word pasteurized anymore. That is a real concern and it could have a, sort of a negative effect of causing anxiety in consumers and distrust

of the word pasteurization as they buy products in the future, if it is misused. And so Tony said there needs to be more research. I'd say go back and look at the research and see that the people have already spoken on this issue; they really don't want that watered down.

And I was a member back in 2001 of the steering committee that FDA appointed to oversee these consumer focus groups that Tony's talked about and I got to sit behind the one-way mirrored window in the focus groups in Calverton, Maryland several evenings and watched these randomly picked consumers wrestle with this issue of well, is it okay to call irradiated foods pasteurized. And they were led down that path by a professional moderator who was hired by FDA to sort of try to move them towards that issue and really flesh out the ideas and get participation from these different panels of folks on this issue and to see whether they could be brought to accept it, even with education about the benefits of irradiation, et cetera, et cetera.

And there was some discussion about potential down side of irradiation, but mostly it was sort of

aimed at irradiation's a pretty good thing, why can't it be called pasteurized? I have to tell you, based on what I saw through the one-way windows and also reading the transcripts of the many other sessions that were held, the response of consumers is almost a hundred percent negative.

There was not, I don't think, one positive voice and I was amazed at how quickly the consumers just read right through this notion that this was an attempt by the irradiation industry to use a trusted term, pasteurization, and to apply it to a term that they weren't familiar with, that they didn't trust, that they were worried that they would lose faith in the value of pasteurization in the future. So I just give you that caution in closing and thanks again for your work on this issue, but as you move forward into the rule-making process, I think we need to take some of these broader concerns into account. Okay, thanks.

CHAIRMAN PIERSON: Okay. Thank you very much. With that, what I'd like to do is again thank the Committee for all the hard work that you've done in this 2002-2004 session. It's been extremely productive, very valuable work and you've

gone through, you know, all the charges.

Of course, we still have one for Spencer to work on, but we, you know, recognize that we wanted to finish through the other performance standards and so everything we anticipated and hoped to have done by the close of the 2002-2004 session has been accomplished and I again want to let you know that, you know, this information is very, very valuable scientific analysis, advice and is very important to FDA, Department of Defense, Department of Commerce, CDC, USDA, in achieving our public health missions and food safety considerations. So with that, again, I thank you very much.

Bob had to, unfortunately, be at another meeting right now, so he can't extend his thanks, but I'm sure that he would like to have that done, also, on his behalf. Again, I commend you for an excellent job done and wish you a safe journey home. Thank you. That concludes the meeting.

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[End of proceedings, 3:01 p.m.]

CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

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

HELD AT: Washington, DC

DATE: August 27, 2004

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