UNITED STATES
DEPARTMENT OF AGRICULTURE

In the Matter of:)
)
NATIONAL ADVISORY COMMITTEE)
ON MEAT AND POULTRY)
INSPECTION MEETING)

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INSPECTION MEETING)

Jefferson Room
Quality Hotel-Courthouse Plaza
1200 North Courthouse Road
Arlington, Virginia

Wednesday,
May 17, 2000

The meeting in the above-entitled matter was convened, pursuant to notice, at 8:39 a.m.

APPEARANCES:

Attendees:

THOMAS J. BILLY
KATHLEEN HANIGAN
TERRY BURKHARDT
MAGDI ABADIR
CATHERINE WOTECKI
ALICE JOHNSON
DALE MORSE
COLLETTE SCHULTZ KASTER
DANIEL ENGELJOHN
NANCY DONLEY
MICHAEL MAMMINGA
ROSEMARY MUCKLOW
CAROLINE SMITH DEWAAL

JAMES DENTON
LEE JAN
DANIEL LAFONTAINE
ROBERT POST
CAROL TUCKER FOREMAN

APPEARANCES: (cont'd.)

Attendees:

JUDITH RIGGINS
PHILIP DERFLER
CHERYL HALL
MARGARET O. K. GLAVIN
GERALDINE RANSOM
JUDY NIEBRIEF
MARK MINA
STANLEY EMMERLING
DEL HENSEL
JENNY SCOTT

P R O C E E D I N G S

(8:39 a.m.)

MR. BILLY: Thank you very much, Mike, and good morning, everyone. I hope you had a restful night. Perhaps a little shorter than usual, but restful.

The morning is devoted pretty much to hearing from the subcommittees that met during the evening to address a number of issues and in particular a series of questions that we posed to the subcommittees.

It's also an opportunity for all the members of the committee, particularly those that didn't sit in on a subcommittee meeting, to hear the results of the subcommittees' work and their recommendations and to react and to give us a sense of whether there's a consensus among the full committee for the recommendations that are being forwarded by the subcommittee.

We'll start with the standing committee that is chaired by Katie Hanigan. This subcommittee focused its efforts on the industry petition, which proposes changes to the HACCP and pathogen reduction regulation, including definitional changes, the recognition of prerequisite

programs and other changes that the petition argues would improve the effectiveness of HACCP as it's applied to meat and poultry.

Let me turn the meeting over to Katie to share with us on behalf of her subcommittee the questions that were posed and then the recommendations as a result, and then we'll have a discussion on the recommendations of the subcommittee.

Katie?

MS. HANIGAN: Thank you. We had a good subcommittee meeting last night. It probably ran about two, two and a half hours. The subcommittee would like to thank Dan Engeljohn. His expertise and knowledge of this subject was essential to our conversation, and he did answer a number of questions for us.

Our charge was to answer the six questions put forth yesterday to us by the Agency. Why don't we just go through? I'd like to go through all six questions and our responses, and then we'll take questions and answers if that's okay.

The first question revolved around the industry

petition relies mainly on the national micro document and doesn't provide any data examples to support it. They further asked for is the micro group aware of any information that could support taking any of the actions requested in the petition.

Our subcommittee came up with the following on that. We recommend the Agency make available as soon as possible to the public as part of the comment process a side by side comparison of the FSIS, FDA, the national micro committee, the CODEX and any other pertinent regulations.

That is a spinoff, if you will, of those documents I had handed out yesterday. They had not been reviewed, approved, if you will, by the Agency, so our recommendation is maybe they would like to use that as a starting point and review them and revise, update, but those were the definitions that we had handed out yesterday.

We would like to see a side by side comparison. We do think it's essential that that be available to the public as soon as possible so that those definitions can be used when the public is trying to develop comments regarding the Agency's petition here.

Bullet Point 2. We recommend the Agency have the HACCP subcommittee of the national micro committee review the industry petition and give their opinion regarding the intent of the definitions of hazard, hazard analysis, the prerequisite programs relative to the current HACCP rule. We had quite a discussion in committee regarding the intent of the definitions and were they being implemented as how they were originally designed.

No. 3 under Question 2, recommend the Agency extend the comment period to allow the HACCP subcommittee to meet and to develop comments on the industry's petition. We do think the July 14 deadline for the comment period is too soon, especially when we're wanting this side by side analysis as well to be available to the public so that they can formulate comments.

Regarding Question 2, would amending 417.2(a) in a --

MR. BILLY: Katie? Katie, can I just --

MS. HANIGAN: Uh-huh.

MR. BILLY: This is just to explore this. Do you think since this is fairly complex it would be better to

sort of have a discussion after each question?

MS. HANIGAN: Okay. That's fine.

MR. BILLY: I mean, I don't want to break it up necessarily, but I just thought there's quite a series of questions here.

MS. HANIGAN: Okay. It's open. The floor is open to any questions, comments. Why don't we start with the subcommittee members that served on this? Do you have any additional comments you'd like to make?

MR. BURKHARDT: Terry Burkhardt. We felt that it would be up to the Petitioner to provide some examples and some data that would support their request for the petition. It was obvious to us that there was nothing like that that was presented.

We had discussion about that and there were some examples that were provided, but for the Agency to respond to this it would seem that they would need some specific examples of what is wrong with the present system, what does not seem to be working properly, so we suggested that as well.

MS. HANIGAN: Also, I think a key point there that

Terry brings up, without the examples the Agency would not know if they have something that could be corrected via additional instruction or if they need instruction to the field, that is, or if they needed a revision in the regulation itself, so having examples submitted with comments would be essential so the Agency could make a decision as to what needed to be done.

Yes?

MR. ABADIR: Can you tell us about this, the definition of hazard and where your discussions lead to in this area and more details about it?

MS. HANIGAN: Yes, and I'll look for subcommittee support as well. What the subcommittee was feeling, and we talked about examples, was that the definition of hazard as being implemented in the field does not take into consideration risk and severity.

It seems like a lot of things are being thrown in under hazard now with disregard to risk and severity, and that's where we wanted the HACCP subcommittee from the micro group to go back and to tell us what the intent of the definitions were so that everybody fully understands.

Does that answer --

MR. ABADIR: Yes.

MR. BILLY: Yes. Cathy?

MS. WOTECKI: Katie, I have I guess more a procedural question. On the second bullet here, the recommendation that the Agency request a particular subcommittee of the micro committee to review this, I think it might be more appropriate that it just go to the micro committee.

Clearly they're going to make the designation to that subcommittee, but we would also want to I think have the full micro committee's views on this as well, so just from a straight procedural standpoint it would seem that the recommendation should go to the full committee.

Then the second is on that same bullet is a question for the subcommittee. What do you expect to get back with respect to their opinion of the intent of the definition of hazard, and is it only for the HACCP rule or is it for this full spectrum of definitions that are cited in the first bullet? In essence, what are you asking them to do?

MS. HANIGAN: Yes. What we're looking for is the documents that were originally developed, because there's two of them from the micro committee. You know, definitely when I look at those documents I think they clearly recognize the value and importance of prerequisite programs, and that's one area where I don't believe, and I'm speaking for myself now, not as the subcommittee.

I don't believe that the Agency has recognized the importance of those programs, and it appears that if we could get the micro committee to tell us the intent of hazard, hazard analysis and prerequisite programs it may give us a sharper focus as to what truly is a hazard based on severity and risk and what is not a hazard and the same as what is critical to food safety and what items can be controlled in the prerequisite programs because it's getting very jumbled up in these HACCP programs.

It seems like everything is becoming a CCP even if it does not pertain to food safety. It seems like we are having more and more quality type items being put into a HACCP program under the term of hazard.

I'm not sure if that answers your question.

Alice?

MS. JOHNSON: Part of the discussion last night centered around the 1992 HACCP paper and then the changes that were made in the 1997 paper. Recognizing that the pathogen reduction HACCP rule was written based on the 1992 paper, there were changes that came from the HACCP subcommittee that were evident in the 1997 paper. One of them was the definition of a hazard and what we considered to be more focus for that definition.

I think the committee had some discussion and thought that it would be good to hear what that working committee in the HACCP subcommittee from the micro committee, what their thought process was in making the adjustments to the definition particularly of a hazard.

MS. HANIGAN: Thank you.

MR. BILLY: Yes. That also applied, incidentally, to prerequisite programs. There was a significant change between the 1992 and the 1997 set of recommendations.

MR. MORSE: Dale Morse. Just a question. We originally were planning on referring it to the whole committee and then were told that the agenda was probably

too full. We could probably accept that to the committee or the subcommittee, but I guess we would be flexible because originally we had it worded that way and then were told it probably wouldn't come up at the August meeting. The agenda might be too full.

Then just a similar comment as the others have made in terms of the petition basically cited the micro committee's intent in at least a couple of places, and we thought that it would be good to turn it back to the committee to just get their opinion on what their intent was in terms of the definition and prerequisites, so that was the reason.

Just another point. I don't know if we meant to add it. I know we had a lot of discussion about requesting the Petitioners to submit additional data. Whether we need to add that as a bullet or we just address this to the Agency, but we had agreed that there should be data presented during the comment period. Whether we need to add that as a bullet, I'll leave that to the committee.

MS. HANIGAN: I guess I think, Dale, you're correct that it should be added, and somehow I think when we

were summarizing it got left off because that was clearly the gist of a significant part of the comment or discussion last night was the Agency could not make any decision without examples being submitted back.

MS. SCHULTZ KASTER: So these are real life examples of the situations where hazard has been applied differently than the micro committee we believe intended or where prerequisite programs were not allowed to do the function that we think they would normally have?

MS. HANIGAN: I'm going to say yes. I'm going to defer the question to Dan, but our understanding was without examples they would not know whether or not they need instructional correction to the field or if they need a change in regulation.

MR. ENGELJOHN: Yes. This is Dan Engeljohn with USDA. To follow up on that, I think the real issue is that in order again for us to make some assessment about the variety of issues that apparently are tied up into this single issue, we really don't have clarity as to what is the problem.

Again, in order to pursue rule making if it in

fact requires a regulatory change we would need to have a great deal of support documentation that's clear as to why the regulation as written is not as effective as what this committee believes that maybe it should be or that the Petitioners asked for.

It's obviously important enough to the industry to have submitted a petition that it clearly would have some type of impact. The issue at this point is that it could very well be that many of those items that are not clear could be clarified through instructional documents like an FSIS directive to our employees.

That would provide more clarity in the decision making process that they should be looking at in terms of what the plant has done in their hazard analysis versus actually changing a regulation because if the problem is with how it's being interpreted and implemented, changing the regulation isn't going to help that and so clearly we didn't get enough information in the petition to have an understanding of what the issue truly is.

MR. BILLY: I think Nancy, and then Dale.

MS. DONLEY: I just would like to ask or make a

suggestion that these prerequisite programs, it would be very helpful if they were all so there was some sort of a summary of some sort that details what goes on in these prerequisite programs and that be made available to the public and just how much is voluntary within these programs and what is, you know, maybe minimum levels of whatever so that it's more easily evaluated by the public just how much these prerequisite programs contribute to the whole HACCP system in general.

MR. BILLY: Dale?

MR. MORSE: I was just going to recommend that we had a first bullet where I think we intended to do something. Recommend the Petitioners provide FSIS with specific examples with data to support the recommendations.

MR. BILLY: Mike?

MR. MAMMINGA: Just an observation. Looking at the first bullet where the subcommittee requested a side by side comparison of FSIS, FDA, the micro committee and CODEX, I think one of the things that kind of centers around the clouding of these issues is the fact that HACCP was not developed by any of those agencies.

They are agencies that have mandated HACCP on industries and have then set about to decide how to regulate the HACCP programs that industry developed and so, you know, prerequisite programs are a part of HACCP. They're required by HACCP as far as what industry is taught by the academia people who developed it. You have to have GMPs and SOPs in order to have a HACCP program. It's a part of it. It's a prerequisite.

So when we try to compare what the industry that developed HACCP as a system of process controls on the one hand to what we as government regulators are going to expect or even require on the other hand, it would seem to me that what you're asking for here is that you really want a comparison of the expectations of FSIS, FDA, the micro committee and CODEX as far as what a HACCP plan will have versus whether or not prerequisite programs are required. They are required. If you have a HACCP plan you must.

I think it might be a little easier as we look at the challenges in regulating HACCP plans to keep our expectations aside from what HACCP is or what HACCP was meant to do. To me, it would be a jumbled up mess if I

could not keep in mind the seven principles of HACCP, the prerequisite program to go with it, versus what I should expect as a regulator to see at a minimum in any given plan.

MS. HANIGAN: I have a question for Cathy. Cathy, if we did request that the HACCP subcommittee look at this, is there a possibility that they can look at it soon like between now and August, or does protocol really require that it goes to the main committee and then get filtered out? You know, we're looking at timeliness when we recommend to the subcommittee.

MS. WOTECKI: Yes. I just don't recall that we've ever made a recommendation to a specific subcommittee. It's always gone to the micro committee.

I can't recall exactly what the rules are of referrals, but it generally goes from one committee to another, and certainly anything that would come from a subcommittee would have to be reviewed by the parent body before it was transmitted back, so it just seems procedurally that it's more appropriate to go to the committee.

MS. HANIGAN: Okay.

MS. WOTECKI: As far as, you know, getting work started between now and August, that would be something that we'd have to discuss with the committee.

MS. HANIGAN: Okay.

MS. WOTECKI: Our chair is not here today, so we would have to talk with her as well.

MR. BILLY: I can add a little more. That committee works essentially the same way as this one, so what would happen is at the August meeting we would forward the request. It would be presented by the secretariat to the chairman. The chairman would ask the subcommittee and any other members of the committee to participate in that kind of a discussion.

It would come back like is occurring here to the committee during a time allocated for recommendations from the subcommittee and then it would be considered, so I think it's better, and I would suggest to the committee that it just be referred to the full committee and that process is what would happen.

Much like this committee, the materials are sent out in advance and then considered and then addressed during

that similar kind of process, so I think there's a reasonable chance we can get that committee to look at this area during that August meeting.

MS. HANIGAN: Okay.

MR. BILLY: While I have the floor, I'd like to also suggest that picking up on the recommendation that Dale made, I also heard you say, Katie, that there was concern expressed about the deadline of July, and it seems relevant if we're asking the micro committee to look at this and we're further asking that examples be provided that perhaps this committee ought to make some -- include in its recommendations a recommendation that the comment period be extended to provide time for the micro committee to do what you've recommended and for the industry to gather together and submit the examples and data and so forth that you've talked about.

MS. HANIGAN: And we did request that. Yes. We have requested.

MR. BILLY: Yes.

MS. HANIGAN: We specifically didn't put a time frame on it, --

MR. BILLY: Okay.

MS. HANIGAN: -- but just wanted it to be extended prior or past the point where the micro committee can look at the document, the industry's petition, and have time to develop comments, so that's why we didn't specifically pick a date like September 1.

MR. BILLY: Okay.

MS. HANIGAN: Current Bullet Point No. 3?

MR. BILLY: Three, yes. Okay.

MS. MUCKLOW: Tom?

MR. BILLY: Yes, because the subcommittee -- my point is that the subcommittee can do this without the time period being extended, so making it more directly related to the work of the micro committee, clarifying that, makes it clearer. We could extend it a month, for example, and the committee may not have met yet. I know that's your intent, but just so it's clear in what you're recommending.

Yes, Rosemary?

MS. MUCKLOW: Tom, to accommodate Cathy's concern about the procedure could it be referred to the micro committee with a request that it be referred in advance or

the materials provided in advance to the subcommittee? Then you get it to the full committee to address the procedural issue, but you also get it in the hands of the people that need to look at it ahead of time.

MR. BILLY: Yes. I wouldn't again limit it to the subcommittee. I'd recommend that it be made available to everyone.

MS. MUCKLOW: Well, certainly, but the subcommittee need to see it ahead of time.

MS. HANIGAN: Well, and part of the extension of the comment period was we are hoping that the Agency or our request is that the Agency make to the public, you know, this first bullet point where we talk about a side by side comparison. It's going to be essential that that information be out in the public so that when the public does their comments that they have that information as well.

MR. BILLY: The way that would likely work is that we would publish a Federal Register notice. We would incorporate or acknowledge what is being recommended here and indicate the desire to have this additional data and information and to get this further input from the micro

committee. For that reason, we are extending the comment period to such and such.

MS. HANIGAN: Okay.

MR. BILLY: That's how that would work.

Yes, Caroline?

MS. SMITH DEWAAL: Thank you. I'm sorry, Madam Chairwoman, that I couldn't come to the subcommittee meeting last night, but I must say I am happy to see the recommendations that came out of the subcommittee. I think they're very good.

I would propose to the Agency that the concept of reentering this rule making on the HACCP regulation is one that I certainly approach with a certain amount of trepidation, having been through it the first time. I think that we can't willy-nilly amend the regulation just whenever anyone seems to have a problem with it, so what I would like to recommend is that the Agency consider the industry petition as part of the larger package of rule making, which may in fact include updating performance standards, developing new systems if we need them, clarifying prerequisite programs.

Whatever might need to be done to the regulations should be done as part of a larger package, and the groundwork that you're laying with this particular petition to make sure that we have all the relevant comments and we know the adequate comparisons between CODEX and FDA and the other questions that you had for us. That should all be groundwork on what is the industry petition.

I'm a little nervous that you're going to proceed down the road of answering this problem or that problem and then suddenly there's another petition that lands on your desk or another set of problems that arise, and so I think to the extent that you open up the rule for updating or for modification that that should be done as part of a package of corrections or amendments or updating.

I mean, clearly the performance standards for salmonella appear to be out of date already. The industries seem to be just doing a wonderful job of meeting them, and the whole concept behind them was that the Agency would raise the bar on occasion so I would just ask that you consider this petition within the context of whatever changes or modernization to the regulation might need to be

made.

Thank you.

MR. BILLY: Alice?

MS. JOHNSON: Nancy had asked a question about prerequisites and how the industry is handling it, and I know we've gotten a lot of paper over the last 24 hours, but, Nancy, there was the role of prerequisite programs in managing a HACCP system that was a published article that Katie handed out yesterday when we started talking about the petition. I just wanted to --

MS. DONLEY: Yes.

MS. JOHNSON: There's a lot of material to be looking over on your plane flight, but I just wanted to remind you that was there.

MS. DONLEY: I'm going to sleep.

MR. BILLY: One of the concerns I have as administrator of the Agency in looking at what we've experienced in terms of HACCP implementation and some of the related issues is that in the 6,000 or so federal plants, notwithstanding the current thinking on prerequisite programs that are recommended and taught as mentioned by

Mike, we see quite a number of plants, primarily the very small plants, that as far as we can tell only have one prerequisite program, which is their SOP.

So notwithstanding what maybe Todd recommended and what the micro committee suggested in 1997, there is not consistency throughout the industry in terms of prerequisite programs. The big plants have quite an elaborate set of prerequisite programs dealing with ingredients and raw materials and other control measures that relate to both safety and quality, and then as you move smaller and smaller in terms of operations many of those prerequisite programs disappear to the point where because we've mandated an SOP the very small plants have to have one of those, but when we look and we talk to people they have that and they have their HACCP plan, and that's what they have. Now, some very small ones do have prerequisite programs. Not consistent.

All I'm saying is as we go through this exercise as a regulatory agency looking at what we're talking about, we need to be cognizant that how this turns out in terms of what's expected from a regulatory perspective could have some significant impact on particularly the very small types

of operations. As we work through this, we need to understand sort of this spectrum of what exists and then take that into account.

Mike?

MR. MAMMINGA: That is a very excellent point you just made. I deal with it every day. I believe one of the reasons that it came that way is, you know, this paradigm shift in thinking takes a little time. Even though we worked with it for three years before we implemented it, longer than that really, there is still a certain thought process that says I'm going to do what I have to do and that's it.

Hopefully we'll change that attitude over time, but we still have to deal with it to start with and so when the Agency says well, you must have an SSOP, you must have generic type E. coli testing and you must have a HACCP plan for the processes that you do, we got away from what they were being taught by the people who taught industry HACCP, and we got more looking at what is the government going to require.

Maybe it was impossible to do this, Tom, without

that happening, but I would like to have industry listen to their teachers and have those prerequisite programs that they were taught, and I'd like to see our expectations as regulators -- you know, they're just not the same, and I'd like to see that delineated so that these small, very small plants that Terry, Lee, Dan and I deal with on a daily basis know just because we have expectations as government regulators that does not relieve you of your obligation to create and implement a HACCP program as it was designed by the HACCP experts.

That's the challenge; to get them to go on and do what they are supposed or should do versus what they have to do to meet basic.

MR. BILLY: Jim, and then Nancy?

MR. DENTON: I fully appreciate what you're saying, Tom, and I think Mike has pretty well hit the nail on the head.

Part of what our faculty are involved in in providing the training for HACCP, as well as sanitation SOPs and GOPs, is to try to equip these folks with the knowledge they need to develop these. As Mike says, it's a very slow

and painful process in order to reach that goal because many of these people have never considered this before, and the education that's required to do it takes time.

I think that most of these folks are trying hard to do this, but it is an educational process that they have to experience before they can achieve what's necessary to make this plan succeed.

MR. BILLY: I think Rosemary was next, and then Nancy. Sorry, Rosemary.

MS. MUCKLOW: What we come face to face with in this issue, and I don't disagree with either Mike or Jim, is the inherently different nature and structure and behavior of small businesses with very few employees who are very hands on by contrast with large companies who have people that are designated to make sure that lots of people will fit into a structured, systematic program.

When you've only got ten employees or less and you, the boss, you clean the toilets, you clean the packaging equipment, you sweep the driveway, you do all of the various things that are needed, he's never needed to have it written down.

He's usually done it because that's the way he was trained and brought up, and now we're taking that and making him put what he does by rote and instinct and hands on knowledge and transfer it into some program so that when somebody comes to his plant they can see a written program. It's a huge transfer process, and he does wonder why in the deuce he's got to do that because he's always done it, and it's in here. Unfortunately, the regulator can't see what's in his head.

I'm sure that Tim and Mike and Dan and Lee see this or hear about it every day from the inspectors going into their small plants. It's going to take a lot of time. I don't know whether we'll ever persuade these people that it is justified that they've got to write down what they've done by instinct, but that's the goal.

MR. BILLY: Yes. I understand. It's not just the state directors that have 2,500 of these very smalls. We have 3,500 under federal inspection, so we share the same set of issues and experiences.

Nancy, and then Collette, and then Lee?

MS. DONLEY: What you had mentioned, Tom, was what

I was trying to communicate that to be able to make knowledgeable and significant comments and meaningful comments it's necessary to know just what is minimum, I guess, as far as prerequisites and what is "voluntary."

You know, we have always -- you know, my organization has always maintained that it doesn't -- we don't care what size plant any type of food comes from. It just needs to be a consistency of safety across the board, so that is why we need to know just what is, if you will, the floor level of prerequisites.

MR. BILLY: Collette?

MS. SCHULTZ KASTER: I just want to clarify because I think I'm getting confused when we got into the discussion about the very small and small plants. Isn't the petition asking that the prerequisite programs be recognized if they are in existence rather than mandating prerequisite programs to the smalls or very smalls?

I think we're just saying that, you know, unlike the directive, and I don't remember the number that came out that specifically indicated that these were not to be married in with the HACCP plans.

I guess I always think of the example of employee hygiene, what they wear and when they wash their hands. Well, that's really not appropriate to the OCCP, but yet it's a major source of potential contamination, and that's the kind of thing that as Rosemary is saying, whether it's somebody verbally teaching the other people in their small plant or whether it's something that those of us in larger plants have written down as part of GMPs needs to be acknowledged at least as part of the food safety system.

MR. BILLY: Lee?

MR. JAN: Since we're talking a good bit on small plants and very small plants that got in and I was mentioned as having some of those I deal with, I did want to make it clear or set it straight that now I would agree with what Rosemary was saying about the attitude of the very small plant operators from the beginning.

I have it up here. Why do I have to put it on paper? I've always done it for 50 years and nobody got sick and all those excuses that we've heard, but when we started educating, working with these very small plants to tell them what's expected beginning with SSOPs, as they have developed

SSOPs they almost all have agreed that it was good for their business. They've adapted to that. They do the SSOPs and have them on paper. It took that getting it on paper, but we see that now that they have it that they do use it and rely on it.

Our biggest problem at least in Texas is that we require SSOPs in custom exempt plants as well, and those operators are even smaller than the very small for the most part, and they really have a difficulty we saw, and even they are improving the sanitation in their plants based on that so even though the attitude has been, I think the attitude has a great deal changed in these very small operators that they do see the value in that so, you know, even though they have been always perceived as difficult for them, you know, they're coming along. I just want to bring that out.

MR. MAMMINGA: The last word?

MR. BILLY: Yes, Mike?

MR. MAMMINGA: My comments that started this had nothing to do with very small plants or very large plants. My comments had to do with HACCP and what HACCP is and what

HACCP requires. It doesn't make any difference if you're a one person plant or a 15,000 person plant. You have to write down what it is that you do, and what you do includes your GMPs and SOPs and SSOPs. I have no feeling for very small plants over very large plants in the principles of HACCP.

What I'd like to do is just recognize that as government agencies we have expectations that are not bound by HACCP or its principles. Whatever regulation we can write and pass we can enforce. It doesn't have to do with anything, whether it's a proper HACCP principle or not, so I would just like to not try to mix and commingle, if you will, what HACCP is with what we have to do or what we think we have to do as regulators. That's the only delineation I'm making.

As regulators we're charged to protect the public health, and we will do what we have to do regardless of HACCP hopefully within its principles. I just don't want to confuse that for industry of any size, what they should do from the HACCP standpoint versus what we may expect. That was the entire point of that. I didn't mean to make it a

size issue of plants. If I did, I certainly apologize.

MS. HANIGAN: Okay. Question No. 2?

MR. BILLY: Yes.

MS. HANIGAN: Okay. Ready to go. I see like 12 minutes and five questions.

MR. BILLY: The others are easier.

MS. HANIGAN: Okay. Would amending 417.2(a) in a manner suggested in the petition result in regulations that provide the level of public health protection required by the FMIA and the PPIA?

Lots of discussion in committee, and clearly the committee did not reach a consensus on Question 2. One subcommittee member expressed concerns that protection could be diminished depending on the definitions and their interpretation and implementation. Once again we're talking specifically the definitions of hazard/hazard analysis in these prerequisite programs.

Four of the subcommittee members felt that the petition would allow the level of health protection required under the Act and why the four felt that was clearly they did not feel that the industry's petition was in any way

trying to relax, if you will, the rules. They were just looking for more clarification in a better focus under these definitions of hazard/hazard analysis in prerequisite programs, so we did not have a consensus, but that is where we ended up.

Questions? Okay. Moving on.

MR. MORSE: Just a quick comment, though I confess I'm the one. While a change may not have an effect on public health, I just thought that there should be some register note of caution. That's partly because I believe that the level of protection is to a large extent dependent on how the regulation is defined, interpreted and implemented.

Just as the Petitioners have a legitimate concern that the interpretation of the term unsafe is too broad, I also think there's a legitimate concern that reasonably likely to cause illness and injury could be interpreted too narrowly.

I think that concern has to be brought forward, so it may not affect the public health, but there's a potential if it became too narrowly defined that somebody might, as an

example, and this is not currently being discussed, but somebody might say well, the level of illness is too infrequent, for example, from SC in eggs or listeria or, you know, E. coli because the numbers are small.

I don't think that's going to happen, but I think there has to be common ground and not one extreme or the other in how this is interpreted and basically implemented.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: If I had been at the committee, the lack of consensus would have been even clearer because I share Dale's concerns. I just wanted to get that on the record.

MR. BILLY: Okay. Go ahead.

MS. HANIGAN: Question No. 3. Should FSIS consider regulatory modifications that would acknowledge the prerequisite programs concept from the micro committee? Our subcommittee said yes, regulatory modification should acknowledge the prerequisite programs as outlined by the micro committee.

And then the other two bullet points. We talked about too much is being placed into the HACCP plan. We need

to focus on the food safety issues. Problems arise when deviations occur in the HACCP programs as all deviations must be addressed with corrective actions, and this becomes difficult when HACCP programs contain items that are not food safety related. Again, if we're missing quality issues in with HACCP programs when you have to write corrective actions, it just gets to be difficult.

We also recommended that the Agency conduct a workshop, and this had previously been discussed in August of 1999 at the technical conference that was held in Omaha, Nebraska. We're specifically wanting a workshop to discuss the prerequisite programs and the roles that they play.

MS. DONLEY: Katie, I guess I'm a little confused by what you said that there's too much in the HACCP plan. The companies write the plans themselves, and if there's too much in it and if it's quality issues it's the companies -- the companies have put that in their own plans. It sounds like an industry or company problem.

MS. HANIGAN: Nancy, speaking from experience because we have 12 plants, we have individual inspectors at various plants that will absolutely insist that we put

things in HACCP programs, and we don't believe they should be there. You know, you can argue and fight, but there comes a point if you're going to have a working relationship with these people you just about throw in the towel and put the darn thing in.

MS. DONLEY: Well, then it sounds like it's an issue within FSIS to do better training with the inspectors.

MS. HANIGAN: And it a lot of times does come down to training issues because when we try to talk with them about risk and severity they do not understand. They clearly do not understand.

MR. BILLY: Mike?

MR. MAMMINGA: I have a question about this where you say all deviations must be addressed with corrective action. Deviations from a critical control point or a critical limit must be addressed, but if you have deviations from something besides a critical limit at a critical control point that isn't -- that does not require corrective action; not documented corrective action anyway.

MS. HANIGAN: And we were referring to deviations from critical limits, et cetera.

MR. MAMMINGA: Okay. Thank you.

MS. JOHNSON: We also, Mike, to go on with the fact that we feel like some of the information in the HACCP plan should be prerequisite because once it's in the HACCP plan if it's a deviation then you do have to go through the corrective action, and it takes the focus away when you have a lot of this other we kept referring to it as stuff last night, whether that was appropriate or not; all the other information that we generally keep in prerequisite programs.

When they become part of a HACCP plan then it takes our focus away from what the true HACCP plan should be centered around.

MS. HANIGAN: Okay. If no other questions, we'll move on.

MR. BILLY: I was just thinking that this is another area where examples and data from industry would be very helpful in terms of informing the Agency and the public about what the issues are specifically, you know, so then it gets into the same point that was made earlier and picks up on Nancy's point about how is this dealt with because regulatory modifications in terms of prerequisite programs

sweeps us back into the earlier discussion about different sized plants, expectations, Mike's point about regulatory requirements versus what HACCP is about, and we would be better informed I think if there were examples.

MS. HANIGAN: By prerequisite programs you're --

MR. BILLY: Well, not just prerequisites, but too much is being placed in HACCP plans. What's the too much? Examples.

MS. HANIGAN: Okay.

MR. BILLY: I think that would be helpful in terms of providing, picking up on Nancy's point, what it is we're trying to address and how best to do it.

MR. MAMMINGA: We have an appeals process now, and that's one issue, but what you're asking for is for some pencil and paper examples of what you're dealing with versus simply putting out fires every time somebody doesn't agree about an NR, and I think that's a very, very excellent point that everybody ought to leave here with is let's give you some feedback.

Of course, in my program it's quite the same, but, still, you don't know unless what's going on specifically.

The appeal process for a specific NR isn't necessarily a vehicle that could help you the most here.

MR. BILLY: Right. Lee, and then Caroline?

MR. JAN: The concern or the question or the comment stated -- I think Alice said that if it's in the HACCP program then you have to answer deviation for critical limit, and we need to move it out of the HACCP program.

If it's a deviation of critical limit, even if it's an SSOP and specifically if it's an SSOP, it still has to be addressed. The corrective action has to be documented and taken and all that, so moving it doesn't really take the responsibility from the plant to do the corrective action and document the corrective action that was taken.

I think the question comes in whether or not it needs to be in the HACCP program, but if you look at the prerequisite as part, even though it's not maybe even in the seven principles, but it's part of the whole system, then it doesn't matter where it is. The plant still has to do the same amount of stuff.

I think one of the Agency positions has been that if a critical control point is required, and it's required

if a hazard is reasonably likely to occur, once you identify that the Agency's position has been and I think still is that you can't say that it's taken care of in a prerequisite program because the question then becomes what if that program was not there and so they want to see it in the HACCP program.

Now, that might need to be, and I would agree and say why can't we recognize that part of that system, but we need to understand that wherever it is the deviation occurred, the plant is still responsible for taking and documenting corrective action and taking steps to prevent future occurrence.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: I was just thinking that I think it is an excellent idea to try to gather some actual examples and to clarify the problem. I think that the trade associations that authored this petition should be enlisted to do that, and that will help depersonalize the data so it's not dealing with specific plants and specific inspectors, but that they can help to blind the information and maybe will identify some of the trends in inspector/

plant interactions that might need additional work.

Also, if this is something that can be fixed without changing the regulation, then let's fix it.

MS. HANIGAN: I think Dan had a comment.

MR. ENGELJOHN: I've sort of forgotten what I was going to say, to be perfectly honest.

MR. BILLY: Sorry, Dan.

MR. ENGELJOHN: I would say it goes back to the issue that clarity here would really help the Agency an enormous amount. We have made attempts to provide generic models, and the industry has done its own efforts at providing guidance to industry so we get into the tricky area of when you start being specific about providing examples of when something should be and when something shouldn't be, should be and shouldn't be in the plan, we still go around in terms of it appears the Agency is dictating something, but clearly there's a problem.

We just need to have some specifics put on paper, and I would think that that, if anything, would help in the instructional materials that we could provide our own employees.

MR. BILLY: Collette?

MS. SCHULTZ KASTER: Just to clarify this a little bit, I don't think this is done maliciously by the inspectors. Some of your best trained HACCP inspectors are just -- I think they're a little bit confused, and they see it's either the old way, sort of the command and control, or the new way, HACCP.

If it doesn't fit into the little box of the old way, then obviously it has to go into HACCP and so they just try to push everything over there, but a lot of times the ones that have, you know, encouraged us to put kind of oddball things into our HACCP plans, it wasn't done maliciously. It was just done because there was no in between area that they saw or were directed that it could go.

MS. HANIGAN: I think that's a very good point. Clearly the inspectors we dealt with, they are not, you know, being malicious about it. They just clearly don't understand.

MR. BILLY: Dan?

MR. LAFONTAINE: Dan LaFontaine, South Carolina.

There's one point that hasn't been made that is an important part of this equation, and that is, and correct me if I'm wrong, that the USDA inspection force -- I'm talking about the field inspection force, the circuit supervisors, the IICs and the inspectors that evaluate HACCP -- have never been, to my knowledge, formally trained in HACCP.

They've been trained in the regulatory implementation of HACCP. They've been exposed to it as a part of their two-week training, but they've never had a full, solid, three day walking through the prerequisite and principles. I offer that as constructive criticism because it is difficult to regulate a program that you've never had the full background knowledge of.

In South Carolina we did that, and it has helped tremendously, although I will admit that my inspectors get very confused also. It's not the panacea, but it's something that FSIS -- the time may be right to take a step back and integrate that somehow into your future training.

MR. BILLY: I can indicate that that is currently underway nationwide. We started with the supervisors, the circuit supervisors and supervisory inspectors in charge.

MR. LAFONTAINE: Okay.

MR. BILLY: It's currently underway.

MR. LAFONTAINE: All right. I wasn't aware of that.

MR. BILLY: Alice? Rosemary?

MS. MUCKLOW: Thank you, Dan. I remember several years ago the very strong efforts that we made as an industry to try to persuade the Agency that as we entered this entirely new era that we have joint training and that the inspection personnel meet the same kind of training requirements as was provided in the final rule, the two and a half or three day training.

I would strongly encourage the Agency at this point to make sure that as it is now entering its new wisdom on training that it meet the requirements set forth for the accredited training program of the International HACCP Alliance where you do have representation. A lot of thought and a lot of wisdom has gone into that training scheme and that predicate training system, and we'd certainly welcome the Agency.

I'm the vice-president of the HACCP Alliance.

We'd certainly welcome the Agency to embrace that accredited training program as it enters what I'd like to call its new wisdom on this subject.

Thank you.

MS. HANIGAN: Okay. Question 4.

MS. WOTECKI: Before we get there, I was going to ask is the committee then, based on this discussion, going to change your response to Question 3 because the question is should FSIS consider regulatory modifications, and on the basis of this discussion there was certainly a lot of alternatives to regulatory modifications that were discussed, so do you want to change that to a maybe or further elaborate the first bullet there?

MS. HANIGAN: I mean, it's open to the committee. I had made a reference or Dale had done a reference here regarding recommending the Petitioners, you know, include examples.

MS. SMITH DEWAAL: I would like to recommend to the committee that we do change our response here because I think the goal here is to fix the problem, and we should fix it as quickly as possible.

Modification of this regulation, whenever it occurs, will take years probably to go through all this analysis and the process, and if FSIS can fix it through better training of their employees, I think that would be the goal here would be to get it as fixed as quickly as possible.

MS. HANIGAN: I guess I wonder about a technical amendment. We've had a technical amendment one time before to this regulation, a technical amendment that clearly says that the prerequisite programs as outlined by the national micro committee. I mean, what harm, if you would, what clarification?

It seems like that would help us because right now in the regulatory language it's just so gray. I'm not sure. If they did an instructional correction, I think you're still going to have district by district, plant by plant interpretation of what is a GMP then.

MS. SMITH DEWAAL: Yes, and every once in a while the horns I have for being a lawyer poke up, but you get into this issue of constantly trying to amend something to deal with very specific situations.

I think if there -- I mean, the entire HACCP regulation was based on the concept of prerequisite programs with HACCP layered on top of those programs, and if a clarification to the inspectors is what's needed, I think we will just get a much faster result.

We risk going in there and trying to tinker with every, you know, well, is sanitation -- is this element of sanitation part of HACCP, or is it part of -- you know, you get into these gray areas where suddenly you're ending up with a very specific regulation that needs to be amended every six months to deal with the latest crisis in the industry.

MR. BILLY: Rosemary?

MS. MUCKLOW: With all due respect, the parties to the petition came in after considerable thought, and I would tell this committee there was significant compromise between the organizations that met to submit this.

This is not tinkering with the regulation. This is a very serious effort to try to correct some things after several years of HACCP that has become apparent at the operating level of the program to make it really work in

plants.

I appreciate the work of the subcommittee and the distinguished service of people who understand what HACCP is both from a science based and from an operating base in the industry, and the industry has not done this before. I don't think it's probably planning to do it again in another six months.

This is a very serious, serious effort, and I think that the people who met last night are probably bringing some very important recommendations to the table this morning. I don't think we'll be doing this again in any great hurry. There are no promises, but it isn't tinkering with this regulation every six months.

MR. BILLY: It sounds like there's not a consensus in the full committee, so --

MS. HANIGAN: Can I just make one --

MR. BILLY: -- if you want to -- I mean, another way of modifying it is saying that there was not a consensus in the committee, the full committee.

MS. HANIGAN: And I am not opposed to showing that there is not a consensus in the full committee. I think a

lot of good information is going to come back when the micro committee gives us their interpretation and intent of these definitions, but I think it would be fairer to say there was not a consensus in the full committee on it because clearly there is not.

MS. WOTECKI: Tom, part of my reason for posing that question was based on the discussion that had gone on here and also by the fact that the way that that first bullet is worded is very definitive, yet back on the first question where you're making a recommendation that we seek further clarification from the micro committee as to their intent in the definitions, this first bullet under No. 3 seems to presuppose the outcome of that, so it seems much more definitive in the context of the answers to the other questions that are posed than is warranted.

MS. HANIGAN: Could I recommend these changes to these bullet points? If I could just read them?

Okay. The first bullet point then would say there was not a consensus in the full committee. Bullet Point No. 2 would have to be changed to say some committee members feel too much is being placed in the HACCP plan. That would

be the only change to Bullet Point 2.

Three would stand as written, and then the fourth bullet point that would be added would be recommend the Petitioners provide specific examples where Agency's inspectors' recommendations for writing HACCP plans have been too inclusive. We need examples.

Would that be acceptable to the committee?

MR. BILLY: Dale?

MR. MORSE: I was just looking at how we got to the way the question was asked, should FSIS consider regulatory modification, so that the yes was sort of to consider.

I think we had a lot of debate whether there would be regulatory changes or whether it would just be interpretation, you know. There's this debate over whether you really need to go to regulations or your interpretation, your better definitions, would handle this. The reason it looked like it was a clear response was the way the question was asked, but I --

MS. HANIGAN: Yes.

MR. MORSE: That was probably not the intent to be

that strong for all the committee.

MR. BILLY: Well, I think the yes by itself, given the language of the question, is okay, but the sentence --

FEMALE VOICE: The second sentence.

MR. BILLY: -- is declarative.

MR. MORSE: Should it be modified to read that FSIS should consider, which is basically rephrasing the answer to be consistent with the question?

MR. BILLY: How about something, Dale, more FSIS should consider regulatory modifications or interpretations that would acknowledge prerequisite programs?

MR. MORSE: That's fine.

MS. HANIGAN: Well, get it fine tuned, and then we'll submit it back to Mike.

MR. MAMMINGA: Yes.

MS. HANIGAN: Is that okay with you? All right.

Okay. No. 4, do FDA regulations such as GMP regulations offer an approach that FSIS should consider? How would such an approach fit within the HACCP concept, and how would FSIS implement such an approach?

We could not answer this question because we did

not have the technical knowledge of the FDA regulations. Our only response was we recommend that the Agency provide the FDA GMP document and what is in the FDA HACCP regulations, and then we'd like to see this discussed again at our next advisory committee meeting.

MR. BILLY: In fact, you need to change it to it's not a document, the FDA GMPs plural, because there's a whole series that relate to foods.

MS. HANIGAN: Okay.

MR. BILLY: I think in the context you're talking about it's relevant to look at all of them.

MS. HANIGAN: Okay.

MR. BILLY: There's the umbrella GMP, but then there is a specific one, for example, for fish that's very specific --

MS. HANIGAN: Okay.

MR. BILLY: -- and a whole series of others for different foods.

MS. HANIGAN: Questions on 4? No? Okay.

No. 5. What will the effects of making FSIS and FDA HACCP regulatory requirements dissimilar? What will be

the effect?

That kind of stumped us, this question. Our response is just basically FSIS and FDA regulations have similarities. Currently there's some differences. They exist in interpretation, implementation and enforcement. The differences also occur because of FSIS and FDA statutory authority and regulatory approaches.

We did not answer that question, but they were already similar and dissimilar, so we did not answer.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: No. Go ahead.

MR. BILLY: The only point I would make here is that there are at least 700 establishments where both FDA and USDA HACCP regulations apply to them, and those establishments do care about differences.

MS. SMITH DEWAAL: The other point I would make is the definition of hazard analysis is so central to HACCP that I think we need to be very cautious in making huge differences, in making changes that would result in big differences between FDA and USDA's HACCP regulation.

I criticize the fact that the two regulations are

so different, and I will provide for the committee an article I wrote that describes the differences between FDA's HACCP regulation for low acid canned food, for seafood with the meat and poultry regulation, and that's a public article in the *Food and Drug Law Journal* that I wrote a couple years ago, so I'll give part of the analysis that I did, but I do think we need to be very cautious with respect to the definition of hazard analysis because it is so central to HACCP.

MS. HANIGAN: Okay. Question 6. Should the changes suggested in the industry's petition be considered in light of their views expressed on HACCP by CODEX and the other countries?

We clearly felt yes, and that was evident by our previous recommendation to include CODEX in that side by side comparison.

MR. BILLY: This is significant because, and someone can correct me if I'm wrong because I haven't looked at it in awhile, but I believe the CODEX HACCP recommendations include both quality and safety in HACCP, so the side by side I think --

I'm not disagreeing with you. I'm just observing that as you broaden this out internationally you get some significant different views about what is included in HACCP. It will make for an interesting comparison.

Lee?

MR. JAN: I'd like to if I may go back just one back to No. 5 because that question is a little confusing to me, I guess.

I'm not able to really comment about the dissimilar parts of the HACCP regulations except for one area that I think is very dissimilar, and maybe the Agency can work with FDA to make it a little more consistent, and that's that HACCP is mandatory in meat and poultry and is not mandatory in similar processes at retail, grinding operations and all the meat processing at retail. There's no mandatory HACCP requirement.

I think that it's kind of related to this question except, I mean, you know, you're saying here making them dissimilar. Well, they're already dissimilar in that area. I think we should -- some effort should be made to make them more similar.

MALE VOICE: I'll vote in favor of that.

MS. SMITH DEWAAL: Can I just ask a question for clarification? I believe the states regulate grinding operations occurring at least like in the back of a grocery store or in the retail operations, so I guess I'm wondering how we could -- I mean, FDA can't mandate stuff at retail because the states regulate it, but correct me if I'm wrong.

MR. BILLY: Dan?

MR. LAFONTAINE: We're off on a tangent I realize, but what Lee is speaking about, and I'll speak for myself, is those meat markets that are in fact regulated by the state health department now, but are doing a significant amount of wholesale product, up to 42,000 pounds a year to wholesale customers that are in direct competition with either state or federal plants with a grant of inspection.

So what we're talking about, Caroline, is those plants, not your average meat market, but those meat markets that are doing a significant amount of business beyond their counter to hotels, restaurants, feeding institutions.

MS. SMITH DEWAAL: And you're saying those are being regulated by the Food and Drug Administrative, because

that's kind of scary given the fact that FDA really doesn't have inspectors to do even many seafood plants and other plants that they have major responsibilities for, so there are major meat plants or grinding operations regulated by FDA today? Is that what you're telling us?

MR. LAFONTAINE: We have the -- you know, as you well know, anyone, we've got the two umbrellas, you might say, the USDA and the state meat inspection programs if they exist, and the FDA and the state health departments, in whatever guidance they may take from the FDA to implement, so what I'm saying is we have meat markets that are putting up to 20 ton of ground beef out to the general public that are not under the same HACCP, SSOP and salmonella testing as those plants that happen to be producing enough to be under a state or federal program.

MS. SMITH DEWAAL: That is an example of a gap in food safety protections which I think is very significant, and the root cause of that is the fact that we have divided federal agencies, and we have inconsistent implementation of the food code by the state and county and local health departments that regulate.

That is truly disturbing to me that you're saying that that much meat is being produced essentially with no regulation.

MR. LAFONTAINE: One more comment, and I'll break it off. Even if the states adopted -- every state adopted the most recent food code verbatim, that would not solve this problem because they would still not be required to have SSOPs, HACCP and salmonella testing as a part of their program.

MR. BILLY: Lee?

MR. JAN: I'd like to clarify that, you know, what Dan was talking about, the retail example, and that's a certain consideration, but I was really saying retail because there's many customers that buy directly from these processors that are not afforded the same protection.

You know, certainly what Dan brought out is of consideration. I think we're going to address that later today. I think it's on the agenda about the retail exemption for HRI, and to your question the states do regulate, but they get their guidance or their direction, and I'm not sure to what extent and how the contracts are

read, but they are basically implementing the FDA, the federal regulations and requirements.

If the federal has no requirements for mandatory HACCP, then how can the states? Most states are not going to be able to take that. They don't have the staff either to put them in there, but that doesn't mean that a HACCP can't be -- shouldn't be required.

The records are there. Let that system at least be better than what's there now, which is nothing except once a year or however often they can get in there.

MS. SMITH DEWAAL: This would be an opportune moment, I think, to mention to the committee members. We were asked to review a draft report from the Health and Human Services Inspector General on FDA's food program.

Apparently about 61 percent of food safety inspections done by FDA right now are being done by the states, and increasingly they're being done under something called partnership agreements, which are unaudited inspections by state government, which are essentially adopted by FDA. This is a very troubling new development.

What it indicates is that increasingly on the FDA

side there is no federal inspection. It's all being done by state government. It raises questions in terms of uniformity, of standards, which we've already seen in the retail sector with restaurants, for example, when CSPI did a report on that topic several years ago, but it also raises issues about the trade implications are huge because how can we guarantee equivalent of food safety inspections with our foreign trading partners when we can't guarantee equivalence state to state.

This report I think is going to raise many troubling questions for people concerned about food safety and the regulatory oversight of the sister agency on food safety.

MR. BILLY: Okay, Katie.

MS. HANIGAN: I just had a question for Mike. Can we get these revised and then back to the committee today?

MR. MAMMINGA: Uh-huh.

MS. HANIGAN: Okay. Thanks.

MR. BILLY: Lee, or Terry, I mean?

MR. BURKHARDT: I just want to make a suggestion. It seems to me in looking at this whole issue that there

obviously is some concerns with the application and implementation of HACCP. It was obvious by their concern that the trade organizations put together.

HACCP is supposed to have been based on a system of cooperation and communication between both. It's obvious something has broken down there. I'm suggesting, and I'm going to be doing it in my state, sitting down with the industry and talking about what are the problems, both with our inspectors in implementation because this is something so new and for the industry because it's new for them as well, and figure out what are the problems. Maybe it's just some growing pains.

I would suggest maybe the industry has done that already or the Agency, but there's got to be some better cooperation and communication between the two. That's my thought.

MR. BILLY: All set, Katie?

MS. HANIGAN: Yes, sir.

MR. BILLY: Let's take a 15 minute break.

(Whereupon, a short recess was taken.)

MR. BILLY: Okay. The next report is from the

subcommittee that addressed the issue of extending USDA's meat and poultry inspection program to additional species. Included in that was the issue of the use of nitrites and nitrates and non-amenable species. Dan?

MR. LAFONTAINE: Thank you. We had a good discussion. We had a good, healthy discussion. We had in addition to the three committee members that were present we had representation from the industry involved in this particular issue in the audience.

The first comment I'd like to make is that Dr. Post and his colleagues put a lot of effort together, as we asked, to do a good literature research, a bibliography of known diseases that could possibly be food borne diseases. To recognize that and to make it a matter of record, we came up with this background statement to acknowledge that and what we felt it substantiates. If you'll just bear with me a minute, I'll read these couple sentences for the record.

"Based on the current USDA FSIS literature review, the summary of diseases known to exist in non-amenable species substantiates consumption of these species could be a source of food borne hazards. Poultry species examples

are salmonellosis, campylobachterosis and pesticide residues. Examples from meat species are salmonellosis, E. coli 0157:H7, brucellosis, tuberculosis, listeriosis, urcineosis and pesticide residues."

To repeat myself, we felt for the record we needed to acknowledge the work done, and that information clearly shows there's a significant number of food borne hazards in these non-amenable species.

Are there any questions or comments on that statement before we go on?

(Pause.)

We did develop two recommendations. First an introductory comment. We have been -- we, the committee, have been dealing with this topic for several meetings now. Once again, Robert and his colleagues have done quite a bit of good research and thought process of all the issues, and it was a consensus of the three committee members that were present that it was time to move on to what we called an action plan.

Our recommendation is that at the next meeting, the November, 2000, NAC MPI meeting, present a concept paper

that includes an action plan with the following four elements. Those four elements are the species to be added as amenable to the Federal Meat Inspection Act and the Poultry Products Inspection Act; number two, the changes that would actually be required to the FMIA, the PPIA; and then the other two big issues, of course, are what is the financial impact of providing inspection and the staffing impact of providing inspection.

I want to add before I stop that on the financial and staffing impact that is a work in progress by Dr. Post gathering what actually is the financial I don't want to say issues, but the financial analysis or cost analysis of this type of a change, so although it's a tasking it's not a brand new tasking.

Let me stop right there and see if there are any comments or questions from my colleagues on the committee.

MR. BILLY: Yes, Rosemary?

MS. MUCKLOW: Has legislation actually been presented up on the Hill?

MR. LAFONTAINE: Yes. There are I had mentioned four bills that are --

MS. MUCKLOW: Four bills?

MR. LAFONTAINE: Right.

MS. MUCKLOW: Are they all in one body or the other?

MR. LAFONTAINE: There are three in the House and one companion on ratites. There is ratites, pigeons, and rabbits, I think, and --

MS. MUCKLOW: Okay. Are they all separate bills, or are they all potential for being blended together or what?

MR. LAFONTAINE: I can't talk to whether they could be blended, but they appear to be all separate.

MS. MUCKLOW: They're all separate?

MR. LAFONTAINE: Well, there's a companion for the ratites, but the pigeon, rabbits and ratites are separately -- were separately introduced.

MS. MUCKLOW: Okay. So all those Congress people may need to talk together and get them sort of blended together maybe?

MR. LAFONTAINE: Well, I think also they've only been introduced. To the best of my knowledge, there haven't

been any hearings.

MS. MUCKLOW: No. No.

MR. LAFONTAINE: No.

MS. MUCKLOW: I'm sure you hear about hearings through the administration.

MR. LAFONTAINE: Tom?

MR. BILLY: Yes. Dan?

MR. LAFONTAINE: Rosemary, this issue of these bills being introduced, and actually I believe one, ratites, was attached as an amendment to the House Appropriation Committee. You know, these type of bills have been introduced year after year and so far have not been enacted, so we felt that notwithstanding what might be happening in Congress that FSIS, in conjunction with the committee, needed to methodically work up a package, for lack of a better word, of what was required as far as legislative changes similar to what we did for the interstate bills.

If they happen to get overtaken by events in Congress, then so be it. That's a different issue, even though it's a collateral issue. So we're not ignoring it, but we're recognizing it's a different issue we can't

control.

MR. BILLY: Katie, and then Lee?

MS. HANIGAN: Question to you, Dan, or perhaps Robert. I was part of this committee last time. How are we going to make sure that FSIS requests money in the budget this time because I was surprised yesterday to hear that money had not been allocated or had been allocated and then had been removed because it would seem a shame to come into November with a concept paper and action plan and then be told no money, so how do we make sure that the money is clearly put in the budget this time and remains there?

MR. LAFONTAINE: Let me start, and then I have to turn it over to Mr. Billy, I think.

It's kind of a chicken and the egg thing, you know. Do you get the legislative process along far enough that you need to be serious about putting the money in, or do you start the money process in anticipation of, you know, so I'm not -- I guess we have to defer to the Agency how to work these things when they anticipate a new requirement.

MR. BILLY: Probably the best way to address that area is to use the example of the interstate shipment bill

that resulted from the work of this committee and the concept paper that was developed here.

Once we arrived at a consensus here in terms of a concept paper, that triggered both the drafting of the administration bill and incorporating into future budget funds that would see the implementation of those changes and so it would be fair for this community to assume that that similar approach would occur.

We need to arrive at a consensus of what we're talking about and have a sense that there's broad support from all the interested parties as represented by this committee, and then there will be a response in terms of dealing with whatever legislative changes might be needed, as well as the resources to carry it out.

MS. HANIGAN: Can I ask you a follow up on that?

MR. BILLY: But I assume part of what this recommendation is about is pinning down what those resources, resource needs, are. That, as I understand, is work underway.

MS. HANIGAN: So as a follow up, clearly there's no funds available for this inspection in the next fiscal

year, correct?

MR. BILLY: Correct.

MS. HANIGAN: So then if we come into November and we have a full committee consensus that we want to move forward with this, when is your best guess that the first fiscal year will come when this inspection is actually going to occur? Would that be 2002?

MR. BILLY: I would be -- yes. Well, you're asking me to predict what Congress might do.

MS. HANIGAN: I guess I would just --

MR. BILLY: You know, clearly Congress is going to decide what actions it chooses to take for the remainder of the session, keeping in mind that this is an election year, so there have been pretty clear signals that there is not much that's going to be in the table and work its way through Congress in the remaining time.

MS. HANIGAN: Okay, but --

MR. BILLY: So the likelihood is that the next Congress in January of next year would be in a position to consider an issue like this.

If we arrive at a consensus and have a concept

paper in November and then proceed to move forward and it's supported by the new administration, then you could expect that action is possible sometime next spring at the earliest, but that time frame, and the soonest that you could have it included in the budget would be a year from October.

MS. HANIGAN: So you're not --

MR. BILLY: Fiscal 2002.

MS. HANIGAN: So you're not permitted to put funds in the budget ahead of --

MR. BILLY: Well, actually --

MS. HANIGAN: Ahead of this process?

MR. BILLY: Actually, that would be happening. The budget goes from the President to Congress in the early part of the year, early 2001, is considered by Congress and then enacted to begin October 1, 2001, so it would be -- it's possible to have this occur in the right sequence is what I'm saying. Possible.

MS. DONLEY: Let me just kind of follow up with Katie's train of thought here, if I'm grasping the train of thought.

Are you kind of coming from the position that we wanted to make sure, and maybe that needs to be specified here, that this must be a fully funded program and that it cannot be done at the expense of taking away from the current level of FSIS inspection, meaning that we're just not going to add a program without additional funding for it? Is that kind of where you're coming from on this?

MS. HANIGAN: Yes, it is, and I was very surprised yesterday to see where the status of this was.

MS. DONLEY: Well, I would make a recommendation then that it be clearly spelled out in these recommendations that we are expecting funding for this, not just adding another thing for FSIS to do, but it must be fully funded as well.

MR. BILLY: Okay. Lee, and then Rosemary?

MR. JAN: One area that I would like to see added to the recommendations in the concept paper would be a provision or some explanation on how product that is currently state inspected can remain to be state inspected and shipped in interstate commerce so that we don't hurt existing industry.

The biggest -- I think the majority of the inspected product today is done under state inspection, and if the interstate commerce shipment bill fails and this passes, then the markets are going to be closed unless some provision is made here for state inspected products.

MR. BILLY: Okay. Rosemary, and then Nancy?

MS. MUCKLOW: I just looked back at our earlier recommendations, and apparently there was a recommendation for a concept paper for the mandatory inspection of any commercial slaughtered birds or mammals for human consumption unless exempted, and then it goes on and on. That's back under Tab No. 4.

Because of my advanced age my memory fails me some days, and I would just like to try to be clear, and if we haven't been clear with the recommendation from this committee then maybe this is a good time for Dan to articulate that recommendation out of this committee.

Is it the will of this committee that we are recommending to the Secretary that he seek authority from the Congress for the inclusion of these other species under the statutory authority to inspect under mandatory statutory

authority?

The dilemma that some of the people that are members of the organization that I have are that if they're making deer sausage, they usually commingle it with some meat in order to get the market inspection on the sausage. If it's X amount of meat and X amount of deer, as long as it meets the X amount of meat they get it under inspection. These are games, and we shouldn't be having these kinds of games.

Is it the will of this committee that we are recommending to the Secretary that he seek the authority as an amendment to the Meat and Poultry Inspection Act that he inspect these other species? I don't know whether we covered that point previously, Dan, or not, whether we've made it that clear.

We can't even begin to talk about money unless we have the basic authority under the law. That's the way the Congress works. They appropriate money for that which they have laws. We don't have this as a clear recommendation, at least not according to this sheet, this summary sheet.

My memory may be failing me on that. I'd like to

go back and see if there's a clear articulation out of this committee as to what we would expect to happen.

MR. BILLY: Dan?

MR. LAFONTAINE: Let me try to answer that. I'll give you my opinion, and we'll see what the full committee says.

First of all, as this thing has evolved I believe it's fair to say there has been a consensus that these non-amenable species be added as an animal. This recommendation, although we maybe don't see it crystal clear, we see an action to do the following.

What species should be amenable and what changes are required to the Acts, so that at least indirectly is saying let's take some actions to head in that direction, so that to me if we vote on this and approve these recommendations we're clearly saying FSIS continue or the committee supports your efforts to amend the two laws.

MR. BILLY: Nancy?

MS. DONLEY: I'd just like to respond to something that Lee had brought up and that is the protection of trade. This came up in the last advisory meeting, as I recall. I

think I weighed it then, as I'm going to weigh it now, is that that is two separate issues.

You can't -- you just cannot ask to have inspection and then be granted as well an immediate exemption to current law, so you just have to take your -- the industry has to -- these industries have to decide what it is that they want most, and that is do they want federal inspection, or do they want to continue doing business as usual.

We cannot just create a caveat or ask for a -- I'll just say this. I'm vehemently opposed to a caveat that would automatically exempt them from having to follow the laws of the current -- the current laws.

MR. BILLY: Okay. Do you want to respond to that?

MR. LAFONTAINE: Adding on to what Nancy said and, Lee, your question, although it's not guaranteed by the time we meet again the first part of November we'll probably have a pretty clear picture if the interstate shipment bill is going to fly or not.

That's not guaranteed, but with an election year there's not going to be much activity, you know, after the

next few months, so it's an indirect way of saying that that question may be answered or cleared up before we meet the next time and look at this issue.

MR. JAN: I'd like to at least reserve the right for the committee that if we go forward with this and the interstate shipment bill at that time has not been successful and it's apparent that it will be not be successful, that the committee does not rely on the decision made today and have opportunity to reconsider its recommendations regarding this issue at that time.

MR. BILLY: Carol?

MS. TUCKER FOREMAN: You know, we may have the interesting thing that a bill that requires the inspection of ratites moves faster than interstate inspection.

Robert, is there -- I've been told that the bill reported by the Senate Agriculture -- by the full Senate Appropriations Committee includes a specific requirement that you expand mandatory inspection to ratites. Do you have any knowledge of that?

MR. POST: I'm aware of that, yes.

MS. TUCKER FOREMAN: So that's in there?

MR. POST: Yes.

MS. TUCKER FOREMAN: That bill is not ordinarily amended on the floor of the House. No action has been taken yet in the Senate, but that's substantially further than we've moved with interstate commerce.

It's also my understanding that there were no extra funds appropriated to cover ratite inspection. Is that the case; that the budget is approved basically as submitted by the Agency so that if there is a mandatory inspection of ratites it would have to be covered out of funds that are appropriated for the Agency and, therefore, in place of activities currently being undertaken?

MR. BILLY: I might be able to address that better. We are troubled by the fact that there is an amendment to the appropriation bill that would require us to mandate the inspection of ratites, but there is no provision of resources to carry that out.

That's done in the context of the inspector shortages and the other issues that we've been trying to address that were described here yesterday, so we are concerned about the point that Katie made. It's an issue

that hopefully as the legislative process continues it will be addressed and straightened out appropriately by Congress.

MS. TUCKER FOREMAN: I just want to say that, you know, ordinarily this sort of thing is done by writing the language in the report. This is an actual amendment, making it substantially realer.

Has the administration conveyed to the Congress or will the administration convey to the Congress that this isn't appropriate without some funds, or will you just oppose the provision?

MS. WOTECKI: Well, Carol, it's a little bit early yet since it still is under consideration within the committee, but clearly it's an issue.

MS. TUCKER FOREMAN: It's my understanding it's been reported by the full committee.

MS. WOTECKI: Oh, has it?

MS. TUCKER FOREMAN: Yes.

MS. WOTECKI: I'm sorry. Having been out of town for several days, I'm a little bit behind.

MS. TUCKER FOREMAN: Yes. I know you've been out there where there are no phones.

MS. WOTECKI: Exactly. Clearly it's something that, as Tom has indicated, we were tracking. We were certainly also very concerned about the lack of additional funds to support it, and we will be working in our responses to the appropriators to convey to them our concerns about it.

MS. TUCKER FOREMAN: I think the committee then is faced with an issue of whether we want to say that Congress should not move forward on this without appropriating specific funds or that Congress should not move forward with it without including other amenable species or that Congress should not move forward.

Those are options available that we can say to the administration we don't advise the Congress, God knows, that we would like you to make that known to the Congress.

MR. BILLY: Mike?

MR. MAMMINGA: The strategy behind the recommendations is found in lessons that we've learned in dealing with the Agency, and the folks that have bills in the Congress right now will probably learn those lessons as well.

In other words, when you raise concerns that there will not be sufficient monies appropriated to carry it out and you have concerns that monies might be taken from some other essential part of the program to pay for that, which is what's been articulated by all the concerns or, as my friend from Texas indicates, concerns that if we make them amenable and interstate commerce doesn't pass then you're going to pull a lot of plants out, all of those things are real --

Thus the USDA studies the points and perhaps raises others that the first thing we need to know is A, what are we going to expect; two, what changes does it require in the law; three, what's it going to cost; and, four, do we have the people to cover it.

These are the four most basic issues that we could say to USDA all right, we're going to have to have you look at this because you're the ones that are going to be most comfortable in writing the proposed legislation, so by asking the Agency to do it they can come back to the committee and through this laborious and yet deliberative process address these issues instead of trying to run around

and stop something on the Hill or support or not support something.

So we're not asking here for legislation word by word at this time. We're asking that the four most basic issues be addressed, and there will be others, depending on interstate commerce, depending on many other things, many things we can't even think of, but this is a place to start kind of like we started with other issues, including interstate commerce.

Let's lay out the groundwork. The legislation will come. The bill will come, and it has its best chance if FSIS drafts it, goes out to their constituents and sits here at this table. We simply ask them to define the first and foremost basic parameters of this legislation. The same thing goes for the national micro committees to come. We cannot resolve that today.

MR. BILLY: Cathy?

MS. WOTECKI: I do think it's appropriate, though, for the committee as part of your background statement to express concerns in view of the discussion that you heard yesterday of resources and staff and also the briefing at

the previous meeting about resource issues within the Agency to express concerns about implementation without, as Mike pointed out, having done the thorough analysis on the impact as far as resources, funding as well as personnel.

MS. TUCKER FOREMAN: I think it would be useful.

MR. BILLY: Dan?

MR. LAFONTAINE: I have quickly drafted a sentence that captures some of this, what Carol mentioned and the other issue of -- the whole issue of funding and somehow integrate this into this document that no changes be made to the FMIA PPIA without concurrent funding for implementation.

In other words, that would be a recommendation of this committee that there not be any changes without concurrent funding to implement that changes.

MS. TUCKER FOREMAN: I'm really quite taken with the recommendations. I think they're such an orderly process. As long as the recommendation makes clear that we think that the department needs to go through this orderly process, as well as having adequate funding available, then I think that would be terrific, Dan.

MR. BILLY: Okay. Caroline?

MS. SMITH DEWAAL: I just can't resist raising the fact that there are many segments of our food supply that aren't adequately covered, and in fact this year in the appropriations process we are fighting right now to get funding for the President's egg safety initiative.

Now, that's a product that causes 600,000 illnesses a year and about 300 deaths, so I just -- as we look at the resource issues of amenable species I really think the committee just needs to be very sensitive to the fact that there -- I, for one, will not support putting money towards this until we get full funding for the egg safety plan and some other things which actually are a higher priority in terms of food safety funding, so I just can't resist adding that point about the rest of the food.

MR. BILLY: Nancy?

MS. DONLEY: Just a brief -- perhaps in the recommendations if we change the word impact to the word needs so the financial needs of providing inspection and the staffing needs of providing inspection makes it a little clearer that it's not at the expense of something else.

MR. BILLY: Dan?

MR. LAFONTAINE: Yes. I want to try to bring this to fruition if committee members have had adequate time to air their concerns. I have no -- first of all, on Nancy's suggestion that would be fine with me to change it to needs if she and other members feel that's more definitive.

What I need to know from the committee is do we need to add any additional words such as what I read a few moments ago, and if we do then I'll do so as I read. What is the pleasure of the full committee to add a sentence along these lines that no changes be made to the FMI PPI without concurrent funding for implementation?

MALE VOICE: Resources for implementation.

MR. LAFONTAINE: Without current resources --

MALE VOICE: Concurrent resources.

MR. LAFONTAINE: -- instead of funding? Okay.

MS. SMITH DEWAAL: Could we make it a little more specific that no changes to the FMI or PPIA until -- on the issue of amenable special or something that just makes it a little more limited because it's a very broad statement this way.

MR. LAFONTAINE: Yes. I mean, I hear what you're

saying, but we're talking about the issue of amenable species as part of this document, so I don't think that's necessary.

MS. HANIGAN: I agree with your statement, Dan.

MR. LAFONTAINE: All right.

MR. BILLY: Good.

MS. JOHNSON: Let's add the statement.

MR. LAFONTAINE: Let me, if it's appropriate as the chairman of this subcommittee. I don't know. Maybe I should defer to you, Mr. Billy. Do we have a consensus?

MR. BILLY: I think you have a consensus.

FEMALE VOICE: Yes. Yes.

MR. BILLY: You have a consensus, yes.

MR. LAFONTAINE: All right. Okay.

Let me go on to the last point then. The other issue was the whole business of nitrites. We spent a fair amount of time but came back full circle that the whole issue is in the hands of the FDA and the national toxicology program, which will report out at least one study tomorrow, so realizing that we're not going to get anywhere on this issue until we hear the latest from FDA, we felt that at the

next meeting a copy of what was said about this issue at tomorrow's meeting and then what action, if any -- well, actually, a briefing on what subsequent FDA action has been taken.

I guess I'll paraphrase that by I would like to suggest that FDA actually come talk to us about that rather than getting it secondhand. If they have very little to say then so be it, but this could be a show stopper on this whole issue. That is our recommendation that a copy of the report be provided and a briefing on the FDA subsequent action.

MR. BILLY: You might want to change the language then. A briefing by FDA on subsequent planned actions.

MR. LAFONTAINE: Yes. Okay. I'll do that.

Any comments or questions on that from the committee? Okay. I think we're finished then. I'll add this sentence in here for everyone.

MR. BILLY: Let's move on to the third subcommittee. It was chaired by Carol Foreman, and it had two issues. One was E. coli 0157:H7 developments, and the second was listeria monocytogenes development.

Carol?

MS. TUCKER FOREMAN: I think the documents are being passed out right now. The Agency asked us to comment on the Agency's current thinking on measures to control E. coli 0157:H7 in a HACCP environment and what additional measures the Agency should take to address E. coli 0157:H7.

We commented on each of the five points of the action plan. Let me get over here. If everybody just refers to their document on E. coli and the page 2 on the action plan, you can read along.

Oh, I'm sorry. We handled listeria first, but I was embarrassed that we didn't finish our listeria discussion, so I was going to act like we ran out of time.

I'll give you a minute to look at the subcommittee's recommendations or comments on the action plan if you want to take just a second to look at those.

MS. MUCKLOW: Which one are we doing first, Carol?

MS. TUCKER FOREMAN: E. coli. Our comments, one through four, were based on the points in the action plan.

(Pause.)

MS. TUCKER FOREMAN: Okay. The first point was

based on available data presented at the recent public meeting, FSIS believes that E. coli 0157:H7 may be a food hazard that is reasonably likely to occur in beef production. The subcommittee was in agreement that in fact it is a hazard to be addressed in the slaughter hazard analysis.

No. 2, following publication of this notice FSIS would expect all establishments engaged in beef production and processing, so on and so forth. We were generally in agreement with that statement, but rather than FSIS would expect all establishments to reassess their HACCP plans, we suggested it read all establishments must reassess the HACCP plans.

On No. 3, redesigning FSIS' redesign of its testing program so that it can operate as a HACCP verification activity, we were pretty much in agreement with that proposal as it was written.

Four, FSIS would revise Directive 10010.1 to reflect the revised testing program. We had some disagreement on that. Some of us thought that the word verification ought to be added in the third line so it said

included verified controls should be verified instead of verification, but some folks thought that that was redundant in the HACCP concept.

On Statement 5, I guess I was sleepy last night. I didn't put that one in. We were basically in agreement with the action plan statement, and then on the question raised up above that FSIS is open to excluding certain non-intact products, the subcommittee had a fairly good discussion there and really decided that FSIS should ask ARS to study the safety of non-intact beef cuts and how they can be served safely.

In other words, we didn't think there was enough data to understand whether or not it was necessary to subject those products to mandatory E. coli verification, but thought that we needed some data. We were particularly concerned.

Actually, Lee, I think you're the one that commented on that. Either now or when the time comes, why don't you --

MR. JAN: My issue was that we have the Kansas study that says that basically if a steak has been needle

tenderized or considered non-intact is cooked to rare it's safe, but I'm not sure that that's a final study and that there's a lot a confidence in that study. It hasn't really been peer reviewed or whatever to make it legitimate.

The Agency has a research service, ARS, and FSIS should ask them to do some independent studies on that. The concern even goes beyond meat and poultry processing, but restaurants, particularly those restaurants, steak houses such as Bonanza or Best Western or Sizzler or those that have some of the less expensive cuts often use these type steaks, and people order them rare or medium rare.

If that's a risk, then that need to be addressed in some manner. Through education would be one way. The other would be, you know, possibly a labeling or whatever. Obviously included in the HACCP system about specifically addressing E. coli it was determined that it is a hazard reasonably likely to occur, so that was kind of where we was coming from on that one.

MR. BILLY: Katie?

MS. HANIGAN: Carol, could you tell me one more time No. 4? I'm not sure. Tell me again how that works.

MS. TUCKER FOREMAN: I'm sorry. The subcommittee was in agreement with the overall action plan proposal, and some members of the committee thought that in the third line there where it says just -- I'll read you the second sentence. "Current FSIS thinking is to provide for reduced Agency sampling in establishments that have included verified controls for the pathogens in their HACCP plans."

Some of the members wanted to insert the word verified there. Others thought that it was redundant, that it was inherent in that HACCP activity.

MS. HANIGAN: I don't think it would be redundant.

MS. TUCKER FOREMAN: Okay.

MR. BILLY: Carol, or Caroline, I mean?

MS. SMITH DEWAAL: Just to speak on that briefly, the language with access to records of plant test results and corrective actions doesn't give me full confidence that what we're talking about is a microbial testing verification program, which seems to be implied in the language, but isn't specific, so that's really what the discussion was about. Thank you for your opinion.

MR. BILLY: Nancy?

MS. DONLEY: I'd like to ask a specific question of the Agency on this to kind of more fully understand what you're thinking, how directly the 10010.1 will be changed.

Let me give you a scenario. Slaughterhouse A does have some sort of a carcass, let's say a carcass sampling program for 0157:H7. Processing Plant B -- I'm going to give you two scenarios. Processing Plant B buys its raw product from Slaughter Plant A. Retailer C buys all its ground product from Processor B. Who would be subject to testing under FSIS' random sampling program?

MR. BILLY: Judy?

MS. RIGGINS: We would collect some set of verification samples at all three sites. We would expect that when the slaughter plant does its hazard analysis that there would be interventions in place to address 0157:H7.

At Plant B, which is processing, we would expect in their hazard analysis to make some determinations about the likelihood of 0157:H7, and some of the things that they might employ would be agreements with their supplier, which is Plant A, that would give them assurance that they are in fact using interventions, lactic acid sprays, steam

pasteurization, hot water pasteurization, other interventions that would minimize the 0157:H7 so that they would have some idea of the microbial load coming into the plant.

They could then account for that and make some decisions based on what they know about their own process to determine what additional steps they would need to put in place at processing.

With respect to C, which I'm assuming is retail, --

MS. DONLEY: Retail.

MS. RIGGINS: -- we would expect that there would be again acknowledgement of 0157:H7 as a likely hazard and that again there would be some serious communication between the processing plant and the retailer to make certain that there are hurdles in place in the processing plant so that when incoming product is received at the retailer they have some assurances about the microbial load that they are receiving in that product.

MS. DONLEY: So how does that differ from what 10010.1 is today?

MS. RIGGINS: Right now it is not explicit about the expectation of the Agency with respect to those communications that need to take place about the hazard, that there is acknowledgement that there is a hazard reasonably likely to occur, first of all, and that there are proper or appropriate communications in the ongoing activity every day, ongoing daily operation of all three components, A, B and C, that account for and address that particular hazard from 0157:H7.

Right now our sense is that some companies are operating independently, are not looking at the whole system, which would be if you're looking at a risk analysis system would be -- it would include all A, B and C activities, and that's what we are trying to encourage through this directive, which would result hopefully in a much more comprehensive approach to 0157:H7 given the difficulty that we have because it's present in low numbers.

It's difficult to detect. There needs to be some systematic approach in the industry, understanding that each component in the industry has a role in addressing this particular hazard. That's what we're trying to --

MR. BILLY: Let me add something. As stated here in four, we would also intend to acknowledge when those kinds of interactions and verification, testing and so forth occurs through providing opportunity for reduced sampling as stated here so that if in fact there are good controls and there's that kind of interaction there would be an opportunity for us as regulators to take advantage of that and focus our sampling activities appropriately.

MS. DONLEY: I guess, Tom --

MR. BILLY: Let me make one other point. Our current sampling directive doesn't include slaughter. This would. You know, given the study that the industry did and another study ARS did and other information that is available to us, it's very clear that more sampling and testing at slaughter can have a very significant impact.

We want to as part of this encourage that because we think that can have some very big ramifications in terms of what happens subsequently in decisions that could be made by large and small grinders and retailers and so forth.

I just -- you know, some of the largest fast food chains have already taken steps in the private sector to

deal with this kind of strategy, and we've seen and they've provided to us information to show us the very positive impact this kind of approach can have. We think that we'd like to see that across the board, so that's the sense of this.

Nancy?

MS. DONLEY: I guess my concern is that there's sampling programs, and there's sampling programs or intervention programs, and there's good intervention programs.

The industry's original plan came up with testing one in every 300 carcasses, and then they wanted to have that exemption -- for lack of a better term, I'm going to use the word exemption -- or non-targeting, if you will, passed along from plants that test, do some sort of a one every 300 carcass swab. Product produced from that plant was non-targeted or exempt all the way through retail.

I find that very problematic, very, very problematic. I don't know if every one in 300 -- I can devise a sampling plant, and I guarantee you it won't be good. One out of every 300. I never knew where that came

from for the generic E. coli, and I don't know where it comes -- I know where it comes from from here. They're mirroring what's going on in generic E. coli testing.

There has to be -- for consumer confidence, there has to be some sort of validation built into these programs that companies are wanting to do, and FSIS has to recognize that these are valid programs and, therefore, will not be targeted or will be "exempt." That's my real concern that we just don't have empty words here. I'm all for giving company incentives to do things, but there has to be something behind the programs.

MR. BILLY: Lee?

MR. JAN: I think, you know, we're talking about testing, and it sounds like we're saying that if we test or if the plants test for E. coli 0157:H7 then the Agency would test less often, or that's the idea here, but I'm concerned that we're saying that testing is a control or a way to control E. coli.

You can't test it away. You test one in 300, if that's what you're using. There's 299 that any one of which could be positive. I think we need to put the emphasis on

controls and have testing of part of that in their HACCP plan, but they identify that it's a hazard, and they implement a control for that hazard, but not state that they must be testing because we've gone through that argument years ago when we were developing this rule that testing for E. coli 0157:H7 is not a good way to control it, so we need to be sure that we --

MR. BILLY: Well, that's why you need to read this action plan in the sequence that it's presented because that's what it's doing. It's showing that, you know, it's a hazard reasonably likely to occur. It needs to be addressed in HACCP.

MS. TUCKER FOREMAN: We said it's a hazard that will occur.

MR. BILLY: Will occur. Sorry. Each of these builds on the other as a basis, so I think it's accomplishing what you're saying. If you just read No. 4 out of context of the others then I can see where there might be a concern, but I think that you need to take this as a sum total, and it's intended to be read that way. I hope that helps.

Caroline?

MS. SMITH DEWAAL: Just to follow up on what Lee is saying, I am comfortable with the way validation is brought into this action plan, but I think the effort of the subcommittee in saying that the word verification really needs to be added to No. 4 because it's not clear to me that the controls that they're talking about are referencing this study, which we talked about this study.

This is the beef industry coalition study showing that in this plants they tested at three different points. They tested with the hide on, -- this is for E. coli 0157:H7 -- prior to washing and following intervention. What the testing regime clearly showed, it was clearly an excellent validation exercise because it showed where they had 0157:H7 on their carcasses their interventions were addressing it.

Verification testing, and the subcommittee talked about this at great length last night. Verification testing is just these zeros following intervention, and yet in plants where you didn't have zeros there you would know that your process was not in control.

I think it was the subcommittee's recommendation

following discussion on this particular excellent study by the industry that the word verification added to No. 4 or the concept of verification meaning this type of a testing regime would make it clearer for everyone involved that we're not just talking about controls, you know, that are unmonitored, but that they need to have ongoing verification that those controls could work.

MR. BILLY: Rosemary?

MS. MUCKLOW: HACCP is a prevention system. The industry has been pleased to work with the Agency to do everything that it can and wants to do to prevent any undesirable biological, chemical, physical attributes that are undesirable in its end product.

It also is anxious to eliminate those defects as early in the process as it possibly can. If we could get rid of it before the animal comes into a slaughter plant, we would. That is a very difficult situation. I'm sure we will be moving more and more to trying to get rid of it in its earliest possible stages.

Given in today's environment that we can't do that, the slaughterhouse is the next logical place. We

cannot test undesirable biological elements out of the product. We can set up systems to substantially reduce any such biological defects, if you will, but there's nothing that happens in a slaughter plant that can absolutely kill that microorganism.

We can do a great deal to reduce it, and I think that the industry survey demonstrates the fact that that can be done, and we should have every possible encouragement to do that, but we cannot reduce E. coli to an acceptable level because there is no acceptable level, and we do not have an absolute kill step in the slaughter plant.

My concern is to make sure that we do not set up a Catch 22 that suggests that indeed the process that we are advocating is a kill step when it is a substantial reduction step, and that needs to be kept in mind as the Agency moves forward.

The industry has demonstrated and is willing to be highly cooperative with the Agency to take every possible action that it can in slaughter operations to reduce this biological hazard. We don't like it any better than anybody else in this room, but we are the narrow part of the funnel

that is trying to make that reduction.

You certainly have my commitment, the commitment of my organization, and I know that the other signers of the material that was developed feel very strongly that this action is one that this industry is committed to. It has spent millions of dollars in order to try to establish these prevention systems and systems that will reduce. My great concern is that we should not set up a system that is going to systematically fail every slaughter plant in this country sooner or later, and that is something that the Agency needs to keep in mind as it moves forward.

I would like to offer you today a preliminary copy of the conclusions that were developed by a task force at the International Livestock Congress in Houston. They were developed by Dr. Colin Gill, who worked with microbiologists from our country, including microbiologists across the spectrum, Dr. Thino, Dr. Nickelson, Dr. Hollingsworth and others, who were all present. These were all distinguished individuals who know a great deal about HACCP systems and testing systems. The list of microbiologists is not here, but it can be provided.

They set up a paper, which Dr. Gill has described as microbiological testing and the safety of beef. It describes what you can and what you can't do in a microbiological testing system, and I would strongly recommend to you that we convene a session at a future advisory committee to describe what can and cannot be accomplished in microbiological testing.

Dr. Gill has certainly described it well in this paper. It will be published for scientific review. It has not yet been published, but if it is acceptable to you I would like to provide you his preliminary copy, and I'm sure it will be available in the scientific literature at some time in the not too distant future.

I think it might be helpful for people to understand what a microbiological testing system can and cannot do. Unfortunately, the microbes go to school every day to learn new ways in which to bypass the systems, the prevention systems that we design to remove them. They are very, very skillful.

Mother nature -- and other people have alluded to that around this table -- is very, very clever in bypassing

the systems that we set up, and our industry, the meat industry that I represent at this table, has been highly innovative and highly invested to make our product as safe as possible. We cannot test our way out of the system.

Mike, I would like to --

MR. BILLY: Okay. Carol?

MS. TUCKER FOREMAN: Going back to No. 4 or, actually, going to all of the points in the action plan, I think the point was made on No. 4 that we're talking about a verified control system that is in the context of a HACCP plan.

I think I'd have to quote back to the committee what I think will become the immortal words of Mike Mamminga that the industry will do what the industry has to do, and the government will do what the government has to do as long as this is a program that is set forth to meet the requirements of having sealed that says the government has inspected the product.

There will be requirements that are outside the narrowest definition of HACCP and those that are necessary to meet the public's assurance that the government is

approving a product that is as safe as it can reasonably be.

MR. BILLY: On that basis, the committee might want to consider then modifying No. 4. I have a sense that there is pretty wide agreement that verification clarifies what we're talking about here.

MS. TUCKER FOREMAN: Well, we had included verified controls. I just --

MR. BILLY: Okay. Yes. I wasn't clear. It seems if you're including it then I don't know if you need to say it, but some found the addition of the word redundant. I don't know if people still feel that way or not, but I would just --

MS. TUCKER FOREMAN: I think I would characterize the committee as not being opposed to the --

MR. BILLY: Okay.

MS. TUCKER FOREMAN: -- notion of verified controls. It was a question of whether that was already inherent in what was said there. If there was an agreement around the table that it reinforces that then we could probably -- based on our discussion, we could probably put it in.

MR. BILLY: Okay. Lee, and then Rosemary?

MR. JAN: If I can make a point? I was the one concerned about or felt that it was redundant because if we have controls under HACCP, one of the seven principles includes verification and so it would seem to me that if we're talking controls, the controls we're talking about are in the HACCP system. Then we've already got verification.

Then when you plug in the verified controls then that implies that someone else has verified that; at least it does to me. Who is going to verify this? FSIS already said they're not in the business of verifying or approving HACCP plans, so then are we now going to get into a business of saying -- is FSIS going to say well, we have to verify it?

That was my concern, and I felt that verification -- being one of the seven principles, it didn't need to be restated. I have no objection. You know, if you feel like you want it that's fine.

MR. BILLY: Rosemary, and then Caroline?

MS. MUCKLOW: I would agree with Dr. Jan, and I would suggest if there is a movement to add the word

verified we need to talk to the extent that is technologically feasible. I would agree with Dr. Jan. The word is redundant.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: My fuzzy recollection is that verification is an entirely separate element of the principles of HACCP. I think verification is -- there is a hazard analysis, and there are critical control points and critical limits and there's verification, so in that sense everything is redundant. You know, controls implies hazard analysis. Controls implies critical. I mean, the bottom line is this is a system. This is a regulatory system. It's got to give consumers confidence that it's working.

We had HACCP in place in the Delmar plant. We had even environmental testing in place. Unfortunately, that wasn't enough to prevent a major outbreak from those products. On these, HACCP works best.

I think that the implementation of this HACCP rule has shown us over and over again that HACCP works best where it is being verified using microbial testing and the tremendous success of the poultry industry and many of the

other industries in reducing their salmonella rates is evidence enough for the public that this system is working and is worth supporting.

I think the simple clarification that we're making here is one that will certainly give the public who doesn't know all the seven principles of HACCP much greater confidence that we're talking about the same thing.

MR. BILLY: Perhaps we'd like to leave the language the way it is is the question.

FEMALE VOICE: What's that?

MR. BILLY: Leave this No. 4 language the way it is, which I understand does add the word verified.

FEMALE VOICE: The committee report's No. 4.

MR. BILLY: Yes. Okay.

MS. MUCKLOW: Excuse me. You're adding the word verified or not?

MR. BILLY: Yes.

FEMALE VOICE: We are.

MR. BILLY: We are, but we --

MS. MUCKLOW: Okay. I would be opposed to that.

MR. BILLY: Okay.

MALE VOICE: Who is going to verify it?

FEMALE VOICE: The plant will.

FEMALE VOICE: The plant.

MS. MUCKLOW: But if you put a system --

MALE VOICE: But different than that they're already verifying under HACCP?

MS. HANIGAN: You know, I just -- this is Katie. I just really think if you are a plant and you're putting a system in place to control whether it's a microbiological hazard that we're talking about here, you have to verify somehow that that system is working correctly.

I mean, I think it's very very clear, and I think the word verified should go in there in case there is concern that people are going to put systems in place and then never verify that it's working; just say there is the system. It's working. How do you know? They won't know unless they verify it.

MR. JAN: If they're meeting the requirements of the regulation, the HACCP regulation, then they are verifying, but I would be -- if you say verified in this thing then we should say plant verified so it's not implied

that somebody else is doing the verification and that that somebody else is going to be FSIS.

MS. TUCKER FOREMAN: Let me just read you the sentence because I think that's absolutely clear from the context of this sentence. Currently, FSIS thinking is to provide for reduced Agency sampling in establishments that have included verified controls for the pathogen in their HACCP plans. It's clear that it refers to the establishment doing that step. FSIS is going to say oh, you've got your verified controls. We're going to reduce sampling now.

MR. JAN: You know, whatever you want to do is fine. I still have a concern that you're implying -- I mean, the establishment needs to find a verified control that they're going to implement.

This doesn't say the establishment is going to verify their control. HACCP already says that. We're going to say that we're talking clearly here about a verified control, and I would say an establishment verified control where it's clear that the person doesn't have to go to FSIS and say would you verify this plan for me before I implement it. That's where I'm having problems.

MS. TUCKER FOREMAN: If you want to put establishment verified controls in front I think that's redundant, but then maybe we'll be equal, and redundancy will allow us to move forward.

MR. JAN: Okay. Two redundancies make --

FEMALE VOICE: Make a right.

MR. BILLY: Included establishment verified controls. Okay.

MS. MUCKLOW: I'm sorry. What was that?

MR. BILLY: We've now added included establishment verified controls, which --

MS. SMITH DEWAAL: Just to be clear, though, it's reduce Agency sampling in establishments that have included establishment verified controls for the pathogen. That's our redundant redundancy.

MR. BILLY: It sounds reasonable. I see most head shaking yes.

MS. TUCKER FOREMAN: In Washington, redundancy is the least of our sins.

MS. MUCKLOW: I'll concede. I'd like to raise a different issue.

MR. BILLY: All right. Hold on.

MS. HANIGAN: Can I ask one -- now I have one question I do have to ask on that. You know, we're talking about intervention systems here at slaughter is what I'm assuming.

We're not referencing, and I'm sorry to bring this up with Ms. Stolfa not here. We are not referencing somebody verifying that chilling, product temperature coming in, is reducing this hazard, are we?

MR. BILLY: I think that would be up -- the way I'm interpreting this is that that's up to plants. There are plants that include -- have procedures in grinding operations, as an example, to address E. coli and to prevent further growth, and they choose to include that in their HACCP plans.

MS. HANIGAN: But we have a zero tolerance for the organism, so controlling the growth of it is not acceptable when we're at zero tolerance.

MS. TUCKER FOREMAN: Since this is an establishment based system, that's your determination as I understand it.

MR. BILLY: Yes. They're just --

MS. TUCKER FOREMAN: Somebody else might want to do it some other way.

MR. BILLY: They're acknowledging that the methodology and the nature of the organism is such that you can't prove that it's not there, so they're taking further precautionary steps.

MS. HANIGAN: Yes. I just --

MR. BILLY: There are plants that do that kind of thing.

MS. HANIGAN: Yes. I just want to make sure.

MR. BILLY: This will provide for that, I guess.

MS. HANIGAN: I just want to make sure that an establishment is not going to verify their control, and if this case, based on the conversation we had yesterday, they say their control is incoming product temperature that that is controlling this organism.

MR. BILLY: I don't know what -- that's up to establishments. I mean, this doesn't require that.

MS. DONLEY: Can I?

MR. BILLY: Yes.

MS. DONLEY: Katie, we talked about this a bit last night in that, and I hope this is how FSIS would interpret it as far as targeting their sampling program in a processing plant, but that incoming temperature could be considered a -- it could be considered a critical control, but it shouldn't negate the need to also have the supplier be doing intervention strategies on the carcass. That's the beginning of where their control of the product comes in is when they receive it.

If they receive it and the product temperature is too high it's clearly -- it could clearly be considered dangerous product and should be turned back. It should not be the only critical -- it shouldn't be the only critical control. I think where it gets really sticky here is because I think you have such different types of operations when you're talking slaughter and you're talking processing.

You know, it's almost as if you're -- the critical control point becomes by nature of the process a different -- it takes on a different identify almost in that in the slaughter plants we would expect -- I would expect -- that a critical control would mean some sort of an intervention

strategy that has been acknowledged to be effective against 0157 in reducing or eliminating it from a carcass and that critical control, once it enters into the processing stage, would be it would have to -- I would think that for this to be, and I'm going to put an idea here, just an idea that FSIS has had.

I would maintain that the only processing plants that would be exempt again, for lack of a better term, exempt from the sampling program, would have to have -- not only be purchasing from suppliers who have an effective intervention step against 0157, but also has a CCP stating that incoming product must arrive at thus and such a temperature. It is dicey here.

MR. BILLY: I think one example that we can look forward to in the future, given what's going on, is that there are grinding operations that are going to be irradiating their hammers and including that technology step as part of their HACCP program.

If they have a verified irradiation control measure, that will have a very significant impact on the Agency's decision regarding sampling, so there's one

example, looking to the future, that in my mind makes sense in the context of the processing end of this that we need to provide for.

Yes, Jim?

MR. DENTON: A quick comment about the recent discussion about the use of incoming product temperature. I can understand that a company improves their situation by an order of magnitude if they receive incoming product in which the temperature is out of compliance with regard to what they've specified from their supplier. They reduce the risk of having something detrimental happen with regard to E. coli 0157:H7.

On the converse side of that, simply having the product within compliance on the temperature does absolutely nothing with regard to indicating that the product does not contain the organism. It can't be a control point. I agree with what you're saying about irradiation. That probably is a control point, but the use of incoming temperature is not going to do it.

MR. BILLY: Okay. I'd like to wrap this up.

MS. TUCKER FOREMAN: Okay. I thought Rosemary had

another issue she wanted to raise.

MR. BILLY: Okay. Rosemary and Mike? On this point, Mike? Okay, Mike.

MS. MUCKLOW: Since we've added a couple of words to No. 4, I'd like to take out a couple of words in No. 2 for balance.

Item No. 1 speaks to our evaluating this as a hazard in slaughter operations and exactly what we're going to be doing in slaughter operations. Item No. 2 conflicts a little bit with No. 1. We should remove the words "and processing" because the activity that is going to occur is going to happen. The reassessment is going to occur of a slaughter operation in order to be consistent with No. 1.

You're shaking your head, Mr. Billy. Why don't you explain why you're shaking your head?

MS. TUCKER FOREMAN: Let me as chair. As chair of this subcommittee, I absolutely disagree with that. It was never discussed in the subcommittee.

The committee clearly has the ability to overrule the subcommittee, but it was not raised by any of the committee members last night, and I would be strongly

opposed to excising that word.

MR. BILLY: All I can say is that it is the Agency's intent to have this apply to both slaughter and processing establishments. That's the Agency's intent.

MS. HANIGAN: I know I'm not entitled to another comment, but --

MR. BILLY: Hold on a minute.

MS. HANIGAN: Sorry.

MR. BILLY: Is there more discussion on Rosemary's question?

MS. SCHULTZ KASTER: Yes. I don't understand then what was meant by No. 1, which is I think where you started from, but we narrowed it down in No. 1 to slaughter hazard analysis and then broadened it back out. How do the two flow together?

I thought that was the crux of the discussion yesterday was again the fertile concept as applied at slaughter, and if you send at high levels to a processor while they will prohibit it from growing further by temperature they will not be able to address the high levels that they've already received.

MS. TUCKER FOREMAN: But irradiation would be one specific case where they would, and I'm sure there are others.

MS. SCHULTZ KASTER: But irradiation isn't going to be available to all the people that are currently -- if you want to talk about economics, not to mention the fact that this will be off facility at some of these locations. I don't know that we want to lean that heavily on that as their option.

MS. TUCKER FOREMAN: First of all, it says -- I think there will be others, but it says that it is a hazard to be addressed and reassess plans to determine whether additional critical control points monitoring, procedures, critical limits, verification procedures, so on and so forth. It seems clearly that that has to apply to processing, as well as to slaughter.

MS. SCHULTZ KASTER: But again, what was meant by the first point where you said slaughter specifically?

MALE VOICE: It was a subsidy.

MS. TUCKER FOREMAN: I think that's a good point. We should have the word slaughter taken out of Point 1

because our --

FEMALE VOICE: Wait. Wait.

MS. TUCKER FOREMAN: -- intention was that it was to be addressed in the hazard analysis across the board.

MS. SMITH DEWAAL: One of the things that changed -- I mean, the reason, part of the reason, that this policy change has been made is because of new data that's been coming out of ARS and other sources that indicates that the cattle coming into slaughter operations may be much more contaminated than we thought.

A bit -- something like 50 percent, depending on the season, may have 0157:H7 in their bodies or on their hide, and so I think the intent of No. 1 was to target the slaughter industry, which in the past hasn't believed this was a hazard that applied to that.

The issue with respect to slaughter and processing I think is appropriate. It's appropriate to broaden it out to slaughter and processing at that point because the processing industry may also not have assessed 0157:H7 as a hazard.

Once they do their hazard reassessment they may in

fact find that they want to add critical control points either at the incoming product level, which means that their suppliers have critical control points in place, or at the post processing level, which could include irradiation or something else, so I think that the way it's currently drafted does make sense given the history of why this policy change is being made.

MR. BILLY: Mike?

MR. MAMMINGA: My only comments are I keep going back to what I thought as we go through this laborious process that we have HACCP, and HACCP and raw product and zero tolerances from a scientific HACCP, what Dr. Gill down there teaches and has taught me, that's different than what the government feels it has to do.

I hate to see the commingling of verification and validation from a regulatory standpoint. I mean, if we want to direct them to do something, whether we want to talk command and control or not, I'm not going to enter into that argument.

If we're going to direct somebody to do something by regulation then let's do that and then let that stand in

the light of day and be exposed to comments from the free world and everyone else that has something to say, and let's bolt these regulatory matters up and down on their own merit.

Let's keep HACCP, what the industry and the academia types developed and prescribed, let's keep it out of things which it cannot address. It cannot address zero tolerance. Doc can tell me if I'm wrong, but you cannot guarantee a zero tolerance in a HACCP plan, so if we're trying to give the consumers confidence, and we all certainly want to do that, then let's hold it up to what it is. It is a government intervention requiring this because of this and not necessarily hold it to the seven principles of HACCP.

Maybe I'm all wet, Carol. I don't know.

MS. TUCKER FOREMAN: No, but let me just make a quick response to that if I might. That's why the government's regulation is named the pathogen reduction and HACCP plan, which clearly implies that the regulatory overlay of a scientific program is what we are about.

MR. MAMMINGA: I have no problem with that. That

is obvious, and I agree with you 100 percent.

What I have a problem with is maybe I'm the only one that sees it this way, but sometimes I see a commingling of what we're trying to do as the government somehow fitting into this scientific system, and I think while our efforts are all in that direction there are certain aspects about what government does that has to be held up and say we're going to do this because we think we have a moral responsibility and some science to back us up.

Let it stand for the light of day for what it is, not a rewrite of a system that none of us developed. It's a fine point, but it's the only way I can keep these things straight in my mind.

Thank you.

MR. BILLY: Rosemary?

MS. MUCKLOW: We asked very specifically Mr. Derfler yesterday what kind of CCP we might ask a processor to institute, and his best answer was checking the temperature of the arriving product. There's been plenty of speeches on that this morning.

Again, and I don't want to be repetitive of stuff

I've said earlier. We have submitted information and data to demonstrate the best possible effort within the scope of Mike's HACCP plan to reduce this biological hazard in a slaughter operation. We have no CCP that a processor can reasonably institute. Whether the government likes that or not, that's the way it is within the structure of HACCP.

MR. BILLY: Do you feel confident saying that in the face of the ability to irradiate hamburger?

MS. MUCKLOW: Irradiation at the end of the line, but I don't think that's going to be done for everybody.

MR. BILLY: But doesn't that make your statement invalid?

MS. MUCKLOW: That does. You're absolutely right.

MR. BILLY: Okay.

MS. MUCKLOW: There is irradiation, but it is the only thing, or final cooking of the product, and that has only recently become available, and I stand corrected, but that's the only CCP that could be available.

MR. BILLY: Well, irradiation --

MS. MUCKLOW: And so I stand and ask that the words "and processing" be eliminated. It won't get past

some people on this committee, but that's my position.

MR. BILLY: Nancy, Katie, Caroline and Mike?

MS. DONLEY: I'm going to make a suggestion that I hope might clear things up, and I'll make my suggestion, and it's going to be in the form of a 1(A) and a 1(B).

What this first statement of Collette's very valid question, and I think this will clear it up a little bit, too. This started out, as my recollection, as I sat in the subcommittee last night, is what we were really recognizing what Caroline had said is that, you know, slaughter plants, we have got to start recognizing it as a hazard likely to occur in a slaughter environment.

But what this statement as written doesn't really say is what we were trying to get that to is that they, that slaughter plants, must implement an intervention strategy, a CCP, that addresses 0157:H7 and that there would be something in there that would, and we know it's not a kill step, but let's try to get to something as close a kill step as we possibly can because there are slaughter facilities out there who are not doing any sort of intervention strategies. That was point number one.

Point number two is that E. coli 0157:H7 is a hazard to be addressed in all beef facilities, all beef plants, so if one was to basically say hey, listen, it has to be -- something tangible has got to start happening at the slaughter plant level that is going to significantly reduce, ideally eradicate, although I know it won't happen, 0157:H7 at the carcass level. Correct me if I'm wrong, but I think that was our intention.

MR. BILLY: Katie?

MS. HANIGAN: Thank you. Just for clarification, when I was talking about a verified -- going to Bullet Point 4, when we were talking about verified controls I made the assumption the whole time there we were talking about slaughter and interventions, and I want to make sure everybody clearly understands that's what I thought we were talking about.

Going back to comments made yesterday, if this document comes out I think the Agency will be absolutely essential that they, one, publish on the website that the 30 day letter that they issue to a number of plants for using incoming product temperature as a CCP to control

microbiological hazards, and a number of us got those letters and were told that that is unacceptable.

If you are changing your mind at this time, I think you need to clearly state so because clearly there's a number of us that got 30 day letters saying that is not acceptable, and I think if you don't issue that kind of directive out, but I think it all gets back to some of the earlier conversations we've had as far as that is not going to control this hazard.

I think we're making a mistake because, Nancy, for us, and I don't have -- I'm a pork producer, but for us that incoming product temperature is not a CCP because the direction I got from the Agency, it's a control point. It's moved back to a GMP because of direction we got from this Agency on it, so the whole time we talked about this No. 4 I thought we were on verified interventions on the slaughter floors.

I would like to see if we're going to go forward with this document that this committee recommend that they publish -- the Agency publish on the website a retraction or a clarification of the 30 day letter clearly stating that

using incoming product temperatures as a microbiological CCP, as the only microbiological CCP, is acceptable because otherwise we're going to end up with this thing out in the field, and the first thing they're going to say is you can't use incoming product temperatures. Here's a 30 day letter. We'll be right back to where we were.

MR. BILLY: Caroline, and then Mike?

MS. SMITH DEWAAL: There's a lot to respond to here, and I'm going to try to resist because I kind of disagree with the statement that was just made, but the point I really want to make goes back to what Mike said.

I agree that the HACCP regulation is a little bit of the Agency adopting something that the industry said was going to work really well and turning it into a regulatory program, and there is some difficulty with that approach, but what the Agency -- what the agencies did, because it was Tom Billy both at FDA and at USDA that did this, they said we're not going to approve the HACCP system. We're going to let the industry design it.

This is going to be hands off. We're going to let you set your critical limits, but we're going to check it at

the end of the line, and we're going to task to make sure that your plan measures up to all the other plans that are out there and so they put in performance standards in some segments of the industry, and they put in micro testing.

What we're talking about when we start looking at validation and verification, there is a role particularly in verification for both the industry to do verification and the Agency to do verification. Those are two different levels. From the standpoint of consumer groups, we have long held that HACCP without government verification is unacceptable to us. You have to show us that in fact it's working.

On No. 4 we're talking about verification by industry, and I agree with that. That's really what the context is there, but there's an incentive built in, and it's reduce Agency verification, so when you're making that tradeoff you're trading off government verification.

We need to know that we've got underlying verification that's going on by the industry, so I just want to -- it's a fine point, but I cannot resist your interesting comment about HACCP and why we're here and why

we're struggling so much because it is trying to marry a quality control program developed by the industry into a regulation.

Finally, the issue of CCPs, though, I have to really weigh in here in terms of, and I'm disagreeing with a number of people around the table. We have this hands off HACCP approach. We say to the industry you design your system. You just make sure the food is safe, and we're going to check you.

Now, that -- when you're looking at beef processing, there are two ways to make the food safe. It's not just irradiation. You could have further cooking, retail cooking of that product, and that is a critical control point post processing, post grinding.

Some of the fast food restaurants actually from my understanding were moving into having pre-cooked hamburgers because that provided them a critical control point, so we have a number -- we know of two just around this table -- of critical control points post processing.

There are also some critical control points in the slaughter operation. It would be ideal if we could get all

the slaughter operations adopting critical control points, but the bottom line is the processor needs to be sure that either they have incoming product which has been subject to a critical control point at slaughter or that they are going to implement a critical control point post processing to make sure that the products are safe.

Again, this all goes back to this hands off approach. If we want to mandate how to produce beef safely, I'm all for it. Let's sit down and design the perfect beef processing system and mandate it across the board, and we'll wipe out a bunch of small plants, but who cares? Consumers will be safe.

But that's not what we're doing. That's not the design that Tom Billy and Mike Taylor and others designed for this system. If we're going to have these incentive based systems, we need to make sure that the government's verification is in place and that the incentives are there to protect consumers.

MR. BILLY: Mike?

MR. MAMMINGA: Gee, that's kind of hard to follow. I will make mention that we have a rule, and the rule has

provisions for basic compliance with the rule. Then we have PBIS with procedures that lay out how we verify that the rule is being put in place the way it's supposed to be, and so we really have in fact two verifications. We have a government verification and the verification that is expected of the plants when they develop their HACCP plans, the verification and validation of the same.

All I'm saying is and all I've said is if we want to mandate something on ourself or somebody else, let's do it that way. Let's say this is what the government is going to do to verify, and then we'll let the public and our constituents address that.

On the other hand, if we choose to go into the HACCP system and say well, on top of that you're going to have to do this and this and this then let's do it that way, but again I just -- this is such a complex situation with so many opportunities for horror that I would just like to keep the two things apart, what we do as the government and what they do in their HACCP system.

If we want to mandate that to them, fine. Then let's try to do that and put it up to the light of day, but

I just have a problem commingling the HACCP system and the government responsibilities under the pathogen reduction HACCP rule. That's just the delineation that I try to keep in my own mind and in my own comments.

Thank you.

MR. BILLY: Madam Chairwoman?

MS. TUCKER FOREMAN: I would move that we accept the report from the subcommittee with the amendment to No. 4, establishment verified controls.

MS. DONLEY: Madam Chairman, let me ask one more question. Do we want to insert the term scientifically?

MS. TUCKER FOREMAN: No. Establishment verified control. I want to leave it just the way it is.

MS. HANIGAN: I vote no. I don't accept that.

MR. BILLY: We've not going to vote here. We'll just have consensus or not.

MS. MUCKLOW: I'm sorry. I didn't hear you.

MR. BILLY: We're not going to vote. We're going to have consensus or not consensus.

MS. MUCKLOW: I made my recommendations on this, and clearly they have not been reflected in the

recommendation of the chairman.

MS. TUCKER FOREMAN: So how would you like to proceed?

MR. BILLY: I think that in the document in the two areas where there was lack of consensus we'll just note it. There were some that disagreed.

MS. TUCKER FOREMAN: I think there was only disagreement now on the issue of processing. Am I wrong? Do we have consensus on inserting establishment verified controls?

MS. SCHULTZ KASTER: Are we in a slaughter plant now, or are we in a processing plant?

MS. TUCKER FOREMAN: We're going to disagree, I think, about whether processing is there so you have to take the rest of the thing as I think No. 4 clearly includes processing plants. If we have no agreement about processing in No. 2, can we go on beyond that?

MS. SMITH DEWAAL: Can I just make a point on No. 4? The reduced Agency sampling is voluntary, so if a processing plant doesn't want to get reduced Agency sampling then No. 4 will never apply to them. They would never --

MR. BILLY: That's right.

MS. SMITH DEWAAL: -- have to have verified controls. All that is is a carrot to get reduced Agency sampling. It's the Directive 10010.1 or some nonsense.

MS. HANIGAN: And I guess why I'm being such a stickler on that is because we're talking about verified controls.

The industry has already been told in past written correspondence to them that using incoming product temperature is not acceptable, yet yesterday that was the suggestion, so we're backing everybody into a corner here saying where do you go from here.

MS. SMITH DEWAAL: My sense was, and maybe Phil can clarify this, but that the Agency was saying you needed to have not just temperature controls. You also needed to make sure that the slaughter plants were using steam pasteurization or some other control system.

MS. HANIGAN: Right, but clearly when we do our HACCP models, that ground beef, and I do not make ground beef, but when you do ground beef it ends up in that raw ground processing category.

You know, we're going to be looking at needing a CCP here. My CCP, the way I understood what I heard yesterday, was my CCP could not be your slaughter intervention. They were asking me for that CCP as well as incoming product temperature, and if I have that as a receiving temperature I have written correspondence from the Agency saying that's not acceptable.

Or? Can we use or? That's the hooker because we've already gotten a written document from the Agency saying you can't use that in a model.

MR. BILLY: Phil?

MR. DERFLER: I just want to clarify because I think Pat tried to explain last night in the subcommittee meeting and even in oral conversation what exactly she said.

I think what she said was that the incoming would be the CCP either through some sort of assurance from the supplying slaughter establishment that the product did not contain or there was no detectible E. coli 0157 or some assurance like that, and then after the product was received the temperature control was important in order to insure that if there was the low detectible level of the pathogen

it would not grow out.

That's what she was saying. She was not saying that receiving temperature was what we considered to be the CCP, so I just want to clarify. This is your show. I didn't want to say anything, but --

MS. SMITH DEWAAL: May I suggest I agree with what the chairwoman said that we are in agreement, I think, on the slaughter plant. Maybe we should just capture that.

MS. TUCKER FOREMAN: And report no agreement on processing?

MS. SMITH DEWAAL: Yes.

MS. TUCKER FOREMAN: Or lack of consensus.

MS. SMITH DEWAAL: I mean, it's really --

MS. TUCKER FOREMAN: It's different.

MS. SMITH DEWAAL: It's really a carrot for the industry, and I think you're actually standing in the way of companies that might have -- like want to use irradiation or some other technique to get that particular carrot. I mean, I think there is agreement on the slaughter piece.

MS. TUCKER FOREMAN: Go ahead.

MS. SCHULTZ KASTER: This might be nitpicking, but

on the members list I think that should reflect the subcommittee makeup that was actually there last night because that was different than the list that shows as members.

MS. TUCKER FOREMAN: Okay. Gary Weber, Nancy Donley and Caroline Smith Dewaal also participated as part of the subcommittee. Was there anybody else?

MR. BILLY: Is there any -- I don't know if what Phil said helps you that they were not talking about receiving temperature. That is not the example. It was temperature after receipt in the plant.

MS. MUCKLOW: That was not what Phil told us yesterday when we asked him in the full committee, but it may be immaterial.

MR. DERFLER: Actually, what I think I said yesterday when I was asked the question is I said receiving would be a CCP, and then Pat expanded on what I said with the temperature, and then later she attempted to correct what she said. I think the record would show that.

MR. BILLY: Last chance.

MS. HANIGAN: I have no further comment.

MR. BILLY: All right.

MS. TUCKER FOREMAN: Do you want to go forward with our listeria recommendations before we eat? There are some of us that get ugly when we're hungry.

MR. BILLY: Boy, is that a strong hint. Let's take a break until about 1:15.

(Whereupon, at 12:10 p.m. the meeting in the above-entitled matter was recessed, to reconvene at 1:15 p.m. this same day, Wednesday, May 17, 2000.)

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

1:18 p.m.

MR. BILLY: I'd like to turn the meeting back over to Carol Foreman, the chairman of the third committee session. Carol, my understanding is you want to briefly revisit E. coli and then move on to listeria.

MS. TUCKER FOREMAN: Yes, please. A couple of committee members at lunch said that they had unanswered questions about the Agency's position on the E. coli action plan and wanted to just get answers to those. Since Phil and Judy are still here, please do that.

Katie?

MS. HANIGAN: Going back to the example that Nancy used yesterday and today with Plants A, B and C, A being a slaughter plant, B being the processor at this time, can Plant B, the processor -- this is my question. Can their verified control be a letter from the slaughter plant saying the trim you received today is free of 0157:H7, and that's based on the fact that this slaughter plant has intervention systems in place?

Would that, one, be considered a verified control

for the processor, and, two, would that reduce the sampling that FSIS will do at the processor?

MR. DERFLER: I think the answer is yes to both questions.

MS. HANIGAN: Okay. That answers my question.

MS. SMITH DEWAAL: Would the company --

MR. BILLY: Subject to verification.

MR. DERFLER: Yes.

MS. SMITH DEWAAL: Yes. Would the company have to run their own verification checks on the supplier?

MR. DERFLER: They have to have some sort of verification check.

MS. SMITH DEWAAL: Thank you.

MR. JAN: Can I add something --

MR. BILLY: Sure. Lee?

MR. JAN: -- or just make a comment? Based on experience, you're not going to get that letter from a slaughter plant to say that it's free.

MR. BILLY: Yes. I mean, that's -- I understand, but --

MS. SMITH DEWAAL: The concept, yes.

MR. BILLY: We didn't get hung up on the specific language. It was the idea.

MS. HALL: I have a question about the E. coli, but also listeria testing that we're putting in place. I'm Cheryl Hall.

What provisions are made or how does the Agency see testing going if products are irradiated? Is there going to be a pull back on the testing, or how are we going to proceed? The microbial testing won't be as important as the quality control and the process itself.

MR. BILLY: Let me do it. What would be relevant from the Agency's perspective is how the irradiation is being used? In what context? Is it part of HACCP, part of the critical control point?

Has the specific irradiation strategy been validated for the stated purpose? Are there records to show that that's what occurring? That would all be weighed as the basis then for making a judgement about reduced sampling.

MS. HALL: Right, and we would --

MR. BILLY: That's the intent.

MS. HALL: Yes. We would also be looking at what other steps are in place that contribute to the irradiation strategy.

In other words, if there are steps that are taken prior to irradiation that lower the microbial load that enable or improve the chances or improve the effectiveness of the irradiation, then we would also be looking at those because it's not just the irradiation, but it's each step that the company has in place that minimizes or reduces in this case the 0157:H7, so we would be looking at the entire system.

MR. BILLY: Or listeria.

MS. HALL: Yes. Listeria would also be another.

MR. DERFLER: We put out a set of Q&As on irradiation, and I think we talked about the HACCP aspects of irradiation. I'm not sure exactly in what context, but I know we addressed HACCP in that. You might want to get a copy of it.

MS. HALL: Okay. Thank you.

MS. TUCKER FOREMAN: I don't know if we want to revisit. My guess is we still don't have a consensus on

removing the word process from the action plan in Statement No. 2, but I suspect that we have less disagreement about that given this discussion than we had before.

I'd be prepared to leave it and move ahead with listeria if the committee is --

MS. DONLEY: Carol, can I --

MS. TUCKER FOREMAN: Nancy? I'm sorry.

MS. DONLEY: Can I get just one more thing resolved in my head? Back to A, B and C. All right. C, the retailer, bought from Processor B, who had the letter from the plant. Processor B doesn't have any other interventions in place. Is Retailer C going to be one of the targeted retailers, or are they on the off list?

MS. RIGGINS: I think it would depend on what Retailer C has in place in terms of specifications from its suppliers. That Component B has no interventions in place, clearly in that case the retailer would be buying from a company that it knows has not done anything beyond that which was done at the slaughter plant.

Therefore, in buying from that company, B, Company C would need to take that into account and to understand

what in fact it's getting, and then if there are additional steps that Company C, the retailer, can take to improve its -- I'm assuming these are -- are these grinding? You're speaking of Retailer B --

MS. DONLEY: Company C is --

MS. RIGGINS: -- is a retailer grinder?

MS. DONLEY: -- taking the stuff and putting it out on the shelf.

MS. RIGGINS: He's putting it out on the shelf. Okay. Then we are faced with the acknowledgement or the recognition that they are buying from a company that has not in fact put in place any interventions, and that would be a business decision on the part of the retailer. Yes.

MS. DONLEY: But that --

MR. BILLY: Let me say something. The problem with hypothetical examples is that you're talking in general terms. It can be easily misunderstood.

For example, it depends on what the slaughter plant is doing. Does the slaughter plant have one intervention? Three interventions? Six interventions? What kind of sampling? Are they sampling carcasses one in

300? One in three? One in 1,000?

Are they -- you see, all of these -- in situations it has to turn on the specifics, so you can have several different kinds of As.

MS. DONLEY: Right.

MR. BILLY: Do you see what I'm saying? Then that influences your judgement about B, which then influences your judgement. What the Agency is trying to signal is that we're prepared to take those specifics into account in the context of our sampling program.

Hopefully in doing that it creates an incentive, at least for some, in terms of their decisions about interventions and control measures and that kind of thing in a way that applies the best science and technology, and then in effect there's a reward for that in terms of the degree to which they're subject to a sampling.

MS. DONLEY: Let me ask a question.

MS. TUCKER FOREMAN: Caroline?

MR. BILLY: I don't think we should pursue this much further because there are too many variables at work here to reach a common understanding. That's what I'm

concerned about.

MS. SMITH DEWAAL: Can I just finish this up?

MS. TUCKER FOREMAN: If everybody is agreed, that will be -- I can't ask to -- let's see what you're going to say. I would like to finish it up because we have to do listeria and lots of other business.

MS. SMITH DEWAAL: The No. 4, which is the committee recommendation where we said establishment verified controls and that we recommended that be added.

MS. TUCKER FOREMAN: Yes?

MS. SMITH DEWAAL: Katie's objection to that had to do with the processing issue.

Katie, do you still have that objection to processing plants being allowed that kind of a carrot in utilizing -- just if they have establishment verified controls they might avoid such as irradiation or cooking, they might avoid, or incoming product that is certified, has that letter that you talked about and subject to verification. Do you have an objection to processing plants being given a carrot to implement this?

MS. HANIGAN: Based on a clarification that I

received this afternoon, as long as the processor can use the letter from the slaughter, I do not have an issue with that.

MS. SMITH DEWAAL: So I'd like to move that No. 4 as you amended it be included in the committee's recommendations.

MS. TUCKER FOREMAN: Okay. It was my understanding that we did that before lunch; that everybody had agreed to that. We did not have a consensus on the word process, but --

FEMALE VOICE: In No. 2?

MS. TUCKER FOREMAN: In No. 2.

FEMALE VOICE: All right. Thank you.

MS. TUCKER FOREMAN: Because if you don't have an agreement on that, that obviously had an impact on what was in No. 4.

Can we move --

MR. BILLY: Rosemary?

MS. MUCKLOW: I'd like to follow up on what Judy just said. Judy, you said you once again inferred that a processor, a grinder of beef, might have interventions. We

all understand that they may have the option of irradiating. What other interventions were you referring to in a processing operation?

MS. RIGGINS: I wasn't referring to anything specific. I think that it will turn on the technology. I think as we learn more about this bug and about listeria as Cheryl talked about earlier, there may be additional interventions that can be made.

I think that, you know, as we learn more we will be able to apply more effective interventions, but I didn't have any one specific intervention in mind when I said that.

MS. MUCKLOW: Do you know of any interventions that can be used?

MR. BILLY: What I'd like to do is I think this is a signal from the Agency that perhaps a policy change might create some positive incentives in this area and be moving in the right direction, so I'd like to move forward. I think we've got a closure here in terms of Nos. 2 and 4.

MS. TUCKER FOREMAN: We've got some direction to the Agency, which I think is understood, assuming obviously that this is the beginning of the process within the Agency,

not regulatory language.

On listeria, the Agency asked for comments on three questions. The first question was for feedback on possible additional measures for control of listeria, monocytogenes, including those in the updated action plan, as well as additional measures that the committee envisions.

We spent all of our time on Question 1, and we never got to Questions 2 and 3, and everybody got tired and went home. I would suggest that we perhaps as a full committee spend -- decide how much time you're going to allocate to this discussion, Mr. Chairman, and then divide it kind of equally between a discussion of the subcommittee's recommendations with regard to Question No. 1 and then maybe a general discussion on Questions 2 and 3 so that the Agency gets some feedback from us on that, but I think to do that we probably have to set some time limits.

MR. BILLY: Yes. I think if we could limit it to about 20 minutes or something like that?

MS. TUCKER FOREMAN: This whole thing?

MR. BILLY: Yes.

MS. TUCKER FOREMAN: Okay. Then would you all

like to spend -- I will ask the committee. Would you like to spend ten of those on the committee's recommendations with regard to Question No. 1 and the other half on a general discussion on 2 and 3? Is that generally --

MALE VOICE: Okay.

MS. TUCKER FOREMAN: Okay. Somebody keep time.

The subcommittee's recommendations, incidentally, with regard to listeria developments, in addition to the members of the subcommittee present, as with the discussion on E. coli, there were other committee members, full committee members, who aren't members of this subcommittee who participated in the discussion; Caroline, Nancy and Gary Weber.

Feedback on possible additional measures for control of listeria. We had several. Explore the use of existing and the development of new methods of post packaging pasteurization for RTE products.

Encourage technical assistance workshops to share experiences. These would be industry driven primarily involving the government, the government providing technical assistance, industry where they have expertise in particular

technical areas sharing it with their colleagues.

Encourage the use of the most effective chemical sanitizers. That obviously has some research implications for the Agency and the industry, and then expand end product testing through an FSIS mandated standard for adequate listeria monocytogenes product as part of HACCP verification.

The floor is open.

MS. SMITH DEWAAL: I will start the discussion. We talked a lot about things we need to be encouraging the industry to do, things they should be adopting, and they should be getting information. There's clearly a lot of incentives for industry to take additional steps to control listeria monocytogenes, and there's a strong desire in industry to control this hazard.

I think the first three really represents, you know, kind of the subcommittee's best advice to the industry on things they can be doing or for research. I mean, post pasteurization techniques and things like that are things that will help industry to address the problem.

Then I think we shifted a little bit to what the

government should be doing to improve their HACCP system and the overall effectiveness of the HACCP systems in controlling listeria monocytogenes. There the recommendation was that the government should mandate that the industry do some product testing as part of their HACCP verification.

The subcommittee spent a lot of discussion on this. We were benefitted greatly by the expertise of Bruce Tompkins, who Rosemary invited to participate. I think he lent a lot of good advice to the subcommittee.

You know, I think at the end, you know, the issue is really one about government verification. The government has a system for checking for products that contain listeria monocytogenes using microbial testing, but that process is going on really at the retail level. It's post past product, and we're trying to get more tests. We're trying to get the industry to take some responsibility here for testing their own product, and we believe that will help prevent some contaminated products from reaching the market.

End product testing is not a guarantee of safety, but for the government this kind of a system will help the

government to identify the plants which are really high performers, the really good performing plants, from those that really need to put additional controls in place to control for listeria monocytogenes.

MR. BILLY: Dan?

MR. LAFONTAINE: Dan LaFontaine, South Carolina. I have a specific recommendation on Bullet No. 3. When you look at listeria monocytogenes, the most important thing you can do is have a solid SSOP program for product contact services, preventive medicine front up, knock the listeria in the head from the beginning.

Just as a side note, in South Carolina we've been working with out plants actually doing environmental sampling and educating them on where they're missing if they get a positive listeria.

My recommendation is this. What we're finding, one of the things we're finding, and I can't prove this, but I think we're running into some situations of biofilm where you've got a hard protein crust and these listeria organisms may be hiding in that.

Here's my bottom line. Reword that to say

encourage the use of the most effective cleaning agents and chemical sanitizers because if you don't have a good cleaning agent that's effective against biofilm and protein build up that can loosen up that hiding place, the chemical sanitizers won't do you any good, and I think the heart of the matter, this whole thing, is just nitty-gritty elbow grease and cleaning and sanitizing.

MR. BILLY: I see a lot of heads nodding.

Rosemary?

MS. MUCKLOW: I did mention last night that we, in cooperation with several other organizations, developed some environmental sampling and testing recommendations. Those are on our website.

We certainly hope that plants will access those and see if they can apply those sampling and testing schemes in their facilities they fit -- small, large, medium plants -- and they are useful tools to help many people who may not have got into this.

MR. BILLY: Alice?

MS. JOHNSON: Two comments on No. 1 that I would like to see added. The first one would be we talked about

-- Caroline talked about industry and recommendations to the industry and recommendations to the Agency. I'd like to see something that the committee comes out with to encourage FSIS to promote as much as possible -- I know you're working with several other agencies, and you have to do a lot of these -- on the whole new technology aspects.

We've got a lot of things that are now available to us that haven't been in the past, but we need to keep reaching for other technologies that might improve things and to get them into the system as quick as possible, so I'd like to make that kind of recommendation.

I'd also like to recommend that the Agency look at getting -- we heard at the meeting on Monday about possible revisions to the listeria or the ready-to-eat directive, and I think that we should encourage the Agency to get the directive out as quickly as possible with I think they called them the interim measures, but I think that would be something the committee might want to consider.

MS. TUCKER FOREMAN: Is there any disagreement around the table on those? Thank you.

MR. BILLY: I think we might accomplish the first

suggestion by just adding the word encourage in front of development.

MS. TUCKER FOREMAN: Yes.

MR. BILLY: I don't know if that's quite what you had in mind.

MS. JOHNSON: Well, we probably need to go beyond post pasteurization.

MR. BILLY: Broader than that? Okay.

MS. TUCKER FOREMAN: You also I think want education technology transfer.

MS. JOHNSON: Yes. I mean, the first bullet --

MS. SMITH DEWAAL: It's also approvals, though, isn't it?

MS. JOHNSON: Yes. The first bullet would be great -- yes, I'm talking approvals, too -- if we expanded it beyond just the post packaging pasteurization because there are other --

MS. TUCKER FOREMAN: And other new technologies, but you also want the sense of --

MS. SMITH DEWAAL: Can I recommend an additional bullet that just said, and we can add some words to this,

Alice, but something like speed approval of new technologies? We encourage the Agency to speed approval of new technologies.

Alice, is there more there?

MS. JOHNSON: No. That's good.

MALE VOICE: They all don't approve technology any more?

MS. SMITH DEWAAL: Oh, they do.

MALE VOICE: Out of the business.

MR. DENTON: I would like to make a comment, if I could, along those lines. We have faculty that are in my program back at the University of Arkansas that are involved in the investigation of new technologies with particular emphasis on the use of single peridenium chloride, which is the active ingredient in Cepacol mouthwash. It's proven to be a very effective anti-microbial.

MS. TUCKER FOREMAN: In order to move ahead with the rest of the discussion, why don't you let us play a little bit? I didn't sense any disagreement, so it's just how we word this.

MS. JOHNSON: I'm sorry, Carol, but just to

clarify. There are some issues with getting this whether we call it a technology or whatever. It's not just related to FSIS. There are other agencies involved, but there are approval processes that are slow in getting some of this in place.

MS. TUCKER FOREMAN: So it's not inappropriate to say approvals?

MS. JOHNSON: Yes. Well, I don't think so.

MR. DENTON: That's just one other piece. That's fine.

MS. TUCKER FOREMAN: I think we got the sense of where you want to go.

The floor is open then for feedback on research, which follows very logically from where we've been. We'll do five minutes on it and five minutes on data needs.

MR. BILLY: Katie?

MS. HANIGAN: After the outstanding presentation yesterday by Roger Breeze, I would recommend that we encourage ARS to develop a similar research project similar to the 0157:H7. It looks like they're answering a lot of questions and have it related to the listeria. I mean, they

did a beautiful presentation for us yesterday.

MR. BILLY: Very good.

MS. MUCKLOW: Tom, is there any related activities of FDA that we could maybe save having to be repetitive in some of the work we do from a research point of view or that the government can look up?

You're working with your sister agencies on this, and they may have some research particularly on packaging and so on because they have as much problem as we do.

MR. BILLY: Yes. They are engaged in research on post processing pasteurization and some new packaging materials that are related to -- you know, that would stand up to that kind of treatment and then could be used, sent to the grocery store and that kind of thing, so cooperation.

MS. MUCKLOW: Maybe some of that could be made available through your website or something so that we can have some referencing.

MR. BILLY: Yes. One possibility would be, picking up on what Katie said, is to arrange for ARS to come back at the fall meeting and lay out a proposed research plan for listeria and also invite FDA to come and talk about

what they're doing.

MS. MUCKLOW: Great.

MR. BILLY: Dale?

MR. MORSE: Dale Morse. Post field electrophoresis or DNA fingerprinting has shown -- has become invaluable in terms of looking at the listeria problem and linking potentially sporadic cases to show that there's a clustering and then potentially linking it back to sources.

I'd just like to see whether research or wherever it's listed to try to support the use of that technology, and it sort of cuts across agencies so that -- I mean, it's now part of PulseNet, but it's still under utilized in terms of in human cases now increasingly tested, but there's this link with food products, and animals need to be further enhanced.

So we bring in FDA, USDA, and I know there's probably some reluctance to do that, have people have food sources listed in type, but that's one way to sort of look at what potential strains are really virulent and pathogenic because it's clear that there's some strains that are in

animals and food that are probably not pathogenic, so there's a whole area of research looking to DNA fingerprinting, which should be I think encouraged and enhanced and would bring the various agencies together as well.

MR. BILLY: That would be CDC that's doing a lot of that in cooperation with us and others, so maybe we ought to amend that to include CDC as well because they're using those tools and working with us to try to develop better understanding.

MR. DENTON: I fully agree with what Dale is saying. I think that goes back to the case with -- I've forgotten the organism in Colorado, but that's one of the ways that you establish the relationship between what you see in food borne illness outbreak with humans to actual source. DNA fingerprinting is probably the most definitive tool we have in that regard.

MS. MUCKLOW: Dale, would somebody -- I was trying to write down and capture the last -- the additions to the first one, so would somebody tell me where we are now in the research, kind of recapitulate for me, Dale?

MR. MORSE: I can write down something. Basically a bullet to encourage use of DNA fingerprint --

MS. MUCKLOW: Okay.

MR. MORSE: I'll draft something, but the concept I guess is to encourage its use and also sort of integration of the data from food, animal and using the various federal agencies or industry, too, would be great to share the technology, so research on DNA fingerprinting and also virulence and pathogenesis, but I'll write a bullet.

MS. MUCKLOW: Thanks.

MS. HANIGAN: I think we were talking about having someone at the November meeting, were we not?

MS. MUCKLOW: Yes.

MS. RIGGINS: Yes. Just a little bit more information that Dan Engeljohn just gave me that as a part of the overall effort of the National Advisory Committee on microbiological hazards to food, the FDA and FSIS are going to engage the committee in looking at the shelf life of deli products.

That would be across the board, meat, poultry, egg products, all those that are sold, you know, in the deli,

cheese, dairy. Just so you know, that is one project that will be ongoing.

MS. TUCKER FOREMAN: Can we spend our last couple of minutes on data needs and sources of data needed to support rule making and education?

MR. BILLY: Well, I think one example is what Dale is currently writing. Getting a better understanding of what's actually causing illness and, you know, the different subtypes and which ones are or aren't involved and patterns there.

All of these are very valuable to educate both industry and consumers. I mean, the more we can understand about this particular organism, the better position we're going to be in to make recommendations. We learned a lot just from the last large outbreak where there was more than one listeria monocytogenes subtype involved, and it took quite a while to sort all that out, but I think that type of data is key to education and even rule making.

MS. SMITH DEWAAL: One of the things that would be very helpful from an education standpoint is trying to get a handle on who is actually at risk. We know pregnant women

are. We know immune compromised adults, but both the elderly and children -- it's a little bit harder to get our hands around how to inform people appropriately because there is some data to suggest that perhaps children are not -- children over the year of one may not be as at risk as other groups like pregnant women or the immune compromised.

It would be helpful to get a better delineation from CDC of the actual at risk groups because having sat through many meetings with them I'm still a little fuzzy on the exact delineation.

MS. TUCKER FOREMAN: I raised at the listeria meeting on Monday the fact that getting information to limited groups within the population without scaring the bejesus out of everybody and yet getting it prominent enough that people know oh, they're talking about me requires some message research, communications research. Without that, I don't think the Agency is going to have an effective education program, public education program.

Anything else?

MR. BILLY: There's another one I'm recalling that Kay Waxsmith has mentioned that one of the confounding

pieces of information in the investigation that occurred with the large outbreak a year and a half ago was that in several instances the people that were ill had cooked the hotdogs. Several was through microwave.

The thinking is that the way they're doing it in the microwave they've not getting uniform heating and that it's a surface phenomenon, and the side down, if you will, is not getting the adequate heating perhaps. This is another example of where you could educate. If you had better information you could adjust, you know, what you're communicating to consumers.

MR. DENTON: I think you raise a very valid point there because most of what we know about control of microorganisms is time/temperature relationships, and I suspect that what -- I don't know this, but I suspect what we're facing in the microwave situation is we might be achieving the temperature, but the time element is not there in a sufficient quantity to assure the production.

MR. BILLY: Could be.

MS. TUCKER FOREMAN: Collette had a comment.

MS. SCHULTZ KASTER: I was thinking when we were

talking about No. 2, and now I'm thinking about it as part of No. 3, that the bullet point in No. 1 that talks about effective chemical sanitizers could be fed into either the research component or the education component because, Dr. Denton, you might correct me if I'm wrong, but I don't see a lot of material in the literature.

What we have is a lot of commercial material from suppliers and sanitizers, and it would be good, especially for these smaller operations, instead of getting the propaganda from the sanitizer and cleaner manufacturers that there was some concrete data and recommendations on that.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: Just one more idea just because we're struggling with kind of what to tell consumers about this as we try to educate them. One of the things, and there may be data on it that's available, but I haven't seen it, is on the growth curves at different temperatures.

I know this is an issue the Agency is planning to work on, but one of the questions -- so I think a piece of information we need is at 45 degrees or 41 degrees, which is a retail temperature, the temperature at which hotdogs will

be held at retail or deli meats under many of the food codes now used in the states, what's the growth?

How long will it take for listeria to reach its maximum level, and should we be advising -- as part of that, should we be advising consumers to freeze their deli meats, or should we be advising to eat them within three days? I mean, how do we handle what may be a very short grow out phase for listeria monocytogenes, so those two pieces of information, what the grow out phase is and what concrete steps we can tell consumers to take to avoid a problem.

MS. HALL: I just had a question, just something I'd like to state. I think there would be a big difference between laboratory adapted strains of listeria versus wild strains, so I hope that's being taken into consideration in the testing.

MALE VOICE: Yes. They do that under CDC.

MS. TUCKER FOREMAN: My time keeper here says our time is up.

MR. BILLY: Okay. It seems like we have a pretty clear consensus here of the number of recommendations. We can get them on paper. I think they're pretty

straightforward. Are you all right?

MS. TUCKER FOREMAN: No, but with the aid of the transcript I'll --

MR. BILLY: Okay.

MS. TUCKER FOREMAN: And Dale.

MR. BILLY: Katie, you have a revised version of yours based on the work we did this morning. Do you want to hand that out? I think it pretty well captures what was discussed.

MS. HANIGAN: Do we need to discuss the whole thing again or --

MR. BILLY: I don't think so.

(Laughter.)

MR. BILLY: Unless someone has a violent reaction and can get past my skull. Anyway, we just want it in everyone's hands.

MS. JOHNSON: Mr. Billy?

MR. BILLY: Yes.

MS. JOHNSON: Something that -- I don't know where is the appropriate place to talk about this, but it was Katie's subcommittee last time so I'm going to bring it up

now.

MS. HANIGAN: Drag me into it again.

MS. JOHNSON: I'm going to drag Katie in. The in-depth verification and the recommendations that were made at the November meeting.

MR. BILLY: Yes?

MS. JOHNSON: They're not reflected. Rosemary mentioned this yesterday, so help me out, Rosemary. They're not reflected in the committee actions in the first of the book.

MR. BILLY: Right. As best we can recall, they were discussed at the subcommittee level and presented to the full committee, but the discussion, as recalled by staff, was that they were carried through as recommendations to the full committee.

MS. MUCKLOW: Could we ask the staff to go back and check that because I thought they did come forward as recommendations.

MS. RIGGINS: Let me say this. We did receive the subcommittee report, and we incorporated many of the recommendations that you suggested. Yesterday I think it

was you mentioned the interview before the in-depth review and, you know, the close out interview. Those are now -- those are in our current in-depth review protocol.

Some of the issues that you raised were about how it would be implemented, and to respond to that what we did do was we conducted a pigtail session with our tech center experts, who are at least in most cases going to be very active members of the team or team leaders in some instances, and so we did conduct a pigtail for the tech center, and then Bill Smith did also have phone conferences with the district managers in whose areas we initiated in-depth reviews to give them more detailed information about the protocol and how it would be implemented.

In addition to that, as a part of the three circuit supervisors that -- we've held one in Denver, one in New Orleans, and we have another one that's scheduled for Columbus. There is a whole presentation that is devoted to the in-depth review protocol, so we are making an effort to respond to the concerns that you raised and the suggestions that you gave us, but that's the venue or the vehicle that we're using to address it because in many instances we know

that, you know, actual contact with the people in the field is a better way to communicate.

MR. BILLY: What I was going to suggest, and maybe this will help you, is that we capture this in writing, including the revised protocol, and make that available to all the committee members.

MS. MUCKLOW: Excellent.

MS. RIGGINS: That would be great.

MS. MUCKLOW: Yes. Excellent.

MR. BILLY: How's that?

MS. MUCKLOW: My concern was an exit interview. There was not a meaningful exit interview.

MS. RIGGINS: Yes.

MR. BILLY: We understand.

MS. MUCKLOW: We're going to go give our report to somebody else, and you'll hear about it some day.

MS. RIGGINS: Right.

MS. MUCKLOW: The most helpful stuff to a plant is to be able to sit down and talk with the reviewers, clarify anything at exit. That's what an exit interview is all about. We'd just like to make sure that that's meaningful.

MS. RIGGINS: Yes.

MR. BILLY: There's full agreement on that.

MS. JOHNSON: And I think that when we look at the recommendations that are in the committee book that if when you go back and check and it was agreement by the full committee, because it sounds like you've made a lot of the recommendations that that just be put into the books --

MS. RIGGINS: Okay.

MS. JOHNSON: -- for the record. Thank you, Judy.

MS. MUCKLOW: Mr. Billy, could I raise one other thing about committee assignments and responsibilities? You determined in advance which committee we're going to serve on. Last evening people didn't faithfully follow their committee assignment. There were some switches and changes.

I assume that you make these assignments with some thought to provide balance to the committee work in order to then reduce what we have to do at the full committee. Could you clarify the policy on that for us, please?

MR. BILLY: Yes. The long established policy is that we ask members of the committee to volunteer to serve on one of the subcommittees, and it's their option. At the

same time, we make it clear, and we have been making clear, that if on a particular issue a member of the committee wishes to sit in on another subcommittee's deliberations, they're free to do so. I think that's been happening pretty consistently.

If we feel that in the volunteering there is, you know, 20 on one and one or two on the other then we'll do a little arm twisting to try to get a little more balance, but other than that it's based on the interests of the committee members.

MS. GLAVIN: Tom, this last time we did not do that. I'm sorry. When we started we had sort of focuses for each committee, and as we moved through some of the issues and got to the issues we had this time they didn't fit very well into the committee focuses that we had, so we named them Committees 1, 2 and 3, --

MR. BILLY: Okay.

MS. GLAVIN: -- and we arbitrarily selected people, so we didn't give people this time a chance to --

MR. BILLY: Sorry about that.

MS. GLAVIN: I'm sorry.

MR. BILLY: That's all right.

MS. MUCKLOW: Some committees were lucky to have any people at all last night, whereas others it looked like it was a mini group of this group. Clearly it would be good to understand the basic policy.

MR. BILLY: On the other hand, it would seem like the smaller the committee the more easily their recommendations seem to be --

MS. MUCKLOW: You've got that right. You've got that right.

MR. LAFONTAINE: It's easier to control two people than ten.

MR. BILLY: All right. I want to move on.

MS. TUCKER FOREMAN: I do want to --

MR. BILLY: Carol?

MS. TUCKER FOREMAN: -- clarify that we have -- am I correct? Did I understood you that we have followed the practice that where individual members have particular interest in an issue before a given subcommittee they're free to float? That's what we've been doing --

MR. BILLY: Yes.

MS. TUCKER FOREMAN: -- for the four years that I've been on the committee.

MR. BILLY: That's correct. In fact, in some instances if a committee finishes its work very quickly they're free to go over to another subcommittee and join in. We want it to be very flexible so we get the maximum benefit of the advice and counsel of all the members on the various issues.

I hope that that kind of flexibility serves your interests well in terms of figuring out where you want to sit in. It might vary from time to time. We'll try to evaluate the approach we took this time versus the previous one, and maybe we'll talk about it some more, but I think it's good to be as flexible as possible.

MS. TUCKER FOREMAN: I would like to point out, Mr. Chairman, that there are only four consumer related representatives on the committee, and it has traditionally been hard for us to have our point of view adequately represented in each of the meetings and so we have, without fail, bounced from one subcommittee to another in order to make up for the fact that the committee structure has some

imbalance in that regard.

We continue to urge you to have more consumer representatives so that we can have as many in each of the subcommittees as we did in Subcommittee 3 last night.

MS. MUCKLOW: I'd like to volunteer to be the chairman of the subcommittee that nobody wants to come to.

MR. BILLY: I hope this is real important.

MS. DONLEY: Just as a point which you might want to consider, is there anything that says you have to keep three subcommittees at all times?

Perhaps you want to vary it from meeting to meeting, and then in certain cases such as the ones that were in the subcommittee last night, the listeria and E. coli, there is certainly a lot of general interest I think that should be open for everyone.

MR. BILLY: Okay. Next I'd like to move on to a briefing. This will be done by Maggie Glavin. Karen Hulebak is unfortunately tied up on another matter. She's going to give you a very brief briefing on the recent meeting of the National Advisory Committee on microbiological criteria for foods.

MS. GLAVIN: All right. You will recall that at your last meeting Karen gave you a briefing on what the micro committee has been doing. That committee has met once since your last meeting, and that was in December.

In December, their entire agenda for the meeting -- it was a one day public meeting and then one and a half days of committee deliberation. The entire agenda was HACCP in fresh juices. This was brought to them by FDA, who is one of the sponsors of the committee, and that's what they focused on during that meeting.

They have not had a meeting since then, and their next meeting is scheduled for August 10 and 11 in Atlanta. Their agenda there is being formulated now. It will include -- we will bring -- FSIS will bring to the committee some questions on handling and transportation of meat and poultry products.

We also will be bringing to the committee -- they are asking them to take a look at appropriate cooking temperatures for non-intact steaks specifically with respect to 0157 in mechanically tenderized steaks. We also will be taking back to them the 0157 risk assessment, which we

anticipated will at that point in time be open for public comment, will be available for public comment, so we'll be taking that back to the committee.

As someone mentioned a little while ago, the question of listeria. Both we and FDA will be asking the committee to look at questions of shelf life and product dating with respect to listeria.

MR. BILLY: And then also the HACCP issues, the industry petition, what we talked about this morning.

MS. GLAVIN: Right. That wasn't on my cheat sheet because that hadn't happened yet, but we will add that. We will ask them to look at that.

Thank you.

MS. SMITH DEWAAL: Do they have subcommittees that are meeting in between the full committee? Are you aware?

MS. GLAVIN: They do have subcommittees. It's my understanding that the meat and poultry subcommittee has not met other than at the full committee in December.

MS. SMITH DEWAAL: Thank you.

MR. BILLY: Okay. Any other questions? Comments? Way to go, Maggie.

MS. HANIGAN: Nothing like bringing us back on schedule.

MR. BILLY: All right.

MS. GLAVIN: Not quite. Only an hour off.

MR. BILLY: Now I'd like to move on to two more briefings. The first is a briefing on the policy issues and options related to campylobachter and, more specifically, campylobachter performance standards. I'd like to call on Phil Derfler to lead that discussion.

MR. DERFLER: Hi. I've got to be careful what I say so I don't cause any more trouble. With me is Dr. Geraldine Ransom from the Office of Public Health and Science so that one of us knows something about campylobachter.

The campylobachter briefing paper is at Tab 10. What the purpose of this briefing really is is to update you. This committee had previously asked and referred the issue of a performance standard for campylobachter to the microbiological advisory committee. The microbiological advisory committee came back and said that they really couldn't answer it, but they came back with seven

recommendations or seven areas that they thought needed to be explored.

The purpose of this briefing is to try and update you on where the progress of the Agency is on each of the points that was raised by the microbiological advisory committee.

The first microbiological recommendation was based on the results of the ARS on farm study, intervention should be developed for on farm practices. Dr. Stern from ARS is doing research on this area. Little work had previously been done on on farm campylobachter interventions. Much more has been done with respect to salmonella.

Although campylobachter and salmonella are different, they have enough similarities to warrant consideration of common intervention strategy. There are four key intervention strategies for salmonella control, antimicrobial spray for hatching cabinets, limited re-use of paper pads for chicks, competitive exclusive cultures and litter abatement to reduce the pH of underfoot traffic.

Dr. Stern is looking to adapt and test some or all of these methods for campylobachter. A limited recent

literature review conducted by FSIS revealed that some interventions found to be successful in controlling salmonella in poultry have not been successful in controlling campylobachter. Campylobachter appears to be an unusual organism with a unique niche in poultry production. It appears to resist intervention strategies known to be successful with other pathogens, but we await the results of Dr. Stern's work.

The second recommendation was that a new method for enumerating campylobachter that was developed by ARS should be used by FSIS. This method has been used by FSIS since October of 1999. What we've done since then is try to compare the ARS direct plating method for campylobachter with FSIS' most probable number method. FSIS is running or has been running the two methods side by side.

FSIS statisticians are now evaluating the data from the two methods, although we haven't reached any conclusions yet. The ARS method has a significant advantage because it requires less laboratory time and expense, but the counts of campylobachter appear to be lower using the ARS method, which may be a problem. If FSIS finds that the

ARS method is satisfactory, it will implement it in all three of the Agency's laboratories.

The third recommendation. Studies should be undertaken to examine the infectious doses of campylobachter. Work on this has been done by OPHS staff. They've done a significant amount of research, and what they've found is there actually is very little data available on this issue. There's only a couple published articles. A relationship of dose to illness cannot be derived from the available work, although they're continuing to work on it.

Recommendation 4 was that a campylobachter risk assessment should be conducted. We've requested money to do that kind of risk assessment in our budget request for 2001, and my understanding is it's still in the request as it moves forward through Congress. If we get to do the campylobachter risk assessment, there is some possibility we may be able to work in conjunction with the Canadians, who I think we understand have been doing or looking at the possibility of doing a campylobachter risk assessment.

Recommendation 5. Irradiation should be

considered for raw meat and poultry products. You know, the Agency has approved the use of irradiation in both meat and poultry, and what we know is that campylobachter is considered to be one of the most irradiation sensitive of the pathogens. However, there's been very little use of it in poultry, so it's not clear that it's being used as effectively as it might.

Recommendation 6. FSIS should work with ARS to evaluate effectiveness of pathogen intervention treatments for both salmonella and campylobachter. As I stated before, the recent literature reviews have suggested that interventions that are effective on salmonella may not be as effective with campylobachter.

FSIS recently did a survey of 48 poultry processing plants. We surveyed our in plant personnel, just as we did with listeria, to try and determine what interventions are in place in those plants. What we intend to do is try and correlate the results of our survey with the results that we're getting from the testing to see if we can identify some of the more effective interventions that are currently in place in poultry plants and perhaps find a

way of dealing with campylobachter that way.

Finally, No. 7 is FSIS should obtain data for one full year of royal or baseline surveys so that a comparison can be made to the previous baseline survey. FSIS started doing a new national baseline using the most probable number method -- that's our traditional method -- in January of 1999. As I stated before, though, we started comparing the ARS method with the MPN method in October.

The results of the comparative study will determine whether the ARS or the most probable number method will be used for the baseline, assuming we do a baseline. We have yet to decide on the specific data that we would use in formulating a baseline if that's in fact what we do.

One of the things that we're doing is we're looking at salmonella data and E. coli data. The samples that we get we're testing for both salmonella and E. coli to see if there's a correlation between either of those pathogens and campylobachter. The salmonella may be important because if there is a strong correlation then the performance standard that we have already may in fact be all that we need, but that's one of the things that we're

looking at.

That completes my update.

MR. BILLY: Lee?

MR. JAN: I'd just like on your last statement, --

MR. DERFLER: Yes?

MR. JAN: -- the correlation that you're doing between you said between two pathogens, salmonella and --

MR. DERFLER: Well, three.

MR. JAN: -- E. coli.

MR. DERFLER: And campylobachter.

MR. JAN: Are you talking about generic E. coli or pathogenic E. coli?

MR. DERFLER: Generic E. coli.

MR. JAN: Okay, sir.

MR. DERFLER: Yes. It's generic E. coli.

MR. BILLY: Okay. Caroline?

MS. SMITH DEWAAL: Thank you. I have a specific question and then a general question.

You say here that a national baseline is underway, but from your oral comments you seem to be indicating that you can't decide on which method to use to do the national

baseline and that that decision hasn't been made, so you don't have a national baseline underway? I'm confused.

MR. DERFLER: We're trying to develop a new national baseline. The question is what is the method we're ultimately going to be using? Are we going to keep with our current method, which takes longer and is more expensive, or are we going to move to the new ARS method that has some obvious advantages and perhaps some disadvantages?

MS. SMITH DEWAAL: And it's not as sensitive? Is that one of the disadvantages?

MR. DERFLER: Yes.

MS. RANSOM: Yes. We're getting slightly lower numbers with that method.

MS. SMITH DEWAAL: Okay.

MR. DERFLER: But whatever baseline --

MS. SMITH DEWAAL: So a national baseline is not underway because you can't decide on the method?

MR. DERFLER: No.

MS. RANSOM: The study is underway, but I think we're referring to publication of baseline figures.

MS. SMITH DEWAAL: Well, you published baseline

figures back in the year is --

MR. DERFLER: 1994 to 1995.

MS. SMITH DEWAAL: 1994 to 1995. Thank you. There is the turkey baseline and the chicken baseline and all the other baselines, so you have baseline data that's a couple years old now. It would be helpful to have data to compare with that that's directly comparable.

MR. DERFLER: But if we do decide to develop a performance standard on the basis of the baseline, we need to have a baseline that we can use in conjunction with a performance standard.

MS. SMITH DEWAAL: So are you running two tests now, the ARS test and the old test?

MR. DERFLER: Yes. Yes.

MS. SMITH DEWAAL: Okay. That sounds good. That was my specific question.

MR. DERFLER: I'm sorry.

MS. SMITH DEWAAL: My general question is so what's happening with the performance standards? This committee, the subcommittee and this committee actually was asking the NAC MCF to talk to us about a performance

standard.

They never did that, and so I'm asking you what are we doing about a campylobachter performance standard because this is all nice, but it's not really getting where the committee was going in terms of the campylobachter issue.

MR. DERFLER: I think the answer to the question is we need to -- we're accepting the recommendations that they made as questions that need to be answered. Once we have the answer to those questions, then we can be in a better position to decide whether or not we're going to go in the direction of a performance standard for campylobachter or whether what we have now with salmonella is adequate.

MS. SMITH DEWAAL: So how many years do you think we are from like having a real public health standard in place?

MR. DERFLER: It depends whether we have to do rule making or not. I mean, you know, we're moving to get this answered and done as quickly as we can. I mean, if we have to --

MS. SMITH DEWAAL: Five years?

MR. DERFLER: If we decide that the best method is the ARS method, it's going to take until October of 2000 before we'll have a full year's worth of data. Now, you know, that's slower up front, but ultimately if it means less cost and quicker results it's probably worth the investment.

MR. BILLY: Just so I'm clear, we started in January of 1999 --

MR. DERFLER: Right.

MR. BILLY: -- baseline based on our --

MR. DERFLER: Right.

MR. BILLY: -- most probable number method?

MR. DERFLER: Yes.

MR. BILLY: And then in October, after about nine months of sample collection, we started analyzing the samples by both methods, is that correct, and we're continuing to do that, so we'll end up with two sets of results, one by each method, and a lot of information about which method we should rely on?

MS. SMITH DEWAAL: Do you have data, though? It

sounds like you already have a full year of data that would be directly comparable to the 1994-1995 baseline.

MS. RANSOM: That's right.

MS. SMITH DEWAAL: When do we get to see it?

MS. RANSOM: We've got the statisticians working on the data right now. We're doing data edits and clean up of data, so we're --

MS. SMITH DEWAAL: Okay. I would recommend you release that as soon as you can.

MR. BILLY: Alice, and then Dale?

MS. JOHNSON: Phil, you talked about a survey on 48 plants.

MR. DERFLER: Right.

MS. JOHNSON: I know NCC and NTF both were a little bit involved with this survey. You sent it out to the IICs, and what you were trying to do is look at some of the information of what the industry was doing on campylobachter, as opposed to some of your results that you were getting?

MR. DERFLER: We were interested in what the industry was doing with respect to campylobachter.

MS. JOHNSON: I understand why you couldn't send it to the industry because of some of the OMB issues and that, but I'd caution you to in your comparison in trying to make some correlations, I know some of the IICs actually went to the plant and asked for specific help, which was appropriate, and we appreciate them wanting to get that information, but some of the questions from what I understand on the survey talked about pre-harvest measures and a lot of information that in plant IICs might not have that might flavor the way the survey is going.

MR. DERFLER: Right, and we're going to do -- you know, we're doing an analysis of that now.

MS. JOHNSON: Anyway, any of the poultry trade groups could help you when you do surveys like that, would be willing to do that, get the right information.

MR. BILLY: Dale?

MR. MORSE: Just to point out, the FoodNet data being collected in eight and now the nine states has shown this interesting drop in campylobachter the last two years. It may be a coincidence, but it would certainly be nice to have had the baseline data of campylobachter, like

salmonella, to see if there had been a drop with HACCP implementation and whether that is reflected at all in the human results, so I guess just reinforced.

I'll certainly be interested in the -- I mean, it's not the same time period, but what's happened with 1994-1995, at least the 1999 year, and then you're continuing it, I guess.

Did you do that in the same plants or same places so that you would have some comparability at least between -- the same method, I guess. Did you use the same method?

MS. RANSOM: No. We targeted young chickens. I'm not sure if they're new plants that came on board, but some of the same establishments should definitely be captured.

MR. BILLY: Same design essentially.

MR. MORSE: So maybe we'll be able to see this data at the fall meeting.

MR. BILLY: Oh, yes. Dan?

MR. LAFONTAINE: I'd like to change the focus just a little bit. Dr. Denton or anybody else, correct me if I'm wrong, but this three year ARS study is a very massive effort on the part of ARS to look at every epidemiological

facet of the bird from the hatchery on through grow out into the slaughter plant, I believe, but for sure through the farm, to see what the ecology of this organism is and in turn what intervention strategies may be possible. I believe they're well into it like probably a year and a half to two years into the study.

What I'm suggesting is that if we invite ARS to come back and talk to us about a possible strategy for listeria, maybe they can give us an update on what the study consists of and where they're at, what they can tell us so far.

It would be very useful to know what's happening in that whole arena because there's a very massive effort out there to tackle this issue at the on farm level, so maybe you can tie these two together if we in fact invite them back and maybe even get Dr. Stern to talk to us directly. I've heard him speak at some other conferences, and he's pretty open, so to speak.

MR. DERFLER: Am I correct on that? By just briefly referring to his study, I wasn't in any way trying to diminish it. We've given money to him as part of the

study to support this.

MR. LAFONTAINE: I mainly brought that up -- well, first so that maybe we can get the information to the full committee, but trying to emphasize how massive and comprehensive this is. It's not a quite look see, but a whole bunch of resources being dedicated to this project by ARS, you know, out of Athens.

MS. HANIGAN: Could you tell me, please, one more time the gal sitting next to Phil Derfler.

MS. RANSOM: Geri Ransom.

MS. HANIGAN: Thank you.

MR. BILLY: Other comments? Questions? Okay. I'd like to move on then.

The next briefing is an update on meat and poultry at retail and again will be led by Phil Derfler.

MR. DERFLER: My understanding is that the briefing paper for this is at the back of Tab 5.

Are you coming? I always have to have a woman by my side. No. I'm only kidding. I know. That was really bad. I'm sorry. Now you can throw things at me.

MS. MUCKLOW: You're right. That was really bad.

MR. DERFLER: Yes, I know. Sorry. I didn't mean it. Honest. I didn't mean it.

MS. MUCKLOW: What a woman, though. Judy Niebrief.

MR. DERFLER: That's right. It's Judy Niebrief from OPPD.

The purpose of this briefing -- the last time the committee met Ms. Mucklow and Dr. LaFontaine expressed some concern about the fact that we hadn't updated the committee on where we were in responding to the committee's concerns about the retail exemption, and so I wanted to or we wanted to provide a briefing. I hope I can do it in a better way.

The purpose of this briefing is to update you on where FSIS is in its thinking on the exemption from inspection that the Meat Inspection Act and the Poultry Products Inspection Act provide for retail stores. Inspection is required where products are prepared or processed, but the statutes recognize that some activities that would normally require inspection occur at retail stores.

They provide that the inspection requirements did

not apply to operations traditionally and usually conducted at retail stores if the operations are being conducted to produce products in normal retail quantities for sale to consumers at the retail establishment.

In issuing implementing regulations, USDA addressed what operations have been traditionally and usually conducted at retail stores and also defines what constitutes normal retail quantity. It also provided that consumers included non-household consumers, as well as household consumers.

The advisory committee has suggested that these criteria may not be appropriate. Last year you suggested that FSIS should assess the health risk of exemptions and assign inspection resources where the risk is the highest. The example that perhaps typifies the committee's concerns about the retail exemption provisions is grinding. Concerns about the E. coli 0157:H7 contamination have highlighted the fact that grinding is not a low risk operation.

MS. MUCKLOW: Phil?

MR. DERFLER: Yes?

MS. MUCKLOW: Have you got this written out for us

somewhere?

MR. DERFLER: I have it written out for me. I mean, I can --

MS. MUCKLOW: Did you say there is a briefing paper on this?

MR. DERFLER: There is a briefing paper at the back of Tab 5. It's different.

MS. MUCKLOW: Okay.

MR. DERFLER: I'm sorry. This is like about the fifth or sixth talk I've given in the last three days. I'm just trying to get through it.

Concerns about E. coli 0157 contamination have highlighted the fact that grinding is not a low risk operation, but, on the other hand, FSIS regulations provide and most would likely agree that grinding is an operation that traditionally and usually occurred at retail.

The decision in the Honey Baked Ham case, which is summarized in the handout that you have, raises a question as to whether the fact that a retail store performs an operation that has traditionally been performed at retail, that that presents some risk would be enough to require

inspection.

The Court found that Honey Baked Ham's retail stores supplying sliced, glazed and packaged product for sale at their own shopping center kiosk, activities that could introduce some risk to the product, did not transform them into a hybrid retail wholesale operation that required inspection.

However, the FSIS shares this committee's concerns about whether risks to consumers result from the retail exemption. As a result, FSIS has been taking a closer look at retail operations.

For example, at the last Conference of Food Protection meeting, which was held in April, FSIS, in cooperation with FDA, proposed to have FSIS' performance standard for certain meat and poultry products, which includes products like roast beef, to be incorporated into the food code as at least an alternative means of compliance with the food code's requirement. The conference voted to take no action on this suggestion, however. Thus, this particular effort is stalled for now.

Using a somewhat different tact, FSIS has under

development two rule makings related to retail. By way of background, it's important to note that even if the requirements for inspection did not apply to certain operations -- the requirements for inspection did not apply -- it does not mean that those operations are not subject to regulation under the Meat Inspection Act or the Poultry Products Inspection Act.

Both statutes provide that with narrow exceptions their adulteration and mis-branding provisions apply to foods not covered by inspection mandates. In addition, the statutes authorize USDA to prescribe by regulation conditions under which products are stored or otherwise handled by those in the business of buying, selling, freezing, storing, transporting or importing meat and poultry products.

Thus, FSIS is developing proposed regulations on how product is to be handled during transportation and storage and while held for sale at retail. That's one of the things that you just heard we're going to be asking the microbiological committee about.

Second, FSIS announced in a Federal Register

notice in October of 1999 when it published a notice to clarify the effects of the Honey Baked Ham decision that it is reviewing the retail exemption regulations themselves. One issue that FSIS intends to consider in that review is what should be the effect on a facility's eligibility for the retail exemption of sales to non-household consumers; that is, to hotels, restaurants or similar institutions of products that are processed or prepared at the retail facility.

In 1998, this committee recommended that FSIS modify its regulation on the retail exemption to provide that any wholesale sale of meat or poultry products processed or further processed by a facility would make that facility ineligible for the retail exemption. Although there are certainly other options that we're considering, this is one approach that we have under review.

I hope this clarifies a little bit in a sort of organized way as to where we are in our review of the retail exemption.

MR. LAFONTAINE: Phil, would you -- that very last part.

MR. DERFLER: Yes?

MR. LAFONTAINE: Repeat that.

FEMALE VOICE: Yes. One more time.

MR. LAFONTAINE: I didn't quite catch what you said.

MR. DERFLER: What I'm saying is that we're looking at the retail exemption and our regs, our retail exemption regulations now. We have them under review.

This committee recommended that if a retail store processes or further processes a meat and poultry product and then sells it to an institution or a hotel or restaurant, then that would disqualify -- that that should disqualify the facility for the retail exemption.

Now, we're not saying we're going to necessarily propose that in our regulation. We're saying that's one of the options that we have under consideration, but it is a recommendation of this committee that sat for a couple years, and I wanted to give you the status. It is one of the options that we're considering.

FEMALE VOICE: Okay.

MS. MUCKLOW: I thought, Phil, that that last

provision, that it would destroy their exemption right now. I didn't realize that's something you're looking at. I thought that if a retail store processed something and then, you know, like nitrite cured or whatever, which it's permitted to do under the retail exemption, I thought it was not allowed to sell that to non-household.

MR. DERFLER: No.

MS. MUCKLOW: Judy is ready.

MS. NIEBRIEF: There's a little -- you made the question harder, Rosemary, because --

MS. MUCKLOW: You're kidding?

MS. NIEBRIEF: Yes, because under the meat inspection regs, unlike the poultry products inspection regs, there's a subsetting of what operations are traditionally and usually conducted at retail, so you went and got into the subset, okay.

MS. MUCKLOW: So that's in the meat regs, but not in the poultry regs?

MS. NIEBRIEF: Both sets of regs essentially say -- now, I'm going to do this very broadly -- that traditionally and usually conducted operations include

essentially everything except slaughter and canning, but for product sold HRI that list is shorter for meat food products.

MS. MUCKLOW: Okay.

MS. NIEBRIEF: And if you ask, I have to look it up before I'd have any confidence.

MS. MUCKLOW: That's okay. That's what I thought it was.

MS. NIEBRIEF: Okay?

MS. MUCKLOW: Yes. Okay. My memory is not as bad as it was or I thought it might be.

MS. GLAVIN: Are there other questions? Dan? Sorry.

MR. LAFONTAINE: I'm going to kind of -- Dan LaFontaine, South Carolina. I may sound like a broken record, but I want to repeat it one more time to hopefully make my point.

What we have now is very small plants across the United States, and I'm thinking 6,000, 2,500 federal and approximately 3,500 -- 2,500 state and 3,500 federal that are wholesalers of meat and poultry, and by the mega reg

they are required to have some very stringent food safety elements in place. The sanitation standard operating procedures, performance standard for meeting salmonella with government testing and implementation of HACCP. That's good. We've accomplished a lot with that in the industry we regulate.

At the same time, we have literally hundreds and thousands of retail stores that are doing the very same single ingredient products, ground beef, cube steaks, pork chops, steaks, roasts, you name it, and are selling on an annual basis up to $42,000 worth of these very same items, and you translate that into ground beef approximately 20 ton of ground beef a year without any additional food safety elements that they're required to implement other than meeting a local health standard, health department standard, that may come by a couple times a year.

What it presents to, and I'm speaking for South Carolina, a question that I cannot answer to anybody when my plant owners say Doc, how can this be? You were going to nail me to the wall if I don't do my HACCP right or whatever, and I could walk right down the street and this

guy is turning out ton after ton of product with this exemption that's grown to $42,000 per year with none of these checks.

It doesn't pass the common sense test, and that's why I'm so passionate on this because it hits me every day in my business, and so that's the problem and that's the problem that needs to be fixed. The HRI retail exemption has grown way out overboard, and it needs to be brought back, either eliminated or brought back to a much reasonable level than what it is now.

That's as straightforward and simple as I can put it, and that's my position and my proposal to where we head on this issue.

MS. GLAVIN: Thank you.

Other comments or questions? Lee?

MR. JAN: I agree with Dan, so it's not only South Carolina. It's Texas and I'm sure Wisconsin and all other states about that issue. One thing that I think needs to be also mentioned is that the recent decision by FSIS that excluded pass through product essentially doubled or more the amount of product the store can produce or process to

qualified or before they reached that $42,000 limit, so instead of reducing the amount that these stores can sell, it actually increased the amount because they can sell pass through plus the $42,000, and that's just --

I'd like to know. You know, it sounds like you have already identified that you need to do something about that. When is that going to happen? When is that going to go away or be reduced to a reasonable level?

MR. DERFLER: I mean, I can't tell you specifically, unfortunately, but I can tell you that we're working on it. You know, we have a lot of things on our plate, a lot of things competing for resources. That's not a satisfactory answer, but it's the only thing that I can say.

MS. GLAVIN: Rosemary, do you have a comment?

MS. MUCKLOW: What is the time line for your review process, Phil? Which fiscal year are you going to get it done in?

MR. DERFLER: I don't think I can add to what I just said. We're working on it, which is better than it's been other times.

MS. GLAVIN: Other comments?

MS. HANIGAN: Yes.

MS. GLAVIN: Questions? Katie?

MS. HANIGAN: Phil, in your summary that you were reading, did you say the Agency had determined that the retail exemption did increase the risk for the consumer? I guess I was writing down stuff that you were saying.

MR. DERFLER: I think what I said in my comments was that they're not necessarily low risk product.

FEMALE VOICE: Terry?

MR. BURKHARDT: Just wondering if the results of the risk assessment that's going to be presented on E. coli and listeria coming out will force that decision to be made a little quicker because there's a considerable amount of ground beef that are produced at retail providing significant risk and a lot of sausage products, ready-to-eat products, that are produced for retail sale, so on an overall risk assessment that certainly might change. I don't know. I'm just expect that it will. I don't know.

MS. GLAVIN: Well, I think the issue Dan was raising and I believe Rosemary was raising was the sale of

those products to non-household consumers. Not the sale directly to consumers, which is part of the law that that is exempt from inspection.

One of the things Phil indicated was the sale to household consumers of those products is exempt from inspection, but we still do have authority to set some performance standards for how those products are handled and held. That is a direction we are taking.

Other questions? Comments?

MS. MUCKLOW: Those products are still subject to the misbranding and adulteration provision --

MS. GLAVIN: Yes.

MALE VOICE: Yes.

MS. MUCKLOW: -- of the law?

MS. GLAVIN: Yes.

MALE VOICE: Absolutely.

MS. MUCKLOW: We need to make sure that that is understood in the record. A lot of people don't understand that an exemption simply exempts them from certain requirements under the Act, but doesn't exclude them or exempt them from adulteration and misbranding.

MS. GLAVIN: That's a good clarification. Thank you, Rosemary.

Dan?

MR. LAFONTAINE: I want to ask the hard question or what I think is the hard question to Phil. First of all, Phil, good tap dance on the time line. I respect that, you know, telling the truth you don't when.

Let me ask the question. Phil, did I hear you say that as a part of this proposed rule making that you plan on addressing in that or as a part of that the HRI exemption? Did I hear you say that?

MR. DERFLER: Yes.

MR. LAFONTAINE: Okay.

MR. DERFLER: Yes.

MR. LAFONTAINE: Okay.

MS. GLAVIN: Even though Tom has come back, I'm going to still be chair and declare a break, but it's only a 15 minute break.

(Whereupon, a short recess was taken.)

MR. BILLY: Okay. We'll get started. Roger Breeze and the folks from ARS followed through, and they've

provided us a copy of their 1999 progress report on the ARS food safety research. I think you each got a copy of that.

In addition, as it turns out they do have this videotape on the automated chicken inspection system, the one that he referred to and that a number of people are interested in, but, unfortunately, they only have four tapes so we're going to reproduce it. We'll send copies to all of the members of the committee. If anyone has a critical need to see it then we do have a couple of extra copies obviously, but we'll make copies and send them to everyone.

Okay. We're now at the point in the agenda that deals with the remaining issues and plans for the next meeting. You will recall that at the beginning when I talked through the agenda I added a topic which was raised at the last meeting by Carol Foreman. She raised the issue of a report that had been put together on 70 or so plants that had received a number of NRs, and we attempted at that time to try to be responsive, but it required us to go back and do some additional analysis and work.

We've completed that and provided you earlier sort of a full report. Just today we provided you what is a

front and back, sort of a page and a half summary of that report.

Maggie is going to lead you through this. Mark is here, as well as Judy, to answer any questions that anyone has in terms of the analysis that we did and our findings.

Maggie?

MS. GLAVIN: Sure. Thank you, Tom. As Tom indicated, what we provided this afternoon was what I'll call an executive summary of our look into these non-compliance reports. It is a fairly complex issue, and this is an attempt to -- it was supposed to be a page, and they cheated and put it front and back, but, in any case, an attempt to put on one page what we found.

As indicated, at the last meeting there was a report on I think it was 70 plants with a high number -- that were under HACCP and that had a high number of non-compliance reports issued in those plants. There was an implication that corrective enforcement action had not been taken in those cases.

What we did was go back and look at those 70 plants and the non-compliance reports for the time period,

which was early 1998-1999, so the early days of HACCP implementation. We also analyzed data from approximately 2,800 meat and poultry plants, so we tried to look at the whole universe to put this look in perspective.

What we found was a number of things. First of all, in the larger sample, the sample that represented plants under HACCP at that point -- it was virtually all of the plants at that time that were under HACCP. We found that non-compliance in the public health procedures that we do in plants, the food safety procedures that we do in plants, was at about a five percent or less level.

I'm not going to say that five percent non-compliance on food safety is acceptable, but it certainly does not approach the alarming level. We found that to be particularly for the very early days of HACCP to be an acceptable level of non-compliance. Not an acceptable, but a level of non-compliance that was within the range that we might have expected.

With respect to the 70 plants sampled, we found a higher level. There definitely were some problems existing in these plants in that sample, and so we looked further to

see what was going on in those plants. What we determined was that in those plants or in quite a few of those plants our inspection force was reverting to the old method of looking at problems and was not taking advantage of the tools provided to them, provided to the Agency, by the HACCP system and the HACCP rules.

Again, I want to remind you that this was in the very early days of HACCP, and so, you know, we believe that this reversion to the old method of inspection was in large part due to the fact that the transition had not been completely made by our work force and that that was what was going on.

What was happening was our inspectors were, when they found a problem, continuing to go back and document that problem over and over again. The problem certainly existed, but they weren't stepping back and looking at what the system was doing and where the system was failing and requiring the plant to take corrective and preventive action, which is what should happen under HACCP when a problem is identified.

So they in some instances failed to do that and

instead simply kept documenting the problem, which is not how we have trained our people to react and not the way the system is designed to take place.

This was a very good description for us of the fact that we have not completely made the change, and this brought to our attention a particular set of plants where we needed to do some more work with our inspectors, and we needed also to increase our oversight of what's going on, what kinds of findings are being made in plants and what kinds of actions are being taken when those findings are made, so we have since that time increased our instructions to our circuit supervisors and our in plant IICs on how to react to problems and how to look at the data that is coming out of plants to insure that the reaction is the appropriate one and one that leads to correction and prevention.

With that, I have both Mark Mina, who, as you know, is are deputy for field operations, who can help respond to questions, and also Judy Riggins, who can help with some of the theoretical HACCP aspects of this.

Carol?

MS. TUCKER FOREMAN: Thanks, all of you. Would

you give me an example, a specific example of a problem that would result in having an NR issued and then tell me -- and specifically one in which you found that the inspector was going back and documenting the same problem repeatedly and how it should have worked with regard to that specific event under HACCP?

MS. GLAVIN: Okay. Well, I'll use the one that was the most frequent one that we found in looking at these 70 plants, and that was zero fecal tolerance. The inspectors were documenting a failure of the zero fecal tolerance standard, and the appropriate action would have been to review -- first of all, to do a non-compliance report, an NR report, informing the plant of this finding and requiring the plant to take corrective action to correct the immediate problem and preventive action to insure that the problem did not recur.

We would also expect the inspector in that case to do a follow up of -- not necessarily a follow up of that particular failing, but a follow up of the system that was intended to prevent that failing from happening in the first place.

MR. MINA: Yes. That's fairly accurate, Maggie. If I may add, in reviewing the system we need to find out what's causing the problem by reviewing the system, meaning we have to look at whether there was a problem with the equipment, whether there was a problem with not hauling the feed from the chicken prior to slaughter. That's part of the system evaluation.

To support an enforcement action, we need to have adequate documentation to reflect system inadequacy. Just identifying the deficiency does not take us to the level of taking the strong enforcement action we'd like to take, and so the inspector did not complete the process. The enforcement actions only documenting the deficiency does not get us there legally.

MS. TUCKER FOREMAN: Okay. Can I ask another --

MR. MINA: Sure.

MS. TUCKER FOREMAN: -- question, a follow up on that? How would the inspector have treated zero fecal tolerance before HACCP?

MR. MINA: Well, they treated it the same way in terms of documenting deficiencies. You see, we're moving

from a deficiency identification system to a system evaluation.

All the inspector did in the past, and that's what Maggie was referring to, is our inspectors reverted to the old system because we were in that transition period. It was just documenting deficiencies, not following through the whole system and making sure that we have adequate documentation to support system inadequacy.

We have to have documentation I think to support the system has failed, and we did not make that point in some of those plants. We have to prove that the system failed.

MS. TUCKER FOREMAN: But help me understand. Say I'm an inspector, and I'm standing there on the line, and I see fecal material going by on the birds.

MR. MINA: Right. Right.

MS. TUCKER FOREMAN: Before HACCP, what did I do?

MR. MINA: We documented that. We used to use another form called PDR.

MS. TUCKER FOREMAN: But what did I do first? Did I tell them to pull the bird off the line?

MR. MINA: Those particular birds are removed off the line and corrected under both systems.

MS. TUCKER FOREMAN: Okay.

MR. MINA: That did not change.

MS. TUCKER FOREMAN: But the first thing I did as an inspector was tell the plant --

MR. MINA: Yes.

MS. TUCKER FOREMAN: -- take the bird off the line?

MR. MINA: That's correct.

MS. TUCKER FOREMAN: Under HACCP, what does the inspector do?

MR. MINA: The same thing.

MS. TUCKER FOREMAN: Okay.

MR. MINA: They pull those birds off the line, clean those birds up and then look at the system that's producing those defects --

MS. TUCKER FOREMAN: Okay.

MR. MINA: -- and make sure the system is functioning.

MS. TUCKER FOREMAN: A bird with contamination

comes off the line --

MR. MINA: That's correct.

MS. TUCKER FOREMAN: -- regardless of where in the plant. Before HACCP, they pull the bird off the line and write an NR?

MR. MINA: That's correct.

MS. TUCKER FOREMAN: Now with HACCP you pull the bird off the line, and you write an NR when the first one goes by?

MR. MINA: Yes.

MS. TUCKER FOREMAN: Okay. Then a second, third, fourth, fifth. It's clearly a systemic problem that day.

MR. MINA: Right.

MS. TUCKER FOREMAN: Then what does the inspector do?

MR. MINA: They have to conduct a system review.

MR. BILLY: It's another instruction that they have, a procedure that they follow.

MS. RIGGINS: They would go back, and they would look and review the documents, and those documents would include the HACCP plan, the hazard analysis.

They would reacquaint themselves with the steps that the company has committed itself to in terms of preventing fecal contamination and would determine what in his estimation or her estimation was not done and what led to that particular zero fecal failure.

MS. TUCKER FOREMAN: And how many NRs might be written on a particular day? You talked about the repeated NR. Did the inspector come back the next day and find the same problem, or was it the next hour or the next shift?

MS. GLAVIN: That varied.

MS. TUCKER FOREMAN: That varied?

MS. GLAVIN: It could be within the same day. It could be several days later.

MS. HANIGAN: Carol, I know at the pork plants we would also go back to the -- we monitor the hogs regularly ourselves. We would go back to the last acceptable check that we had, if you will, and then recheck all those carcasses back also.

MS. TUCKER FOREMAN: So how did a plant get 700 and something NRs in a period of one year?

MR. MINA: These are fairly large plants, and they

produce 250,000 probably chickens a day. They might get one or two NRs a day, and that adds up to a large number quickly. That does add up quickly.

MS. TUCKER FOREMAN: Actually, you raise a very good point that I'd like to pursue just a minute. How many inspection tasks does an inspector perform in a shift for which an NR might be written? Not different tasks, but how many times could you write an NR theoretically in one day?

MS. GLAVIN: Well, because we have both assigned tasks and tasks that -- unscheduled tasks, it's really not possible to give you a number because an inspector can at his or her discretion repeat a task or add a task that isn't scheduled for a particular time in order to meet the needs of the situation.

MS. TUCKER FOREMAN: The reason -- I thought that one of the documents you gave me made a reference to the number of inspection tasks in something in terms of a couple of thousand per day.

MS. GLAVIN: Uh-huh.

MS. TUCKER FOREMAN: One thousand or 1,300 a day. Does that figure sound familiar?

MR. MINA: No.

MS. TUCKER FOREMAN: No? Okay. I have to go back and go through.

MS. HANIGAN: It doesn't have to be a scheduled task. If you're running a double shift operation, single slaughter, and then you've got double shift processing going on, and if you have four -- just fictitious; four day inspectors, if you will, they do not have to be on a certain task to write you an NR as they are I hate the word patrolling, but as they are going through their facility.

They may see something that you have not identified, which they will document on the NR, so if you've got four day inspectors and on one given day each one of them identifies something, you could generate four NRs off of your first shift in a given day. I mean, that's just a fictitious example, and then clearly the same thing could happen at night when you're talking about how could you get 600 NRs in a year. It could happen.

MS. TUCKER FOREMAN: I assume that there are more opportunities in a poultry plant than they are in a hog plant?

MS. JOHNSON: Yes. If I could, I was just --

MR. BILLY: Yes. Just before you make -- I also want to get a little more discipline in the terms. We moved away from the term task as associated with the old system of PDRs where we had somewhere on the order of 500 different tasks that inspectors were asked to carry out. When we shifted to HACCP, we shifted to the term procedure and reduced that to about 50 procedures. I don't remember the precise number.

The procedures, as Mark has described, include our focus on answering the question whether the system is under control or not. Obviously if they spot something like has just been said by Katie and others you can write an NR, but the follow through involves -- includes a trend analysis, which is built into the NR procedures process, and when you start to see repetitive failures then that's where you go in a document why it's failing and get the right information that forms the basis for taking more stronger action with the plant.

So it's not just about those particular birds that you found fecal material on. It's why it was happening, is

it repeating itself such that it brings into question the preventative controls that are in the HACCP plan. If it brings into question that, then taking action regarding the effectiveness of the HACCP plan for whatever reasons it may be occurring.

Sorry. Alice?

MS. JOHNSON: That's okay. As far as I'm going to talk from some past experiences in some chicken facilities in that I was sitting here trying to count up how many line inspectors I can remember and how many floor guys there were, and then this is strictly in the slaughter area. There were 33 inspectors on line. I was trying to remember. It was when I worked for the Agency, so they were the GS-8 floor people. There were at least eight, and this plant ran two shifts. That's strictly in the slaughter area.

Now, all these birds had to go somewhere, so they went into cut up, and there were two processing inspectors there, and there was another further plant where they -- a part of this plant where they did the cooking, and there was an inspector that was a higher level, GS level, in that level, so that plant had just on floor people at least 12

inspectors, and each inspector had tasks that they would be performing, and they would be writing their it was PDRs back then, but it's equivalent today, so, you know, the 33 just in the slaughter area, you know, some on line and some on the floor.

MS. TUCKER FOREMAN: But I presume they wouldn't have been writing PDRs for the same problem because they'd be in different places in the plant.

MS. JOHNSON: Well, but if you consider that on each slaughter line the inspector is doing so many checks for the fecal, and help me if -- this is the way --

MALE VOICE: Yes. That's right.

MS. JOHNSON: -- I understand it was set up, because I haven't been in the plant. You know, there are at least just in the slaughter area eight lines that are having so many fecal checks a day. You know, if there's a problem on any one line then you're subject to have NRs.

MR. JAN: I'd like to maybe put this in a little more practical perspective or actually what happens on the regulatory side. When you say numbers of NRs, that by itself doesn't tell you a lot. What you have to do or

inspectors need to do is when a deficiency or deviation is identified, they do generate a NR, but part of that NR includes a response by the plant, which is corrective action and preventive measures.

If those preventive measures appear to be acceptable, the plant can go about its business, and if it fails again in that same area they have another opportunity to try another preventive measure, but at some point as long as these deficiencies are from the same root cause or for the same thing and the plant is failing to take action, then the Agency can take stronger enforcement action, but those PDRs have to be connected.

If you look at the raw numbers, there are a lot of numbers in a plant, and it depends on the complexity of the plant and its operation. There may be PDRs or NRs that are generated and they're not related. It may be in an area that the plant did take corrective action, it was successful, and that was fine, but when you have a lot of procedures that are being conducted there is a possibility that over a year's time you'll have NRs that develop and are not related, the plant took corrective action and a

preventive measure so it didn't happen again.

So, you know, I'm not saying that 700 is a good number or not a good number. You have to look at, I guess, as you did the percentages, but I think the key is the plant's response and where the procedure or the deficiencies have a repetitive nature that the plant just failed to control. At that point, the enforcement action comes from the top down basically.

MS. TUCKER FOREMAN: If you were to -- following up on that, if you had a plant with some -- I raised a couple of plants that had very high numbers of NRs, but there was no indication of any enforcement action having been taken.

I guess, number one, why would you have a plant with a whole bunch of NRs and no enforcement action having been taken? Was that strictly associated with the newness of the system, or would that happen again today?

MS. GLAVIN: It should not happen today. It shouldn't have happened then. Our analysis of these particular plants was that in many cases the documentation was not there on what was going on in the plant.

Was the plant taking corrective action? Preventive action? Was it because the inspector was not doing what Lee just described, which is building a nexus of connected, repeated problems that the plant's HACCP system did not, perhaps could not resolve, and that's what provides the basis for us to take our enforcement actions?

Some of these plants we found that there were enforcement actions taken, but when -- what should happen is if we see a lot of NRs, you know, what seems to be a high number, knowing the plant, of NRs coming out is we should find out and enforcement action is not there, we should find out what's going on.

We should make sure that the inspector is appropriately moving from a particular procedural problem to what has gone wrong with the system and what has the plant done or not done to correct it.

MS. TUCKER FOREMAN: Why would you have a situation where a withholding or a suspension had taken place after a number of NRs and then the suspension was held in abeyance?

MS. GLAVIN: Well, when we suspend a plant from

operation, when we suspend inspection from a plant, the plant then provides us or has the opportunity to provide us with their plan for correcting the problem.

If we are -- if our inspection personnel are satisfied that that action will in fact correct the problem then we will allow them to operate with the suspension in abeyance to demonstrate that in fact their corrective action is capable of correcting the problem.

MS. TUCKER FOREMAN: So a suspension being held in abeyance is really a continued yellow flag warning --

MS. GLAVIN: Yes.

MS. TUCKER FOREMAN: -- that the plant is on notice that you don't think --

MS. GLAVIN: Yes.

MS. TUCKER FOREMAN: That you're aware that things weren't working well before?

MS. GLAVIN: Yes.

MS. TUCKER FOREMAN: So being held in abeyance is not a withdrawal of your concern about the problem, but allowing the plant to operate under increased scrutiny?

MR. MINA: That's correct.

Can I add one other point that's important? We have also developed a data system that we're still working on and improving on that will help us kind of raise flags about those plants that have high NRs or have potential problems. We are training our supervisors to use the data system and our district people to use the data system.

One of the things that we do when that flag is raised, we send a compliance officer to the plant to review the documentation to make sure that we have appropriate documentation to reflect system inadequacy so we can take a stronger enforcement action. It's a learning process for our work force.

MS. TUCKER FOREMAN: Can I ask just one more question before you let somebody else in? Do you have access to -- let's see. These plants went in in 1998. We're talking about real big plants here. The data that I have are for that first year.

Would it be possible to look at some of these same plants if you don't run the whole data set, just run a random sample, to see if the number of NRs issued in these big plants is still running high, or now that the system has

been working for a couple of years if both the plant and the inspectors are more schooled in their functions, and have the number of NRs dropped, or have they stayed the same?

MR. MINA: Okay.

MS. TUCKER FOREMAN: That would be really helpful to me.

MR. BILLY: Mike?

MR. MAMMINGA: One thing I haven't heard interjected into the discussion is the very first categorization of an NR. Is it food safety, or is it other consumer protection?

When you have -- when you're looking at raw numbers or the numbers of NRs plus what is appropriate for the Agency to do, it's absolutely, positively essential that you know whether you're dealing with a food safety problem or whether you're dealing with other consumer protection. I think that should certainly be a part of this data exchange here on what you're looking for.

MS. TUCKER FOREMAN: Yes. I think that when I gave the Agency some of those numbers that they were broken out into food safety and OCPs.

MR. MAMMINGA: Yes. It just wasn't mentioned here, and I haven't heard the conversation.

MS. TUCKER FOREMAN: No. Thank you. No, it's not, but it has --

MALE VOICE: I think it's in the folder.

FEMALE VOICE: It's in the Romberg paper. It's in the Romberg paper that was in your --

MS. TUCKER FOREMAN: That's a good point. A good point.

MR. BILLY: Alice?

MS. JOHNSON: Dr. Mina, when you're talking about the automated system and the database that the circuit people will be having, and I know that you guys are doing some really good work with trying to get the districts and the circuits up to speed with this. You're still just looking at raw numbers, as Mike just said. Is that right? I mean, as Mike said, it shows NR numbers. It doesn't talk about --

MR. MINA: No.

MS. JOHNSON: Okay.

MR. MINA: No. We go further than that, and we do

some analysis. We have not perfected the system yet, but we're working on it. It's not just raw numbers. We try to interpret what those numbers mean.

MR. BILLY: But she means it breaks out the food safety from the --

MR. MINA: Oh, yes. Oh, definitely. Yes.

MS. JOHNSON: It does break out food safety.

MR. MINA: Oh, yes. Yes. All of those.

MS. JOHNSON: It breaks out non-food safety. It also breaks out the size of the plant?

MR. MINA: Yes.

MS. JOHNSON: I know back in the olden days --

MR. MINA: And by shift. By shift, type of plants.

MS. JOHNSON: And the number of pounds run through the plant?

MR. MINA: Uh-huh.

MS. JOHNSON: So the circuit people aren't just being flagged with here's a number and --

MR. MINA: No, no.

MS. JOHNSON: Okay.

MR. MINA: No. That's part of the training to kind of train them on how to use the data and what's in the data system.

MR. BILLY: That's the training that's going on now.

MS. SCHULTZ KASTER: But the responses are not factored in, right? It's generation of the NR, but there's no plant responses factored into the analysis, correct?

MS. GLAVIN: That's right.

MR. BILLY: Well, in a sense it is in terms of whether the follow on procedures are carried out by the inspector, so we can actually keep track of the procedures that the inspector is doing.

If you have a -- I don't remember the numbers, but if you have an 0/1 then it triggers another procedure and are they proportional. It actually gives us a chance to look at that. That analysis is in part what is the basis for this report --

MS. GLAVIN: And that's what is important.

MR. BILLY: -- and our observation.

MS. GLAVIN: It's a chance to look at it. A

report on NRs by plant is only -- can only serve as a flagging device. It can't -- your question is right on target. It can't tell you what's going on, but it can flag someone. Gee, maybe we ought to look at this plant and see what's going on.

MR. BILLY: Nancy?

MS. DONLEY: I hope you can clarify something for me. Every time I think I'm finally getting it I get confused again.

Carol asked very specifically, and she asked it twice, that under the old system and under the new system a bird is spotted on the line. Pre-HACCP and HACCP, a bird is spotted with fecal contamination. It's taken off the line each time.

What has happened that it's addressed at that point in time? Why is it in my head that under HACCP the bird remains there? It goes through the rest of the system because the rest of the system may address the problem.

Also, this bring back to the talk of remember with the walkie-talkies that you could -- you know, the one could say to the other inspector watch out for what's coming down

the line. Let's make sure it's being taken care of. So that contradicts this doing things immediately, or am I messing a couple things up?

MR. BILLY: You've got regular HACCP inspection and the old style inspection all mixed together there. We don't have the walkie-talkie. You know, under regular HACCP we don't have that.

MS. DONLEY: That's the pilot study?

MR. BILLY: That's the pilot study with the radios and so forth.

MS. DONLEY: But in regular HACCP now, too, I really thought, too, it was waiting to see if the system worked and that the bird would not be pulled off. That is not the case. Under regular HACCP, birds get pulled off? They don't go through the system?

MR. MINA: On prior contamination, there is limited time to reaction. Conceptually you're correct, Nancy, that we want to make sure that the system works, but we're not going to see fecal material on a carcass and let it go out. We are going to give the plant a reasonable amount of time to react, but we're not going to let

contaminated product go out. We will take action before that contaminated product leaves the plant.

MS. TUCKER FOREMAN: So if an inspector sees three birds in a row quick with fecal contamination on them, they're not going to -- you know, we can see that be noted pretty fast.

Under the old system, he would stop the line and tell the plant employee take that off. Under HACCP, does he say stop the line and take that off, or does he let it go down the line to be assured that HACCP will take care of it, but stop it before it goes into the chiller?

MR. MINA: That's correct. That's correct. Now, three birds. You made a very interesting point. Once in maybe 20 birds you get one with fecal material is different than if you have three or four coming down the line with fecal material on them. That indicates that you have a problem probably up the line with equipment, or someone is not doing their job right.

Normally what you would see is one bird maybe every -- I don't know -- 50 birds, but if you have three or four in a row you have a small, serious problem then. Then

we'll just let it down. We'll stop.

MS. TUCKER FOREMAN: Somebody stops even that one in 50 before it gets to the chiller?

MR. MINA: Yes.

MS. TUCKER FOREMAN: I'm sorry. I had raised an issue, and I found that in this Part 2 of 2 on the handouts there's a document about quarterly regulatory and enforcement report, and it starts -- I'm just raising this because I raised the numbers issue.

It says Table 1A provides numbers of NRs and PDRs issued between April 1, 1999, and June 30, 1999. That's a three month period. During this period, FSIS performed 1,115,001 inspection tasks at non-HACCP plants and 766,433 in HACCP plants, and it shows the number of PDRs in those non-HACCP plants.

Out of 1,115,000 inspection tasks, there were 2,225 PDRs issued. I was impressed that that was a very small number. In the 766,433 inspection tasks performed in HACCP plant --

MR. BILLY: Procedures.

MS. TUCKER FOREMAN: Procedures. Excuse me. What

did I say?

MR. BILLY: Tasks.

MS. TUCKER FOREMAN: Okay. Procedures. I'm sorry.

MR. BILLY: That's all right.

MS. TUCKER FOREMAN: Procedures.

MR. BILLY: We're going to help you.

MS. TUCKER FOREMAN: It doesn't say that here.

MR. BILLY: Then we'll need to fix that, too.

MS. TUCKER FOREMAN: Okay. There were 29,354 NRs issued, so you had fewer tasks, fewer --

MS. MUCKLOW: Procedures.

MS. TUCKER FOREMAN: Procedures. Thank you, Rosemary.

Fewer procedures, more NRs, even a year after the HACCP program was in place. There were fewer PDRs issued under the old system than there were -- substantially fewer than under the new one. A year afterwards, is that still because the inspectors aren't used to it, or is this a more rigorous thing? Are we going to continue to have more NRs? What's happening here?

MR. MINA: We're making progress, Carol. The change is very fundamental and very significant for both the plants and our inspectors, and I think we're making progress. We still have room to improve, and I'm not going to sit here and say the system is where we want it to be.

We, as someone mentioned earlier, are holding three supervisory meetings this year, and the focus of these meetings is how we apply HACCP and HACCP past the implementation, you know, the practical aspect of HACCP.

MS. TUCKER FOREMAN: Well, I just say that if you've got that kind of -- you had fewer procedures, more NRs issued under the new system than you did under the old that canard about HACCP means have a cup of coffee and prayer, I don't think those inspectors have had a lot of time to sit around drinking coffee and praying. It looks to me like they're writing NRs all the time.

MS. GLAVIN: Carol, I think it's a little bit hard to compare the two systems.

MS. TUCKER FOREMAN: I agree.

MS. GLAVIN: They're apples and oranges. You know, what gives us some confidence that the new system is

working is the performance standards which show that the product is cleaner going out the door.

MS. TUCKER FOREMAN: I think the drop in salmonella indicates that as well, but there has been the implication that this is --

MS. GLAVIN: Right.

MS. TUCKER FOREMAN: -- a less rigorous system.

MS. GLAVIN: Right.

MR. BILLY: Alice?

MS. JOHNSON: I want to jump back for just a minute and make a comment on something that Nancy said just to be sure where everybody is on the same page here.

Under we'll say the pre-HACCP days, the HACCP and under the HAMP project we are still -- it's the point at where the inspectors are doing their zero tolerance checks are still the same. The plant has been allowed to take care of the process.

Under traditional and HACCP, the inspector is on line, and if there is contamination in the bird the bird is pulled off line. If there is on-line reprocessing, you know, the bird goes down, and then the bird is checked after

the final wash. The bird is checked in all plants after the final wash before it goes in the chiller whether the industry agrees that that is the end point or not.

That's what the Agency has deemed appropriate, and that's where the checks are being done. Any bird that is found after the final wash that has contamination is pulled off by either the inspector or if the plants are doing their checks.

Carol, yes, they'll stop the line because as a trade association person you get calls all the time -- you know, they stopped the line -- if there's an issue on that. Even under the HACCP inspection models project it is expected that pre-chill, and that's where the checks are done and the birds are pulled off the line, so I just wanted to make a clarification on that.

MS. TUCKER FOREMAN: Thank you.

MR. BILLY: Okay. Thank you very much. We've had --

MS. TUCKER FOREMAN: I just want to say thanks for the presentation and for the material. I understand that virtually all this material is already available out there

on the website and other places, but I don't have all day long to sit and play around with your website, and I could.

MR. BILLY: We're going to wrap up now, and I want to do two things. One, we need to talk a little bit about the next meeting, and I've made some notes about items for the agenda, which I'll run through and ask the committee to add any others that they feel are important or that I've missed, and then we have a request by three people from the public to make brief presentations, so by then I think we'll finish pretty close to 4:15.

Here are the items that I made notes on over the course of the meeting. The first item was based on the presentation that Dr. Wotecki made, perhaps getting into a little more depth discussion on this area of precaution. There seems to be some interest in the committee about that area, and I'll leave it to the committee in terms of whether you'd like to have a little more in-depth discussion about that as it relates to U.S. laws and what some of the issues are there.

One of the reasons that's important is that the CODEX committee on general principles will be addressing

that subject area again next April, and in addition there's growing interest on reactivating what's called the CODEX meat hygiene committee. One of the ideas on that that's being talked about among the various countries is to update the guidelines and recommendations of the meat hygiene committee to reflect what is now going on in countries around the world based on HACCP requirements and other requirements that have been put in place over the last eight or nine years since that committee last produced a set of guidelines and recommendations.

I think it's up to the committee to decide the degree to which it wants to spend any time in this area, but this subject of precaution as it relates to risk assessments and some of the things like we're talking about, the E. coli risk assessment. We're talking about the listeria risk assessment.

We in the United States are using this as required by law to provide the basis for judgements about regulatory actions, new regulations or changes in regulatory requirements, that kind of thing, and part of risk assessment is evaluating the adequacy of the data and using

appropriate caution in making decisions in that process, so it might be an area that the committee wants to look at a little more, perhaps not, so I'll leave it to you to think about while I mention the other items, and then we'll come back to it.

We talked about the possibility of presentations on specific ARS projects, and one was the Beltsville project, which is related to this videotape and was briefly mentioned in the summary that we were provided. Also, a suggestion was made to get a more in-depth presentation from Dr. Gill and the work that was done by Dr. Gill and others in terms of looking at this area of microbiological testing and the role that it should play or can play.

Another area was talking about presentations by ARS, FDA and CDC regarding listeria and research and maybe a new technology related to control of listeria, better understanding of listeria, and then finally also the idea of getting a presentation from ARS similar to the one on E. coli 0157:H7 regarding campylobachter. Perhaps if not a research plan or program, what a proposal would be from them for a similar kind of focus in that area.

Those are the notes I made. Obviously there are several items that we're currently dealing with that will carry over to the next meeting as well. Those are my notes, and I'd just like some reaction from the committee on those items and any others that you would like to suggest.

Carol?

MS. TUCKER FOREMAN: By the next meeting, you're going to have data on -- I know this is a continuing issue. You're going to have data on the HAMP plants? Isn't that right?

MR. BILLY: Yes. Yes.

MS. TUCKER FOREMAN: And you can do a presentation?

MR. BILLY: Yes.

MS. TUCKER FOREMAN: Are there training -- I assume there's no training film video for inspectors working in HAMP plants, or is there?

MR. MINA: No. We don't have a tape.

MR. BILLY: But we could give them a pretty good briefing on the training.

MS. TUCKER FOREMAN: Oh, I was just trying to have

the notion of a side by side, a video of inspector tasks in a HACCP plant and a video of inspector procedures or activities in a HAMP plant.

It struck me that might be a visual aid, but I realize that's an ongoing issue, and I certainly think that -- has had at least one public meeting between now and then and coming back for further education on HAMP and the status will be helpful to me.

MR. BILLY: Rosemary?

MS. MUCKLOW: I think it would be useful for us to know more about how we interrelate both maybe with CODEX and also with the quad group and how that all helps the international movement of product because international integrity is very important to our meat and poultry inspection system.

I would have one request to you as the chairman of CODEX, and that is if they're going to reinstitute that committee, why don't you call it the meat and poultry hygiene committee?

MR. BILLY: That's going to be one of the suggestions.

MS. MUCKLOW: Good.

MS. TUCKER FOREMAN: Thank you.

MR. BILLY: Caroline?

MS. SMITH DEWAAL: I think that any discussion of microbial testing should be prefaced or should be introduced with the data from USDA on actually the success of the HACCP program. I think it would probably be a good time, too. The committee has been in place it will be four years, I guess. You will have data really on all three years of implementation. The smallest plants you won't have probably two of the quarters, but I think it would be a good time to do kind of an assessment of how is HACCP going, what are the actual impacts and results.

I also think you should -- I have heard Dr. Gill speak, and I have tremendous respect for him, but I think you should maybe think about a panel of people to talk about it because, you know, there are very different views about it.

I've heard him speak and thought he represented really one end of the spectrum, but clearly we'd like to see some evidence of what is happening right now, what HACCP has

given us and where the micro testing program has shown itself to be useful, as well as perhaps listening to several experts talk about where it should go.

MR. BILLY: Other suggestions? Jim?

MR. DENTON: To go back to one of the recommendations from Katie's committee on Question No. 4 recommending the Agency provide the FDA GMPs and have that as a topic for discussion at the next meeting if that's an acceptable recommendation.

MS. HANIGAN: I have one question on the date of that meeting just because it's Halloween night, for those of us that have children.

MR. BILLY: You're welcome to bring them.

MS. HANIGAN: No. I don't think you'd want them. Complete in costume?

MR. BILLY: How about with costumes?

MS. TUCKER FOREMAN: Are you going to send them out dressed as chickens and pigs?

MR. BILLY: We may have a few spare cow costumes around.

We'll look at that. Fair enough.

MS. SMITH DEWAAL: I second that comment.

MR. BILLY: Okay. Yes, Lee?

MR. JAN: I don't have a topic, but I would like to mention in the materials that we got this time there was a very nice calendar that had a good, strong food safety message. I think it was very user friendly, but I was disappointed to find out that it's not going to be printed next year. I asked to buy at least 4,000 copies and give them out in September, but I wanted a 2001 because September in Texas is food safety month, and we have a lot of opportunities to spread the food safety message.

I don't know if maybe some of the consumer groups could take this on as a project and make that available in the interest of education, but if you look at that calendar that's the kind of material that needs to be available in homes, I think.

MS. TUCKER FOREMAN: This is the Fight Back calendar?

MR. JAN: Uh-huh.

MS. TUCKER FOREMAN: The people who fund Fight Back are the Food Marketing Institute and the American Meat

Institute. I'll send you a list of the people.

MR. BILLY: The Turkey Federation. There you go, Alice.

MS. DONLEY: And some of the groups have no money.

MS. TUCKER FOREMAN: The Egg Board. There are some trade associations that have declined to participate and make their resources available, but it's in constant need of funding. We'll see what we can do.

MR. BILLY: All right. I'm going to now move on to the public comment period. The first person that signed up is Stanley Emmerling, who is representing NAMP. He has some general comments.

MR. EMMERLING: Thank you very much. I appreciate the opportunity. NAMP is the North American Meat Processors Association, and I'd like to applaud the efforts of the committee. I think they've done a lot of hard work, and there's been some good stuff come through.

I'd also like to recognize that the Agency, as I heard it answering and being involved, is really listening and paying attention and trying to move forward with the concerns.

I want to direct these comments specifically with respect to the identification of E. coli 0157:H7. The real key to food safety is really prevention, and really I didn't hear that word very often. It came up occasionally during the conversations, but we're really more talking about addressing what's happening and how you cast UCCPs or everything else. Those are sort of like band-aids on cuts and bruises you get, but it doesn't go about making it perhaps safer right from the very beginning.

Now, some of the other species groups, which seems to be vertically integrated as you listen to what goes on here, seem to be addressing it on a farm to table type approach, but with respect to the E. coli, which is really in ground beef, and we now have, and this is a thing that's very important to our membership as well as the non-intact issue. It would really be more helpful if we were doing something more about preventing that coming into the slaughterhouse, doing something wherever it is possible back on the farm.

You know, I've addressed this with you and others continually, so it may be something you wish I wouldn't

bring up again, but it is really critical to the livelihoods of our people who are small processors. We take that product the way the slaughterhouse gives it to us. We can have a control point, or now you're telling me if I have a letter and all of that, but the problem is if the incident occurs the person whose name is in the newspaper and the public press releases is the name of that processor and the one that has to pay for the product because he can't sell it and usually doesn't have cooking facilities, ends up dumping it and takes a great economic loss.

I think that if you could take a look, and, you know, you're already setting the agendas and things, but it would be nice if it would be possible to set an agenda where you would look at prevention from the very beginning to see how you can avoid the problems, the pathogens coming into the slaughterhouse or, if not that, containing them as best as possible within the slaughterhouse so that down the line those people who take that product and which helps the stream of commerce work because if all the meat is going to have to be sold from the packing house I can believe there is going to be a down turn in the use of certain kinds of

animal products.

That's the main thing that I would like to point out to you, and I hope that perhaps you would be able to address that prevention end of it right from the very beginning.

Thank you for the opportunity.

MR. BILLY: Thank you.

The next person is Del Hensel from the National Bison Association, who wishes to speak on alternative species inspection.

MR. HENSEL: I, too, would like to thank this committee for all the hard work they've done. You've had to listen to me now for the third time in a row.

My name is Del Hensel. I'm with the National Bison Association. We represent 2,500 basically small producers, and what I'd just like to do is clarify a few issues that have been brought up at this meeting.

Excuse me for reading this, but I've got a lot of figures down here, and I couldn't get them all straight in my head. The NBA, along with Wyoming State University, did a very concise census last year, and we came up with the

figures that there are 200,000 bison in the United States. These numbers are increasing 20 percent every year.

Now, Dr. Post has some pretty good preliminary research done. One of the parts of his research is the documentation on numbers of animals killed under surveillance inspection by state and federal inspection plants. Now, I would assume those numbers are accurate because those are paid for, and everybody keeps track of that inspection. His research shows that there were 12,000 under federal and 2,900 under state, total animals killed 15,000, and that's in this document you have here.

Like I said, we have 200,000 animals in the United States. We kill over 20 percent of those every year. Now, we kill feeder animals mainly, a few females and cull animals. That's 40,000 animals on a conservative figure. That means there's 25,000 animals that are not being inspected if my figures and their figures are correct, okay? That's 27,500,000 pounds of bison meat that's being sold to the public.

I don't know how much meat you eat, but bison is a product that's not consumed in large quantities. So how

many people? Out of 27,500,000, maybe the average person eats three pounds a year. How many millions of people are we exposing to uninspected meat here? I think it's quite substantial, and I think it's not a very good subject.

For the last two days I've been here, and I've heard some of you, who I well understand you have concerns about money going into this project that would be taken possibly from some of your projects. I understand that, but what I'd like to explain here, I don't think we're talking about a lot of money on alternative species.

Now, what I'm going to say about bison is pretty common among all of the other alternative species. Now, with us about 15 years ago we got together with USDA, and we set up a voluntary inspection program. With that program, we pay $38 to $39, in that range somewhere, to have our bison inspected.

Now, I would assume, I would have thought, that at that time 15 years ago all the research would have been done to put that in place. In other words, the procedures are there. I would have thought the toxicology studies or whatever it is -- not toxicology, but pathogenic studies --

would have been done at that time.

I see in this brochure here, in this paper, that all these other animals are inspected under federal inspection, so they must have had a program that they put in place. What I'm saying is is the inspection we're paying for not the same inspection that they're getting for free? In other words, does USDA have to do something else in order to put us into the Meat Act? That part I don't understand, and I won't make a big thing out of it now, but it seems to me it should be.

Okay. Let me just say one more thing about how this procedure works. When you take bison to a federally inspected plant, that plant is usually already set up for beef, okay, so the inspector is there. When you take in the bison, he goes and inspects it. He comes back. He writes down at the end of the day how much time he spent on that inspection, and the producer is charged $39 an hour for that time.

Well, that's time he isn't -- the government is reimbursed for that time because he's there anyway, so you're not talking about a new cost. You're talking about

the fact that we subsidize the USDA in that regard because our producers are paying USDA for that inspection.

Now, according to these figures there's 12,000 being slaughtered under federal inspection. Dr. Post, his preliminary figures say that, and this seems a little high, but probably we'll use that. Point eight two tenths of an hour per animal is the time spent inspecting bison. Okay. At $38 an hour, that's $31 per animal.

Now, if you take 12,000, which is what's being done now, and that number might increase because people would be more apt to go get inspection, but let's use that number. That's $374,000 a year that USDA is being reimbursed by our industry for our inspection.

I know that you can take numbers and do with them what you want. When USDA comes back with their study it may look different, but I think this isn't too far off, and I think this is typical. I've talked to the ratite people and the squab people and some other people, and I think this is typical of what's happening. We're paying for that inspection.

For less than $1,000,000, you can protect I'd say

several million people from the fact that they're getting uninspected meat. Unless somebody's figures are wrong, I think that's where we're at.

Could I answer any questions? I know you've been here a long time, so nobody is crazy enough to ask anything.

Thank you very much.

MR. BILLY: Yes. I have a request, which is perhaps you could provide us, the Agency, that information in a letter to us?

MR. HENSEL: Yes. Okay. I definitely will.

MR. BILLY: I appreciate that.

MR. HENSEL: Okay. Thank you.

MR. BILLY: Those numbers are very interesting, so thanks.

MR. HENSEL: Okay.

MR. BILLY: The last speaker is Jenny Scott from the National Food Processors Association who wants to speak on listeria testing.

MS. SCOTT: Thank you, Tom. I promise not to hold the committee here hostage too much longer. It's a beautiful day out there, and I know you'd like to enjoy it.

I'm Jenny Scott with the National Food Processors Association.

The Agency has indicated in its action plan that it's going to revise its listeria monocytogenes testing program. We heard the committee here today recommend that we implement or that the Agency mandate product testing for the industry. Obviously industry is going to disagree with any mandate for product testing, but we do recognize that product testing does play a role in the control of listeria monocytogenes.

What we think is a way forward here is for FSIS to issue immediately, and for those of you who don't speak the regulatory lingo, immediately is faster than soon. We think that FSIS should immediately issue the revised microbiological sampling directive, 10240.2, that would provide for reduced Agency testing in exchange for industry testing. We think that the Agency should allow that program to work and evaluate the results of this directive before they mandate any kind of product testing.

Also, as we move forward here we need to think about testing in the context of risk. The focus has been on

ready-to-eat foods, but we think that that may be a little bit too broad. On Monday, Bob Buchanan gave us a little bit of a heads up on what the listeria monocytogenes risk assessment is going to say. He indicated that the highest risk was from foods that support the growth of listeria monocytogenes, foods that are exposed to less than optimal cold for an extended period of time.

He also said, and I'm going to quote here, "Foods that do not support growth are of little risk," so we need to keep that in mind as we move forward with our product testing, and this goes for both industry and for FSIS.

We shouldn't be testing frozen foods or foods that have barriers to growth of listeria monocytogenes. We need to use our resources more wisely than that. FSIS testing should also take into consideration listeria monocytogenes controls that an establishment has put into place, and they should focus more on those establishments that lack the resources to implement extensive controls and verification testing.

Thank you.

MR. BILLY: Thank you very much.

I'd like to thank the committee. Once again, you did an outstanding job. I know many of these issues are difficult, complex issues, and we appreciate the effort that you put in in trying to deal with them and, you know, trying to find a consensus in terms of approaches and recommendations.

We will pay very close attention to the recommendations that were put forward. There's a lot of good work that you've done that will be helpful to the Agency.

I also think that we're maturing as a committee, and some of the topics that we dealt with this time and are pointing towards next time are important topics in areas where good advice and recommendations can be very helpful both to FSIS, as well as ARS and other agencies, so I appreciate that very much.

I also again want to thank you for being willing to work in the evening. That's where a lot of the real work of this committee is done, so we appreciate your indulgence in that regard.

It is a beautiful day, so go out and enjoy the

rest of it. If you're traveling home somewhere, have a safe trip. Thank you all very much. We're finished.

(Whereupon, at 4:16 p.m. the meeting in the above-entitled matter was concluded.)

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CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

National Advisory Committee on Meat and Poultry Inspection
Name of Hearing or Event

N/A
Docket No.

Arlington, Virginia
Place of Hearing

May 17, 2000
Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 260 through 484, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by John DelPino, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

5-17-00
Date

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5-17-00
Date

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