UNITED STATES DEPARTMENT OF AGRICULTURE

NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS MEETING

Empire Room
Omni Shoreham Hotel
Washington, D.C.

Thursday, January 24, 2002
9:00 a.m.

Committee Members Present

DR. KAYE WACHSMUTH, Chair
DR. DAVID ACHESON
MR. DANE BERNARD
DR. LARRY BEUCHAT
DR. ROBERT BUCHANAN
DR. CATHERINE DONNELLY
DR. FRANCES DOWNES
DR. DANIEL ENGELJOHN
MR. SPENCER GARRETT
DR. TSEGAYE HABTEMARIAM
DR. MICHAEL JAHNCKE
DR. JOHN KVENBERG
DR. ANNA LAMMERDING
DR. JOHN LUCHANSKY
DR. CAROL MADDOX
DR. MARGUERITE NEILL
DR. ROBERT SEWARD
DR. WILLIAM SPERBER
DR. BALASUBRAMANIAN SWAMINATHAN
DR. KATHERINE SWANSON
DR. DAVID THENO
DR. ROBERT TOMPKIN

A G E N D A

Public Comment

Ted Wiener, Director
Food Safety Program
Food Marketing Institute

Caroline Smith-DeWaal
Center for Science in the Public Interest

P R O C E E D I N G S

9:02 a.m.

Convene Plenary Session

DR. WACHSMUTH: Anybody have anything? All right. What I'd like then is to turn the chair over to John Kvenberg who will report from the Subcommittee on Blade Tenderization/E. coli 0157:H7 and at least get us started on the discussion.

Report of the Subcommittee on Blade Tenderization/E. coli:H7 and Discussion

DR. KVENBERG: Thank you, Madam Chair.

Well, the subject that we were addressing is E.coli 0157 and its association with blade-tenderizing beef, otherwise known as non-intact beef, and the subcommittee, in August, met in response to questions that were asked by -- asked of it, that were formulated at FSIS, and if I could, I'll just preface that by saying that one of the drivers of this was two situations, one in Michigan and one in Canada, from foodborne illness investigations that involved blade-tenderized product.

In August of 2000, there were two human isolates of 0157 identified by the Michigan Department of Health, and in these cases, this was a, I believe, chain-operated restaurant, small local chain-operated restaurant.

The second was information we received and reported in -- from Quebec Center in Animal Health in Canada that occurred in October of 1999. Again, the risk factors identified here were roast beef cooked rare and a second reported situation where the risk factors included again rare cooked beef.

So, to preface this, I guess the word you could use is a paucity of outbreak information that we

had to work with relative to outbreak situations that occurred.

The first question that we were asked is, based on the available information for non-intact products, could you ask -- could you answer several questions relative to 0157 survival in steaks and in roast beef products, considering the traditional cooking process for these products can be very rare or rare?

The subcommittee concluded that there was sufficient information to address steaks, which is what we dwelled on in the second question, but there was just no data to really address the question that was addressed to roast beef products.

The question that we addressed is, do non-intact blade-tenderized beef steaks present a greater risk to consumers from 0157 compared to intact beef steaks if prepared similarly to intact beef steak products?

The conclusion that we reached was based on studies that were done at Kansas State University relative to a comparison of the steak materials that were tenderized by one pass through a blade tenderizer as compared to steaks that were not, and the only

heating characteristics that was studied in the Kansas State study was broiled steaks, bearing in mind that grilled steaks and other formation of steaks are also ways of preparing this, so the heating kinetics in this study dealt specifically with the broiling process.

The results of the Kansas State study said, I think the first interesting point is that through the tenderization process and misting the 0157 on the surface of the organism, then putting it through a single pass of the blade-tenderization process resulted in an internal core inoculation of three to four percent of the surface contamination of the product. So, there is internalization of the product.

We had some discussion, since the study was based on examination of translocation to the geometric center of the cut of meat, was that the cold spot of the meat? We don't -- there's some data gaps that will come through on our studies.

So, the first point, I guess, that we drew a conclusion, and we went through this again from the draft you've seen earlier and was handed out this morning, would focus on the Point A of the second question, and our finding so far is that non-intact beef steaks do not present a greater risk to consumers

if the meat is oven broiled, emphasis added, and cooked to an internal temperature of a 140 degrees or above. That seemed clear from the data that was reviewed.

The data became more variable at temperatures below 140 degrees, coefficient of variation was growing large, but looking at the data and in some depth yesterday afternoon, we can state that there is an achievement in tenderized product of a log reduction of 3.2 logs reduction in blade-tenderized product and a 5.2 log reduction for intact beef steaks at a temperature achieved instantaneous at a 120 degrees Fahrenheit and that's about as far as we could take the particular conclusion.

One of the questions that we've been asking is, what's the significance of the log reductions, and what would be the value to achieve the safety given an unknown quantity of what would be expected on the surface of a product?

It calls for cooking instructions for the industry to, if the conclusion is reached that blade-tenderized steaks actually need to be treated differently, what would that recommendation be?

In addition to those questions, we were also asked to address yesterday an additional question by --

that was posed to us, does the available scientific evidence support the need for labeling requirements to distinguish between intact and non-intact products in order to enhance public health protection?

I think that might be a point that would warrant further discussion by the full Committee. In the subcommittee deliberations yesterday, we concluded that there wasn't sufficient data at this time to warrant a response to the question, but I think the full Committee ought to have a discussion of what might be an appropriate recommendation.

It's clear that research needs were identified, and they are listed at the tail-end of this document, and therein, I think, is a point for discussion, where the data gaps are, to more fully understand the situation, and what we're really talking about with blade-tenderized products.

We don't have quantitative baseline data for 0157 or other information or data on indicator organisms basically for comparison, including other pathogens that might be brought to bear on answering this question of what the recommendation should be.

There's not data collected from various types of establishments on this question of inoculum. More

research could be applied to the survival of 0157 in core beef samples following cooking at the specific temperatures. We don't -- we thought that there was information that could be gained from that.

As I stated earlier, both industry and consumer practices relative to cooking of beef products, other than the information so far provided by Kansas State in the broiling process, needs to be developed so we have a better understanding of that, and as is any recommendations for exactly how tenderization is conducted, that is the number of passes through the tenderization process, would change the dynamics.

The assumption of the Kansas State data was a single pass, and a very limited information survey conducted by Kansas State said it was the practice of some establishments to make more than a single pass. It was rare but there was at least one report of up to eight passes through the tenderization process, which would change the dynamic of the inoculum inside tenderized steaks.

I guess to summarize this, a better understanding of the variability of the internal temperatures and exactly what's going on, even with the

data so far presented on broiled steaks, would be helpful, and a quantification of the D and Z values. They use a cocktail strain of five types of E.coli to get some indication of exactly what the thermal destruction kinetics of 0157 used in the Sporing study are would be helpful.

The status of the research that was done at Kansas State has been completed in the thesis and articles have been prepared for publication but are still internal within Kansas State University and will publish shortly.

I'd like to also make the Committee aware that information we learned yesterday, that additional researchers are reporting out information on blade-tenderized products today. The Western Cattlemen's Association in Denver is having a meeting and a conference where information on risk assessment, the organisms of Listeria and Salmonella on production of cooking blade-tenderized steaks, is being reported by ABC Research Laboratories.

Silliker Labs has got information relative to a survey they have done on retail samples to determine levels and the types of pathogens in non-intact beef products.

At this same meeting, the Kansas State University research is being presented on what we discuss here today. There's a discussion, and I don't know the topic, of the Canadian Beef Information Center. This is also more information that's coming to light.

So, I think it would be -- the Committee should be aware that reports of additional information and research is currently going on, and it's a work-in-process.

So, with that, basically that's an overview of where we are today, and I think I would propose, Madam Chair, that we open up the full Committee for discussions and recommendations.

Clearly, I think what we're pointed here is filling in data gaps, additional information, and then coming up with a formulation of recommending to USDA where we can fill data gaps and come up with finite recommendations to the questions that were posed.

DR. WACHSMUTH: Okay. I guess the best way to proceed would be to take it from the beginning. Start on Page 1 and ask if anyone has any comments just on the General Background or Question 1 to get us started, and then if we can make our way through the

report, I think what I'm hearing is the subcommittee would like for this Committee to tell the agency the data are not there to answer the questions the agency has posed, and the subcommittee would call for more data or maybe recommend that the agency call for more data.

Any comments from any members? Dave?

DR. THENO: Thank you, Madam Chairman.

I've served as a subject matter expert to this Committee and have reviewed the Kansas State data at some length and have at least cursory knowledge of some of the items that are going to be discussed at this meeting today in Denver, I believe.

One of the -- there are certainly a number of gaps that exist in the data. One of the pieces of information that does come out of the Kansas data is that if contaminants are on the surface of a muscle mass, and you are needle-tenderizing, they are trans-located throughout the body of the product.

Question 2, where it goes down, do they present a greater risk to consumers if prepared similarly to intact beef steaks?

Kansas State used a broiling methodology, and if you use that assumption, things don't seem to be a

problem. The concern is, is that a product like this could be requested by a consumer to be served what's called "blue" or "blood rare" or whatever you want to call it, but in essence cold centers, and the data, as John alluded to, I think, is it three to five percent or two to five percent, something along that line, that from the surface, is pushed down through the muscle mass, and if in fact that would happen and products were served with centers less than 120, that any organisms that were there would likely survive and be passed on.

So, one of the things is what percent of these products are, you know, served that way, and another question is, would a restauranteur, if requested, be able to tell the difference between a needled and a non-needled product as they receive it at their restaurant? Without labeling today, they would not.

So, in fact, I would guess that most people in the serving side of the restaurant business do not know one from the other. The purchasing people may, but certainly the operators would not, and at the retail, yes. There's a retail component to this. If it's not labeled or aware of it, and it's sold through

the retail case, the consumer would not know at all.

So, I think that that's another gap in the knowledge. I do not know if that's being addressed or discussed at the Denver meeting.

DR. WACHSMUTH: Is this information anywhere in the report or these concerns or are these concerns --

DR. KVENBERG: Well, actually --

DR. WACHSMUTH: -- in the minds of other Committee members? John?

DR. KVENBERG: We simply left it that we didn't feel that the information was sufficient enough to make a recommendation for labeling. Perhaps what Dave Theno is saying is that in terms of guidance that may be put out or information to both the consumers and to food restaurant information should be developed. That's not in our report at this time. Perhaps it should be. It's just that we're really at a loss as to exactly what to recommend, other than the way Dave Theno presented it, is that cold centers would -- could intuitively present foodborne outbreaks associated with cold center steaks.

The data ended at a 120 degrees, and we don't have anything below that. So, there's no science

behind the question that we're aware of. The research ended at cooking to an internal temperature of 120. That's all the information that currently exists.

DR. WACHSMUTH: I guess what I'm hearing from here, though, is -- and Dave's comments, it sounds as if there are some facts. I mean, there are data that organisms go from the surface into the center, two to five percent.

DR. KVENBERG: That's true, and it's in the report that --

DR. WACHSMUTH: That's true. You'll have the report then. Yeah.

DR. KVENBERG: Basically, that was part of the Kansas State study, that the internalization was there as we stated previously. Inoculation to the core of the sample would result in three to five percent what was on the surface to be down to the center of the core of the steak.

DR. THENO: We spoke with one of the principal researchers yesterday on a conference call, and they acknowledged that the study was designed really on the conservative end, if you will, of the inoculum on the surface, and, you know, they felt it was a worse case scenario.

But nonetheless, even at -- and they used two levels of surface inocula, that there was translocation at high and low levels to the center of the product.

DR. WACHSMUTH: John?

DR. LUCHANSKY: Good morning, everyone.

I think John did a nice job of trying to convey some of the issues that we as a subcommittee struggled with yesterday, and I think one of the critical issues in our deliberations was the way the question was phrased, and so I wonder if the Committee needs to re-evaluate what the actual question would be.

In the strictest sense, it was, is there a difference between blade-tenderized and non-tenderized. We didn't really -- we really weren't asked to say what constitutes safe or how much of a difference would be significant. We just took it the way it was written, and we debated that question using a single data set and that was the Kansas State data set, and as John intimated, it has not yet been peer reviewed.

We were very lucky that we had an opportunity in August and yesterday to talk at length with the folks at KSU, and they were very helpful, but from a strictly scientific point, that was brought out by several Committee members, Carol being one.

The way that the sample was taken to determine residual or remaining viable cells did not necessarily address whether those cells were at the surface of the meat or whether they were in the center of the meat at the time the sampling was done.

So, Dave's point about where the bacteria are and how much heat gets to them and how many may have survived might be another scientific question that needs to be addressed, but again to reiterate, whether a three-log reduction is sufficient or a five-log reduction is sufficient, wasn't the charge that we were given.

We were simply asked to determine whether there was a difference between tenderized and non-tenderized and really the only data set we have was the KSU data set. So, I want to hopefully not to belabor the point but to bring that for discussion.

DR. WACHSMUTH: Dave?

DR. ACHESON: Two points. One is that I think from what Dave's saying, is that if we believe that on occasion, there are live 0157 getting to the center of steak that will essentially remain cold, and from what we know of the epidemiology in ground beef, we can assume that as few as 10 of those, 10 to 50,

that may be an infectious dose. That may be enough to impose disease in a susceptible person.

I think, so we really don't need many in there, and if it's a rare event, where it's essentially not heated at all in the center, then I think we've got a serious issue to that.

The other part of this is that I think getting the epidemiology to link rare steak with 0157 outbreaks is going to be almost impossible. It's got to be an extremely unusual event, but if we're right, then maybe some of these rare steaks are responsible for sporadic 0157 infections.

The epidemiology is just not there, and we don't have the resources, as far as I know, to go chasing sporadic cases. So, we're never really going to get there. So, I think what I'm leading to is that we really do need definitive data, and to pick up on John's point, to show that there are a certain number of live 0157s getting to the center of the meat as opposed to from the surface down, which I remember was an issue, and then I think if we know that, we know what the infectious dose is, we should be in good shape to move forward.

DR. WACHSMUTH: Is that captured in the

questions, do you feel?

DR. KVENBERG: I think some --

DR. WACHSMUTH: I'm thinking in terms of how we might need to revise the report, if we do, to capture the things that we're saying right now.

I think it's there in a way. It says survival of 0157 in core beef samples following cooking.

DR. KVENBERG: Madam Chair, I would point you and the Committee to the Research Needs, the second proposed research needs. David, that's getting to your point. The survival of 0157 in core beef samples following cooking at specified temperatures.

Does that rendition get us to where you want to be?

DR. ACHESON: I think that's exactly the data we need, and based with what we know of consumer habits that David alluded to with people who eat blue steak.

DR. WACHSMUTH: Okay. Dane, welcome.

MR. BERNARD: Thank you, Madam Chair. Dane Bernard, Keystone Foods.

As the subcommittee deliberated this, I'm sure the question of how do we get to the exposure assessment piece came up, and I think some of the

questions that you asked in terms of data needs address that.

Specifically, is there any way that we can use existing data on E.coli, a certain number of those, maybe A-7, to try to come up with some estimate of how many micro -- 0157:H7 might be on the surface that could be in fact translocated?

As Dave said, Kansas State did a job, and we all as microbiologists have done challenge studies. You've got to use enough bugs that you can detect them after you run the study and that tells you it's possible.

The other piece is how likely is the contaminant to have been in a location where it could have been translocated in the first place and that's what you need to do, kind of a risk estimate, so that you can make a decision on the risk management decision as to whether to label or not or whether there are other options you have.

So, I'm wondering if there's some thought about how we can get to that piece.

The other question I have for the subcommittee deals specifically with Question 2, Answer A, Madam Chair. I don't know if you want to go to that

point yet or not.

DR. KVENBERG: Madam Chair, could I respond to one point?

Maybe it wasn't clear in the research need identified, and we could modify it, but in our first, very first research need identification, Dane, was pointing out the lack of qualified -- qualitative baseline data on 0157 that's presenting itself on primal and sub-primal cuts.

I think that's where we thought, when we went to the exposure assessment, the data that would be useful may lie. Maybe if you want to look at that and modify. That was our best guess on that point to where we could go get the data.

MR. BERNARD: That gets to it. My question specifically is, do we have information before us today where we wouldn't have to enter into new data-gathering? Is there something we can use today?

On our subcommittee, we talked about data we don't have, which is the E.coli data that industry collects, but if we could access some of that, make some assumptions about how many of those were H7s, is there a way to use that kind of information? That was the nature of the question.

DR. WACHSMUTH: Okay. John, do you have data like that available? Are there data on these cuts of meat or the surface of untenderized cut?

DR. KVENBERG: I'd actually defer to John Luchansky. I don't know the answer.

DR. WACHSMUTH: Okay. John?

DR. LUCHANSKY: Again, just yesterday, we became aware or cognizant of some data that Russ Flowers is going to present in Denver, and I don't know if the rest of the Committee has the agenda for that meeting, but he will be talking on a national survey to determine levels and types of pathogens in non-intact beef products, and if the information was correct that we received, that would be at the retail level, and they were unable to find 0157:H7.

Now, the absence of evidence is not evidence of absence. What was the threshold for detection? How many samples? We weren't privy to that type of information, but that might be a start in the right direction, although certainly having more data would obviously be -- allow us to make a more informed decision about the levels likely to be found and then to extrapolate as to the levels that might then be internalized and the temperature and time regimen that

might be needed to effect a positive outcome.

So, I think we're going to be actually getting the executive summary of that conference today, and so the information should be available shortly.

DR. WACHSMUTH: The other thing we might do is craft another research need bullet to put in this report because the agency can use this report to take to ARS or to others and say, you know, the advice of our Microbiology Advisory Committee is that we need to get this information. It would help stimulate that research, I think.

John?

DR. KVENBERG: Well, drawing from discussions we had yesterday, I don't know what the viability of it is, but there is information on E.coli in beef products, and what comes to mind is I don't know if it's indicated or indexed, maybe that's a thing to look at to see if there's some indirect way of measuring information you can't get directly.

There is industry data out there on E.coli. There's just not information on 0157 and that seems to be the driver here. I don't know the applicability of it, but again if we had some basis for making a comparison and could extrapolate from the data that's

known on E.coli generically, that might be useful.

DR. WACHSMUTH: Yeah. As I look at it, I think you've got everything in Research Need Number 1. That should be sufficient.

Dave?

DR. THENO: Along that line about available data, National Cattlemen's Beef Association did some carcass survey work, and while it's not germane to primals, at least it relates, and I will ask if they will release that information to the Committee.

Skip, was there an AMI study, a survey, of carcasses or primals? I recall there was a request or it was contemplated. I just don't know if it was ever funded or completed.

DR. SEWARD: Yeah. I don't know. I'll ask. It was before my time, but I'll ask on that and see.

DR. WACHSMUTH: Okay. We have quite a few flags up. Next, I'm going to call on Bob Buchanan.

DR. JACKSON: He's not here.

DR. WACHSMUTH: Oh, he left? Carol Maddox, and then go around to Bruce.

DR. MADDOX: The one thing that I agree that trying to obtain this additional data regarding on the contamination that occurs in the field on sub-primals

and primal cuts is important, but I think the one thing that we need to be cautious about is the way in which we collect the data on core samples as opposed to the current data which we have which is limited, because it was based on log reductions and cross-sectional samples of steaks.

DR. WACHSMUTH: Okay. Thank you.

Bruce?

DR. TOMPKIN: This is Bruce Tompkin.

Perhaps a worse case in the matter of whether you can stretch it this far, if you consider that we're talking about a blade-tenderizing steak. A worse case may be a ground steak, and USDA does have extensive data on their survey for 0157 in ground beef where the data show that the prevalence is something less than one percent and that's using a method that involves an enrichment of 325 grams, which is about a 12-ounce steak, I think.

That's actually arrived at by enriching five individual 65-gram samples, and the agency has been able to go back into some of those results and determine how many of those five sub-sample units were positive, and Walt Hill provided that at one time.

But it is a way to arrive at a concentration

for 0157, excuse me, in a mass of meat that would be -- was ground. Now, there's some things about grinding that actually could lead to a different distribution, but the basic idea may be applicable and helpful.

Another -- I did have a question, and I don't see it addressed in the questions here or in the information. What is the quantity of this material? If you think in terms of what is the exposure to consumers, how much of -- how much blade-tenderization, blade-tenderized beef steak, roasts, are actually made available to retail establishments?

DR. KVENBERG: Madam Chair, we discussed that question in passing, but it's not in the report. Does Dan have the -- Dan Engeljohn maybe can --

DR. ENGELJOHN: This is Engeljohn.

I would say it's identified as the Research Need 5, the proportion of blade-tenderized meat distributed to retail establishments.

DR. KVENBERG: Thank you.

DR. WACHSMUTH: Does that get it, Bruce?

DR. TOMPKIN: Yeah.

DR. WACHSMUTH: Okay.

DR. TOMPKIN: It's the quantity.

DR. WACHSMUTH: Right. Okay. Okay. Bob?

We'll come back to Bob. You were out when I called on you, but we'll call on you again.

DR. BUCHANAN: Yeah. I do apologize, and if my question was asked in a different manner.

I did want to ask the question on the five cocktail strain that was used to do these experiments. Was this an uncharacterized group of strains or are these well-characterized strains that have been put in a reference collection, etc.?

DR. KVENBERG: We revisited that question yesterday afternoon on the telephone call, and the strains that are involved in that, I guess, basically what's needed to be done, and it's something that I think they intend to do at Kansas State, is to do thermal-kinetic studies on the cocktail of the five strains they used. It's common strains. It's information we didn't have before us at this point.

We identified it. I think it's obtainable. It could be identified as a research need, but the type -- the five strains that went into them, I think, are enumerated in the thesis.

DR. MADDOX: We have an additional piece of information that we obtained yesterday with D AND Z values on the 0157:H7 strains that they used and the

cocktail.

DR. BUCHANAN: Because I was going to say that --

DR. MADDOX: They're not identified as recognizable strain designations. We just know the D AND Z values of the cocktail.

DR. BUCHANAN: Because if they were, different strains have been put to the culture collections, there's a great number of these that have had their thermal-resistances characterized. So, I'm just wondering if that information is available, just it hasn't been dug out of the literature.

DR. WACHSMUTH: Okay. This may be addressed in Point Number 7 under Research Needs or do you need to add something to that?

DR. BUCHANAN: Well, that's my point. There may not be a research need, if they've already been well-characterized. We just would -- they may not have personally characterized the D AND Z values for the strains, but if they're well-used strains in terms of experimentation, there have been numerous studies on the thermal-resistance of E.coli 0157.

DR. WACHSMUTH: Okay. Skip down to -- is this to this point, John? Go ahead.

DR. LUCHANSKY: I agree, Bob, and we can get that information, but knowing how often some strains get passed it, then, you know, maybe it would be worthwhile just to go ahead and run the values anyhow for them, and they are commonly-used strains and you can compare them. Since so much emphasis is going to be placed on those five strains, it would be nice to check them out.

DR. WACHSMUTH: Okay. I'm going to go to Peggy.

DR. NEILL: I think it would help the flow of the document. There are a number of things that we've been talking about here this morning which are not in the document, and they had to relate to positioning them, I think, just under Question 2 because that is the point at which in the document, it is being asked about risk to consumer.

It makes a better rationale to look at the laboratory aspects, if you know that there have been instances in which transition by such a mechanism has occurred.

In a related fashion, on the top of Page 2, under the Situations Discussed by the Committee, the consensus is Number 1, Additional Data from Michigan

and Canada Outbreak Reports.

There is no reference preceding that in the paper as to what they are, you know, whether it's a document or a privileged communication or something along these lines. So, the way I would suggest trying to blend this in would be to insert what would probably become two paragraphs under Question 2 that would relate first to what is known on the basis of epidemiological data, the outbreaks and sporadic cases, and make explicit the fact that distinction of the blade-tenderized versus not is not gathered in the current mode of investigation for cases, so that you lay out a rationale that says, yeah, there have been a few times in which this has occurred, but in actual fact, the entire surveillance system really is not picking up the distinction.

Then the second point that I would probably bring in, and I don't know quite how you do it, would be the point that has been brought out so far twice, that we really don't know the extent to which these products are in retail trade, and that even for those that are, probably many persons, either in commercial operations or individual consumers, would not be able to recognize it per se.

I think if you lay out that in a more explicit fashion, that makes a much better rationale, and it makes the report clearer for when you go forward with the next set of paragraphs that pertain to what are in essence laboratory experiments.

DR. WACHSMUTH: Okay. As the, at least for a short time, the potential recipient of such a report, I think that Peggy's correct because the agency won't have access to all of that information, the points that you brought up in the beginning.

So, I think the best thing to do would be to try to craft a couple of paragraphs during the break or lunch and maybe we could get those just one sheet of paper back to the Committee to adjust the report, because it comes across much stronger. I think it gives the agency more guidance in terms of the need to do this than the current report.

John?

DR. KVENBERG: Madam Chair, may I suggest that we get together with -- as you suggest during the lunch break and craft this, with Peggy's help, we can put an insertion into the report on her comments, and I guess with that, that basically is, in addition to research, I think I'm hearing an additional

recommendation relative to how epidemiological information is conducted and maybe we need to have -- within the paragraph that we're going to be crafting on that, is to pose that question to CDC for its guidance to states and locals on their investigations for asking the question, so that data could be captured. Maybe we could get that in there, too.

DR. WACHSMUTH: If it's possible. Okay.

Larry?

DR. BEUCHAT: Larry Beuchat.

We've heard some discussion, and I think the essence of it is that there is need to consider more research, more information, not only on the beef itself but on the microorganism, and my questions follow up on, I think, what Bob was -- the direction from which he was coming.

I have not read the thesis nor any of the reports that have come out of Kansas State or Silliker or elsewhere, but the questions that I would want to find answers to would be the nature of the organism itself, the heat-resistance of each strain of the cocktail that was used, the physiological age of these cells, the influence of fat content in the beef.

We know that fat can protect. The rate of

thermal-transfer is influenced by fat content. The pH of the meat. A number of factors that I think would be very useful to the subcommittee in terms of gaining insight as to the behavior of these five hopefully well-characterized strains in meat and beef with a range of characteristics that would be exemplary of what would be on the market.

These are just added points that I would look for in making -- feeling better about making recommendations on the time-temperature relationship for inactivating whatever number is targeted that might be on the surface and transferred to the center.

DR. WACHSMUTH: Maybe it would be possible for the subcommittee to amplify the Research Need 7 to include something like that.

John?

DR. KVENBERG: I guess that brings me to a point I wanted to bring up in discussion at some point, and that is, the fate, if you will, or the future activities of the subcommittee.

I think, although we can come back with a response to the agency on the questions as they were posed today, I ask the question, is there usefulness for additional work by keeping the subcommittee engaged

on the issue in light of new information we haven't seen yet, the peer-reviewed information, and future work that we may be able to report back additional information and findings on these questions that are being posed at a future meeting of the Committee.

I don't know what the thought of the charge is, if the idea was this would be the completion of our work. I think we could offer additional review, if we were to continue.

DR. WACHSMUTH: Well, I think you've completed the assignment the agency gave you. You might -- another addition to this report may be that other data are being generated almost as we speak or at least being presented as we speak, and let the agency come back, let the agency read this report, react to it, and then they'll come back to the Committee.

But for now, I think the subcommittee has dealt with the information it had, and it's completed the task.

Okay. Okay. One more assignment. Rather, it's not quite complete. Thank you very much.

Okay. We are running a little early. Unless there are objections, I'd like to go ahead and start the Hot-Holding Temperature.

Okay. What I'd like to do then is ask Dan Engeljohn to give us the Report from the Subcommittee on Hot-Holding Temperature and start the discussion.

Report of the Subcommittee on Hot-Holding Temperature and Discussion

DR. ENGELJOHN: Thank you, Madam Chairman.

I'm going to walk us through the handouts that I gave this morning which are the slides. They're just a condensed version of the report. The report has not changed from the version that you were sent prior to the meeting as well as what's available out at the table. So, in the interest of getting us through the introductory and summary, I'll just walk you through these slides.

First, the hot-holding issue was initiated by FDA partially to respond to questions that are contained within the current Food Code. FDA provided a thorough background document of which all of you have a copy. I thought it was very well done and had a lot of important information that facilitated the group's work.

The subcommittee comprised eight people. All eight individuals attended the subcommittee that was held November 13th in Washington, D.C., and I thank the

Committee for making that effort.

We also received input from industry members that day as well as from FDA and FSIS individuals who were there to answer questions.

The first question is, should the hot-holding temperature in the Food Code be changed from a 140 degrees Fahrenheit to a lower temperature, and if so, should there be an associated monitoring and record-keeping?

The second question, is there an increased risk to food safety if the temperature is lowered from a 140 degrees Fahrenheit?

The third question, if a margin of safety needs to be associated with a lower temperature, what should it be?

Fourth, what minimum time temperature parameters for hot-holding would ensure food safety?

And the final question, should there be monitoring and/or recordkeeping requirements associated with hot-holding at temperatures less than a 140 degrees Fahrenheit?

These questions became important in part because the issue came before the Conference for Food Protection previously at which time, the voting

delegates declined to accept the recommendation that came forward on the lowering of the 140-degree temperature requirement in the absence of record-keeping.

To answer Question Number 1, the response that the Committee came up with in summary is that the temperature can be lowered if an associated dwell time is associated with a lower temperature, and the Committee believed that HACCP is an appropriate framework for hot-holding.

On the second question, non-compliance with the current requirement of a 140 degrees was apparent. FDA provided information to show that roughly, I think, a quarter of the industry that was surveyed had hot-holding temperatures out of compliance with the 140-degree requirement that's currently in place.

The subcommittee concluded that there's substantial safety margin at the 140-degree current requirement. We also recognized that abuse, gross abuse represents -- probably represents the outbreaks that have occurred with regard to hot-holding, and that if the temperature is lowered from a 140 degrees, the safety margin would in fact be smaller.

For Question Number 3, regarding margin of

safety, we looked at information related to the equipment capability and found that there's a wide variation in the ability of equipment to maintain temperatures, fluctuated from plus or minus 20 degrees to plus or minus 5 degrees or so, and that temperature capability was probably a very crucial aspect to what needs to be built into any safety margin.

In addition, to define the safety margin, we believed that we had to address the -- what we viewed to be the primary organisms of concern being Clostridium perfringens and Bacillus cereus, Staphylococcus aureus was also listed within the reference material, but we focused our attention on Clostridium perfringens and B. cereus.

We believed that the safety margin should be set above the growth -- the maximum temperature for growth range for those two particular organisms.

We also identified that we believed a 130 degrees was the minimum temperature for hot-holding, below which there was the possibility for growth. So, I think our conclusion was that a 125 degrees was probably the best representative temperature at which growth would not occur, but because of the capability of the equipment and the ability to monitor and

maintain temperatures, we identified a 5-degree safety margin and identified the 130 as the minimum temperature.

For the minimum temperature parameters for hot-holding, we also looked at information provided in the FDA document that related to a one-log growth for C. perfringens. That one-log growth has some history in part. There are other federal requirements related to growth of Clostridium perfringens, in particular within the FSIS regulations that we have in place for ready-to-eat products for which there's a cooling requirement. We've established a one-log growth maximum for that particular product.

We don't actually have a regulation related to hot-holding, although we've had policies in place for a number of years. Many of our establishments do maintain hot-held products within the federal establishments, and we've generally recognized in FSIS as a 130-degree minimum temperature.

So, in looking at the information provided and using the one-log growth maximum information, the modeling information in part that was provided to the ARS Pathogen-Modeling Program, we determined that there could be a time-temperature relationship established

for ensuring food safety, using a 130 degrees as the minimum temperature.

We then established, based on the information provided, that a maximum time of four hours at a 130 degrees would be equivalent to a maximum time of eight hours for 135 degrees or an indefinite period of time for hot-holding at temperatures of a 140 degrees or more, which is the current requirement.

And for the final question, should there be monitoring and recordkeeping, we did have information provided to us that generally, the retail establishments do have monitoring of some sort in place, although it's sketchy as to whether or not the very, very small establishments or operations have as much information or as much control as the larger ones that do have the opportunity to go through some of the training that's provided, but that generally, we believe that there was monitoring that was occurring but recordkeeping was in fact something that probably was not occurring and that we believed as part of a HACCP program, it is important to have both monitoring and recordkeeping. That recordkeeping, of course, includes documentation that should be maintained.

That answered the five questions that we

viewed FDA had asked us to respond to. Having gone through that information, we then determined that there could be some recommendations that could go forward to facilitate ensuring food safety with regard to hot-holding.

One of the primary issues was in regard to educational materials to be provided to food service and retail operations on how to ensure that food is properly maintained in terms of temperature. One of the issues that FDA did identify with regard to a concern had to do with evaporative cooling and the concerns raised with that as an issue.

We did look at the information that was provided and believe that in fact, the information was not sufficient to determine that we could make a decision that evaporative cooling needed to be addressed within the recommendations. So, we identified that we didn't have enough information to address that issue further, but that there clearly was evidence available to us that temperatures varied considerably from surface to the internal temperature in a variety of food matrices, that stirring of foods, putting lids on foods, replacing and replenishing foods was problematic in that even though the temperatures

are highly variable, cross contamination has been identified as a problem with regard to some epidemiological evidence.

So, educational materials was an important aspect for which we believed there could and should be more information provided to industry.

The second issue is providing information about equipment capability and that there does seem to be a great deal of variability with the equipment that's out there and being used and that more information and knowledge can be developed about equipment capability used for food service in particular.

And then, also, that recordkeeping was important, and we had identified that recordkeeping was important for at least 30 to 60 days. In part, that would be a time period that we believe these types of foods would be available to consumers to eat and that if there was going to be a foodborne problem with that product, that that recordkeeping for that period of time would be appropriate.

Certainly keeping the information for longer than that period of time would be advisable as well. The fact that recordkeeping seemed not to be a part of

the establishment's operations, we believed, was an important aspect to draw attention to.

The second recommendation related to assessing the impact of changes regarding the hot-holding temperature and the use of time. In our discussions, we were provided some information that time is used as a food safety control and that lowering the temperature, thereby increasing the amount of time or decreasing the amount of time that product can be held, may in fact jeopardize or conflict with an existing requirement within the Food Code. So, we just raised that as an issue.

Oh, sorry. And then, finally, with regard to the information that FDA did collect, we thought that was useful and quite helpful, although there was more information that we believed should be designed into the surveys that would be conducted, primarily related to the food matrix, the holding time below the minimum temperature as opposed to just collecting information about what temperature the product was held at, and then just the procedures that industry uses for ensuring temperature is maintained would be an important aspect to capture in any future surveys that the agency would be doing.

So, open to comments.

DR. WACHSMUTH: Very nice, and we actually had the document from the subcommittee in advance of the meeting. So, I'm assuming everyone's read it, and if you have any comments, this is the time.

John?

DR. KVENBERG: Thank you, Madam Chair.

Just one point relative to the temperature requirements and the way the Code states it, and I think we did cover this ground. Is that the Food Code recognizes time as a public health control, and the four-hour requirement is basically there.

So, I'm just trying to get an interpretation. I was on the working group, and I think I understand it, but I just want to make sure that we're saying this the same way.

As a practical matter, within a four-hour time frame, knowing that the food is being out at hot-holding, the requirement would be at 130 with a time-dated -- the time it was offered for retail basically would be sufficient, if the investigator found that below a 130, it would have to be removed.

The question is, if we're getting in this middle ground of a 135, I guess that would kick in a

record requirement of temperature monitoring over a longer period. I think that's what we really are saying here, is within the four-hour requirement, the only thing there is the timing of the presentation of the hot-holding process and that would be consistent with the rest of the Code as time as a public health control.

Am I right?

DR. ENGELJOHN: Right. I would just follow up, and please, any of the subcommittee members, if you have other memory about the issue to bring forward, that would be great.

But as I recall, part of the issue was we were provided information about the time control as a public health factor or safety procedure, in that it was very detailed in the sense that the time the product's taken out and a time record is kept, and so there's a process in place that's quite specific to that which is not as rigorous or may not be as rigorous for the hot-holding for which, you know, that's -- the issue would be, you might need to take a look, I think, at those two procedures simply because with hot-holding, it's a looser type of control than what we were led to believe on the time as a control factor.

So, I think that was part of the issue. So, there's some very critical procedures in place, very specific, about when product's going to be taken out, when it's going to be out of the container or out of the heated environment or wherever it's taken, and those differences in procedures between hot-holding and the other may present a problem.

We raised it because we thought it might have some concern.

DR. WACHSMUTH: Okay. Fran?

MR. BERNARD: Thank you. Dane Bernard. Oh, I'm sorry.

DR. DOWNES: Thank you.

The other practicality issue that we discussed at that -- in that deliberation was the issue of the local inspector or sanitarian assessing both time and temperature without records and that if there were to be changes in the time allowance and temperature, that they would have to have assurance that that had been held for that amount of time at that temperature.

MR. BERNARD: Thank you. Dane Bernard.

My question also has to deal with the time-temperature issue, and first, I have a difficult time

understanding how we derived the time frames.

Looking at the reference material, it says that if we hold it at 130, it should be safe for the extent of time that it's presented for sale. Considering the pathogens we're looking at don't grow till below 125, I have a difficult time determining how we said, based on a one-log growth criterion, that we've got four hours at 130 and eight hours at 135.

I assume, and I guess this is the point, that the concern here is non-uniformity of temperature in the food product, and if that's the concern, I think we ought to spell out a bit how we arrived at those times based on that assumption.

What's the temperature distribution within the product? How did we arrive at that assumption? How did that assumption lead us to conclude that four hours and eight hours at those temperatures were appropriate?

DR. WACHSMUTH: Okay. Dan, can you answer?

DR. ENGELJOHN: I can answer it in that in the information that we reviewed, it became apparent to the subcommittee that there's a lack of in part control of maintaining a uniform temperature within the food as it's presented at retail simply because of the nature

of the food, the liquid products being different than the solid mass products, and that there's a high degree of variability there for which I think the cold spots within that product are not known, and it appeared to us that the level of control that the retail operations have was not that consistent or uniform or nor possibly capable of maintaining those temperatures. But these time-temperatures would in fact be for the coldest spot within the product.

MR. BERNARD: Thanks.

I think you can see the difficulty I'm having because if the bug doesn't grow at these temperatures, we're saying that these times and temperatures will prevent a one-log growth. What we haven't said and what we haven't been transparent on is what are the assumptions regarding temperature distribution in that product?

We have got to be making some statement with these times; otherwise, it's a leap in logic. There's a gap here in our logic, and we've made an assumption that there are zones in that product that are at a 125 or less, and to compensate for that, we feel as a Committee that we need to have time controls at the lower holding temperatures.

I mean, that's what we've said. I'm not sure I agree completely with the argument, but essentially that's what you're asking us to check off on as a Committee. My question to the subcommittee is, what are those temperature assumptions, and can we be transparent in the document about what they are?

DR. WACHSMUTH: Thank you. Yeah.

John, is it to this?

DR. KVENBERG: Yeah. Just to the point, and Dane refreshed my memory or maybe you do or don't know the issue.

But, Dan, when we discussed this in the subcommittee, part of the issue that was brought forward was evaporative cooling. We're talking about cold spots. I mean, we maybe didn't go through this in enough detail to put the science to the question, but there is a lack of real research data and maybe that isn't in the report and it may be helpful, that part of the concern is that the hot-holding temperature is going to fluctuate for various reasons, and one of the research needs that maybe could be put forward into this is examining the thermal-kinetics of hot-holdings at these temperatures to where you would have areas.

As Dane said, you phrase it as cold spots,

but I've heard concerns being raised relative to evaporative cooling and the way equipment is constructed. So, there is a science around this, but I don't think it's published. So, I guess my thought is, if there's something we could put forward, we could point out the need for studies relative to what temperature variability would be in a hot-holding. That's the only thing I could offer.

DR. ENGELJOHN: This is Engeljohn.

I would add that in the materials that were provided, Table Number 8 is the information that we did look at that identified the differences found within some operations within Maryland with regard to surface and internal temperature.

So, that was part of the basis for identifying that there are in fact widespread differences of temperatures within a product itself, not necessarily within the container but within a food matrix itself.

We can certainly add a research need to clarify that more.

DR. WACHSMUTH: Would that satisfy you then?

MR. BERNARD: I think adding a research need is appropriate, but I think the language that we would

put forth in our report should be specific and say this is why we are recommending -- making this recommendation, is that there's an unknown here, and we think this is an appropriate way to fill that gap until specific data is collected or something of that nature.

To me, it just said, well, we know it doesn't grow here, but to keep it from growing a log factor, we're going to put in 130 for four hours. It just doesn't make sense.

DR. WACHSMUTH: Okay. Can you work on that?

DR. ENGELJOHN: That sounds fine.

DR. WACHSMUTH: Okay. Is it this?

DR. SWANSON: It's this.

DR. WACHSMUTH: Okay.

DR. SWANSON: Yeah. It's this.

Now, I would just want to support the discussion or the need for more discussion here because as you read through the Committee's conclusions, 125 is the cut-off point. You've got a 5-degree margin of safety on top of that, and then to say, well, you need time on top of that makes people kind of wonder where it came from.

You have to have a little bit more there to discuss. It's because of variability that exists.

Because in answering these questions, the assumption is that's the minimum holding temperature is a 130. So, it just -- the logic doesn't fly. So, we need to have more in there to substantiate those times or some wording around unless you have exquisite control because there are differences in liquids versus solids, and it looks a little too arbitrary to me to really support. The science just doesn't seem to be there to support those times and temperatures.

DR. WACHSMUTH: Okay. I think we should give Dan an opportunity to craft a sentence to add to that that addresses the concerns.

Bill?

DR. SPERBER: Yes. On this particular point, this is Bill Sperber.

I was a member of the subcommittee, and as I recall our discussion and thinking on this, we arrived at this conclusion, we think, for good reasons.

The current Food Code regulation requires hot-holding at 140 degrees, a minimum temperature, with no time requirement, and we know from reports and from industry representatives at our subcommittee meeting that this is not fully complied with. There's a fairly significant level of non-compliance with the 140-degree

holding requirement.

So, our logic is that if there is to be -- 140 degrees is a very significant margin of safety over, say, 125 for the maximum growth temperature of the pathogens of concern. If there is to be any reduction in minimum holding temperature, there should be more teeth in the Food Code, more power given to public health inspectors to enforce the minimum holding temperatures.

So, we put in the time recommendations and not a mandatory but at least a subtle recommendation for recordkeeping, so that there be some evidence of compliance with a lower minimum holding temperature that would have a much smaller margin of safety in it.

So, I don't think 130 or 135 is unreasonable at all, if it is better controlled, than current practice. If current practice can't be improved, then you might as well leave the regulation where it is.

DR. WACHSMUTH: Is that Bob?

DR. BUCHANAN: Well, I guess having, you know, quickly looked at your report, I guess that's -- and having listened to your presentation, I guess one of the questions I would ask is, if you get such a small percentage of compliance at the current

temperature, what information or data do you have to think that you wouldn't get that same rate of non-compliance at the lower temperature and have a worse situation?

I'll give you an example that has nothing to do with food safety but it does have to do with safety. On Interstate 95, when they raised -- when the speed limit was 55, everyone did 75. When they raised the speed limit to 65, everyone did 85.

There is at some point where yes, the people won't go higher than the posted speed limit because they're too afraid to drive that fast, but what are your expectations that you'll actually get the same -- at least the same level of compliance?

DR. WACHSMUTH: Okay. Katie?

DR. SWANSON: Hot-holding temperatures for many products is not like driving down a highway because many times, products are held hot so the consumers get right hot soup. So, you can't drop it down too far. There are data out there about what is the appropriate temperature to present an expected hot product and have it taste hot to consumers, and so you could get data that would be appropriate there, if you got the right channels.

There are also reasons why somebody might want to hold it at a lower temperature and that's related to quality because it will dry out faster at a 140 than it would at a 130, but I -- my recollection of the exact temperatures are pretty low, but I think most consumers want it to be at least above a 130 for it to taste hot instead of tepid.

DR. WACHSMUTH: Okay. Bill Sperber, John Kvenberg, and then Bob again.

DR. SPERBER: Yeah. This is Bill Sperber.

We were told generally that the level of non-compliance with the current regulation was about 25 percent. So, we're thinking that any requirement for recordkeeping would improve compliance, whether the minimum holding temperature stays at 140 or if it's reduced.

But if it's going to be reduced, we would certainly expect some additional tools that would ensure better compliance so that the foods would be held safely.

There are two rules of food safety. Two of the commandments of food safety are to keep hot foods hot and keep cold foods cold, and the zone in between, the century of doom or whatever you want to call it

between roughly 40 degrees Fahrenheit and 140 Fahrenheit, needs to be controlled.

I know this is not exactly part of the Food Code, but in general, over the last 30 years or so, it's been kind of FDA practice that if you're in this range between 40 and 140, the practice is you keep hot foods above 140, cold foods below 40. You can be in between for up to four hours max. So, that partly underlines our selection of four hours maximum at 130.

Strictly speaking, you could be at 120 or 110 or 70 for four hours, and the food would still be safe, but, of course, we couldn't regulate that.

DR. WACHSMUTH: Okay. John?

DR. KVENBERG: Thank you, Madam Chair.

I actually have data, and I think we looked at it during the subcommittee report and wasn't included as a chart. Maybe this would be helpful.

Information that was gathered was the range and frequency of distribution of hot-holding temperatures across the United States, and the sample size was 1,288 observations across all types of food establishments on hot-holding, and the results in very brief summary were, the findings were that 70 percent were determined to be at or above a 140 degrees, 30

percent were over -- were below 140 but over 130, 17 percent of the observations were below 130, above 120, and nine percent of the population observed was below 120 degrees.

So, there is a frequency distribution and sort of a bell curve that we looked at to at least help Bob Buchanan's question about what observations we had to consider in the working group, and so that's basically it.

Right now, as it stands today, our survey was nationally-based. I don't know if it's statistically valid or not. I can't answer that. That's kind of the thumbnail, 70, 30, 17 and 9 percent.

DR. WACHSMUTH: Okay. I had Bob next, and then going to Dane, Bob.

DR. BUCHANAN: And I guess it was that distribution that elicited my question and comment.

Is there any indication at all that that distribution would stay the same and wouldn't shift to the left if you used a different standard?

I do have to reflect on Katie's comment. Yes, in a real world, that's -- your supposition might be true, but when I think of this kind of hot-holding, I think of school lunches and teenagers that have 30

minutes to eat lunch, and they're not likely to be complaining or not eating. They eat and go.

So, I think it's assuming that below a certain temperature, consumers will complain is not necessarily a good control measure to put in place.

DR. WACHSMUTH: Okay. Dane?

MR. BERNARD: Thank you.

Dan, in your presentation, you mentioned that most of the outbreaks were associated with catastrophic failures on holding temperatures, is that correct?

And part of the same question is the compliance issue, but if the ultimate objective is, as we all think it is or feel it is, that the holding temperature is an essential part of the food safety network, are the things that result in food safety problems just the failure to totally comply, not to be at 135 versus 140, or 130 versus 135? Is it the steam table was off?

Thanks.

DR. WACHSMUTH: Okay. David?

DR. THENO: Bob, to address a couple of your concerns, certainly within the food service industry, the compliance that John talked about is a general survey.

It's my sense, and I don't have a quantification for this, that where a time-temperature requirement is put in place, which is what Bill alluded to as being below 140, that compliance is substantially improved, that in fact these time-temperature relationships are special events and allowances really that require more things. So, I think you'll find actually better compliance where you might be below than you might on the general 140.

As to your observation that there's a maximum speed limit that you raise and no one drives faster than that, I'm from California, and I disagree with that totally, unless it's the speed of light. Physical constraint may stop Californians.

And to your concerns about the school lunch program, I actually consult to the San Diego School District and their School Lunch Program, and those programs also are using HACCP-based systems now and time-temperature relationships.

So, I know that they aren't all there, but I can tell you that as a group, the school boards are trying to get to those kinds of places. Contract feeders that are involved with that, major feeders are Sodexho Marriott, Aramark, are using HACCP-based

systems.

So, I think we're seeing substantial improvement relative to these kind of control systems over there, also.

DR. WACHSMUTH: Okay. Dan Engeljohn, then Frances Downes. You want Frances to go first?

DR. ENGELJOHN: I would just point out, we did have the information, John, you referenced in our materials. It's Table 10, Figure 1. But we have different numbers there. So, you might have an updated one. You might want to think whether or not we need to include that information here just because the numbers are different, the total numbers. So, you might have a more final report or something.

And then, secondly, the FDA did provide us information that one state actually has a 130 degrees for its hot-holding temperatures, but we don't have information or weren't provided information about the compliance within that state at that lower hot-holding temperature. That would be, I think, important information to at least look at to see how establishments there are complying with that and whether there's a different non-compliance rate there than there is in other states that do have a 140

currently.

DR. WACHSMUTH: Frances?

DR. SWANSON: I'd like to respond to Dane's concerns about the gross temperature violations being associated with outbreaks.

We did discuss that issue and partly recognized that sporadic cases or small clusters are not going to become apparent to public health because generally, people don't seek medical care for Clostridium perfringens or Bacillus cereus due to the shorter duration and less severe symptoms as compared to a Campylobacter or Salmonella infection.

And secondly, if they would go to seek medical care, clinical laboratories do not generally provide testing for those specific organisms. So, there was a recognition that we're aware of the big events but not the smaller more sporadic events.

DR. WACHSMUTH: Bob?

DR. BUCHANAN: Important interesting comment about South Carolina, and there might be a natural experiment there, if you can find out when they changed the temperature and look at some of their disease information.

Unfortunately, you don't go to CDC for those

data because I happen to know that reporting has been uneven up until recently.

DR. WACHSMUTH: I guess that could be a recommendation to consider.

Bob?

DR. BUCHANAN: Dan, can I ask a question about your Table 12 in the document? And this is just to point something out that either may be confusing or I just want to verify how you came up with those numbers for the sake of transparency.

Can I ask on what basis the numbers were derived? Oh, okay. Well, it's our document. Never mind. I'll go find our own people.

DR. WACHSMUTH: Okay. Any other comments? Are we going to -- I guess my question should be to Dane Bernard.

Given the extended discussion on the reasons for including the time and the temperature, do we still need a sentence that we asked Dan to craft earlier about the variability?

MR. BERNARD: I'm sorry. You're asking if adding some words to that comment? Yeah. Absolutely. I think we need to explain at least the fact that there's a data gap and that we're recommending this

approach because there is a data gap, but we know that there are temperature variations and to compensate for that lack of information to be specific at this point, the Committee feels this is appropriate, rather than just say we know it doesn't grow here, but we're going to require you to do this time and temperature anyway.

DR. WACHSMUTH: Well, I asked because I thought I heard several explanations from that subcommittee, but we still should work on that sentence.

Okay, okay. I think this is a good time to break.

Oh, Dave? Sorry.

DR. THENO: This is not on topic, but Madam Chairman, I apologize that I will -- my presence is required in San Diego in the morning, and so I'll be leaving you early today.

But I would like to welcome all of you that are attending the IFP meeting to San Diego. We have a fledgling IFP chapter, the Southern California Chapter, that will be hosting, and any of you that have the opportunity to come by the Jack-In-The-Box Support Center or want to see our Food Safety Systems are welcome to, and we hope to see all of you in San Diego

this summer.

I thank you for the morning and the time this week.

DR. WACHSMUTH: Thank you. Sorry you have to leave us.

Okay. Let's -- I'm thinking now of where we stand with some of the other documents in terms of what type of break we should take. Public Comments?

I would be concerned that there might be someone who would arrive at 11:30 to comment, and we would be on break. So, let's take a break for a half an hour and come back and see where -- in the meantime, we'll get a status on the different reports.

(Whereupon, a recess was taken.)

DR. WACHSMUTH: What we're going to do is rearrange the schedule so that you all will have as little down time as possible. I know all of you value your time. You should.

The solution that we've come up is to have Dr. Buchanan introduce the topic Criteria for Shelf-Life Based on Safety and Full Committee -- well, we'll have a discussion of that, as soon as we have the Public Comment, and then we will wait until after lunch to have any discussion on that. So, you've got a set

of slides. You'll have the presentation.

So, after lunch, we'll have any discussion on that topic. That way, if someone's waiting until lunch to come here just for this topic, they'll have an opportunity to hear the discussion and take part in it or at least hear it from the audience or have public comment.

So, what we'd like to do to get us on that schedule is to see if we have any public comments at this time. We don't have anyone signed up, I don't think.

Okay. If you'd introduce yourself?

Public Comment

MR. WIENER: I'll hold this because it's kind of short.

My name is Tim Wiener. I'm the Director of Food Safety Programs with the Food Marketing Institute. We are the trade association for supermarkets here in the U.S. Our members make up approximately three-quarters of all the supermarkets here in the U.S. We also have membership in over 60 different countries.

The issue that we would like to discuss this morning or provide comment is on the hot-holding issues. This was an issue that we had presented to the

2000 Conference for Food Protection. It was initiated by the industry, and I am thankful that FDA was able to pursue this and push it forward for discussion for the National Advisory Committee.

There are several things I do want to point out and some issues that we would like to make sure that everybody's aware of. Currently at this time, two states, not one, have adopted a 130 degrees as a hot-holding temperature requirement and one state is currently pursuing this adoption. The second state that adopted it was the State of Arizona, Department of Health.

Through their Food State Task Force, they brought in industry representatives, county and state regulatory folks and academia, and they sat down, and they looked at the science, and they evaluated. At that time, the science proved that a 130 degrees was considered safe.

The second issue, and this is something that I do want to point out, is the difference between what is considered safe versus what is considered out of compliance.

When the FDA did their Risk Database Report several years ago, they were looking at temperatures

out of compliance to the current FDA Food Code. They were not looking at the safety issue. The draw and the ties were: are these out-of-compliance issues tied in with safety and foodborne illnesses?

At that time, and I think at this time, I don't know if we can conclusively come to say a 140 degrees, a 135 degrees or a 130 degrees can be tied to a foodborne illness associated with either Bacillus or Clostridium perfringens.

So, the issue should be distinguished between what is out of compliance and what is safety. The data that FDA was able to provide, and FMI has worked through the University of Wisconsin Food Research Institute to obtain some additional data, clearly indicates that a 130 degrees is safe.

The issue now comes in at what temperature do you allow one-log growth? At a 130 degrees and above, a 130 degrees is still safe and would not provide for one-log growth. To go back and cite a quote that Dane Bernard had this morning. "Is it possible for growth of these bacteria at these temperatures, a 130 degrees and above?" No.

How likely will this occur? I don't think we can answer that question because there hasn't been a

whole lot of challenge studies at these temperatures, but what we do know, based on peer-reviewed literature, is for Clostridium perfringens to survive, it has to have 13 amino acids that are usually commonly associated with protein or soy-based food products. They cannot synthesize this. So, that's important because when we look at a 130 degrees for hot-holding for the other potentially-hazardous foods, that may not be protein-based or soy-based. It may not be an issue.

One of the things I do want to bring to point in regard to several recommendations that came out at the subcommittee is in their final recommendation, having FDA pursue developing educational materials. I would recommend that the recommendation should be -- have FDA work with industry and academia to develop educational materials, the reason being is the industry is a key stakeholder in this whole issue.

If you go back and you read the Preface of the Food Code, it says both the industry and the regulatory agencies have the responsibility for public health. We are the front-line workers. We can reach that audience a lot quicker, a lot more effectively, than regulatory agencies can. Make us part of the stakeholders and let us be your communicators.

One more issue I did want to bring up is the issue of the time constraints that was associated with the temperature requirements.

The state regulatory agencies, the local regulatory agencies, and the industry are looking toward the federal agencies, FDA, USDA, CDC, for sound science to ensure that the public health is protected. When guidelines, statutes and rules are pushed forward, that there is no supportive science, then what we end up with is non-uniform subjective oversight, both by the regulatory agencies and by the industry, and what that results in is inappropriate data being reported, conclusions being tied to foodborne outbreaks associated with in this situation Clostridium perfringens, where it may not be an issue.

An example. A lot of individuals have prior to this meeting come to the conclusion that anything less than a 140 degrees contributes to the foodborne illness involved in Bacillus cereus and Clostridium perfringens, where the data here came out and clearly indicated it is a gross abuse of temperature that leads to these illnesses.

When we went back and looked at the information from the CDC, from Washington State and New

York State, we were surprised that the information was not captured, but we were also surprised that the information that was available showed that it was gross temperature abuse, all the way up to a 110, 115 degrees, that contributed to foodborne illnesses involving these target organisms. It was not temperatures at a 130 degrees and above and that is our concern.

What we are looking for is the science to say yes, this is safe, but we're also looking for the science and applications that the industry can use and that we can take back to the state and local governments that they can apply as a regulatory oversight tool.

Thank you.

DR. WACHSMUTH: Thank you for your comments.

Anyone else? Public Comment? The microphone is open. Did you want to make any remarks, David? Okay.

(No response)

DR. WACHSMUTH: All right. Then I think we can move on to the Shelf-Life Issue, and we'll ask Bob to introduce that at this time. I think he has a PowerPoint, and you have some hard copies of that.

Bob?

Introduce Criteria for Shelf-Life Based on Safety and Full Committee Discussion

DR. BUCHANAN: Okay. If I can get this to work, here we go.

What I want to do basically is in the next few minutes take you through -- you should have received two documents related to this new request for a working group, one that is a -- that says Request for Scientific Parameters for Establishing Food Safety Use-by Dates for Refrigeration -- oh, they don't have it? Oh, good. Okay. Then I will introduce this, and you will be getting a formal charge. Okay. We will try to find what happened to the documents that you were supposed to have received.

But I want to go over briefly as a result of that the -- what we do have to date in terms of a general introduction, and then we'll take additional questions, I believe, after lunch. This is a chance just to get it started.

It is a new, and we put this in parenthesis, performance standard-type of working group because you will be developing what could be interpreted as a performance standard. The specific title of the

request that's coming to you is a Request for Requisite Scientific Parameters for Establishing Safety-Based Use-by Dates for Refrigerated Ready-to-Eat Foods.

What I want to do in the next few minutes is to give you a little background, pose some of the questions, and then talk about some of the parameters that we anticipate you're likely to consider but it certainly will not be an all-inclusive list.

The reason that we're here is that this came out largely, even though it's been a long matter of discussion, this came to us as a critical issue as we completed the Listeria monocytogenes Risk Assessment, which again I'd like to just take a sidetrack for a second and thank all of you that have been involved at multiple steps in the way of getting that document out, that we greatly appreciated it and used the input of the Advisory Committee, and it was one of those beneficial sources for us to be able to bounce off the assumptions and the data that we used and the approaches we took. It was an important part of our overall review process.

But anyway, the risk assessment, one of the things that the risk assessment emphasized to us was the importance of both the duration and temperature of refrigerated

storage in regard to the risk of Listeria monocytogenes infections via the food supply.

This, by extending the period of refrigerated storage as we've seen over the last years as our technologies have gotten better, that increases the potential for growth of psychrotrophic pathogenic bacteria, and in the case of the Listeria monocytogenes risk assessment, of course, was Listeria, but also we see issues like that with other potential psychrotrophic pathogens, like Clostridium botulinum.

So, as I've gone through this introduction, you will see a focus on Listeria, but please keep in mind the fact that we're interested in all psychrotrophic pathogenic organisms.

We also have gone through a discussion about "will extending the refrigerated storage period also increase the likelihood that the product will be exposed to transitory periods of abuse, temperatures that would rise slightly above those that are -- would prevent growth of the organisms of concern?"

This has been identified, and you were -- the Committee was certainly a thought of mine in establishing part of our Action Plan for Listeria monocytogenes that came out at the same time as the Draft Risk Assessment, and

I will, if you have not seen it, we can provide copies of both the Risk Assessment and the Listeria Action Plan, but an objectified, sub-objectified, and this is a direct quote from it.

"FDA and FSIS will seek the advice from a scientific advisory committee on the scientific basis for establishing a safety base use-by dates, use-by date labeling for refrigerated ready-to-eat foods."

You might note that I put these together late at night and haven't proofread them since.

So, let's talk a little bit about background. Currently, there are various types of date labels that are used on food products and just taking three examples that we've seen in the marketplace, and in fact, we've discussed here in the Committee at different points, we see “consume-by” date labeling. We see “best if purchased by” date label, “best if used by”, and there are a variety of other different modifications of these labels.

These labels, as far as we know, are almost -- are exclusively used to describe some product quality attribute and that's what they've really been the basis for their use. However, based on our focus groups to consumers and the discussions that we've had

with various other stakeholders, consumers interpret these labels as meaning “safe to consume until”, and so there's this significant disconnect between how the message that's coming across on these labels and how the consumer is viewing them.

Okay. And so, what we're looking for is your advice and assistance in developing a scientific framework for the establishment of not “quality-based” date labeling, but “safety-based” use-by date labels, and what we're looking for is to establish a working group that will deal with some of these issues and then present that for the full Committee, take advantage of the broad background of the full Committee and then provide that advice to both FDA and FSIS as we move forward in attempting to implement our Action Plan to see if safety-based date labels are reasonable and what we would have to do to approach them.

Now, in coming to you for advice, we have four specific questions that we're going to be asking your input on. These questions are: what are the scientific parameters that we need to consider in establishing safety-based use-by date labels for refrigerated ready-to-eat foods?

Two. Should safety-based use-by dates for

refrigerated ready-to-eat foods be established using mathematical modeling techniques? If so, what modeling approaches are best suited to the development of safety-based use-by date labels for refrigerated ready-to-eat foods?

Question Number 3 is: what data need to be acquired to scientifically validate and verify the adequacy of a proposed safety-based use-by date label for refrigerated ready-to-eat food? So, once you've decided what your date label's going to be, how do you determine if it really is that? You validate the label, and then also, how would someone subsequently actually verify that that date label that's on the label is actually the one that is appropriate?

Question 4 is: what effect do the multiple factors that influence the growth and survival of Listeria monocytogenes, i.e. strain differences, food matrices, production and distribution systems, consumer susceptibility, you can think of a variety of others, have on the establishment of safety-based use-by date labels for refrigerated ready-to-eat foods?

We know that the growth of Listeria monocytogenes, and I might note other psychrotrophs here, are influenced by a great number of factors. How do we and to what

extent should we deal with those factors in the development of the label?

Oh, and the fifth question: what impact would “safety use-by date labels” likely have on the control of other foodborne pathogens in ready-to-eat foods? And so, again, this is reminding you that while we anticipate that the primary focus of the working group will be on Listeria monocytogenes, we are also interested on what will be the impact of such a date label on both other psychrotrophic pathogens and also for mesophilic pathogens, such as Listeria monocytogenes or E.coli 0157.

The working group would have -- we're going to ask -- start the working group off with the following members. I will be chairing the working group and acting in part to get you in touch with the people that will be supporting your activities.

The list of these individuals on the working group are here listed on this slide, and we will be getting that formally to you in the documents that come out asking the questions. However, I would encourage and invite any of the other members of the Committee, since you're going to see this anyway at some point, if you have free time, and you want to be involved in some

of the working group meetings or if you have data that you think would be of interest or you have opinions, please don't wait until the full Committee meeting. We would love to have you sit in on the sessions and provide your insights as we go along, and again this is the long tradition of NACMCF that any member can sit in on any working group session, but this is the group that we're really going to be looking to to do the heavy lifting on this subject.

Now, we're also attempting to do this in accordance with our Action Plan in a timely manner, and this is an aggressive time line that we've put out for you and part of my job is to try and realize this time line. We're looking for a completion in October to November of 2002 for your recommendations to the Committee.

We anticipate that this will require two to three working group meetings between now and next September, so that we will be ready to make a presentation to the full Committee in or around October or November or whenever the full Committee meets during the Fall of that period.

We will be attempting to do as much of the work as possible by e-mail and by correspondence.

However, we feel that we're likely to have to have these face-to-face meetings in order to get through some of the thorny issues that are certain to arise in this complex subject.

FDA does plan to support the working group as much as we can to make your work, let you focus on the scientific issues. We will have two formal liaisons that will be working with the subgroup, acting in the role of getting the materials you need.

These are Dick Whiting and Andreas Keller, and they should be in the audience. Can I get you two to wave or stand up? They're there for us to use and not abuse too much but certainly use them to identify the things that you need.

We will provide shortly some initial thoughts in a document and some of the factors that we think that may have to be considered in the deliberations. We are completing a literature review of documents that we feel may be of interest to you in your deliberations, and we'll be providing those by mail to the working groups.

If there are specific technical experts that you feel would be beneficial to the deliberation of the working group, we would request that you identify them,

and we will see about getting them on board to help us or at least identifying the type of technical expertise you need, and we may be able to match our list of technical experts against your specific needs, and then the last one is just to indicate if you can think of anything else that will make these deliberations go more smoothly, allow you to get the science you need to bring to bear, please don't hesitate to either address those questions or needs to me or to the two FDA liaisons, and we'll try and get the help that you need.

Okay. We will be providing you a document that just went through some of the thought processes we had in coming up with this request and some of the areas that we think it's likely that you're going to have to consider in addressing this highly-complex scientific question, and I do want to reinforce, we understand fully that what we're asking you to take on in developing this framework is a highly-complex issue that involves a great number of factors, and so we're -- some of the things that we believe that you're going to have to be dealing with is the selection of the target organisms for which you base the date label around, the selection of the safety-based endpoint.

Traditionally, we talk about things like one-

log cycle of growth for a number of practical reasons. Identification and selection of the maximum practical shelf life has been a subject of great debate, and it's one that we think that you'll probably need to get some technical expertise in or at least some background information.

Do you develop a date label based on just the maximum shelf life on the date or do you assume, for example, that consumers will keep it a certain amount of time beyond the date label, and if so, how much -- how long is that? And so, we'll talk about some of the values that have been used typically by industry in developing, for example, quality attributes.

Differentiating foods that do and do not support growth is certainly an area that is of interest and will have a direct impact on whether or not you're going to be date labeling a product, and certainly one of the resources that we will be providing you is that FDA has had commissioned through IFT an evaluation of a system for looking at what is referred to as potentially hazardous foods, those that do and do not require refrigeration.

So, we'll be providing some of the background information we've acquired there, and I think that

there were a number of you actually that were involved in that process that are sitting around the table. So, you'll get to relook at your own work at some point.

We think that there's probably going to have to be a substantial amount of expertise available to modeling growth of pathogenic microorganisms and considering things like general versus product specific models, and we have a number of sources of expertise that we can draw upon there, and likewise, I know John has a whole research team that is working on that, and we've already been in contact with them about the possibility of assisting us.

Certainly, one of the issues we think that's going to come up in your deliberations is the impact of spoilage as a potential control measure, and there should be a discussion, we anticipate, on the relationship between spoilage and safety, and we're anticipating trying to get some information to you.

One of the issues that we would like you to consider in your deliberations is how do we deal with biological diversity in the development of these performance standards or criteria?

For example, do you deal with the most -- the fastest-growing pathogen or do we in some way look at

the diversity of the organism? The diversity of foods and the variance from food product to food product is certainly one that we're going to have to take a look at, and then when you start getting into issues related to spoilage, we anticipate looking at the diversity of microflora associated with any particular refrigerated food. May be a scientific issue that we'll have to address.

We also would ask you to think about during your deliberations, approaches for validating safety-based use-by date labels. How does someone not only propose to use a date label in conjunction with their food but actually be able to provide some kind of scientific rationale?

We also are interested in being able to develop approaches for verifying safety-based use-by labels and do note that I separate the two-process validation and verification, and you can go back to consideration of passive definitions, if you want, to distinguish the two, but one's up front and one, you test after you're implementing.

And then, we also would like you to consider some alternatives that are out there in coming up with them or ways of verifying through on a continual basis.

There have been a great deal of discussion about time-temperature indicators -- integrators. We've had comments and deliberated on time-temperature integrators in this Committee on at least three separate occasions and in fact have made recommendations about them, and so we will be asking you to -- the Committee to revisit those -- that technology.

Okay. I think that brings me to the conclusion of my presentation in terms of a brief introduction. We will be providing you with two documents. One will be a two-page charge to the working group and to the full Committee itself in terms of the issues, so that you have that document in front of you at all times, and we do encourage you, and I will be encouraging the chair, to go back and reread that on a continuing basis, so we don't lose the forest for the trees.

And then, again, we do provide in more detail some of our initial thoughts, and again these aren't all-inclusive. We're just, you know, throwing things out for you to consider, some of our initial thoughts on some of the issues that may come up.

I would say from a personal basis, I find

this an extremely challenging question to bring before the Committee. We are looking and you will note in this case, we have not provided you with a document ahead of time, other than just some general first thoughts on our part, and so we are looking for you to start this one on a whole cost basis and work to the principles, and we will be around, if you have ideas or concerns on how this would interface with the regulatory agencies.

We certainly, through the FDA liaisons, and they can get us some contact with the FSIS liaisons, certainly be willing to bring these people in to talk about, you know, the practicality of certain approaches, etc.

So, with that, I'll turn it back over to Kaye.

DR. WACHSMUTH: Got a little information on the documents. We'll be receiving all those at once in the mail.

DR. BUCHANAN: Okay.

DR. WACHSMUTH: This is certainly important to FSIS as well as FDA. They've both worked on the document. I think they're pretty thorough documents. They've had to clear general counsels and such, and I

think that's what taken so long, but you'll receive everything at once in the mail, and I guess, did you want to say anything about the charge or this is enough?

Okay. We'll talk about the strategy that Bob's outlined after lunch, as we said. So, we'll have an early break for lunch and come back at 1, when Mike Jahncke will begin the Report on Codex, and perhaps by the time that's over, we will have the document for Performance Standards, and we'll take another break to work, read that document and hopefully have that discussion this afternoon.

John?

DR. KVENBERG: Madam Chair, if we're about to break, could I just ask the Subcommittee on Blade-Tenderization to hang around for a few moments, and we'll see -- we were going to get together with Dr. Neill relative to those revisions.

DR. WACHSMUTH: Okay. Well, you should meet over in that far right corner.

DR. KVENBERG: Fine.

DR. WACHSMUTH: Anyone else have -- Bruce?

DR. TOMPKIN: Bruce Tompkin.

Considering the short window that's been

proposed for the refrigerated product labeling and so on, I didn't see in here in the plan that a summary or a listing of cases, outbreaks, attributed to refrigerated foods would be provided to help identify the foods that have been involved in foodborne illness through conventional refrigerated storage and so on, and so, I think it would be helpful if CDC were to be asked -- I keep going back to CDC because they have all the data, but if they could be asked to provide to the Committee a summary of that kind of information.

DR. WACHSMUTH: I know at one time, CDC had a nice packet of Listeria information.

DR. SWAMINATHAN: Thank you, Madam Chair.

Unfortunately, I will have to leave this afternoon. So, I just wanted to bring up a couple of things.

I think with this aggressive time line that Bob has put forth, it would be very useful for the Committee members to have these documents, the Risk Assessment, Listeria Risk Assessment, the Action Plan, and just to amplify on what Bruce was saying, I would like to see five key references or documents that Bob and others at FDA feel would be very useful to the Committee members, should be provided to the Committee

as quickly -- subcommittee as quickly as possible, so that we can get up to speed, and I would like to suggest that we should have our first meeting of the subcommittee as soon as possible to start deliberating and dissecting the issues and begin thinking about the issues.

It is a very complex issue, and it's going to take quite a bit of discussions to get the task done by Bob's deadline.

DR. WACHSMUTH: This is true. Just for a little historical value for people who retire, the first meeting of this Committee that I attended as a CDC representative in the '80s, this was the topic, and we discussed the integrators, and there was great debate. So, you have quite a challenge.

Did you want to add anything, Bob?

DR. BUCHANAN: Yeah. We're going to have to get ahold of your schedules, but we're anticipating early March for the first working group meeting, probably late April/early May for the second, and then the third some time around July.

We are going to attempt to be pretty aggressive about getting everybody together or as best we an. You should be receiving the literature review.

We actually took pity on you because we figured you didn't want to be carrying 40 pounds of reprints home with you, and you certainly didn't want to carry the Risk Assessment home.

So, we will, as much as possible, where we have electronic versions, we will attempt to put them on CD-ROM disk and send them to you that way. However, some of them, we -- scanning them in turns out to be more time and effort than just putting them in the mail. So, you should be receiving a fairly good-sized literature review. Again, we took pity on you, so that you didn't have to carry them back on the plane.

DR. WACHSMUTH: Bruce?

DR. TOMPKIN: This is going to be all refrigerated foods, is that correct? It's not just FDA foods? It's -- I know the agency -- FSIS has a lot of interest in it. So, it's across the board.

DR. WACHSMUTH: Yes. FDA is taking the lead in running the subcommittee, but it's very much an FSIS concern.

Was there a flag? Dane?

MR. BERNARD: Thanks.

Has this -- I don't have much memory of the past Committee activities on this particular topic, but

the question is, is there anything in the Committee archives that should be revised -- just brought up? Where did the Committee net out in previous discussions? Is there anything there that's informative, so that we don't replow old ground?

DR. WACHSMUTH: Okay. We'll take a look through the filing cabinets and see if we come up with anything. Also, any members who have memories or documents, that would be welcome.

Katie?

DR. SWANSON: Will the IFT potentially-hazardous foods document be made available? Because one of the considerations in there was the need for time-temperature control. It was focused primarily at shelf -- well, "shelf-stable products", products that could be held at room temperature, but some of the principles in that was related to matching time and temperature, and it might be useful for the Committee.

DR. BUCHANAN: We're already in contact with IFT to get it in an electronic format, so that you don't -- again don't have to lug around a fairly substantial document. As much as possible, we're going to put all these things on a limited number of CD-ROM disks and get them out to you.

DR. WACHSMUTH: Okay? And during the lunch, that will give the two subcommittees who reported out a chance to pull together the sentence or paragraph and maybe we can finalize that at lunch as well.

Okay? If there's nothing else, we'll take a break.

(Whereupon, at 11:44 a.m., the meeting was recessed, to reconvene this same day, Thursday, January 24th, 2002, at 1:00 p.m.)

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

1:08 p.m.

DR. WACHSMUTH: One reminder. Brenda is requesting your calendars, so we can plan the next meeting. If we do it soon enough, we might be able to get a nice hotel like this hotel again. So, either Brenda or Karen Thomas, when you have your calendar ready.

Okay. It looks like some people were busy over lunch. We have some new documents. But I think what we'll do is first apologize to anyone in the audience who was using the old schedule. We did have Bob Buchanan present the shelf-life proposal before lunch, and we did also say at that time, we would continue the discussion after lunch, and Bob's slides are available as a handout.

So, at this time, I'd like to open it again for first any comments from Committee members and then

any comments from the public since we went a little out of sequence. You must have been very clear, Bob.

Mike?

Introduce Criteria for Shelf-Life Based on Safety and Full Committee Discussion

DR. JAHNCKE: Michael Jahncke, Virginia Tech.

I have just one general comment. As the subcommittee gets together to focus on this issue, it is an interesting complex issue, and I know in the slides, it is alluded to, but I would just want to re-emphasize the many unique differences of different commodities and how they're handled and distributed.

There's one example, and I'm sure we've been doing some work with the smoked fish industry, and for instance, the smoked fish industry, when they process a product, many times they freeze that product, then they ship it out to the retailer or wholesaler and that wholesaler or retailer thaws the product out and then sells it. That adds another twist to, you know, a use by date on this, and when is the -- how do you establish it for that and some of the problems with that.

I'm sure there are other food product commodities that have their own unique twist to it.

DR. WACHSMUTH: Bob?

DR. BUCHANAN: Certainly, what we're looking for here, and it would be helpful to talk a little bit about our expectations, is that we're not looking for every possible commodity and the details of them to be articulated by the working group.

What we are looking for is some well-thought-out general principles and a framework around how to approach individual commodities and some of the key questions that need to be asked about their characteristics, about the way they're transported or stored, so that we can provide advice, both to ourselves and to others, about how to go out and develop a safety-based standard and be able to come out with the right answer in terms of the procedure they need to have.

MR. GARRETT: Madam Chair?

DR. WACHSMUTH: Spencer?

MR. GARRETT: Thank you. Is the mike on? I can't tell.

I certainly agree with what Bob Buchanan's indicated, and I would presume from your answer, Bob, then that perhaps what Dr. Jahncke has indicated would be one of the key questions relative to, you know,

fishery problems.

DR. BUCHANAN: Certainly, I think one of the things that, you know, I will be challenging the working group to during the process is to pick a couple of commodities and put those commodities aside, develop your principles, and then go try your framework out and see if you come up with -- see if the framework you've developed then allows you to answer or to pose and then answer all the correct questions for those commodities and that's a way of validating the framework you have, and so if you feel that there's certain seafood commodities that represent a unique challenge or one that we ought to bring up, I'd certainly encourage the working group to identify those.

DR. WACHSMUTH: Okay. Are there any -- oh.

DR. DONNELLY: Bob, I had a question from your presentation. It seemed like the focus of the Committee's work was going to be on products that had a sell-by date or some kind of labeling, yet when you look at the Listeria Risk Assessment, there are many products produced in retail food establishments, like deli salads or deli meats, that aren't going to be packaged with any sell-by or use-by date, and so there's kind of a dichotomy.

Are we intentionally going after manufactured foods that would have that sell-by date or is it more broadly inclusive?

DR. BUCHANAN: I certainly think that, you know, the principles that we come up with as a result of these deliberations will have an impact beyond just the specific question that we posed to you.

You need to start somewhere, and basically the questions that have been addressed to us deal with regulatory issues associated with labeling, and so the approach that we're going to take is deal with those and the knowledge that we gain will probably spill over into other areas.

DR. WACHSMUTH: Go ahead, Spencer.

MR. GARRETT: Thank you.

Just to point out that for some retail establishments that have central kitchens, in fact, do have sell-by dates or use-by dates on them.

DR. WACHSMUTH: And those places also purchase items that have sell-by dates.

Okay. Are there any public comments then before we move to the next agenda item?

(No response)

DR. WACHSMUTH: Okay. Good. Glad we didn't

mess anyone up by switching the times.

What I'd like to do now is ask Michael Jahncke to lead us through the Report from the Codex Subcommittee.

Codex Subcommittee Report and Full Committee Discussion

DR. JAHNCKE: Thank you, Madam Chair.

All of you should have the two documents in your original packet you were provided with the draft of the Codex Committee and Food Hygiene and also the charge to the subcommittee. So, that was in your documents.

This morning, you should have received the subcommittee's review on the Discussion Paper on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures and also a red-lined document of the Codex Committee on Food Hygiene.

We met -- our subcommittee met on Monday and also the last couple of days to finalize this. We were given instructions at our subcommittee meeting. Mike Weir, one of the U.S. delegation members of the U.S. Codex Group, met and gave us an overview of the purpose of this document, and we were given the instructions that what they wanted at this point was for the subcommittee and then followed by full discussions by

the entire Committee to give some guidance to this document, to give some suggestions to it.

It is a long way from being a final document. It's, as I believe, going into Step 3, and there's a long process in Codex from there. As we were told, what the U.S. delegation was looking for at this point is to provide -- to go over this document, provide suggestions and guidance of how it could be improved, where it could be changed, how it could be expanded, what could be added to it, subtracted to it, and they will take these suggestions over the next few months and rewrite this document.

This will be sent out to their draft country partners for further revisions, and then, in October, this will be brought up on Level 3 at the Codex Food Hygiene Meeting that will be held here in Washington in October.

So, with that in mind, keep in mind, also, for those of you that are not that familiar with Codex, there are some very unique terms that are specific to Codex that are found in the document. Our subcommittee, when we went through this, we had these discussions because there are some very specific terms to Codex that have very unique meanings.

As we went through this document, we were charged -- there were five questions that were presented to the subcommittee, and there were several parts to each of the five questions. As we went through the questions, we also realized that to really do justice to this, not only did we have to answer the questions, we had to make some changes and modifications to the document, basically some strikethroughs and some moving of sections, so it flowed a little bit better, and suggestions for how to better present the document, so it's a little more understandable.

So, we went through and did a red line on this, and what I'm going to do is walk us through our questions that we answered and then related to this document.

We noticed, and we recognized the document like this. Keep in mind, the purpose of a document like this that's going to be presented to, I think, in the Codex Food Hygiene Group, there's approximately a 162 countries, and these serve as general guidance documents to these countries, gives them something to develop and implement in their countries as general guidelines.

As we were looking at this document in the first read-through, we also were very cognizant of the fact that although HACCP is not explicitly specific in this document, it is mentioned right at the end of the document. There are HACCP-like terms scattered throughout this document, and with that, as we went through the questions, one of the first things as we did a general read-through this, we as a subcommittee realized that what would be helpful for this document is to have a scope or a purpose inserted at the front of the document, and we added some verbiage in there.

Again, we were instructed not to write this document but just to give some examples and guidelines, so the authors of the document can take this and redraft it. But we did feel that a scope section needs to be added to the front of it, and the scope needs to clearly address and differentiate between validation activities and verification activities and delineate differences between processing plant production procedures, such as thermal processes, chemical controls, which can be validated, versus employee behavior practices, good hygienic practices, which are difficult to validate but should be verified.

We felt that this document should in ways

elaborate and address food control measures that are under a company's direct control versus those, such as retail food service, consumer handling, storage, etc., that are beyond a company's direct control.

The reason we did this, because as we looked through the original document, in sections, there were some mixes and matches of different ideas. There were some things that were put in and proposed as validation activities, but as we reviewed it, they appeared to be more verification activities. So, we felt that in the beginning of the scope to put all of this into context would help future readers of this document be able to follow it and make it more useful.

We also recommended, since again this document is not based on HACCP, but there are a lot of HACCP-like statements and words that are in this document, and at the end of the document, there was four or five lines that did specifically address HACCP, and we felt that that needed to be moved into the scope, perhaps be expanded upon.

We also felt that what would be helpful in this document, at least as we looked at it from the subcommittee perspective, that a glossary of terms needed to be put up front. Now, there are definitions,

there are terms defined in this document on Pages 2 and the top part of 3. We felt that a glossary of terms, defining things, such as food hygiene, validation, verification, process variability, uncertainties, should be put right up front, right underneath the scope, again to help set the stage for the document and allow the reader to have a very good solid understanding of what they're going to be expecting as they go through this document. So, that was our overall thought process on this.

Then, as we looked up the questions, there were a series of five questions, and each of the questions had three parts. Some had two. On Question 1, the question, there were three parts to it. The Question 1 related or was specific to the sections in this Codex document. Question 1 directed the question to prerequisites to validation, which is located on Page 3 of the Codex document.

The reason I'm giving you that page is because if you page through this, unless you have a reference to what the question is relating, it's very difficult to follow. So, it relates to the prerequisites of validation, and the question was -- there were three prerequisites that were put into this

document, and the first question was, are the stated prerequisites necessary, and as a subcommittee, we decided yes, all three stated prerequisites are necessary but with some modifications, and if you take a look on Page 3, what we did on the first prerequisite was modify that statement to include the words "evaluate the reasonable likelihood of occurrence and the potential impact to the consumer."

So, that statement reads, "Identify specific hazards to be controlled, evaluate the reasonable likelihood of occurrence and the potential impact to the consumer. These hazards include microbial, chemical and/or physical hazards."

Then what we recommended was that the next two prerequisites be switched in order. It just flowed a little bit -- we thought it would flow a little bit better to have the identification of the food hygiene control measures followed by establishment of performance criteria for processes.

The second part of the Question 1 that we were asked, are there other prerequisites that are critical but have not been adequately identified? We as a subcommittee were not able to identify others. Now, you, as a full Committee, you may have some

additional suggestions, and in the discussion part of this, I would encourage all of you to provide some guidance on that.

Another part of the question was, do all these prerequisites have the same degree of importance, and looking at the three that were stated, the subcommittee decided no, that Number 1 was the most important because if you determine, as these activities are conducted, that there are no identified specific hazards to be controlled, then Numbers 2 and 3 don't apply.

Although we do indicate as a guidance that even if they don't apply, the general principles of food hygiene practices still apply, even if no specific hazard is identified, but we point out in here that those types of activities are very difficult to validate. You can verify those activities but not necessarily validate them. So, we pointed that out and that needs to be identified in the document. But we also indicate that if there are specific hazards, the control measures must be validated.

As we've paged through the document, the next part of Page 3 was not related to any of the questions, but we took a look at this, and there's a segment here

that talks about nature of control measures, and they've broken it up into three sections, Controlling the Initial Levels of a Hazard, Acquiring Documentation, Testing to Specifications.

On Page 4, we have a subheading on Preventing Unacceptable Increase of a Hazard, and Reducing the Level of the Hazard. We added in a fourth item that we felt they ought to include and consider, a subheading of Education and Training, and we recommend that the draft -- the people drafting this add some initial bullets recommending education and training for plant employees and management.

The next question that the subcommittee addressed relates to the Approaches to Validation on Page 4, and we were asked the question, have the scientific basis for the approaches to validations been adequately justified?

There were three items in there, and as we looked at these, again it gets back to, as I said earlier, in this document, there are items put in here that were alluded to being -- that you could validate. We were looking at some of these activities more being verification methodologies than validation methodologies.

Looking at the three statements, we determined that only as written, the Approach Number 1 is a scientifically-based validation activity. Numbers 2 and 3, which are located on Page 5, we have a strike-out on those. These are -- we recognize that the concepts in those two are important, but those are really verification measures and not validation procedures. But they can provide useful data for validation purposes.

So, we recommended that Items 2 and 3 remain part of the document but maybe put into an annex, to pull it out of here, so it's not confusing. This document's supposed to be dealing with validation. Pull that out of here, put it into an annex, expand upon it a bit, give some examples of how -- what they're looking -- how this can be done and how this can be used to support validation activities.

We were also -- another question was, are these approaches sufficient to promote validation of food hygiene control measures, and again we indicate that Number 1, yes, with some modifications.

If you look on Page 4, under Item 1, on the approaches, we did some minor editorial. We struck through peer-reviewed and felt that scientifically-

valid experimental trials were a little more clear. We also recommend that incorporated into that Item 1, that the data collected for that validation studies can come from other places besides experimental trials.

There are other sources. There's scientific literature that can be used. Government regulations or action levels that have to be observed. Equipment manufacturer specifications on their equipment.

We also feel that additional explanations need to be put in here to indicate that any control measures that are put in place and validations that are done are really plant-specific and need to be validated on a plant-by-plant basis and that it may even include doing some scale-up trials.

Question 3, we really answered Question 3. It was what elements should be further elaborated? We answered Question 3 as we addressed Question 2 and the response to Question 2, basically saying that Items 2 and 3 are important but really are verification measures. That needs to be moved into the annex or it needs to be further developed with some examples and also add additional information to Item 1 that's indicating there are other sources of data for the validation purposes.

Question Number 4, are the factors being considered in validation complete? That refers to on Page 5 the section which was previously labeled "Factors to Consider and Limitations of Validation". The question was, are factors to be considered in validation complete, and as our subcommittee looked at the document, we said no, that the information in this section needed to be revised and refer to this Codex document.

What we did with this, we had trouble understanding or trying to put a handle on what they meant by "factors". So, what we did, we struck that and suggested a new title being Limitations of Validation. We had a section, as you see, underneath there. There's an underlined area. Those words were at the end of this particular section. We felt that was important to move to the beginning of this to sort of lay the groundwork for this particular section.

As you can see, we went through and made some editorial suggestions and some wording suggestions for each of these sections. There are various subheadings in this particular area. In fact, this area probably -- this area took us the most time to sort through.

Our goal on this was to try and keep the

flavor of the document, and we may have gone through and struck out more than is necessary, but the people on the Codex Committee can certainly go back and reuse the words that are in there. So, we tried to be concise. We also tried to make sure that everything focused on validation.

The title of the Constancy of Control Measures, we did some strikethroughs, but the message we wanted to get across was the constancy of control measures varies by method. The greater the number of control measures that require validation, the greater the potential for variability in the validation process of the final product.

We changed -- turn over to Page 6. We did additional strike-throughs on all of these, some of this just for readability, again just trying to ensure that the new readers of this document pick up the main thrust in an easy way.

We did some strike-throughs, and we have the next section as Process Variability, and variability that occurs in each step of a food-processing operation and must be considered when conducting a validation study. Variability occurs in each step of the food-processing operation and must be considered when

conducting a validation activity or validation study.

There may be a few on here that should be struck through that weren't and that is just due to the operator of the Compare Software Program which is myself. As you go through, it's not a zero defect program, as Spencer's so found of saying, and the next section, they have Limitations.

We felt that -- again, we had a problem putting a handle around that, and plus the fact we changed the title of this section Limitations. So, we struck that and simply say “sampling plans and analytical test methods” and rewrote the sentence that was in there, we thought, was a little more clearer, indicating the reliability of analytical testing is directly related to the precision parameters of the analytical methodology used and the statistical sampling plans employed.

The next section, we did some strike-throughs, changed the subheading to being Necessary Extended Validation, trying to keep the flavor and again trying to focus on things that can be validated and that was our goal of the subcommittee, since this document is specific for validation.

The extended validation required would be a

function of how well the science is established and the parameters affecting the process are known. For procedures with a single control measure that are well-established and utilized, such as the pasteurization of milk, the process has become so standard, that approval of parameter changes can be given by consulting a time-temperature chart. Novel processes with multiple control measures, for example, potato salad, will require far greater resources for validation.

The next section that dealt with Maintenance of Control Measures, I'll just read through it. We did a lot of strike-through here. In certain cases, it may be important that control measures that lie beyond the responsibility of the producer or processor be validated. For example, cold chain distribution of ready-to-eat foods.

The key point in this regard is that the safety of the product is maintained. As noted above, adequate additional control measures may require the use of other safety margins and/or verification activities applied elsewhere in the food chain which are beyond the processor's control in order to provide consumer protection. These additional control measures should be validated where necessary.

The last or the next-to-last section of this was on Resource Constraints, basically indicating that validation activities are often resource-intensive, and areas as product sampling, analytical testing requires significant resources, particularly when applied in an appropriate statistical fashion. The extent to which activities can be undertaken will place limits on ability to validate food hygiene control measures.

Turning over to Page 7, we indicated that this section here, that wording there was moved to the beginning of that section. We felt that it set the tone for that a little bit better.

We could not -- another part of Question 4 was, are there additional factors that should be considered, and again the subcommittee could not identify any others, and part of that question was, do all the factors have the same degree of importance? The factors or limitations, as we suggested, are -- we felt were all interlinked, and it wasn't really possible to rank any of these limitations by degree of importance. All of these must be considered important, and our subcommittee could not separate any of them and/or rank them by priority.

The last question about this document was, is

the information that was presented in the original Codex document, when validation or revalidation is needed, sufficient and reasonable in relation to the goals of being protective of public health, fostering scientifically-based food safety systems and developing practical advice and validation or control measures.

We indicated yes, but again with modifications. The modifications we suggested, again for readability and easier understanding, this is on Page 7 of the document, we changed the title a little bit to add in to which validation/revalidation is needed, when is validation/revalidation required.

If you look down in the document, there's some subheadings. The original subheading was Level of Risk. We felt that level and severity of risk added -- was important to add in there.

The last paragraph, we separated out a little bit. It was all under Historical Experience. We kept that in and suggested the following wording. If little or no experience exists with respect to the control of a hazard, validation of control measures to control the hazard must be undertaken. Care is needed, however, to avoid assuming that a food production or processing system is safe based solely on historical experience.

Then, to bring out the fact that this is not only a section on validation but on times when it has to be -- when the system has to be revalidated, we opened -- we put a new subheading in of “Process Innovations”, using most of the words that were already in the document, indicating that the addition of new technology creates new systems. Minor changes may also result in a new system, multiple minor changes will certainly result in a new system and requires revalidation. Also, new data, such as new clinical information, new detection methodology, may indicate that the previously-used food hygiene control measures were less effective than previously thought, and require revalidation of the system.

Any processing, packaging, distribution or marketing innovations or scientific data indicating the emergence of new pathogens, etc., will require revalidation of the system.

The last segment of the original document was on “Focused Validation”, and we had as a subcommittee a difficult time trying to follow what the authors of the document meant to say in that section.

We recommended that that section requires a rewrite because as we read it, at least as some of us

read it, it seemed to imply to us that if resources are limited, validation is not necessary, and our subcommittee disagrees with that particular implication. I don't think that's what the authors meant but that's how it came across in the write-up.

If you turn over to Page 8, that's the section that did address HACCP specifically, HACCP Validation. That information, those four lines, were moved into the scope of the document, again to set the stage for what's going to be incorporated in this document.

With that, that's basically a walk-through of what we did. Again, keeping in mind, this document is a guidance document, and our charge was not to rewrite the document but to go through it, offer suggestions and guidelines, so the authors of this document can take the suggestions, use that to rewrite the document and keep it focused entirely in the area of validation, and anything that alludes to the verification, more important, moved out of the main text of the document into an annex, would -- certainly could be fully -- more fully developed.

And with that, Madam Chair, that's the Report of Codex Subcommittee.

DR. WACHSMUTH: Very nice, very thorough job.

As Mike said, I just re-emphasize, this will be -- there will be a lot of other inputs into this document before it becomes final. So, I don't know that we have to wordsmith to the nth degree, but certainly any concepts or other people have different ideas about the approach the subcommittee had?

Bill?

DR. SPERBER: Yeah. Mike, on the bottom of the second page of your notes, the alternative approaches to validation, --

DR. JAHNCKE: In the notes? Okay.

DR. SPERBER: -- you're talking there about additional sources of information that could be used for validation. The scientific trials regulations, etc.

DR. JAHNCKE: Hm-hmm.

DR. SPERBER: I don't see that that's been carried over into the document.

DR. JAHNCKE: I noticed that, too, just before this happened. I can -- I will --

DR. SPERBER: So, you're going to do that?

DR. JAHNCKE: -- move that over, yes.

DR. SPERBER: Good.

DR. JAHNCKE: I noticed that, also.

DR. WACHSMUTH: Spencer, and then Dane.

MR. GARRETT: Yeah. Thank you, ma'am.

I have about three very quick comments. One, this is a very important document that a lot of things are waiting on. For example, I attended last week the Executive Board of the ISSC, and I'm in charge of heading up the group that's putting together the validation procedures for post-harvest treatment of molluscan shellfish to reduce Vibrio vulnificus to non-detectable levels.

In that, in working with our colleagues in FDA, we intend to again eclectically cherry-pick out of here what, in terms of the laboratory validation procedures and other commonly-accepted and understood laboratory validation procedures are, relative to reducing pathogens to non-detectable levels.

So, again I can't emphasize this is a very important document, and there are other things even within Codex, I think, that are kind of waiting for this.

Secondly, and I know we're not supposed to rewrite the document, and I certainly applaud that. Secondly, though, I would think for our drafting

partners, these definitions are very important under the glossary of terms. So, I would suggest that we do in fact provide our drafting partners our own definitions first because I know how this works, and they very likely would carry through the document.

Then finally, the only other comment that I would have would be on Page 6, where you're talking about Limitations of Sampling Plans and Analytical Test Methodologies, I do think that you need to indicate in there that when sampling plans are used, those samplings should be not only stated but they also should -- their performance characteristics should also be included and referenced with the sampling plans, and you'll find that in other Codex documents, for example.

Thank you.

DR. WACHSMUTH: Okay. Dane?

MR. BERNARD: Thank you, Madam Chair.

Just as an overall comment, thanks, Mike. Good report, good job.

One of the things, though, that I think we should consider, and I apologize for not having had the time to read through this thoroughly, but as you note, there are many HACCP terms in here, and we should avoid using any language in here that modifies those HACCP

terms beyond what the Codex guidelines on HACCP already say.

Again, I don't know specifically, and I might even be incorrect here, but let's look at Page 3, Item 1, which you modified a bit. Basically, what we're talking about here is doing a hazard analysis. What you've talked about here are the elements of a hazard analysis, and I don't think we want to redo hazard analysis description in the document.

Maybe the best solution as you have modified on Page 1, you've moved the reference to HACCP up front, and to maybe further modify that paragraph where you've moved HACCP up front and reference the fact that the HACCP plan during its development includes a hazard analysis which should serve as the identification of those hazards needing validation and let it go at that. That references it back to the Codex HACCP document.

Any time we come across those HACCP terms that we need to address in the validation document, it should reference back to the HACCP guidance rather than elaborate further in this particular document, if that makes sense.

Also, on Page 5, you talked about limitations. We get into a discussion of uncertainties

and how they should be considered as we establish performance criteria. I'm not sure that is where this needs to be in the document.

Performance criteria should come well before this document. I think we should limit the document to a discussion of validation of identified hazards within a HACCP context and limit it to that scope.

Thanks.

DR. JAHNCKE: Thank you, Dane. Good points.

I mean, these are all things that, as we were looking at it, we also discussed and struggled with and tried to come to some type of a consensus about how to deal with it.

Thank you.

DR. WACHSMUTH: Okay. Bruce?

DR. TOMPKIN: Thank you. This is Bruce Tompkin.

On Page 2, this concept and definition of validation is important. However, I think that the last -- the bottom paragraph in particular deals with the ALOP, the FSO, and the performance criterion are important because they define what constitutes a validated process or process step and perhaps that should be highlighted or have its own section.

You've got to know where you're going or what must be -- you're trying to validate a process as being acceptable, but what is acceptable, whether it's in terms of achieving an ALOP or an FSO or performance criterion. I think that could be highlighted somehow.

I think that that whole idea of the FSO and the performance criterion from a Codex standpoint's going to have to evolve eventually.

On Page 4, there's actually 3 and 4. There are three factors influencing the level of a hazard. It's the initial number or whatever, and then how you can prevent an increase, and then how you can reduce it, and there are many ways that influence -- many factors that influence those three. They're the three basic ones, and yes, education and training is just one aspect that can influence the number or the presence of a hazard, but I think that that one should come out and be deleted.

I know it was inserted. I feel that the three alone are the basic core factors, and then on Page 5, this Item Number 2 up at the very top, Collection of Microbiological and all this data, and that was to be placed in an appendix or some place, an annex.

Actually, that information that's generated through surveys of in-plant processes determines the initial number, and you can't validate a process unless you actually understand the level of the hazard to begin with, and so I feel it should be an integral part of this document as a basic requirement for validation.

Let's see. I think that was it. Thanks.

DR. WACHSMUTH: Okay. Bob's next.

DR. BUCHANAN: First, I'd like to thank the subcommittee for addressing in such a timely manner this document and providing the detail that they did and also quickly learning Codexese and addressing the document in terms of the language that is used by the Codex Committee.

I also want to emphasize the importance of this review. Certainly because of the importance of this document, it's basically holding up several other projects in Codex.

We are -- while this is at Step 3, this is one of the documents that's considered for fast-tracking. So, it may actually go much quicker than one would normally think of a Codex document.

I would like to focus a couple of questions on this, so that the delegation can use it effectively

and understand your concerns. In particular, I'd like to turn to Page 5 and the follow-up question somewhat what Bruce had asked, and it had to do with the collection of microbiological, chemical and physical data; that is, basically you run a plant for awhile to determine what your in-plant process capabilities are, and this is normally what we would consider in process control a process capability study.

I also ask, in classifying these is verification attributes, did you keep in mind that typically, the arena we're playing with here is the introduction of food in international trade? So, particularly with the item, statistically-designed surveys, often what we will have is a historically-regional product that has been produced and consumed for a long time in one region of the world has now been introduced into international trade, and the countries in so doing and validating this process that makes this food and introduces it will draw on a long historical record of the safe use of this food.

In this current way, while it is actually verification data or data that's been acquired on products, it's being used in conjunction with a validation process that is introducing it from Country

A into Country B, and with that type of interpretation, would you still consider that that is a verification tool and not a validation tool?

DR. JAHNCKE: That helps a lot on helping to clarify the approach on this, because when we first looked at this, our first blush at this and discussions, for instance, if you read through on Item 2, talking about intermediate and finished product sampling and testing.

We looked at that as a way of verifying that the system was working properly and that was our interpretation, and 2 and 3, we felt, went together, and so we looked at it. Your explanation now, at least in my opinion, helps to put it in a little bit different context, but when we first looked at it cold, at least our read on it, maybe some of the examples and how it's worded in there need to be modified a bit to give -- to emphasize that, because as we read through it, it appeared to be that this was primarily verification activities, and we thought that on a validation document, it added confusion.

But I think with some additional verbiage and some changes, at least in my opinion, and certainly the rest of the subcommittee can chime in, probably would

be able to stay there with some additional explanation.

DR. WACHSMUTH: Does anyone want to address that specifically? Okay. John, and then Spencer, and then I'll get back to the -- I have a list of flags.

DR. LUCHANSKY: Yeah. Obviously we -- John Luchansky.

We struggled with that for quite awhile, and I think in terms of establishing a glossary, you know, might be a way of clearly delineating the concepts of verification, validation and -- but taken strictly in terms of what in my mind constitutes a validation versus a verification, without the luxury of having verbiage to elaborate and give specific examples, I think if the purpose of this document is on validation, again I would go with the more strict definition of that, and by that argument, this still in my mind seems to be verification, although helpful up front, like Bruce said, in the collection of that information. It all depends what the respective Codex Committee would view as their interpretation of validation.

DR. WACHSMUTH: Okay. Spencer, and then I think Bill, on this point as well.

MR. GARRETT: Thank you.

DR. WACHSMUTH: Okay.

MR. GARRETT: The last to Bob's comments and then the latter comment goes straight to the point that I was saying, that I think that in the glossary itself, we need to begin to put in our own definitions or explanations of what we mean by these terms.

When we're validating a thermal process or a process to reduce bacteria that has some physical dimensions and so forth, that's one thing, but when essentially you're trying to do a conformance assessment, and I like to use phrases like that, conformance assessment of a food control system, and there are certain auditing terms one might want to use or concepts, all of the concepts one might like to use.

So, a laboratory validation scenario is one thing, but then a conformance assessment-type verification or validation of a conformance assessment verification is something other. So, it's just something to think about because this is food and international trade.

Thank you.

DR. SPERBER: Yes. Bill Sperber.

In our subcommittee deliberations, I felt that we were trying to work with at least one hand tied behind our back because the scope of this document is

proposed guidelines for the validation of food hygiene control measures, and right there, we get into a problem with definitions between what food hygiene means to the rest of the world and what food safety control means in the United States, and we concluded on our subcommittee that food hygiene encompassed loosely what we would call HACCP and GMPs in the United States.

Where our hand got tied behind our back was that we were told at the outset that in this document, we really could not address HACCP for some political considerations with other countries, maybe it was lesser-developed countries, and we couldn't understand that because without being able to refer to HACCP and critical control points and critical limits, you really can't get into validation.

Almost everything that we validate in a food safety system are critical limits at a critical control point in a HACCP system. Almost everything we do with GMPs is really a verification-type activity, and those things can't be validated.

Employee practices, for example, personal hygiene, how do you validate the effectiveness of hand-washing, of wearing a clean uniform, of wearing a hairnet? Some of the activities mentioned in here.

Inspection activities. How do you validate those? Those in themselves are verification activities.

So, we, in our very limited time, only one day, we tried to push this document into the direction of including HACCP. This Committee itself is bedrock HACCP. We've been pushing that for over 12 years. So, I don't know how we can put forth an international document that is supposedly guidelines for validation of food hygiene control measures without addressing HACCP square on, particularly since Codex themselves have published a HACCP document in complete harmony with our own.

DR. WACHSMUTH: Okay. I think that this is dangerous, if you will, when any of the sponsoring agencies would bring a topic to the Advisory Committee. You're going to get their advice, and you're going to have to deal with that.

Katie's been up for quite awhile. Is it related to this, Katie?

DR. SWANSON: No, it's not related to this.

DR. WACHSMUTH: Okay. You want to address this, John?

DR. KVENBERG: Yes, thank you. John Kvenberg.

Yeah. My placard went up and down because Bill covered a point that I wanted to get into. I just would like to add a little bit to the remarks.

This is a tough thing to do, but basically in the context of the international arena, just to elaborate a little further to what Mike briefed us on, the drafting partners we've been dealing with, I think, are fully on board with the entire concept of HACCP. It's France. It was International Dairy Federation.

The concern is in the larger context of making the whole concept of validation move forward, the game seems to be, is to be able to get this concept moved forward and consensus agreed, so we were struggling with utilizing the terms under the context of conducting a hazard analysis, regardless if it's HACCP or not. That seemed to be the sensitivity.

So, that was at least driving some of us within the working group as we were trying to grope with making it HACCP but not calling it as such in order to aid acceptance of the document that was being drafted. Is that fair? That's basically what we were asked to do. So, that was said but not put into the actual charge.

Thank you.

DR. WACHSMUTH: Okay. Bob?

DR. BUCHANAN: Just to respond to all of you, really what we're looking for, the delegation's looking for is making sure that the science and the issues being addressed are appropriate. Don't worry about the political spin or the political limitations or how we have to get that through the Codex process. We'll take care of that and try and make sure that everything is there, but we're really looking here for the core science that's underlying the validation process.

So, again, Codex has a strong foundation in HACCP. It's a strong believer in HACCP, but on the other hand, we have issues associated with language and developing countries, and there are issues like this that we look for a consensus more than laying down a bright shiny line.

DR. WACHSMUTH: Okay. I think one thing that's important in the context of this meeting, though, is that all of the members would understand and agree with what the subcommittee did. So, if we could address that at the same time that you're commenting.

What I'm hearing right now is you can leave these comments the way they are, and the delegation can deal with harmonizing with the international

constraints, if everyone's in agreement with the approach.

Spencer?

MR. GARRETT: Thank you, Madam Chair.

Just two points very quickly. First of all, I agree with everything Bob said, and secondly, relative to what food hygiene means, you know, like comparing what we generally consider it to be in this country versus in the Codex lexicon, food hygiene in the Codex lexicon, as you know and many know, is far beyond just sanitation and so forth. It includes all, you know, food safety issues as well. So, there is a little bit of disparity of what we understand that to mean.

Thank you.

And my suggestion would be, quite frankly, I think that we've gotten quite a few very good comments on how to deal with this document and realizing the subcommittee only had one day, if the sponsoring agency could just take these -- leave the document as it is and take the referenced comments that have been made here this afternoon and incorporate them in their considerations on how the U.S. should modify the document, and I think that would certainly suffice.

DR. WACHSMUTH: Okay. I think that's a good suggestion. We just need to make sure that everyone's in agreement on the basics because this is not going to be a formal document that's going to go further in the process.

So, I'll get back to the order that I have the flags now. That'll be Katie.

DR. SWANSON: Okay. Thank you.

On Page Number 7, the section related to Historical Evidence, I certainly agree with your addition of the decision should not be safe based solely on historical experience. However, the strike-out that you have, I believe, went a little too far because you do need, as Bob pointed out, to consider historical evidence for certain products.

Many times, as scientists, we don't want to rely on that. We want to rely solely on data, but there are products out there that we ignore that have extensive historical experience, an example being Wonder Bread. There is really no need for extensive validation studies to document the safety of a product such as that, if you're not doing something drastically different to how it was handled in the past.

By the strike-outs that you have, you seem to

have removed everything in here that suggested that sometimes you don't need to do extensive validations.

DR. WACHSMUTH: Okay. Let's address that. Mike?

DR. JAHNCKE: I think you're right, and I think part of the strike-outs was due to the operation of the -- trying to get back to some of our words, back to some of the computer operations. I'd have to go back to look at some of our original notes on that.

I mean, in our discussions, we did recognize that prior history is a way -- can be -- is very useful, --

DR. SWANSON: Yes.

DR. JAHNCKE: -- and it was not our intent to strike all of that out.

DR. SWANSON: Okay.

DR. JAHNCKE: But we did want to emphasize that even if you have prior history, you still have to be -- that is still not foolproof, and you still have to be careful.

DR. SWANSON: Yes.

DR. JAHNCKE: But it was not our intent to completely strike out that. If that's how it appears, it's not our intent to completely strike out that

concept.

DR. SWANSON: Okay.

DR. WACHSMUTH: Okay. Anna?

DR. LAMMERDING: Thank you.

I just want to reiterate, also, that I agree totally with what Bruce Tompkin said, that I think part of validation is actually what happens in your own operation.

The second comment is to do with semantics. On Page 7, Level and Severity of Risk. These are really concepts that are embodied underneath the terminology of risk. Severity of human health impacts is a part of how you define risk, and the high potential for adverse health effect is a matter of -- the likelihood that something's going to happen, go wrong, and how bad is it going to be if it does go wrong?

So, that's only like the wording, and again it's within the Codex umbrella, and the third point I want to -- would like to make is the concepts under “Focused Validation”. I would disagree that's -- the way it's written, it implies that if resources are limited, validation is not necessary.

From the strike-out material, that's not the

impression I got. Rewording may be suitable, but I think it's a valid point to emphasize or reiterate that we really should be focusing on the important aspects of a process and somehow that could be brought into, instead of wasting time on trivial aspects, to underline the fact that we are concerned about important parts of the processing procedures.

DR. WACHSMUTH: Okay. Good. Dan?

DR. ENGELJOHN: Yes. I think there's a real need to provide -- for this document anyway to provide additional guidance on how to transfer scientific literature to validate a process, and I know you said you were going to add that on Page 4 under Number 1. It was something that didn't get added here, but in that section, halfway down the paragraph, in the sentence that begins, "For certain well-established processes", I would suggest that sentence should be struck.

The concept there is mentioned again on Page 6 under the Necessary Extent of Validation, and I think it goes to the issue of pasteurizing milk and using a single temperature. I think there's the potential that that sentence on Page 4 could in fact be misinterpreted, particularly by just using a

temperature and procedures for which this process is well established.

There may need to be a definition then for what well established is. I'm just looking at it as on a first read, it looks like a verification statement. You get back to Page 6, and it explains it further and why it's a validation, and I think it should be struck on this page because it's mentioned again.

DR. WACHSMUTH: Okay. Bruce, and then Dane.

DR. TOMPKIN: Yes. Well, validation is very important to us domestically as well as for the international community. So, this is the beginning perhaps of something that may be further developed for internal use, domestic use.

So, it's well that we do it right, but with regard to definitions, there has been, I understand, as this develops, we go forward with our recommendations. If the next version is going to include definitions, and as we revise it and then submit it, I would encourage that we go with current definitions that are either National Advisory Committee or Codex, preferably Codex, definitions, and that we not create new ones.

That's all I had to say about that.

DR. WACHSMUTH: As the person who's struggled

with the chair of the Hygiene Committee, I think you're absolutely right. Anywhere you've got a precedent that's already been accepted internationally, that would be, of course, your first choice, and then the work that this Committee has done publicly, I think, is a good second.

Bob?

DR. BUCHANAN: Yeah. Just for those of you that are not familiar with the Codex process, and I'd have to also rely on Kaye and Mike to validate the statement that I'm going to make or possibly verify it, is one of the traditions in putting together Codex documents is that you don't make up new definitions for words that are accepted on the international -- by the international community, and I do not believe that any of the words that are used in this document have not been defined before in Codex documents, and as such, we would typically not repeat them in these documents.

It would be accepted. You go. There's a glossary of terms that we use in Codex, and I believe that every one of these words has an official definition that we've used before.

Mike, can you verify -- verify would be the appropriate term.

DR. WEIR: For those who don't know me, I'm Mike Weir with FDA and the delegate to the Hygiene.

I think that's right, Bob, and also, I know we talked early on in the session, the first day, we talked about the International Code of General Practices in Food Hygiene, and it should be clear that we should do that and any other documents that can cross over to provide those definitions, it would be helpful to do that.

DR. WACHSMUTH: Okay. Dane?

MR. BERNARD: Thank you.

A couple of points have come up which kind of bring me back to my initial comment about limiting the scope of the document. We don't want to venture to redefine hazard analysis nor do we want to, I think, try to recreate some perception that we want to redo risk assessments or anything like that in here.

We need to limit or I would recommend that we stipulate to the U.S. delegation that we limit the scope of the document merely on how to validate rather than what it is we are to validate. I think we have to go with a presumption that the hazards have been identified either according to a hazard analysis, a risk assessment process or some other process already

defined within Codex. Just lead in with that, and then anywhere where we talk about severity and likelihood and those kind of things, we don't need to address in this document.

I think the document has done a good job of addressing the whole range of control procedures that may need to be validated, those that are personnel-based and all that. So, I think those are in here, and I think that should be the focus, and we need to limit the scope of the document right up front by saying that the hazards should be appropriately identified using already-accepted methodologies within the Codex framework and then go on with talking strictly about validation.

Thanks.

DR. WACHSMUTH: Okay. And part of my opening comment was that some of this will just be automatic. I don't think the Committee will allow some new definitions. There's a fallback that some of this will just be automatically corrected, harmonized, if you will, with Codex language.

Are you still up, Dan? Oh, I'm sorry. I think the best thing or the thing that I would like to do now is ask Bob or even Mike, if he wants to come to

the microphone, and if you have enough to work with the delegation. Is this enough in this discussion?

DR. BUCHANAN: Well, as head of the U.S. delegation and also in expressing the appreciation also not of just the U.S. delegation but also all of our drafting partners around the world, and there are a number of countries that are involved in this, I want to express my sincere thanks for a job well done. The points you've brought out, the areas that you need for further explanation or modification are going to be very useful to us.

I think you're right on target in terms of providing us the kinds of feedback that we need and the kind of scientific credentialing that we need to fast track this document and to get it forward, and I'd like to thank you for a job well done.

We'll be working with your working group to get the last of the information out from you and get it in a formal transmittal form that we can then say that we've been to the Advisory Committee, but I think that you've done a marvelous job, particularly considering the tight time constraints that we put on you in terms of time to sit and cogitate on that, but it was exactly what we needed, and so I again would like to end by

thanking you for a job well done on this.

DR. WACHSMUTH: I'll take my prerogative as the chair. I've noticed this was a fairly energized discussion. I don't know if you want to wait until after the international document has run its course, but it seems that there's a need for a domestic document, and the willingness of this group to work on it is pretty obvious.

Mike?

DR. JAHNCKE: Madam Chair, just as point of procedure. What would -- what is the next step for the subcommittee on this particular document? Bob mentioned, you know, resubmission. I just want to get a clarification of what is expected of our subcommittee.

DR. WACHSMUTH: I'll let Bob do that, because this was done at the request of the delegation. That's why I asked if he had what he needed.

Go ahead.

DR. BUCHANAN: What I would like to see is basically the two documents that you provided us, which is the strike-out version with your recommended changes, and then the accompanying text that provides the rationale for those recommended changes and your

evaluation of the original four questions that we posed to you in that text would be fine.

So, basically, I'd say that you -- other than going possibly back and rethinking about some of the discussion that took place around this room, you're 99 percent of the way there in terms of what we need, and then I'd just like to see a cover letter from the Committee transmitting it from the Committee to the U.S. delegation, so that we can use this as part of our documentation.

Mike, is there something that I've forgot?

DR. WEIR: No, not really. I just wanted to mention that this will be going out to our drafting partners after revision for review and then to country comment considered by the Committee at its next session, and we are at an early stage on this document.

I suspect that there will be continued and probably significant effort, and it might be possible or might be likely that we may want to come back and to help clarify. So, we may wish to leave that door open, if possible.

DR. WACHSMUTH: Okay. On a procedural note, you'll have to help with this a little bit, I think. It may be more appropriate to have a letter from the

subcommittee and then the whole Committee won't have to endorse the letter and the document here. The subcommittee could refer to the discussion that occurred at Plenary. That might keep us from getting into some red tape.

DR. BUCHANAN: Whichever is the way that you would like to proceed. However, I would like to request that considering that we have to get country comment, this out to country comments shortly, we'd like to get it within the next four weeks.

DR. WACHSMUTH: That's why I think we go with the subcommittee. Okay. Okay.

Thank you.

That brings us to what would be a break, but I think instead of a break at this moment, we now have the document from the Subcommittee on Performance Standards, and maybe Spencer could take some time to introduce it at this point.

How would you like to proceed? It's up to you.

Report of the Subcommittee on Microbiological Performance Standards for Meat and Poultry

MR. GARRETT: Thank you, Madam Chair.

What I would like to do, and I can do this in

less than probably five minutes as opposed to last time, and just merely indicate within the document, the nature of the changes that we made essentially were they occurred, and for some of them, what the reasons were, if they're not intuitive. Okay.

DR. WACHSMUTH: One thing. When I referred to break, I think what we want is a working break, so that everybody has a chance to read. We won't talk about this until we have a chance to read it.

MR. GARRETT: Yeah. Exactly right.

The document was passed out. I believe it was during when we came back at 1:00. It's entitled "Chairman's Interim Progress Report: Microbiological Standards for Raw Meat and Poultry Subcommittee", dated January 24th, 2002. It was either passed out or it was on -- I know there are extra copies on the table in the foyer.

One of the first changes is we changed the title. So, we no longer -- we now have MPSRMPS. So, I said that's probably the Royal Mounted Police Service, but what we tried to do was to make the document just a little bit more frankly easier to read. We made some formatting changes at the request of the comments that we had just so we could kind of lay out some general

principles and then go to some recommendations.

Let me say that in our formatting, we're not -- and there will be some editorial -- there should be some further editorial things here, but they're nothing of substance at all, just formatting.

But I think we pointed out just some editorial changes on the first page indicating some of its on former standards to verify the adequacy of HACCP systems and that was one of the comments we took from the Committee.

We also, on the first page, we indicated we put a heading called "Background", so all of this on the first page, if you would, is background. You'll notice that we did not change the absence of Page 2. There's still no Page 2. Oh, I'm sorry. I better get my glasses on. Just don't let her pick up that water glass.

On the top of Page 2, we added an introductory paragraph, if you would, before the four key questions, showing the duality of what's actually being asked us, and it says, "The subcommittee recognized the dual nature of FSIS's charge, which seeks advice from both the general scientific principles for the establishment of performance

standards, and the application of those principles to the possible modification to the current Salmonella performance standards for ground meat and poultry. As a means of addressing both needs, the agency representatives and the subcommittee agreed to modify and change the order of the questions" and so forth, and it just goes on.

Right after the fourth question, we also put another little transitional -- remember, we said we would put in transitional bridge paragraphs. This is one of those. "The scope of this document is limited to the consideration of enteric pathogens that are transmitted by direct or oral/fecal route. The principles for the development of performance standards for other pathogens may require consideration of different factors and as such were not considered in the current deliberations."

On Page 3, again at the top, we indicated what prioritization was to address the issues as we move forward. We also put in another sidebar statement called "Findings". That would probably be changed to something else, but we're trying to just -- it's a formatting issue. We're just trying to -- we didn't want to harshly just jump in to what we're doing.

Also, on Page 3, under Question 1, we just put in general principles for developing risk assessment that's been previously described and then putting in the references which some of those still have to be inserted, and we indicated that these should be consulted prior to any evaluation of risk.

We also put in on Page 3 the next paragraph and indicating that -- and again, this is taking into consideration the deliberations that we had, and we had some of this wording in there.

"The performance standards should be a means of achieving public health goals. As such, the stringency of the performance standards should be proportional to the stated public health goal. This implies that a possible link to the performance standard and public health through a consideration of risk. This consideration" -- and this is what I want to highlight, the next sentence.

"This consideration of risk may not necessitate in all situations an in-depth quantitative risk assessment which requires extensive resources and time, particularly if it would unnecessarily delay timely protection of public health."

DR. WACHSMUTH: Spencer? Can I interrupt one

second?

MR. GARRETT: Hm-hmm.

DR. WACHSMUTH: I think because we didn't have references for the documents up in the beginning, it might be good to explain that those are more or less risk management documents that talk about when you need a full risk assessment and when an evaluation of risk will do. You can't tell that, I guess, because we're a little vague in references, but it's not how to do risk assessment.

MR. GARRETT: Right.

DR. WACHSMUTH: It's the management part.

MR. GARRETT: Okay.

DR. WACHSMUTH: Sorry.

MR. GARRETT: With that understanding.

On Page 4, at the top of Page 4, in the second line, we changed risk assessment to risk evaluation, just to, if you would, still pick up on that theme.

On Page 5, there was a change on Page 5 as it deals with the information needed to complete exposure assessments, and we talked about different kinetic modeling and activation and so forth, but we added a new one, which is, on the top of Page 5, the last

bullet, "Consumer preference for consuming undercooked ground beef should be considered in the equation."

We understand that can be estimated, and there have been some publications on that.

In terms of Question 2, Question 2 represents -- on first appearance, it might represent a total rewrite, but it's certainly not. What we did is we moved paragraphs around, again trying to be faithful to laying out what in fact are general principles and what are considerations and then what are some recommendations, and so everything that we have under the General Principles, it appeared in the old documents.

On Page 7, again here, we laid out recommendations, and we did add some new sentences. Under Recommendation Number 1, we put in an example for what that data need was. For example, test for E.coli and include the data in the existing Salmonella Verification Program.

On the third recommendation that begins with "Analytical Tools", we had to rewrite that a little bit because getting regression analysis out was a little bit more difficult than we realized, but we got regression analysis out.

We also, if you recall, in our last document that we reviewed, Question 2 had three parts, A, B and C. After we took into consideration the comment to be absolutely certain that you're not confounding the use of an indicator organism with an index organism, we found that we probably were. So, now we only have two parts. This new document reflects that.

Also, on Page 7, the last paragraph, taking into consideration the comment that was made that our previous efforts seemed still to be focused rather toward just bacteriological performance standards, that there might be others, there might be dead cells, there might be genetic material, we may want to use PCR and so forth.

We added another -- that paragraph that says, "It should be determined where a broader microbial indicator can be used as a performance standard. Examples of such broad microbial indicators would include the class of microorganisms, microbial metabolite, or a specific genetic sequence."

However, I would say personally, though, since we have added that, I do think we need to add the cautionary statement that Bob Buchanan indicated, that when you're looking at something that has received a

bacteriocidal treatment, and you're doing a quantitative standard, then you have to be very careful how you use that type of technology because it would in fact bias your standard.

We also added a new recommendation. This new recommendation appears on the top of Page 5. Excuse me. It's not -- now, I better get my glasses. That new recommendation states, "The data from the Salmonella Performance Standard Program from the year 2001 should be made public so as to provide guidance to industry in order that commercial operations may assess their process control relative to the industry."

In terms of Question 3, we did nothing because we elected to -- since we're not quite through with Question 3 yet, we didn't -- in the short time that we had to address issues, we just let that stay as it were.

On Page 10, under Definitions, the definition of a quantifiable variable has been slightly changed at the request of a member, and this definition now states, "Quantifiable Variable. A variable that has a numerical value, e.g., CFU per gram."

Again in terms of Page 11, there was just some minor reformatting but nothing of particular

interest. All of this dealt with -- again, Page 4 -- rather, Question 4, rather, was reordered with some of the paragraphs and so forth, but there was not substantial changes made.

As a matter of fact, the goal in Paragraph 4 -- Question 4, rather, was to make it more readable. That was our charge, and so we made it more readable, if I've got my glasses.

But we did, on the penultimate next-to-last paragraph on Page 12, we did change that just a little bit to make it more readable, which says, "Once selected, performance standard and acceptance criteria will determine the sampling plans and corresponding inherent probabilities in concluding that a process is nonconforming when it actually is (Type 1 error), and a process is conforming when it actually is not (Type 2 error)."

And Madam Chairman, that's pretty much it. Now, it's my understanding that what you'd like to do is take a working break and actually take sufficient time to read the document, so we can discuss it.

DR. WACHSMUTH: That's correct. I think there's absolutely no need to tell you how important the document is to the agency. So, what I believe our

goal should be is to endorse as much of the document as the Committee is comfortable with, so we can again get that advice back to the agency. So, if it's one question or two questions or three or four, we'll go with -- I don't think we have to send the complete document. I would hate to hold it up, particularly since 3 looks like we're going to have to do some more work.

I had something else, but it's gone. How long do you think it will take everyone to read this? More than a half an hour? Bruce?

DR. TOMPKIN: Go ahead and settle that first, please. I have another question.

DR. WACHSMUTH: Okay. It's a half an hour, unless someone would like more.

(No response)

DR. WACHSMUTH: Okay. Bruce?

DR. TOMPKIN: Okay. Specific to the goal, it would be the intent then for us as a full Committee during Plenary tomorrow, probably, to vote or reach a consensus on this written document, is that correct?

DR. WACHSMUTH: That's correct. Or today, if you can do it today.

DR. TOMPKIN: Okay.

DR. WACHSMUTH: That would be difficult but maybe not.

DR. TOMPKIN: Okay.

DR. WACHSMUTH: Have to take a read and see whether it is possible.

We do have the luxury of one more night, if there's small things that we can change that would make it acceptable to the Committee. That's one reason it would be nice to get as far as we can today.

Spencer?

MR. GARRETT: I was just scratching my head.

DR. WACHSMUTH: Your flag's up.

MR. GARRETT: Oh.

DR. WACHSMUTH: Okay. About -- I've got 25 till 3. So, about five after.

(Whereupon, a recess was taken.)

DR. WACHSMUTH: Before I turn things over to Spencer, we do have the revised comments on the hot-holding. It's a one sheet, and I hope that maybe this evening, you'll get something on the non-intact issue, and we'll just discuss those at the very beginning of the day tomorrow before we get back to performance standards, assuming we'll be talking about performance standards. That way, we just can concentrate on the

performance standards now.

The other thing, one of the members pointed out to me that some people have had urgent business and have had to leave, and I see quite a few empty chairs. I know that applies to Swami, I think to Peggy and Dave Theno.

What I need to know is will there be others who will not be here tomorrow? Could you let me know? Show of hands?

(Show of hands)

DR. WACHSMUTH: You'll be gone tomorrow? And you'll be gone tomorrow?

DR. DOWNES: Frances Downes.

DR. WACHSMUTH: Yeah. I know. What we need to do is count how many people we have here. 16. I think that does it. I have to check with our exec sec. I think it's over 50 percent, we have a quorum. So, I didn't count. I just counted the seats. It looks like 16 to me. Did anybody else count?

DR. TOMPKIN: It looks good.

DR. WACHSMUTH: Okay. Well, we should have a quorum tomorrow.

John?

DR. KVENBERG: Thank you, Madam Chair.

Just a point of order. We -- relative to the blade-tenderized document that we've been feverishly working on, we had an initial draft that went through subcommittee review. It's currently being redrafted, and the hope is that we will have a document this evening before we close for comment.

I guess for those people who'd like to provide written comments, even if they're leaving, we can consider them tomorrow. It looks like we will have a revised draft for completion tomorrow for you. We may have to go through the edited text in full Committee. So, it will take a little bit of time to do it, but if people are leaving, I guess, I don't know what your preference would be. We will have a draft tonight for review.

Thank you.

DR. WACHSMUTH: Okay. Good. I saw someone on the way to work on that document. So, make sure you check the table, if you don't have anything in front of you. Hopefully, it'll be in front of you before we adjourn, and everybody can look at it tonight, and we'll discuss that and the hot-hold in the morning.

I think those should both be pretty straightforward.

Now, I'll turn it over to Spencer. Spencer, I'm going to give you the chair and just keep an eye to your right because these guys seem to be hard to see once you get going.

MR. GARRETT: Thank you, Madam Chair.

Where we are is to review the document and hopefully adopt it, but it would be my intent to, as I did yesterday, go question-by-question-by question or section-by-section.

The Background section appears on Page 1 and 2 and part of 3, down to Question 1, including Findings.

DR. HABTEMARIAM: I have a question on Page 2.

MR. GARRETT: Okay. You'll have to -- I didn't hear you. I'm sorry.

DR. HABTEMARIAM: On Page 2, --

MR. GARRETT: Okay.

DR. HABTEMARIAM: -- the questions. That middle paragraph about the scope, that first sentence, that reads "transmitted via direct oral/fecal route". I think it would be useful to rewrite that better.

If I understand it, we're talking about basically enteric pathogenic organisms that are

foodborne and lead to foodborne human illness. The wording that we're using, "transmitted direct oral/fecal route". I mean, there should be a better way of doing that.

MR. GARRETT: Okay. So, as I understand it, what you would suggest doing then in the first line would be between enteric and pathogens, put foodborne?

DR. HABTEMARIAM: Yes, foodborne, because you say that in the line.

MR. GARRETT: Surely.

DR. HABTEMARIAM: Enteric pathogens are foodborne and lead to human illness. That basically is what we're saying. I think it would be best if we say it that way.

MR. GARRETT: Okay. Are there any other comments on that? I see two others. Skip Seward and -- Skip, first, I think, then Dr. Tompkin.

DR. TOMPKIN: There are many pathogens, enteric pathogens that are fecal/oral. Viral, for example. I think it really should be transmitted by raw meat and poultry, by raw meat or poultry. That's really the scope of this document.

DR. HABTEMARIAM: And lead to human illness.

DR. TOMPKIN: That's fine.

MR. GARRETT: Okay. So, as I understand the way it would read then, it would be, "The scope of this document is limited to the consideration of enteric foodborne pathogens" -- excuse me -- "that are transmitted by foodborne pathogens" -- excuse me -- no, no. Do it again, Bruce.

"The scope of this document is limited to the consideration of enteric foodborne pathogens that are transmitted by raw meat or poultry and lead to human illness."

DR. WACHSMUTH: I'll give you a hint from the few years I've chaired. At this point, when we're trying to get a document through, the most constructive comment you could make is a suggested change. If something's wrong, try to raise your flag with the answer, and it'll move it a little faster.

MR. GARRETT: Bob?

DR. BUCHANAN: My apologies for being out of the room for a minute, but could I hear the rationale on why these general principles would be limited to meat and poultry?

MR. GARRETT: Bruce?

DR. TOMPKIN: I think in this case, the title of the document is, of course, Raw Meat and Poultry,

and these principles, while we're trying to make them very broad in some cases, they are really directed toward raw meat or poultry, and in responding to the questions, that's what we're really dealing with. The questions have to do with raw meat and poultry.

MR. GARRETT: And it is the title of the document. Is there exception? Skip? Well, it's still on -- is it on this or on another -- okay.

Okay. Without exception then, change is so noted.

DR. BUCHANAN: I do have to respond. I think you've restricted the use of some good general principles when it's unnecessary to restrict them.

MR. GARRETT: It's not my intent or I don't think -- well, we'll find out when we get there, but I don't think the general principles are going to be removed.

DR. WACHSMUTH: I think what the answer to that would be, that the Committee can use these principles in other ways. Right now, this group is simply responding to the charge from FSIS.

There will be other -- if you've noticed on your -- some of your paperwork, there are performance standards that will be done for seafood, and there's a

C for Other, and it may be possible for the people who chair those subcommittees to take as much as they can from this document. In that way, you sort of generalize them.

MR. GARRETT: And in addition to that, there are other questions that need to be answered, even by this Committee, that can still use these general principles in their deliberations of those issues.

Bill Sperber?

DR. SPERBER: Yes. On this statement that we're just considering on scope, wouldn't we have to include in there indicator organisms? Scope of the document? In close consideration of enteric foodborne pathogens and indicator organisms? Because as it is right now, you're only going to be considering pathogens for your performance standards.

MR. GARRETT: Well, I presume then, you'd have to say and indicator and index organisms. Without exception? Katie?

DR. TOMPKIN: Spencer?

DR. SWANSON: How about --

MR. GARRETT: Wait a minute. Katie?

DR. SWANSON: -- "the scope of this document, it is limited to consideration of performance standards

for raw meat and poultry products"? Would that fix it? No? Okay. Never mind.

DR. TOMPKIN: Microbiological performance standards.

MR. GARRETT: David?

DR. ACHESON: If we add Bill's suggestion, some of those indicators don't lead to human illness. So, that's not going to connect. So, we have to take that out.

DR. TOMPKIN: We could strike the human illness because that's redundant.

DR. ACHESON: Yeah. We could.

MR. GARRETT: Bob?

DR. BUCHANAN: Since you define indicator organism later on, I don't think it's particularly necessary to include it, but it doesn't hurt.

MR. GARRETT: Would you also have index? We define that in the same place. But then, what do we do about the -- you say, "The scope of this document is limited to the consideration of foodborne pathogens and indicator and index organisms."

DR. BUCHANAN: Could you repeat that again, Spencer?

MR. GARRETT: "The scope of this document is

limited to the consideration of enteric foodborne pathogens and indicator and index organisms that are transmitted by raw meat and poultry." Okay?

"The scope of this document is limited to the consideration of enteric foodborne pathogens, indicator and index organisms transmitted by raw meat and poultry."

Skip?

DR. SEWARD: Okay. Just two small points here. On the very next sentence, "The principles for the development of performance standards for other pathogens", I would add in there after that, "or as measures of process control may require consideration of different factors and as such were not considered in the current deliberation."

MR. GARRETT: Did you say "as measures for process control or for measure"?

DR. SEWARD: As.

MR. GARRETT: Any comment on that?

DR. BUCHANAN: Spencer?

MR. GARRETT: Bob?

DR. BUCHANAN: I'm not sure that that's necessary, but what is necessary is based on the changes you've made to the first sentence, you must

indicate that the development of performance standards for other pathogens or other commodities.

MR. GARRETT: Yeah. That's fine.

DR. SEWARD: So, for other pathogens or other commodities as measures of performance controls.

MR. GARRETT: No. Just and other commodities.

DR. SEWARD: And other commodities.

MR. GARRETT: Or other commodities. Anything else on Page 2?

DR. SEWARD: Just in the next paragraph, the third line from the bottom there, I think that question should read, "what special considerations need to be attended to in the development of quantitative baseline data, and for the use of quantitative baseline data for the development".

So, in other words, move "quantitative" down to before "baseline data", and then replace the word "development" after that with the word "use". That correlates to the question that's actually in the document, if you go to that question.

MR. GARRETT: Okay. So, --

DR. SEWARD: It's just not written quite as it is later in the document.

MR. GARRETT: Yes, thank you. I see the transposition of the word "quantitative" before "baseline".

DR. SEWARD: Yeah. And then, after that, where it says "and for the development", that development should be the word "use", U-S-E.

MR. GARRETT: Okay. And that accurately reflects the question.

DR. SEWARD: Right.

MR. GARRETT: Anything else on Page 2?

(No response)

MR. GARRETT: Anything on Page 3 relative to the top of the page, including the Findings?

DR. SWANSON: Spencer?

MR. GARRETT: Katie?

DR. SWANSON: I believe we missed one that we discussed last evening. That was the sentence immediately after Findings. I believe we had inserted "The subcommittee believes that performance standards that meet the principles as outlined in this document are valuable and useful tools."

MR. GARRETT: That is correct. "The subcommittee believes that performance standards that meet the principles as outlined in this document are

valuable and useful tools." That change would carry over later on in the document, if I'm not mistaken.

Without exception? That brings us to Question 1, and Question 1 is -- runs from 3 to 5. Are there any changes or recommendations for Question 1 that appear on Page 3 of the document?

Bruce? Bruce, then Dane. Bruce first.

DR. TOMPKIN: In the paragraph beginning with "Performance standards", I think it's helpful to reinsert or to insert again the definition of a performance standard at this point. This is where we're really introducing the principles.

So, I'd suggest "Performance standards define the expected level of control at one or more steps in the process", just as we stated up above, and then Performance continuing, "Performance standards can be used as one means of achieving public health goals."

The next sentence, I don't quite understand. Just reading it, I don't remember what it was to convey, and I don't know that we need to retain it.

MR. GARRETT: Before you do that, let me make absolutely certain that I've captured your first two interventions because, quite frankly, I haven't.

DR. TOMPKIN: Okay.

MR. GARRETT: So, would you --

DR. TOMPKIN: In the process of capturing, I don't know that it'll get captured.

MR. GARRETT: No.

DR. TOMPKIN: Uncaptured.

MR. GARRETT: No, no. I understand.

DR. TOMPKIN: "Performance standards define the expected level of control at one or more steps in a process."

MR. GARRETT: And that has already been stated?

DR. TOMPKIN: Right under the Findings, that sentence --

MR. GARRETT: Hm-hmm.

DR. TOMPKIN: -- that we just tinkered with, --

MR. GARRETT: Right.

DR. TOMPKIN: -- we've made that statement there, where we endorsed the use of performance standards.

MR. GARRETT: Right.

DR. TOMPKIN: Now, we want to build it into these principles.

MR. GARRETT: Okay. And where would you

insert that?

DR. TOMPKIN: It would be in the second paragraph, where it says, "Performance standards should be". I would suggest we change that to read, "Performance standards define the expected level of control at one or more steps in a process."

MR. GARRETT: Okay.

DR. TOMPKIN: And then, the next sentence could be, "Performance standards can be used as" --

MR. GARRETT: Wait, wait. Slow down. "Performance standards can be used as one" --

DR. TOMPKIN: "Means".

MR. GARRETT: -- "means".

DR. TOMPKIN: Just the rest of the sentence. "One means of achieving public health goals."

MR. GARRETT: Okay. Dane, Skip.

MR. BERNARD: Thank you, Chairman.

I would agree with Bruce's questioning of the next sentence. However, if it is to remain, and I don't know exactly what it is intended to say, but if it is to remain, I would suggest that we modify it by adding after the words "public health goal", the following insert, "and the impact of the standard on meeting the goal."

By adding that insert, then it more or less flows into the document by linking to our later reference to estimates of risk.

MR. GARRETT: Dane, I'm sorry. Would you repeat that again?

MR. BERNARD: I would be more than happy to. Where it says, "The stated public health goal" add the following "and the impact of the standard on meeting the goal."

I think Bruce's question should really be discussed. What does the sentence -- what was it intended to mean and should it remain?

MR. GARRETT: So, then you're agreeing with Bruce's insert, and you're just merely indicating after "goal" and "the input of the standard in meeting the goal"?

MR. BERNARD: And "the impact of the standard in meeting the goal".

MR. GARRETT: Impact, rather.

MR. BERNARD: Right.

MR. GARRETT: Is there any exception to that?

DR. SEWARD: Yes.

MR. GARRETT: I'm coming down the table. The next person down here.

DR. SEWARD: It's me. I don't have a comment on this particular --

MR. GARRETT: Okay. Just stand by. Is your comment -- the next comment relative to this? Okay. If you'll just hold it? You have an exception to this?

DR. BUCHANAN: Yes, I do, and I'm open to wording that changes the words but not the meaning of the sentence. I'll give you an analogy. The goal may be to send a rocket to the moon, but if the rocket you design only gets as far as Chicago, your likelihood of ever reaching your goal is not proportional to what you've given in terms of the technology.

Conversely, if you have a goal, and you develop a performance standard so that you meet that goal, you better make sure that they're in some way proportional, that the degree of stringency, how high of a bar you set, gets you to that goal.

So, there has to be some kind of link between the two and that's what that sentence is there to imply. I find that, Dane, your addition, the wording you have added when you take a look at what a public health goal is, that is by definition an impact on public health.

So, I don't see that -- your added phrase is

just repeating what a public health goal is.

MR. GARRETT: Let me make an observation from the chair before I recognize Dane.

DR. WACHSMUTH: Yes, this is one of the cases where members should address the chair.

MR. GARRETT: Well, no, please. Let me make -- well, you know, one way or the other now.

The point simply is, I do want to make an observation, that oftentimes, you know, words get confusing, like what is a goal versus what is an objective, and I tend to agree with Bob.

If you take a look at some of the goals that are out there, goals often are, you know, not achievable. You progress to a goal, but you may not achieve the goal. However, you may achieve certain objectives along the goal, in trying to reach the goal. Some would argue that's what food safety objectives are all about, but I'm not going there.

So, I was just thinking that one fix might be, Dane, for you to consider, and I understand, I think, what your issue is, I would just say should be the means of achieving public health goals to reduce foodborne illness. So, you at least indicate what the public health goal is.

Rather, if you're trying to make a direct link, quantitative linkage, between the performance standard itself and a measurable quantitative reduction of the goal, that's something else again.

MR. BERNARD: At the top of Page 4, we're talking about estimating the likely impact of performance standards for Salmonella in ground products would have on public health. That to me is the key.

Does the standard itself move toward the goal? Just by stating one has a goal doesn't necessarily make the performance standard the appropriate measure. So, I found the sentence incomplete as written without something that links it to what we're saying at the top of Page 4, and that's what I was trying to accomplish with that.

MR. GARRETT: And that's why I indicated to reduce foodborne illness as opposed to. So, clearly the goal is to reduce foodborne illness without attempting to quantitate that reduction.

Then I think that would -- I think, I may be wrong certainly, that that would take care of your concern and Bob's concern.

DR. BUCHANAN: I don't think we're in fundamental disagreement, maybe just a little

misunderstanding, but I found the sentence just not to link with what we said later on in the paragraph.

MR. GARRETT: Katie?

DR. SWANSON: I'm a little confused, and I'd like to seek clarification.

Dane, are you talking about adding your phrase at the end of the first sentence in the paragraph as typed or the second sentence?

MR. BERNARD: The second.

DR. SWANSON: The second sentence. Okay. And I think Spencer was looking at the first. Okay.

MR. GARRETT: You're absolutely correct. But we still have a disagreement.

DR. SWANSON: But at least we're on the right sentence, same sentence.

MR. GARRETT: I'll take that. I'll accept that. But my insertion could work under either one.

DR. SWANSON: Exactly.

MR. BERNARD: May I address my colleague directly?

MR. GARRETT: Sure, sure.

MR. BERNARD: What do we mean by "stringency of the standard"?

DR. BUCHANAN: "Stringency" is a term that

describes how -- to what degree you need to do something. "Stringency" is basically an accepted term when you -- in describing performance standards, and it's been defined and articulated in a number of documents, both within Codex, within ICMS, etc., and again, it describes the degree to which a process must operate.

The more stringent that you have a process or a standard, the higher level of control is needed. It is just -- we've had discussions, for example, here in the Committee. Passive is a -- passive as an example is a concept. It's a process. It does not inherently articulate the degree to which a hazard must be controlled.

When you establish that through establishing a critical limit, you establish the stringency of the system. Likewise, when you're talking about a performance standard for any process, which can have any of a variety of degrees of control, there has to be a decision about how -- to what degree you're going to control the hazard. That defines the stringency, and in turn, that should be proportional to the goal that you're trying to achieve.

If you're trying to achieve -- again, if

you're trying to achieve such that you can only have one carcass in a million has Salmonella, but you have a performance standard that the end result of it is, is that one in a hundred could have Salmonella, the performance standard and your goal are not the same. They don't lead you to the same conclusion. You will never get there from here.

Conversely, and again using an image, you don't swat a fly with an atomic bomb. So, you wouldn't want to do it. There's some point -- the whole point of this is to match up the degree of control with the standard, so that you're reaching the endpoint that you're trying to get to.

MR. GARRETT: Dane, with that understanding, do you still wish to add that?

MR. BERNARD: I -- well, Bob and I can wrestle this later, I guess, if the rest of the Committee thinks I'm off base. We can take it up later, but I still would like to see -- it seems we're getting the cart before the horse without linking the risk management tool, the performance standard, with having some effect against the public health goal before we make the statement regarding the stringency, and we don't do that until the top of Page 4, unless we

modify that slightly to provide that linkage.

DR. BUCHANAN: And I think what you have to do is look at the three top sentences of that paragraph in line with the question in the section that's being asked. Those three sentences in that paragraph say that the purpose of performing a -- the purpose of establishing a performance standard is to reach a public health goal. That performance standard should be related to the public health goal, and that, finally, that implies you have some means of relating the two.

If you have no means of relating the public health goal to the performance standards, and we presume in this question that you're going to do it through some risk analysis process that is some evaluation of the risk, that's how you do it. So, you have -- here's where you want to get to, and in order to do that, you're going to have to be able to articulate in some way the risk that's associated with this process, and it's really just a lead-in on why you have to have some evaluation of risk.

MR. GARRETT: Well, again, I would ask the two of you, my proposed fix, to reduce foodborne illness, does that at least begin to make the bridge

over to the top of the next page?

MR. BERNARD: I agree.

MR. GARRETT: You agree? Good. Katie? On this issue, we have agreement.

DR. SWANSON: On this -- okay. Maybe I'll just -- I think I have a potential fix.

MR. GARRETT: I think we got one.

DR. SWANSON: Okay. Then I'll stop. Never mind.

MR. GARRETT: But, hey, never let it be said that I needed the power of the mike. I mean, I think if we want to hear it, let's hear it.

DR. SWANSON: Want to try it? Okay. If we delete the sentence that contains "stringency" and the second one and say "consideration of risk is needed to link the performance standard to the stated public health goal", would that get us where we need to be?

MR. GARRETT: In my judgment, if you're just merely to indicate what I'd indicated, to reduce foodborne illness and leave those sentences and then turn the page, you'll have it.

DR. SWANSON: Okay. Never mind.

MR. GARRETT: Provided Dane agrees.

DR. TOMPKIN: I'd like to see it fixed, but

keeping everyone here as we fix it, I think it might be best to proceed through the rest of the document and see whether or not we had -- what -- how this process is going to go, whether there are going to be more of these issues.

I don't have very many, and it may be possible that we could just come up with a sentence or two that addresses this thing. I have a proposal. Katie's proposed one. Dane. I think it's possible to retain the concept that stringency should be related to risk. That's really all we're saying, isn't it? And it can flow very well with some slight changes.

MR. GARRETT: Okay. We'll hold this in abeyance then, this paragraph, and proceed --

DR. SWANSON: To Skip.

MR. GARRETT: You had your flag up down there. I can't -- okay.

DR. HABTEMARIAM: It was just a small point about consistency, you know. On Page 3, we refer to risk assessment, to risk analysis, risk evaluation and so on. Just for consistency, the question was risk assessment. Otherwise, we have to define terms. That was the point I wanted to make.

MR. GARRETT: Yeah. Well, I think that --

DR. WACHSMUTH: Is it a low battery?

MR. GARRETT: Doesn't appear to be. The question that he was pointing out is that there seems to be a use of different phrases or words. Risk assessment, risk evaluation and so forth, and he's wondering about the need for consistency, and I believe as we go through the document, that was done by design. As you go through the document, we talk about the formal risk assessments taking a structured process and a long period of time and consuming a lot of resources, and oftentimes you don't need to do that but you can just do a risk evaluation, and I think that is actually -- the -- okay. Between -- yeah. Okay. Fine.

Any more on Page 3?

DR. SEWARD: Yes. I have two points. One, the second-to-the-last paragraph, the last word, I would recommend changing "performance" to "public health risk", to tie it in to what's stated in the first sentence. Unless there was a reason to use the word "performance" there, I -- second-to-the-last paragraph, last word. "Overall public health risk".

MR. GARRETT: Wondered about that myself. Without exception. Your second one then.

DR. SEWARD: Last sentence on the page,

before -- and I would say, "and thus influence the decision to", and I would insert, "adopt a performance standard, or accept one performance standard over another." Very last sentence. Seems to me we'd want to have the option there to use the risk assessment to decide if you wanted to adopt one in the first place as well as accept one over the other.

MR. GARRETT: So, agreed then. "The key factors that contribute to risk and thus influence the decision to adopt a performance standard or accept one performance standard over another."

Seeing no exceptions. Skip, you've got to put your gizmo down. Thanks.

Moving on to Page 4 then. I didn't mean it.

DR. SEWARD: Just a point of clarification, I think, on the -- let's see. 1-2-3 -- fourth paragraph that starts off "FSIS", in the second-to-the-last line, where it says, "Such information would have additional value in determining initial loads of Salmonella in raw meat and can be used in validation of thermal processing."

I'm not quite sure if that raw meat, for example, refers to trimmings, for example, or ground beef, but if it refers to trimmings, then I would

suggest that we have a comma after "meat" and put in the phrase "taking into account the temperature profile during distribution, and can be used in validation of thermal processing", because I think it ties in to what we were trying to say before, but I'm not sure what that's referring to in terms of raw meat.

DR. TOMPKIN: I have an idea why it says that.

MR. GARRETT: Oh, good. Bruce?

DR. TOMPKIN: If I may, Mr. Chairman?

Basically, we are required to validate our processes to eliminate Salmonella, Listeria and so on, in beef and the other products that we cook and process, and that's really what that was all about.

Knowing the initial level of pathogens, such as Salmonella, in the raw material will enable establishments to validate the thermal processes. That's how it would be used.

MR. GARRETT: With that understanding, Skip, is your insertion still relevant?

DR. SEWARD: No. If everyone else is okay with it, then so am I with that.

MR. GARRETT: Any exception?

(No response)

MR. GARRETT: Okay. Dane?

MR. BERNARD: Thank you, Spencer.

On Page 4, the fourth paragraph, the one that begins with "as the dose response appears to be adequately addressed", 1-2-3-4, the fifth line, which begins with "substituting", small edits here.

The word "the" is not correct there because we said up in the previous paragraph there really is no prevalence data, and we're recommending that it be collected or estimated. So, I'm moving to strike the word "the" from prevalence data, and there's the word "and prevalence data" and insert the following "the" --

MR. GARRETT: Hold on. I just scratched out the "the". Where's the "the"? Where's the next one?

MR. BERNARD: It's in the same sentence.

MR. GARRETT: Yeah. Okay.

MR. BERNARD: Read on. "Prevalence data and the above-referenced dose response relationship", and then in the next paragraph, "FSIS can develop prevalence data" instead of "such data".

MR. GARRETT: Any more?

MR. BERNARD: Yes. The third bullet at the bottom of the page, "method and degree of cooking", you had added the bullet which to me those were pretty much

the same, "consumer preference". We could modify the third bullet there by adding "including consideration of consumer preference for undercooked ground beef" and avoid some redundancy.

Thank you.

MR. GARRETT: Are there any objections to -- I take it there's none to the first two. How about combining Bullet 3 and Bullet -- whatever it is, the last one?

(No response)

MR. GARRETT: Seeing none. So agreed. "Method and degree of cooking and consumer preference for consuming" -- oh, "including consumer" -- yeah.

MR. BERNARD: Consideration of consumer preference.

MR. GARRETT: Very well. Any more on Page -- this is obviously hot stuff we're talking about here. Okay.

John?

DR. LUCHANSKY: It's okay if I'm on Page 5? The first paragraph, the second sentence. "Specific agencies must be determined by a risk assessment team", and can only be determined by a risk assessment team or can others look at a risk assessment determine what the

modifications are?

MR. GARRETT: Yeah. No, no. I don't think it's the -- I'd like to hear some other --

DR. LUCHANSKY: I think it's sufficient to say that if anyone can identify the date of it, that's of value. So, I don't know if we just strike risk assessment team. It doesn't change the meaning necessarily.

MR. GARRETT: Well, I think the issue -- maybe it should be turned around just a little bit. This relates to risk assessment. So, maybe it should say, "A risk assessment team must consider the data." I mean, this whole question relates to risk assessment, does it not?

DR. LUCHANSKY: I was actually trying to make a different point.

MR. GARRETT: Oh, okay.

DR. LUCHANSKY: I agree with what you just said, but I think as long as anybody can critique the data and identify the need, then that's of value. It might not necessarily be somebody on a risk assessment team that identified that void.

MR. GARRETT: Could you get by with --

DR. LUCHANSKY: If you'd like a team to then

assess whether or not that's a valid answer, that's fine.

MR. GARRETT: Bob? Could you say it just by a risk assessment team or others? Could it be that simple?

DR. BUCHANAN: I'm trying to remember what we're talking about here in terms of specific data needs. I think this refers to specific data needs for the risk assessment.

DR. LUCHANSKY: I took it to mean we were.

DR. BUCHANAN: I'm not sure that that's what was implied. I think it was you need the input from the risk assessment team in terms of what data they need to do the risk assessment and that needs to be communicated to the risk managers.

DR. LUCHANSKY: It doesn't read that way to me. It would be nice to clarify it.

MR. GARRETT: Then, could you say -- let me just suggest perhaps it to be determined by the risk assessment team for the conduct of the risk assessment? Would that help?

DR. LUCHANSKY: What's wrong with saying basically any valid comments would be considered and specific needs must be determined? It's saying must be

determined by a risk assessment team. It doesn't have to be. If there are --

MR. GARRETT: No, no. That's fine. I just want you to state what you want in there. I mean, could it be just or others?

DR. LUCHANSKY: I guess I lost the question. Whose job is it to identify the needs of a risk assessment or likewise after one is done, whose job is it to determine what research needs there might be to interpret the question?

MR. GARRETT: I would think the risk assessment team would determine their data needs, but I think anybody can critique whatever output a risk assessment team and the validity of how it was conducted.

Okay. I see Tsegaye down there.

DR. HABTEMARIAM: Yeah. Tsegaye. I think it's an important point. May I suggest a multidisciplinary team? I know risk assessment issues could be identified by the team, but the problem often is that the biology lacks, and I think we need to make that point. I don't know for sure what this refers to, but generally, risk assessment in the absence of good biology is empty and those defeat each other, but

that's what I suggest. You know, we believe very strongly in multidisciplinary team.

MR. GARRETT: David?

DR. ACHESON: I was just going to suggest that we put in specific dates and needs for the risk assessment must be determined by a multi-disciplinary team.

DR. LAMMERDING: That's pretty close to what I was going to suggest, but the most important aspect is we're not telling people how to do risk assessment. We have guidance documents for that or the conduct, but the most important concept here is in relation to the specific risk management question posed. So, whoever's posing the questions or whoever's determining the data needs, it's not that.

MR. GARRETT: John, does that -- is that better?

DR. LUCHANSKY: Would the suggestion of a multidisciplinary team satiate the concerns that were just expressed?

DR. LAMMERDING: We can just say specific data needs will be further determined for the risk assessment in relation to the specific risk management question posed. So, we're not saying that.

DR. LUCHANSKY: Yeah. I guess that's -- I like that.

MR. GARRETT: Okay. Would you repeat that?

DR. LAMMERDING: "Specific data needs will be further determined for the risk assessment in relation to the specific risk management questions posed." I'd suggest ending there.

MR. GARRETT: So, you're getting rid of "posed by the requester"? So, "specific data needs will be further determined for the risk assessment team in relation to the specific risk management questions"?

DR. LAMMERDING: I'd suggest delete "team" and just for the risk assessment.

MR. GARRETT: For the risk assessment. I'm sorry.

Is there any exception?

DR. BUCHANAN: I guess, are we losing the concept? Again, I could live without this sentence all together. But I think that the -- let's look at what this sentence says. You have a bunch of risk managers. They want a risk assessment done to answer certain questions. Someone's got to tell them what data is needed in order to answer the questions that they want answered.

You could have as many people in the world have their own opinion on what is needed, but somebody's got to -- basically, the guy that's got to do the risk assessment has got to come back and say if you want the risk assessment done, here is the data and this is the questions you want me to answer. Here's the kind of information I have to have. If you don't give me that information, I'm going to make it up.

MR. GARRETT: You know, a fix to that might be --

MR. BERNARD: Is that how this works?

MR. GARRETT: Now, we know. Now, we know. Rumors to that effect for years. But, you know, Anna, you changed the word "must" to "will", but I think to pick up on what Bob's saying, specific data needs must be determined.

DR. LUCHANSKY: I guess my point originally when I saw the word "must", that that's very exclusionary to me, and I guess the most important part is that it is done in relation to what was being asked for. That's the most important, but as much as people can get.

MR. GARRETT: Well, how about must be determined by a multidisciplinary team?

DR. LUCHANSKY: I think the specific data needs should be determined in relation to the what the requester was asking for. So, it's just what's being asked for.

DR. SWANSON: So, strike "by the risk assessment team" and everybody's happy?

MR. GARRETT: Right. That's a Codex solution.

Any more on Page 5?

(No response)

MR. GARRETT: Then I'll go to Page 6, which brings us to Question 2, and since we've agreed with -- the Committee's agreed to Question 1, except for the second paragraph on Page 3 that needs more to be said.

Any questions on Page 6 relative to Question 2? Dane, then Katie, then Bruce, then Bob.

MR. BERNARD: Thank you.

Anybody else? This is my time. Let me go with the easy one first. Down at Number 5, under General Principles, there's some redundancy there with the list above. "Both pathogens must have similar survival and growth characteristics and a shared common source." Those are bullets in the above list, and the first sentence, we said, has to be consistent with the

list. So, I would move to strike that.

MR. GARRETT: So, you're striking the --

MR. BERNARD: "Both pathogens must have similar survival and growth characteristics and a shared common source" because they're in the list, and we referenced the list.

MR. GARRETT: Hm-hmm. Without exception? Very well.

DR. BUCHANAN: Could you repeat that, the intervention, please?

MR. BERNARD: The second sentence in Number 5, which reads, "Both pathogens must have similar survival and growth characteristics and a shared common source" is redundant because both of those points are covered in the list, and the first sentence references the list. Merely editorial.

I also question the last sentence in Number 5, which says, "The control measures for one pathogen should be effective for the second pathogen", as to why that needs to be -- although I can see that it depends on where you take the sample. If you're using interventions before you take the sample, I guess that's appropriate. So, I withdraw my intervention.

MR. GARRETT: Any more?

MR. BERNARD: Point Number 1, under General Principles, first sentence, I'm wondering in the context of this document, if the sentence that reads, "Micro Performance Standards are intended to effectuate a decrease in the presence of enteric pathogens in food commodities, herein meat and poultry products". I read that as qualified sufficiently for this document, but I just wanted to call everybody's attention to it and see if that was -- if we had narrowed it enough for the document by that parenthetical insert.

MR. GARRETT: Since you've brought that particular one up, this is just an editorial thing, would it not be better to get rid of the "herein" and just say "in meat and poultry products", "meat and poultry product commodities" or something like that? Raw. Oh, yeah. My God. Raw. Right. And then we can -- but it's just an old English thing with me.

Okay. Any comments specifically on what he's recommended? It's without exception, we move the "both pathogens". I didn't see any, and then "enteric pathogens in raw meat and poultry product commodities" or just "raw meat and poultry"? We have a different lexicon in seafood than you do in products and processed products and production is different for us

than what you folks say.

So, would it be correct to say "in raw meat and poultry", include "raw meat and poultry commodities"? I take it as a carcass is a commodity, is it not? Raw meat and poultry's fine, period. Okay. Thank you.

Any exception to that? Okay.

MR. BERNARD: I have one more.

MR. GARRETT: Oh, one more? Okay.

MR. BERNARD: Back to Number 5 again, and the first sentence, "One pathogen can be used as an indicator of the", should we insert state or, because that is how we have defined indicator, or should we remove -- we can go either way because we've defined it above.

MR. GARRETT: I would think we should say state or, yeah. It bears repeating. Is that it for you?

Okay. Then I think that Katie was next. Weren't you next on the Hit Parade?

DR. SWANSON: In Number 3, there are other types of performance standards enumerating microorganisms. So, I would suggest a fix that says "Microbiological Performance Standards", insert "that

involve detection and enumeration of a microorganism", then delete "that can be classified as an indicator or an index organism."

MR. GARRETT: Any exception to that? I mean, if there's an exception to it, you know, wave your flags since everybody's got so many flags. Okay. Honestly, I think I said Bruce next. I honestly forgot the order. I'll start writing.

DR. TOMPKIN: Number 2.

MR. GARRETT: Number 2?

DR. TOMPKIN: Just insert "raw" before "meat and poultry" at the end of the sentence.

MR. GARRETT: Without exception? Then, Bob?

DR. BUCHANAN: Just two comments, Spencer.

One, in the last two lines on Page 6, the -- should be changed to read "detection of the number of E.coli in ground product may not be" delete "is", "as direct a measure for the concentration of fecal contamination", and then I'm not sure whether an "as" should be inserted after that, "as on" or whether "on" is the correct form. It seems to be awkward there.

And then, going back to one comment --

MR. GARRETT: I think "as" would be the correct.

DR. BUCHANAN: "As".

MR. GARRETT: Hm-hmm.

DR. BUCHANAN: And then, going back to Number 5 above that, I tended to agree with Dane, that I'm not sure that the last sentence in that Number 5 is necessary nor even valid.

MR. GARRETT: I thought it was deleted. Well, there's a tremendous difference between the two.

DR. BUCHANAN: One, I don't think it's necessary because that concept is in the five criteria previously stated, just as we eliminated this sentence before.

Two, it may not be that it has to be identical to all control measures. It is just the critical control measure that you're using it to indicate. So, for example, on-the-farm control measures that would reduce E.coli may not impact Campylobacter but in-plant control measures would likely -- that you did to E.coli would control Campylobacter. So, it can't be so universal in the way it's worded.

MR. GARRETT: Yeah. Without exception, to drop the sentence? Seeing none.

Any more comments on Page 6?

DR. TOMPKIN: Yeah. I want to go back to Number 3. It's the change that Katie made. I don't think that makes sense the way the change was made because it indicates that the performance standard is an indicator of an index, unless I've got it in the wrong place.

Did you have Microbiological Performance Standards that involve detection and enumeration of a microorganism can be classified as an indicator?

DR. SWANSON: That's what I had.

DR. TOMPKIN: That doesn't make sense.

DR. LAMMERDING: Could you read what you have, please?

DR. SWANSON: That's exactly what I had. The issue that I had with this is it suggests as written that Microbiological Performance Standards always involve detection and/or enumeration of the microorganism and that isn't necessarily true.

MR. GARRETT: Let me read this, Katie, and just follow the -- "Microbiological Performance Standards that involve the detection and/or enumeration of a microorganism can be classified as an indicator or index organism." I think there's some disconnect.

DR. SWANSON: There is some.

DR. LAMMERDING: Could you give us an example, Katie?

DR. SWANSON: Well, I'm thinking of a five-log reduction, that's not detection or enumeration. You're looking at a temperature differential and that is a performance standard. It is neither an index nor an indicator.

MR. GARRETT: The five-log reduction of a bacteria is an enumeration.

DR. SWANSON: It's not an index or an indicator.

MR. GARRETT: Is a five-log reduction a state or a condition?

DR. LUCHANSKY: Mr. Chairman, you may just leave the sentence the way it is and just insert "may" or "can" before "involve", so it's not all exclusive or inclusive. Would that be a fix then?

MR. GARRETT: Katie, would that be acceptable?

DR. SWANSON: Yeah.

MR. GARRETT: So, just say "may be classified".

DR. LUCHANSKY: "Microbiological Performance Standards may involve" --

MR. GARRETT: Oh, "may involve".

DR. SWANSON: Yes, that works.

DR. WACHSMUTH: Could I interrupt, Spencer, for a second?

When the members speak, the raising the flag, remember part of that was so that we could make sure on record we knew who was talking. So, just sort of give your name if it's appropriate, if you don't raise the flag, so we can make sure we know who said what.

Thanks.

MR. GARRETT: Okay. If I could take the chairperson's prerogative, Katie, would you now read the sentence to us, please?

DR. SWANSON: This is Katie Swanson.

"Microbiological Performance Standards may involve the detection and/or enumeration of a microorganism that can be classified as an indicator or an index organism."

MR. GARRETT: Thank you.

Any more comments on Page 6?

(No response)

MR. GARRETT: Moving to Page 7. Dan?

DR. ENGELJOHN: This is Engeljohn.

In the paragraph beginning "Salmonella

Performance Standards", I'm sorry, in the last paragraph in that section, after "within the grinding facility", I'd like to add a sentence that says, "Purchase specifications" --

MR. GARRETT: No, no, no.

DR. ENGELJOHN: Sorry.

MR. GARRETT: Slow down first.

DR. ENGELJOHN: All right. In the last -- second paragraph under "Salmonella Performance Standards", last line, I'd like to add a last sentence after "grinding facility".

MR. GARRETT: Pencils are poised.

DR. ENGELJOHN: All right. "Purchase specifications with microbiological limits" --

MR. GARRETT: Slow down. "Specifications with microbiological limits" --

DR. ENGELJOHN: -- "for various microorganisms" --

MR. GARRETT: -- "for various microorganisms" --

DR. ENGELJOHN: -- "are one measure which grinding" --

MR. GARRETT: Wait a minute, wait a minute. "Are one measure which" --

DR. ENGELJOHN: "Grinding operations can use to control, i.e. limit," --

MR. GARRETT: To control what?

DR. ENGELJOHN: "Control (i.e. limit) contamination".

MR. GARRETT: So, that sentence would read --

DR. BUCHANAN: Repeat where it's going.

MR. GARRETT: I just want to read the sentence.

DR. BUCHANAN: Please repeat where it's going.

MR. GARRETT: Yeah. This sentence would be in the -- at the top of Page 7, under the side header, "Salmonella Performance Standards", the second paragraph, the last line of the second paragraph, begins with "Acquired". It would be inserted after the period.

"Purchasing specifications with microbiological" -- can't read my own writing -- "with microbiological limits for various microorganisms are one measure which grinding operations can use to control (i.e. limit) contamination."

DR. BUCHANAN: One more time with feeling.

MR. GARRETT: Sure, Bob. "Purchasing

specifications with microbiological limits for various microorganisms are one measure which grinding operations can use to control (i.e. limit) contamination."

Did I faithfully do that?

DR. ENGELJOHN: And then, I have one more.

MR. GARRETT: Let's -- okay. Let's deal with this one first. Any objection?

John?

DR. LUCHANSKY: Just for point of clarification. Is "various" a little bit too vague? Do you want to say something like "targeted", "specific" or "select microorganisms" or do you want to leave it "various"?

Dan, what was your intent? I'm John Luchansky.

DR. ENGELJOHN: "Select" is fine. I don't see that as a problem.

MR. GARRETT: Okay. Dan, you're going to have to speak in the microphone. They can't hear you down there.

DR. ENGELJOHN: Engeljohn.

"Select" is fine. I'm okay with that.

MR. GARRETT: So, before "selective

microorganisms"? Okay.

Bob Buchanan, then Bruce Tompkin.

DR. BUCHANAN: Bob Buchanan.

Two points in terms of this sentence. I think one, that we need to articulate overtly in this sentence that purchase specifications are a form of performance standards to make sure that this in some way ties back to the general discussion at hand, and two, I think I would modify this sentence to specifically, since this is a paragraph on Salmonella Performance Standards, I think we need to be a little bit more specific in the sentence, saying Salmonella, and then if you want in parenthesis (and other pathogenic microorganisms), but I think in terms of the continuity of the paragraph, it should be focused on Salmonella.

So, again, modify this sentence to indicate that this is a form of performance standard or performance criterion and then target it to Salmonella.

MR. GARRETT: Bruce?

DR. TOMPKIN: I like it the way it was.

MR. GARRETT: Dane?

DR. TOMPKIN: Because it's not truly -- performance specifications, standards, however you want

to state them, are intended to meet a performance standard. They are not specific -- they are not performance standards unto themselves.

MR. GARRETT: There are purchasing performance standards. I mean, there's government purchasing standards as well. Just want to make sure everything gets on the table here, folks.

Dane, then Dan, then that's it.

MR. BERNARD: Thank you, Chairman.

I have other things on this page, but I'd like to get from Dan what the addition of this sentence does for us.

DR. ENGELJOHN: This is Engeljohn.

I felt it was important to add some context to a statement that's made later in the document back on Page 10, where we're identifying -- at the bottom of Page 9 and top of Page 10, where we're identifying that we need to identify studies that discriminate between controllable and non-controllable factors affecting frequency and concentration of contamination, and I believe it provides context later on for what would be controllable and not controllable.

MR. GARRETT: Dane, with that understanding, do you now understand the reason for the sentence?

MR. BERNARD: I appreciate that. I'm wondering if we should not do something more overt to link with that, because it's still -- I mean, it's -- I don't disagree with it. I'm just trying to see if we need to clarify it a little bit more, but I won't hold up the proceedings for that.

MR. GARRETT: Okay. Now, I would ask, do you agree with Bruce? I mean, Bruce liked the way it was the first time. I mean, the issue -- I'm trying to address now Bob's insertion, which essentially would read, "Performance standards" -- excuse me. Being performance criteria.

Dane?

MR. BERNARD: You're asking my opinion, Mr. Chair?

MR. GARRETT: Yes.

MR. BERNARD: I'm in agreement with Bruce. I think Bruce was talking about Bob's intervention specifically in terms of purchase specs being a form of performance standards.

I don't want to get into a rather protracted debate over that one. So, I would just as soon leave it as it was.

MR. GARRETT: Is that fine with you, Bob, or

would you like to engage in a protracted debate? I'm not being cynical.

DR. BUCHANAN: I guess my comment is a rose by any other name. Purchase specification is a standard imposed by the company.

MR. GARRETT: Or by the purchaser. Could be a government. There are school lunch purchasing specifications.

Skip?

DR. SEWARD: Well, just to that point, I'm not sure that all purchasing specifications are standards, unless a lot of companies are perhaps using those incorrectly, but there are some purchasing specifications that have microbiological guidelines, for example, that are not purchasing laws. They are -- give guidance for purchasing, and yet they're in the broadest scope, a purchasing specification.

So, it's not a standard from the standpoint that you're going to accept or reject product based on that purchasing specification. So, I don't think in general sense that all purchasing specifications are performance standards. So, I tend to agree that that's not --

DR. BUCHANAN: Then I have to reflect back.

If we're going to allow a purchase specification to be a general guideline that does not have to be adhered to or would not be adhered to, then I don't agree with the rest of Dan's sentence because it will not have an impact and nor is it an effective tool.

If it's just there to have something on paper and is neither enforceable nor followed, then I don't agree with the rest of the statement because it will have no impact because if it's ignored, how is it going to be a useful tool for in some way influencing the level of Salmonella on the ground beef?

MR. GARRETT: Maybe I could suggest a fix from the chair. If we were to say "purchasing specifications with microbiological limits for microorganisms may be one measure", so that they're in fact adhered to, they work. If they're not adhered to, they don't and don't go moving on whether they're performance standards or not.

Catherine?

DR. DONNELLY: I agree with Bruce and strike that whole sentence because I think it's a stronger scientific document without any reference to purchasing specifications. I think now we're straying into economic and other considerations, not sticking to the

science that we were required to do.

MR. GARRETT: Bruce?

DR. TOMPKIN: Clarification. This is Bruce Tompkin.

Which sentence did you mean? The one that was added by Bob?

DR. DONNELLY: That starts with "purchase specifications".

DR. TOMPKIN: Oh. Well, actually, if I may, the proposed sentence that Dan offered, "purchasing specifications" and so on, really can be referenced by an article published by Dane Bernard and others in Environmental Sanitarian and so on, and we do endorse and support this as a good management approach to controlling contamination. So, I think the concept is sound, and we do use it.

MR. GARRETT: From the chair, as I understand it, you're supporting the sentence as it was first --

DR. TOMPKIN: Yes.

MR. GARRETT: -- proposed?

DR. TOMPKIN: As proposed by --

MR. GARRETT: Bob has proposed be modified.

DR. TOMPKIN: Sure.

MR. GARRETT: Would you also support changing

the word "are" as to "may"?

DR. TOMPKIN: That's fine. Yes, I do support that.

MR. GARRETT: And then, would that solve everybody's problem? Dan, would you agree with that as well? Any objections to that?

So noted. So, it would be may be. So, "performance specifications with microbiological limits for various microorganisms may be one measure which grinding operators can use to control (i.e. limit) contamination."

Any more on Page 3 -- 7? Where are we? Dan?

DR. ENGELJOHN: Engeljohn again.

On the same Page 7, I'm sorry, on the paragraph before that, where it references the PR HACCP rule and the Philadelphia report, I think that we should make those attachments, so that there is some context to what those statements are, and I'd be glad to write up a summary of the two, rather than have the entire documents. I can put the pertinent summaries as an attachment and reference them.

MR. GARRETT: Well, they're actually referenced as attachments. We have 27 references. Do you want to just attach those, too, to the document?

Is that your intent?

DR. ENGELJOHN: I guess I would ask the question. Do you want the entire documents referenced or just the sections?

MR. GARRETT: Generally, I've been taught when you -- if you're going to -- you don't attach an incomplete reference. So, I would suggest that if people are interested, they can just go to the reference or it's as you wish, but it's difficult to address an incomplete reference.

John?

DR. LUCHANSKY: Just because I brought it up, I wonder. When you reread the sentence that Dan proposed, you said "various". Did we take Bob's suggestion for Salmonella or mine to say "selected"?

MR. GARRETT: Yes. I misread it. I'm sorry.

DR. LUCHANSKY: Okay. So, it would read then for "Salmonella and/or selected other microorganisms". Is that what's on the table?

MR. GARRETT: "Purchasing specifications with microbiological limits for selected microorganisms are one measure which may".

DR. LUCHANSKY: For Salmonella and/or selected microorganisms? Bob indicated he wants

Salmonella in there.

MR. GARRETT: No.

DR. LUCHANSKY: No?

MR. GARRETT: No. It's not just restricted to Salmonella.

On this sentence, are we done with this sentence? Bruce?

DR. TOMPKIN: I have one brief comment on the sentence before.

MR. GARRETT: Well, I take it we're done with this sentence? Very well.

"Purchasing specifications with microbiological limits for selected microorganisms may be one measure which grinding operations can use to control (i.e. limit) contamination." One measure. One measure.

Okay. The sentence above that? Bruce?

DR. TOMPKIN: Yes, thank you.

It's very simple. Over in the far right-hand side of that sentence above, where it says, "raw products", I would suggest we use "raw ingredients" just for clarity.

MR. GARRETT: Got acceptance? I'm not that familiar with your -- I mean, can you have more

ingredients than that, than just meat or poultry or meat and --

DR. TOMPKIN: It's really beef trimmings, but that's the same thing, but you leave it ingredients, then it's -- you're safe.

MR. GARRETT: Bill Sperber?

DR. SPERBER: This is Bill Sperber.

Would you accept raw materials?

DR. TOMPKIN: That's fine.

MR. GARRETT: Dane Bernard?

MR. BERNARD: Thank you, Chairman.

Right under the major heading "Salmonella Performance Standards", I would move that we begin the paragraph with the "Salmonella Performance Standards were designed to reflect process control and slaughter and ground beef operations", strike --

MR. GARRETT: Dane, Dane. Wait. Slow down. You're going to have to talk slower or louder or something.

MR. BERNARD: Sorry about that. I move to strike the first part of that sentence, all the way up to the comma.

DR. BUCHANAN: Where are you, Dane?

MR. BERNARD: "Salmonella Performance

Standards", the major heading. It doesn't read well. We'd probably need to add a good deal to it, and I'm not sure that it's worth the effort.

We went through a long discussion that this is the major source of Salmonella. I think we all agreed, but there are other potential sources of Salmonella when one looks at the picture and just to be brief about it, let's just start with the "The Salmonella".

DR. WACHSMUTH: Point of clarification.

MR. GARRETT: So, what you're saying --

DR. WACHSMUTH: When Spencer started, he mentioned that we're reformatting to address questions that came up yesterday and last night, the duality of the paper and that's why in the beginning, it's the General Principles. Then it goes to exactly what the agency asked and what the agency is implying.

That's why the headings are there. So, be careful. I mean, even though it looks -- may not look like it belongs in a sentence, it's a bridge. It's one of those bridges that we're trying to build.

MR. BERNARD: I'm sorry, Madam Chair.

The heading I'm not talking about, but you say the first part of that sentence is necessary

because of a bridge that needs to be there?

DR. WACHSMUTH: I thought you were suggesting eliminating the heading.

MR. BERNARD: No, no, ma'am.

DR. WACHSMUTH: Okay.

MR. BERNARD: No, ma'am.

DR. WACHSMUTH: Fine.

MR. GARRETT: So, as I understand it, you're recommending deleting the first line and the second line up to the comma after "occurs", is that correct?

MR. BERNARD: That's correct.

MR. GARRETT: And you would then start the sentence, "The Salmonella Performance Standards were designed to reflect the process control"?

MR. BERNARD: Correct.

MR. GARRETT: Bob?

DR. BUCHANAN: Just a small point. I don't think they were designed to reflect process control. They were designed to verify process control.

MR. GARRETT: Could we agree that they were designed to verify process control? Could we agree then to Dane's suggestion to delete the first line and the second line up to the comma? Without exception.

Are there any more -- Dane?

MR. BERNARD: Thank you.

In the next paragraph in that same section, Mr. Chairman, "The subcommittee points out that when" and it now reads "HACCP systems", I would like to substitute for HACCP systems the following, and I'll read it, and then we can talk about it.

Instead of HACCP systems, "conditions contributing to cross-contamination or growth are effectively controlled". There are several things that may contribute to Salmonella that may be outside somebody's specific HACCP plan, but basically we're talking about opportunities for contamination and growth.

MR. GARRETT: Can you read that slowly? "Conditions contributing"?

MR. BERNARD: "When conditions contributing to cross-contamination or growth are" --

MR. GARRETT: Wait, wait, wait, wait.

MR. BERNARD: Sorry.

MR. GARRETT: "To cross-contamination" --

MR. BERNARD: "Or growth" --

MR. GARRETT: -- "or growth" --

MR. BERNARD: -- "are effectively controlled in ground beef operations", and then we would strike

"are adequate and verified".

MR. GARRETT: So, it would read, "The subcommittee points out that when", are you keeping the "when"? I don't think you are.

MR. BERNARD: Yes.

MR. GARRETT: You are? Okay. "Conditions contributing to cross-contamination or growth are effectively controlled in ground beef operations", and then it's just period?

MR. BERNARD: "In ground beef operations", then strike "are adequate and verified", and then it reads, "as proposed."

MR. GARRETT: Oh, okay. So, after "controlled", there's a comma, then it says, "the measure of Salmonella". Now, here's the "reflects" again. Would you rather have the word "verifies the microbiological" -- well, I don't know. It's beyond me.

Bob?

DR. BUCHANAN: I don't want to particularly object to the wording or the substitution, but I would point out conceptually that if such -- if growth and cross-contamination were uncontrolled but not part of a HACCP plan, that you have an inadequate HACCP plan or

the implementation of the HACCP plan is inadequate.

To have missed those two in a HACCP plan, if those are the major sources of the problem, and I do have a concern that somebody wasn't implementing HACCP very well.

MR. GARRETT: Katie?

DR. SWANSON: This is Swanson.

I think the intent of this section was supposed to be reflecting on how current performance standards are working, and the sentence as it reads, I think, is better suited for that purpose.

If the standard is there to measure or to verify process control, what this sentence is pointing out is that it doesn't really work because if HACCP is in place, the Salmonella that you find is just a reflection of what came in on your incoming ingredients and stating it as it is currently drafted, I think, is more effective in making that point.

DR. BUCHANAN: I'd also, in that regard, like to point out that if you go back to this Committee's HACCP documents, the inclusion of incoming material for consideration in your hazard analysis and hazard plan was an integral part of all of our recommendations, and I have some concerns about this section in terms of if

you are not controlling your incoming material, then you're not following our own guidance.

MR. GARRETT: Dane, then Bill Sperber. Dane first.

MR. BERNARD: I will, because I'm in such a darn good mood and still jet lagged, I'll withdraw my intervention.

MR. GARRETT: Bill?

DR. SPERBER: Yes. This is Bill Sperber.

I hate to do this to you, but I think it's got to be done. The first sentence that's been changed to the "Salmonella Performance Standards were designed to verify process control", I think we need to strike the word "verify" because it's a heavily-loaded term from our HACCP procedures, and verification activities are activities that occur quite regularly, daily, weekly, monthly.

Salmonella Performance Standards are enforced or evaluated very infrequently, like maybe once a year. So, I think at best, we could say the "Salmonella Performance Standards were designed to indicate process control" and even process control is very loose because all you're doing is indicating that you're within a national baseline that was determined in 1995, and some

products might have 10-percent contamination and others might have 50-percent contamination and that's all that you're indicating by collecting the performance standard data.

So, I would move that we replace the word "verify" with "indicate".

MR. GARRETT: Any support for that insertion? Dan Engeljohn?

DR. ENGELJOHN: This is Engeljohn.

Bill, I don't agree with that. I think "verify" is the proper term. To make it more accurate, if it's designed for the agency or for FSIS to verify process control, it gets at it a little more clearly, but we do use "Salmonella Performance Standards to verify process control".

MR. GARRETT: Would you accept that explanation, Bill?

DR. SPERBER: Yes, I'll go along with that. I'd just like to make one further point in the second paragraph, is that when you're talking about HACCP systems in a grinding operation, I assume that's what's meant by a ground beef operation, that there really is no reduction step or CCP in a grinding operation, and so without a CCP, you don't have a HACCP system.

So, perhaps we should rethink the use of HACCP systems in that first sentence of the second paragraph there.

MR. GARRETT: Yeah. I think it's a duality-type issue. The way I read it, if you have your effective HACCP systems in a ground beef operation, I guess that's where you're getting your cuts and your primals and all that kind of stuff. I don't know your lingo.

But then when it goes to a grinding operation, in other words, if it's adequate, where the raw material's being prepared, and then it goes as raw material to the grinding operation, the grinding operation should theoretically be okay. Is that what we're saying? Provided the subsequent transport and so forth was appropriate. Is that what this sentence is saying? I thought that's what Katie was inferring. Did I do that about half right?

DR. SWANSON: I think so.

MR. GARRETT: I could be half wrong. But, see, I think that that's what they're saying. They're going from a ground beef operation to, as I understand it, to -- and I see where you're coming from because it says ground beef operation, to grinding. Maybe just

ought to say in beef operations are adequate and verifiable.

DR. SPERBER: You mean, --

MR. GARRETT: Bruce?

DR. SPERBER: -- if it was coming from a beef slaughter operation --

MR. GARRETT: Yeah. Or something like that.

DR. SPERBER: -- to a grinder.

MR. GARRETT: Bruce?

DR. TOMPKIN: This is Bruce Tompkin.

The current discussion over whether it's controlled through HACCP prerequisite programs is a longstanding debate that has been underway between the agency and the industry, and I don't think we're going to resolve it in this particular document, unfortunately, and so, and my sympathies are with Bill in the sense that it's really a matter of where you place these prerequisite programs, such as checking incoming raw materials.

It's where you're going to upgrade -- if you're going to upgrade them to a CCP and hold ingredients before they're used, that, you could kind of fit that in to the CCP, but otherwise, I would generally agree that this is controlled through

prerequisites rather than through HACCP.

MR. GARRETT: Bob Buchanan, then Dan Engeljohn, then Skip.

DR. BUCHANAN: I'll just reflect again on past work of the Committee, that identified for beef slaughter and the production of beef products, that maintenance of the cold chain was of such importance that we identified it as a CCP unto itself, and so again, at some point, it was the recommendation of this Committee that we consider the cold chain HACCP.

MR. GARRETT: That took care of it? What I sense is a consensus, if you would, to keep this sentence as written. Is that essentially true? All right.

Moving on, any more on Page 7?

DR. BEUCHAT: Spencer?

MR. GARRETT: Yes?

DR. BEUCHAT: A minor point. Number 2, about two-thirds of the way down the page, the word "shows" should be "show".

DR. WACHSMUTH: I think we could finish Question 2, and then we need to open for Public Comments.

MR. GARRETT: That's fine.

What I was suggesting doing was perhaps taking a break when we finish Question 2. Could we do that or should we have the Public Comment first? If the Public Comment was indicated for a certain time, then I --

DR. WACHSMUTH: Public Comment is scheduled for 4:45.

MR. GARRETT: Okay. Fine.

DR. WACHSMUTH: I don't think we had anyone sign up. Let's just ask if we have --

MR. GARRETT: Is there anyone from the public that's going to speak? Would like to -- oh, there is.

DR. WACHSMUTH: We do have one.

MR. GARRETT: Sure we do. We have people from the public here.

DR. WACHSMUTH: We did have someone sign up.

DR. SMITH: Can I just -- a procedural issue. After Public Comment, you'll be continuing for how long?

DR. WACHSMUTH: It's a good question. I was just asking the exec sec. It depends on many things, like the mikes, the recorder. Hang on one second. We're going to find out how long we can stay.

MR. GARRETT: Well, can I continue while

we're finding out?

DR. WACHSMUTH: Sure.

MR. GARRETT: On the top of Page 8 then, we did add a new bullet, which indicates "The data from the Salmonella Performance Standard Program in the year 2001 should be made public, so as to provide guidance to the industry in order that their commercial operations may access their process control relative to the industry."

DR. TOMPKIN: Spencer?

MR. GARRETT: Bruce?

DR. TOMPKIN: That really doesn't fit in that section anymore, the way it is. You know, this material has been revised, and as much as I would like to see that retained, I don't have a good place to put it, but it should be pulled out of there. It really doesn't have to do with the indicators, the use of indicators and so on.

MR. GARRETT: Well, should it go under Risk Assessment? Would that be a better place to put it?

DR. BUCHANAN: Spencer, can I recommend that that may belong in Question 3?

MR. GARRETT: Say again?

DR. BUCHANAN: You're talking about Number 5

in that list right now?

MR. GARRETT: Yes, under Question 2. I'd like to try to get a closure to Question 2.

DR. BUCHANAN: Right. And --

MR. GARRETT: Could we agree that we're going to keep the statement and then just find a home for it? Is that the --

DR. BUCHANAN: And my suggestion was that that may be best considered under Question 3.

MR. GARRETT: 3?

DR. BUCHANAN: Yeah.

MR. GARRETT: Because it deals with data?

DR. BUCHANAN: Yes.

MR. GARRETT: That would be your understanding?

DR. BUCHANAN: Yep.

MR. GARRETT: So, that then will move to Question 3 and then that brings us to completion of Question 2, and do we now have information pertaining to about how long we can be expected to go on?

DR. WACHSMUTH: You can have another hour.

MR. GARRETT: Very well. Well, let me point out several -- a couple points here. One is that I would like to discuss at least the General Principles

that we have for Question 3, the text that we have for Question 3, realizing that the data issues, the data issues are -- we're going to have to consider later, and I have another comment before we close on that and then go to Question 4.

Now, what we can do, if you would like, it would be this evening, to go to Question 4 first while we all seem to be into this thing and then take Question 3 up in the morning, but I do think, even though we're deferring parts of Question 3 dealing with the data, we should, though, reach agreement in our Plenary Session here on the text just as we are the other three questions.

Mike Jahncke?

DR. JAHNCKE: Mike Jahncke.

I don't want to jump back, but I want -- as we're going through this, I want to make a general comment on Question 1 and this is just very general.

When I first read through the information on Question 1, I found it difficult to follow, and I realized after looking at Question 2 why. Question 2 has nice subheadings. I think on Question 1, everything sort of runs together, and if the subcommittee can get together and just find some

appropriate subheadings to break that up, I would -- I think it would make it much easier to follow because that's really the -- makes the rest of the document confusing if that part is tough to follow.

MR. GARRETT: I think we certainly could do that. As I indicated at the beginning, there's still some formatting issues with which we have to deal, and I was hoping that we could probably go ahead and approve this since it just deals with formatting or subheadings and let's do that perhaps even after we leave. Staff do it or somebody will do it.

Bob?

DR. BUCHANAN: I just -- I'm trying to think of a practical limit on whether or not we're going to survive another hour today and still be addressing this in a manner that we're not going to have to go back and fix it again tomorrow morning.

So, I'm not sure. I'm getting to the point of diminishing returns personally.

MR. GARRETT: Okay. Well, I tend to agree. My major professor said that the person with the fullest bladder is the most alert person in the room, and I can tell you folks, I'm pretty alert right now. You see how quick I am off the dime on some of these

things?

But would we like to go ahead and have our Public Comment period now or would you like to wait five minutes and then have our Public Comment period? I'd kind of like to wait five minutes, if we could.

DR. WACHSMUTH: Spencer, I'll take the chair from you.

Let's ask Caroline, who signed up, her preference. Would you like to speak or would you like to wait five minutes?

DR. SMITH: If you don't mind, I would be very brief.

MR. GARRETT: Fine.

DR. WACHSMUTH: Okay.

MR. GARRETT: Go ahead. You know, being a Brubeck fan, I understand take five.

Public Comment

MS. SMITH-DEWAAL: So, I'll be very brief.

This is clearly a work-in-progress, and I think you have made some progress since yesterday, but I have significant concerns after listening to the debate.

I hear very solid strong advocacy and representation on behalf of Keystone Industries,

ConAgra, Farmland, Cargill, but I'm not hearing an urgency about getting the performance standards in place for ground beef to protect the public. I'm not hearing the same level of urgency or advocacy, but seeing the Committee now take out any reference of fecal contamination in the meat supply, and I saw a very effective filibuster of the issue of connecting the clear connection between performance standards and public health goals, and I know the subcommittee's going to go back tonight and iron that out.

But I'm not confident in how it's going to come out. So, I have -- and I also see that the subcommittee and the Committee may now have adopted the concept of a full-blown risk assessment, maybe not a qualitative risk assessment, yet the suggestion is that you take the model, this five- or six-year model, used for E.coli 0157:H7 in ground beef and now just use that model to address it in Salmonella.

I can guarantee you that's going to be another two- to three-year process at best. I mean, I haven't seen one of these that went quickly. So, I don't think -- you know, maybe there is some urgency, maybe I'll hear it tomorrow, but this paper continues to look like it's being dominated by the food industry

and that it's going to delay a needed public health measure for ground beef.

Just one last comment. This last sentence you've been talking about, where, you know, if the HACCP systems are in place with ground beef operations, and they are adequate and verified, you shouldn't have the microbial condition of the meat coming out of the grinder affecting incoming product.

That's exactly the issue in Supreme Beef, and the Committee's now come out and said, well, it's all incoming product. Where's your critical control point? This Committee couldn't tell us, and I can tell you that consumers want to know what the critical control point or measure is for meat coming out of that grinder.

The Salmonella Performance Standards told us more than what the incoming product was. It told us what the conditions were inside the grinder. If the meat coming out is contaminated, it means the grinder itself is contaminated. Tell me where the critical control point is. Tell me how it's going to be verified short of testing the meat coming out of the grinder.

So, you know, I know the Committee decided to

keep this sentence. I think that sentence is very dangerous. I'm not sure it does what you meant it to do, and I think it deserves being struck.

Thank you.

DR. WACHSMUTH: Caroline, before you sit down, could you be specific about the sentence?

DR. SMITH: It is under Salmonella Performance Standards, Page 7. It says, "The subcommittee points out when HACCP systems in ground beef operations are adequate and verified, the measurement of Salmonella reflects the microbial condition of the raw products acquired from grinding and not the process control within the grinding facility."

That was a critical point in the lawsuit. We are -- we were amicus to the lawsuit, and I reviewed all the pleadings. That's a very critical point, and this Committee's now said, oh, it's all incoming product. Well, where are your critical control points, and how do you ensure -- what's the one on the grinder? What's the critical control point that ensures that that cross-contamination isn't happening in the grinder?

Bill Sperber doesn't know. I don't know who

knows in this -- on this Committee, and that sentence, I think, is very problematic. It says this Committee says it's all incoming product. Well, where's your critical control point?

Bob Buchanan has said that this Committee has previously said that incoming product is a critical control point. I believe that, Supreme Beef did not. They didn't believe that their incoming -- they were responsible for their incoming product, and the meat they were putting out was highly contaminated. About 50 percent of the first round of samples were contaminated.

So, I mean, this really -- I think this sentence deserves to be struck. I think Dan Engeljohn's intervention is helpful because purchasing specifications are a control element, but I think that this really falls in directly to the Supreme Beef argument, and I'm surprised to see the Committee commenting on it.

Did you have any other questions?

DR. WACHSMUTH: Nope. That was fine. Oh, I did have one comment. I know the attempt was made last night to avoid the recommendation that there has to be a five-year risk assessment. The references that were

added were references to risk management which stated a different kind of evaluation, not a risk assessment.

So, the impression -- if you got that impression, then the subcommittee did not do what it thought it was doing.

DR. SMITH: Can I just -- and maybe Under Secretary Murano wouldn't want to answer this, but I think a conservative reading of the sentence on Page 4 that says, in parenthesis, I believe -- oh, no.

"The subcommittee notes that appropriately-substituting prevalence data and dose response relationship for Salmonella in the FSIS Risk Assessment for E.coli 0157:H7 in ground beef may provide a means for developing a risk assessment model for Salmonella in ground beef."

A conservative regulator reading that may interpret that sentence to say they told us to do a risk assessment, and this is how we have to do it. Unless you also have a sentence that says do it soon and do baseline data while you're waiting for this risk assessment, this risk assessment model, I mean, Kaye, tell me, how many years have you been working on it?

DR. WACHSMUTH: Too long.

DR. SMITH: A very long time, and just

substituting a few little numbers, I tell you, it's going to take years. I can't imagine that we'd see any risk assessment in less than two to three years.

DR. WACHSMUTH: I think my point is that the subcommittee agrees with you, and so if you have that impression, then we probably -- the subcommittee needs to work with the text because I don't -- that was not the intent.

DR. SMITH: Okay. Well, thank you.

MR. GARRETT: Madam Chair, before you leave, let me just point out a factual statement that appears in the report on Page 3 in the 1-2-3- -- under Question 1, the second paragraph, the fifth line, if I'm right -- fourth line, begins with "consideration of risk".

"The consideration of risk may not necessitate in all situations an in-depth quantitative risk assessment which requires extensive resources and time, particularly if it would unnecessarily delay timely protection of public health."

DR. SMITH: And that, I appreciate the intent of the subcommittee and the Committee including that in. I think that that is a very important sentence in this document.

MR. GARRETT: Well, let me continue to read

then, if I could, Caroline.

"The decision to undertake a formal quantitative risk assessment versus a qualitative evaluation of risk requires consideration of multiple factors, such as the availability of quality of data, the degree of consensus", get this, "the degree of consensus of scientific opinion, time constraints and the potential consequences for the decisions reached."

DR. SMITH: And that -- those as general principles, I think, are absolutely on target, and I actually like the beginning of the paragraph without some of the recommendations made by the esteemed Dr. Tompkin, but where the straight connection between the performance standard and public health, those are very important principles.

The problem is that you also give general principles, but you also have specific principles going to the E.coli -- the Salmonella Performance Standard in ground beef, and I'm concerned that this sentence on Page 4 would be interpreted as your specific recommendation, not the general principle. That would be my concern.

MR. GARRETT: Okay. Thank you.

I believe Dr. Buchanan wants to make a

comment.

DR. BUCHANAN: Just to provide a bit of explanation to make sure that we're talking about the same thing, is that, the sentence in question was inserted because FSIS thought it important for the Committee to point out our discussion about the fact that you could shortcut a full risk assessment if it was deemed that that was necessary by not rediscovering the wheel but basically by using the framework that had already been established for E.coli and in its place cutting off a year's worth of time by using that framework but then using the data that we have available on Salmonella.

So, while you may have interpreted it and while it may in fact give that impression to, when taken out of context, the desire of the Committee was to actually point out a method to FSIS on how they could basically knock a year's worth of time off the clock if they felt that a risk assessment was needed.

MR. GARRETT: Okay. With that understanding then, could we take a -- well, gee, if we're going to come back in the morning, we don't have to take a five-minute break.

DR. WACHSMUTH: No. I think Bob brought up a

good point about the quality of the discussion. We went strong this morning. We got through all the documents, and I think you've made good progress this afternoon.

I believe we may do better to refine the text that we have right now, the suggestions that we have, and then tomorrow morning, we'll start with -- we'll finish off the hot-holding and the blade-tenderized, and then we'll have the rest of the morning to do this, and those should be short discussions.

MR. GARRETT: Fine. Well, what I would suggest is that our subcommittee get together very quickly. I want to remind us that we have to go back to this other paragraph on Page -- where was it? Page 3.

DR. WACHSMUTH: That's exactly what I'm suggesting.

MR. GARRETT: Yes, and if we could just go ahead and resolve that.

DR. WACHSMUTH: Resolve those --

MR. GARRETT: Yeah.

DR. WACHSMUTH: -- before morning.

MR. GARRETT: Okay.

DR. WACHSMUTH: And review anything in the

context of --

MR. GARRETT: But I would still be willing to take a five-minute break before we all get together again or you all can go on. Well, I'll tell you what, why don't you go ahead without me? You'd probably do it anyway.

DR. WACHSMUTH: Okay. So, we will officially end the proceedings.

MR. GARRETT: But let's stay in this room.

DR. WACHSMUTH: And the microphones and the reporter will now go, but we have the room, I was told, even all night, if you want it.

So, the official public meeting is now over.

(Whereupon, at 5:07 p.m., the meeting was adjourned, to reconvene tomorrow morning, Friday, January 25th, 2002, at 9:00 a.m.)