# UNITED STATES
# DEPARTMENT OF AGRICULTURE

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| In the Matter of: | ) | |
| | ) | Docket No.: 99-020N |
| NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION MEETING | ) | |

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THE UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

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Thursday,
May 6, 1999
Quality Hotel & Suites
Courthouse Plaza
Jefferson Room
Arlington, VA

The meeting in the above-entitled matter was convened, pursuant to Notice, at 8:35 a.m.

BEFORE: MARGARET O.K. GLAVIN
Chair

APPEARANCES:

Jeanne Axtell
Terry Burkhardt
Nelson Clinche
Mary Clutshall
Charles Danner
Dr. James Denton
Philip Derfler
Caroline Smith DeWaal
Nancy Donley
Carol Tucker Foreman
Cheryl Green
Kathleen Hanigan
Dr. Alice Hurlbert
Dr. Lee Jan
Collette Schultz Kaster
Peter Kuhmerker
Dr. Daniel LaFontaine
Loren Lange
Michael Mamminga
Micheal Micchelli
Geri Ransom
Judith Riggins
Bill Smith
Dr. Kaye Wachsmuth
Dr. Catherine Woteki

P R O C E E D I N G S

MS. GLAVIN: Hi, I am Margaret O. K. Glavin. I am here in place of Tom Billy. Tom is not feeling well today, so he asked me to substitute for him. And so if you don't mind, we'll go ahead and get started. Mike needs to do a few little housekeeping chores.

MR. MICCHELLI: Good morning. My name is Mike Micchelli. I'm the coordinator for the meeting today. It's the National Advisory Committee on Meat and Poultry Inspections. Welcome.

Myself and Cheryl Green are here to help you. You can approach us, great. If you have any questions or concerns, things you need, just please let us know.

Just a few administrative details before I turn it over to our chairperson, Maggie Glavin, who's the Associate Administrator of FSIS, as well, is that if you haven't registered, even though you registered yesterday, we need you to reregister today. You don't have to do it right now, but at break just please go back and register.

Also, if you've drive, you'll need to reput down your -- they keep track every day -- your license plate numbers so they don't give you a ticket. The parking is free, but at break you can go back and just register your car.

If you're planning to make a public comment, there

is a public comment period at the end of the session. You'll need to register to do that. If you don't want to do that right now or at break, but you decide maybe at noon or whatever, you can register all up -- right to the last minute. Okay? And so, about a half an hour before the public comment period.

We do have a phone message board that you can receive incoming calls. There are public phones where you can make outplacement calls located on each of the floors. One is right outside the Washington Room, but you can receive a call and get a message, and we'll put it on that message board. And some of you yesterday did something innovative, you wanted to meet people without the phone, so you left them a message, "Please meet me here at a certain time." So, you can write those messages on there, too, if you'd like. Whatever you make use of that.

The phone number, and I'll speak slowly, and that's also on the message board if you don't want to take it down right now is (703) 524-4726. And I'll repeat that, (703) 524-4726.

The restrooms are straight back. There's a mens and ladies' room straight back and to your left. There's also restrooms on each of the floors, as well, if that's busy.

Now, if you're curious about what this is, this is

a yellow line. This is our just attempt -- we're not trying to keep you, you know, like separation. We like to be commingled because you're very valuable, and we really appreciate your being here, but during the meeting and during breaks if you could wait for the Committee members to cross this yellow line before you talk to them or talk to the Administrator or the chair people, that would really keep a little semblance of order up here at this side of the yellow line. We're more concerned about our side than your side.

So, with that, I'd like to turn it over to the chairperson, Maggie Glavin, who's the Associate Administrator of the Food Safety and Inspection Service. Thank you.

MS. GLAVIN: Okay. Thank you. I'm glad to have the explanation. First of all, Tom called and said after one day with this group he was sick, and then I come in and I see this chain, and I thought, "God, what kind of an audience do we have? What did they do?" I'm a little nervous now.

In any case, since there are some new members, and I was unfortunately not here yesterday, I would be grateful if we would go around and just do a quick introduction again, if that's okay. And I'm Maggie Glavin. I'm Associate Administrator of FSIS.

MS. GREEN: I'm Cheryl Green. I assist Micheal Micchelli on the National Advisory Committee.

DR. WACHSMUTH: Kaye Wachsmuth, Deputy Administrator for the Office of Food and Nutrition.

MS. RANSOM: Gerri Ransom, Office of Public Health and Science, Microbiology Division.

MS. AXTELL: Jeanne Axtell, Office of Field Operations.

MS. DEWAAL: Caroline Smith DeWaal, Director, Center for Science in the Public Interest, Member of the Committee.

MS. KASTER: Collette Schultz Kaster, Director of Food Safety & Technical Services with Premium Standard Farms.

MR. BURKHARDT: Terry Burkhardt, Director of the Wisconsin State Inspection Program.

DR. HULBERT: Alice Johnson with the National Turkey Foundation.

DR. JAN: Lee Jan, Director of the Texas Meat and Poultry Inspection Program.

MS. HANIGAN: Katie Hanigan with Farmland Foods. I'm the manager of food safety and a new member to the Committee.

MR. LAFONTAINE: Dan LaFontaine, South Carolina Meat and Poultry Inspection Department.

MS. DONLEY: Nancy Donley, Safe Table's Our Priority.

MR. DENTON: Jim Denton, Poultry Center and Department Head in Poultry Science at University of Arkansas.

MR. MAMMINGA: Mike Mamminga with the Iowa Department of Agriculture, Director of Meat and Poultry Inspection.

MS. GLAVIN: Thank you for doing that. There are a few faces I was not familiar with.

I gather our agenda for this morning is reporting back from the subcommittees. The first subcommittee to report back is the one that dealt with the qualifications of personnel conducting HACCP tests and developments in the campy program.

So, Katie, is the report?

MS. HANIGAN: Basically, last night we were allotted two hours, and I'll just quickly go through how we did it. We spent -- we allotted one hour for each topic. The first 15 minutes was for the Committee to ask for additional background information. And then we had a half hour of discussion, and we tried to wind it up in the last 15 minutes of our meeting.

So, starting with the inspection methods, if you will, subcommittee, qualifications of personnel, we had a

good discussion and we appreciate the Agency's forward thinking as to qualifications of FSIS staff members in the future. I thought Jeanne did an outstanding job of explaining what the thought process was and where we were going. We had good discussion. And we were specifically asked to look at the disciplines that should be considered as qualifications for the inspectors. Specifically now, the GS-696 series, which is the consumer safety officer.

So, the Committee reached the agreement that based on the information given, we thought they should not allow or exclude engineering and computer science programming degrees as initial qualifications. We questioned that.

And we also found that they should add some other academic backgrounds. And we do have a few pen-and-ink changes here, and I'll go through as we get to them.

Anatomy is one. Biological and agricultural engineering. And then food science and animal science. We did discuss both of those with processing options. And this is where we have a pen-and-ink change. We realize that that's probably not -- processing option is probably not available at all the universities. We said it'd be helpful, but not mandatory. So, we'd like it to show food science, animal science and poultry science was included on our flip chart. And we inadvertently left it off this list, sanitary science and public health.

The Committee also agreed that basic knowledge of statistical process control and microbiology are essential and relevant to the work of the agency. Training or course work in SPC and micro may be required, and they can either have this formally at a university prior to employment or once employed, they can gain this knowledge after employment through additional university courses, et cetera.

The subcommittee strongly believes that interpersonal relations skills are essential, and that the agency should determine how internal and external candidates possess these skills through interviews and other appropriate means. Much discussion last night did focus on inspectors' ability or inability to communicate with the plant.

So, those were the two things we were asked to do. And I know I'm allotted time until 10:30 this morning. So, I just wanted to open it immediately to the Committee members that were part of this subcommittee, and ask if this report is correct or if there's any additional changes before we open it to the full Committee at the table.

So, Jim, is this correct as reported?

MR. DENTON: I think that's essentially correct. Most of our programs at the University of Arkansas, whether they be food science, animal science or poultry science are very heavily based in the biological sciences, chemistry and

microbiology types of course work. I feel like that any of those disciplines would have the same type of training across the country.

We do have a little bit of a unique situation where we are because we have processing options within the two commodity departments of animal science and poultry science, which provide even more focus within the processing sector. Biological and agricultural engineering I think has enough biological science in their curriculum that they can deal with this. They are also well trained in statistics as are the food scientists. And I think that that's a real key element. That's addressing the young people that are coming out of the program right now that would make the new part of the workforce.

With regard to the existing workforce, I think that there's an awful lot of well-trained people based on the comments that I heard Jeanne provide last night. I think there may be some catch-up work to be done on the statistics and the statistical process control issues, but that should be relatively straightforward and fairly easy to accomplish.

MS. HANIGAN: Thank you. Alice, comments on this qualifications?

DR. HULBERT: No. Katie, I think you and Dr. Denton have done a good job representing what the Committee

said. Thank you.

MS. HANIGAN: Okay. Terry, comments from you?

MR. BURKHARDT: Oh, I agree. That's fine.

MS. HANIGAN: Okay. Caroline?

MS. DEWAAL: I agree, too.

MS. HANIGAN: If it's okay with you, Maggie, we'll move on then.

MS. GLAVIN: Do you want to do both your topics, or do you want to have discussion on this one?

MS. HANIGAN: Why don't we do general discussion on this one -- that's a good point -- from other Committee members?

DR. JAN: I would just have one question. When I was looking at the report, I had the sense that you were looking for a degree in these areas. By looking at the OPM, it seems that a specific degree is not required, just 30 hours in those particular areas. Is that where this is going?

MS. AXTELL: The way the discussion was going last night, we were looking at these as both disciplines that resulted in degrees or coursework coming out of these disciplines and field. So, it would be -- it was my understanding the subcommittee was approaching this from the standpoint that coursework in these areas would be creditable under the OPM standard. And that was the advice

being put forward.

DR. JAN: Okay. The reason I brought that up is if we were looking at disciplines, there's a discipline that I don't know how many universities have it, but it's fairly new, biomedical science, that would fit right here. But if you look at just the hours, then I think biomedical science degree would qualify. So, that's the reason I was asking that question.

MS. HANIGAN: Okay. Other questions?

MS. GLAVIN: Are you proposing adding biomedical science here?

DR. JAN: As long as it's not specifically required, these degrees, I think the courses taken through that curriculum would fit the bill.

MS. HANIGAN: One other comment on that, the Committee did have a comment that we felt the agency had some qualified people out in the field now and did not want to rule any of those people out because perhaps they had been or received their college education 10 or 20 years ago maybe when some of these degrees were not available. So, we were trying to be careful as to not ruling in or ruling out too many.

MS. GLAVIN: It sounds like -- I'm sorry. Dan?

DR. LAFONTAINE: There's a related issue that was brought up yesterday, Maggie, that I want to bring up now

that relates to this. As you see, the title talks about qualifications for industry and FSIS individuals. And what I -- to briefly repeat what I said yesterday, this particular scenario did not deal with the industry qualifications. And I was talking primarily about the whole business of the inspection -- HACCP-based inspection models.

There was a sense -- well, my recommendation was that since it had not been addressed in the FSIS briefing that it be tabled, and that part of it be deferred to the next meeting. So, I'd like to -- I wanted to bring that up in a more formal way and see if the Committee agrees with me, so we can plan on that for the next meeting, if appropriate.

MS. GLAVIN: Reactions?

MS. HANIGAN: I think it's probably a -- Katie Hanigan at Farmland. I think it's a subject that needs to be addressed. And I wasn't sure, Maggie, when we bring up some of these issues because we also talked about the original report that was submitted by Dale Allan to this Committee. It had seven parts. And qualifications of FSIS employees was only part one. So, I put on the table as well, when and how do we address the other six pieces of that report that was presented to this Committee in November?

MS. GLAVIN: Well, that's really the Committee --

we look to you all for guidance on the issues that you think are good for you to take up. Can you sort of go through this, or have you done this yesterday, so that the other members know what the seven parts are, or do they know?

MS. HANIGAN: Yes. The letter was dated September 11 from Dale Allan. And the title of the report was "FSIS Field Execution Task Force Report." And I received this as my packet from Mike in preparation for this meeting.

MS. GLAVIN: Okay. So, everyone has it if it was in the packet?

MS. HANIGAN: Right.

MS. DEWAAL: Let me just clarify. This is from AMI.

MS. HANIGAN: Yes, yes. And the seven areas that were identified as needing to be addressed to further enhance HACCP in the field was qualification and certification of inspectors, performance measures for the inspectors, personnel management, FSIS training. And I think that would dovetail well in with employee training by the industry. Communication, interaction of field operations and compliance, and protocol for inspection methods.

I think some of those subjects do dovetail in well with what Dan is asking.

MS. GLAVIN: Well, my memory from the last meeting

was that one of the -- was very much what Dan just expressed. And that is that the question first arose with respect to the inspection models project as to what qualifications industry personnel ought to have as they begin to take on certain responsibilities under the models project. Then, it was broadened out to, "Well, if we're talking about industry qualifications, what about inspector qualifications?" So, that was the sort of the two emphases in the original issue.

I do think a discussion on your consideration of industry qualifications with respect to the models project would be very useful. Those of you who've been following our work with Australia in terms of the project they are hoping to inaugurate with respect to beef slaughter, know that they, in fact, have some positive educational requirements for the industry. And I think they go so far as to certify industry employees, or at least that's their proposal. I don't think they've moved in that direction yet.

And I think that's one of the ways in which this question arose as we move through the models projects and see the plant taking on responsibility for certain things, should there be standards, requirements? If so, what should they be?

Do you want to spend a few minutes here discussing

that so that we can really flush it out for a fuller discussion at the next meeting?

DR. HURLBERT: Maggie, I'd like to postpone this discussion until the next meeting. And maybe it would be possible to be briefed at the next meeting by some of the plants that are in the models project and see where they're headed and what type of training they've given the inspectors, their people, and what they feel they should give the people who will be performing the work. I'd like to hear what's going on where they are right now.

MS. GLAVIN: Lee?

DR. JAN: I think we'll also need a little more information from FSIS as to what extent the industry is going to be involved in sorting and then reporting livestock that were not eligible for slaughter. Are they going to be -- are they going to just not report those, or are they going to be reporting those to some statistical as not acceptable because of some disease? That'll make a difference whether they need to be -- what type of training or formal education they need.

MS. GLAVIN: Okay.

DR. JAN: Basically, there, they'll be making diagnoses. They need to be qualified to diagnose the disease.

MS. GLAVIN: Right. Well, certainly, any decision

on either passing or condemning will be made an FSIS employee. But you're right. When you get into sorting, some things may not -- some things may be sorted out and so never come to the FSIS inspector. And so, that's a very good point because our animal disease reporting system is very important.

MS. HANIGAN: Perhaps also, in addition what Alice is requesting, at those plants that are working under the inspection models, I'd like to know the qualifications of the FSIS employees, formal education and experience, years in the industry, that currently hold those jobs. I think that would be a good comparison.

DR. HURLBERT: Maggie, it'd also be interesting either through a paper that Mike or Cheryl could send out beforehand to have a little bit better understanding of what they're doing in Australia and what type of training programs they're looking at.

MS. GLAVIN: Yes. I think we'll do that in writing because we have a very full description. In fact, you can get it off the Australian Web page if you want to see it ahead of time. They have a very full description of their program, which includes their requirements.

Nancy?

MS. DONLEY: I would like to ask the subcommittee if any discussion was about having continuing education

and/or certification requirements for this new GS -- what level is it? The 696 series?

MS. GLAVIN: Go ahead, Alice.

DR. HURLBERT: Nancy, we had talked about that in the open Committee, and when we got into the subcommittee, we focused basically on the task at hand, which didn't allow us to explore that area. But I think with what Katie is proposing we look at next meeting with -- you know, go in more depth on inspector and industry training, that there are some issues that we can discuss on continuing education, certification, things like that.

MS. DONLEY: So, you wanted to reserve that then for specifically the pilot model?

DR. HURLBERT: No, not necessarily.

MS. DONLEY: Discussion?

DR. HURLBERT: I think that -- you guys help me out on this, but I think what we decided last night was that that was not part of the Committee's charge.

MS. HANIGAN: That's correct. We did say very much on task -- tried not to get into performance measures, et cetera, but I do think it needs to be addressed so that both industry and Agency employees basically possess the same skills, knowledge level. And I think there needs to be degree of performance. How do you measure the performance of the industry employee? How do you measure the

performance of the Agency employee?

DR. DENTON: The only comment that I recall from last night's discussion in which we touched on the issue of continuing education was very specific to the statistical process control and statistics issue. And that was addressed primarily to meet part of what was anticipated being the requirements of the position.

Now, we did not get into the discussion at all with regard to certification. I think we're going to have to deal with that at a separate time.

MS. GLAVIN: I think we've got a couple of things going here, and they, obviously, are intertwined. But they also somewhat separate. One is where this topic came from, which was the qualifications in the models plants, which is talking about the qualifications in slaughter plants that are moving to a new type of inspection. So, that's sort one set of things.

I think the subcommittee moved to not only those qualifications, but the qualifications because talking about 696 series of our workforce of the future generally in a HACCP environment. And at this stage, those are a little bit different topics.

Caroline?

MS. DEWAAL: I just want to express one concern that I had that was slightly off task, and Katie really

cracked the whip on our group, but very successfully, I might add. But the vision of moving to the 696 position is very similar to the FDA inspector positions. And those inspectors see the insides of plants less and less. They spend a lot of time doing investigations of foodborne illness outbreaks. They check labels. They do lots of things other than actually inspect food plants.

So, I was cautioning the Department while I generally like the 696 qualifications, that I think the job description should be modified to make sure these folks are staying inside the plant doing a job that makes sense there. I mean, they can also be doing in distribution and other things, as well, but sometimes if you create a job description that's too far afield, they end up out in the field all the time and not inside a plant doing inspections. So, that was one caution I had.

The other thing, looking at this issue of certification and also on Dale's list, performance measures for inspectors, I think that we do need to look at issues of how to -- once classifications are made, how to continue to evaluate those employees to make sure they're doing the jobs that the Agency needs them to be doing. And that might be part of the agenda for the next meeting.

MS. DONLEY: Nancy Donley, STOP. Just so, because I, too, was kind of grappling here. This paper, your

recommendations taken off of what was the chart or here taken says, "Qualification of FSIS inspectors and industry personnel in HACCP establishments." Is this something right now -- really, it sounds like what was really being discussed is today's environment with FSIS inspectors doing all the inspection tasks. So, really -- this really pertains just to FSIS inspectors, and not company plant -- industry plant personnel right now.

So, my suggestion would be is that we just -- we rename this so we don't create confusion and just call it qualifications for FSIS inspectors.

MS. HANIGAN: I think that's a good point, Nancy. And to be even more clear, we were specifically talking about the GS-696 position, which doesn't even exist. So, these qualifications that we were asked to address last night were 696 consumer safety officer. We never did talk about qualifications of industry personnel ever.

MS. DEWAAL: We would have needed another 15 minutes for that, right?

MS. HANIGAN: Or an hour.

MS. GLAVIN: Yes. Dan?

DR. LAFONTAINE: To pare back with what you said, my recommendation to the full committee is at the next meeting, we have two topics. One of them is qualifications of FSIS inspectors in a HACCP environment. And that would

be a follow-on to the efforts that were started today or yesterday and today.

Then, the second topic which should be considered by the same subcommittee because they're -- they are interrelated would be minimum qualifications of industry personnel and HACCP-based inspection model plants. That way there's hopefully a clear focus of the two tasks at hand and they're doable.

MS. GLAVIN: I believe we have some time on the agenda later today what the topics will be next?

MR. MICCHELLI: Yes.

MS. GLAVIN: Okay. So, I know Mike has taken good notes on those two suggestions, and I suggest that we circle back to that at that time.

Are there sort of other proposals that people want to get up either to further elucidate what Dan has put on the table or maybe as an other option? Caroline, you had another comment?

MS. DEWAAL: I just -- and maybe I've been doing this too long and remember the battle over seafood HACCP, but one of the issues particularly with the small plants is, as we require certification -- HACCP certification of in-plant workers -- it becomes an expensive proposition. And for most -- I mean, for a lot of the industry, they can clearly afford it. I know, for example, in the seafood

industry, this was rather controversial. So, I am just raising it.

It's wonderful to envision a system where everyone is HACCP-certified or you have at least one HACCP-certified person in every plant. The vision and the reality are hard to meet sometimes. So, I'm just thinking of that.

MS. GLAVIN: Katie?

MS. HANIGAN: Maggie, just for the record, I want to make sure we're changing the title of this document that we have. And it will be titled, "Qualifications of Consumer Safety Officer (GS-696)." So, we're all in agreement as to what this was.

MS. GLAVIN: Okay.

MS. HANIGAN: Thank you.

MS. GLAVIN: Katie, Mike's telling me that if you would give him the edited copy, he'll have it redone and recirculated to the Committee because sometimes, at least for me, when I hear it, I think I understand it. When I see it, I'm not so sure.

DR. HURLBERT: So, Katie, we're taking out "Qualifications of FSIS Inspector (Consumer Safety Officer) 696 Series?" Is that right? We're taking out anything to do with the industry?

MS. HANIGAN: That is correct.

DR. HURLBERT: Good, thank you.

MS. GLAVIN: Okay. So, we'll get a redone version of this, which includes the pen-and-ink changes you mentioned earlier and this change in title, and everybody take a look at it and make sure it is what you think you're agreeing to.

MS. HANIGAN: Okay. The next subject that our subcommittee addressed was campylobacter, and very much ran this the same way. We had 15 minutes of background and appreciated the work that Gerri did on regoing through the background with us. We had a half-hour of discussion. Then, we wrapped this up as far as recommendations. And they're handing out our recommendations. And this is what the subcommittee arrived at.

After looking at the data, we concluded that FSIS' data is incomplete to conclude the value of campylobacter prevalence being used to establish the performance standard. And we did agree that the prevalence data appears unlikely to be used.

We also spoke about the risk assessment, and that it is in the planning stages and need to evaluate sources along the farm -- from farm to table, intervention placement, and as well as infectious dose.

It was so noted in this Committee that the committee felt the salmonella performance standard was established prior to a risk assessment being done.

And the subcommittee supports the Agency's direction to establish the campylobacter performance standard including evaluating methodology, completing the baseline study and initiating the risk assessment.

This Committee is requesting that the micro committee evaluate and recommend back to us the options for defining campylobacter performance standard, whether it be quantitative versus qualitative, and alternatives to a campylobacter performance standard. That accomplishes the same public health objective.

And as you can imagine, this was a very healthy discussion last night. And we are looking for direction from the micro committee in their May meeting back to our committee.

At this time, I'll open it to subcommittee members only, and I'll start with Caroline at this time. Comments on this for accuracy?

MS. DEWAAL: It looks highly accurate the way I remember it at 9:15 last night. And I think the discussion was very good on this topic.

I think that nobody's completely happy with it. There are things that I would have liked to see, mostly not in here, and things that I think others on the subcommittee also were not completely happy with, but it is definitely a consensus document.

And I also just want to note, I think that the -- Alice's representation of the turkey industry was very healthy and very good. And they clearly want to be leaders. She was very concerned that nobody come away with the impression that they don't support the right public health answer here. And I understand that.

But I think overall, that these conclusions are good.

MS. GLAVIN: Okay. Terry?

MR. BURKHARDT: Katie, do you want to define healthy for us? I'm just joking. It was a very good discussion. We are all very supportive of the efforts the agency is taking in this area. All concerned about the food safety implications. We think we're on the right direction.

MS. HANIGAN: Alice?

DR. HURLBERT: I ought to fool you all and not say anything, but I'm not going to do that. Caroline, thank you.

My only concern with the wording, and we discussed this last night, with the definition of performance standards as we defined it in the subcommittee. And in driving home last night, I got to thinking about the micro committee green book, and I think the definition of performance standard is a little different there.

I want to be sure that we define performance

standard in the subcommittee as we know it in the HACCP rule that would indicate Agency testing. And I don't want to -- and I think Caroline -- we all talked about it. We want to be sure that the micro committee understands we want scientific assessment. And however the need for testing is evaluated based on the information from the risk assessment, then that's what our performance measure for public health should be.

And we don't want to lock in that it has to be an Agency testing program just for the sake of testing. We'd like to test and have any testing be meaningful. And I think that's up to the micro committee to give us direction on that. And we did have fun last night.

MS. HANIGAN: Jim?

DR. DENTON: Thank you, Katie. I, too, applaud the Agency's willingness to deal with the campylobacter issue head on with regard to improving our public health situation. I'm a little bit concerned with regard to the language that's in here. And I realize part of this is part of the consensus building process, but I'm afraid that we've contradicted ourself just a bit by making the statement that we support the Agency's direction to establish campylobacter performance standards.

And then, later in the same discussion, we request input from the National Advisory Committee for

Microbiological Criteria with regard to defining alternatives to campylobacter performance standards that accomplish the same public health objective. I think that we probably need to state this as a public health objective and not restrict the Agency with regard to the approach that is taken in meeting that public health objective.

Simply stated, it's an issue that I deal with every day in the research environment. All I want the sponsoring agency to do or sponsoring company is to tell me what they want with regard to the objective, but don't restrict us in how we approach dealing with that particular issue. And I think we need to leave that open so that the Agency can explore all the potential options that we have from dealing with campylobacter in the public health framework.

MS. HANIGAN: I guess then I'm going to refer your question to someone at the Agency. Based on how we've worded this, have we restricted ourselves? And that was a healthy part of last night's conversation.

MS. GLAVIN: Okay.

DR. WACHSMUTH: Quite the contrary. It doesn't look very restrictive at all to me. So, I'm suggesting that you support our evaluation of the performance standard as we're beginning to look at it with a new baseline and things like that. Yet, you're also looking for any alternative

that would achieve the same public health objective. I think that's -- you know, those things are compatible. And I think the micro committee would love to deal with something like this. I think they'll enjoy it.

MS. GLAVIN: A question I have is in the final paragraph, you say: "The subcommittee request, the full Committee to evaluate and recommend back to the micro committee the options." What are you recommending back? What you are evaluating to the micro committee?

MS. DEWAAL: We're asking the micro committee to report back to us.

MS. GLAVIN: To you? Okay.

MS. DEWAAL: Yes.

MS. GLAVIN: I have the acronyms backwards. Thank you. Thank you.

MS. HANIGAN: We're clearly looking for direction from the scientists and the microbiologists in this field.

MS. GLAVIN: Okay. Jim, were you going to offer a changed wording?

DR. DENTON: I just object to I think the word establish performance standards. What we really are in the process of doing is evaluating campylobacter performance standards and any other option that we have available to us for meeting that stated public health objective. So, rather than establish, I think evaluate.

MS. GLAVIN: Well, I think Gerri in her presentation talked about evaluating the need for the performance standard.

DR DENTON: I agree. I'm just thinking about that being consistent with what the direction that the agency's going. Maybe it's not as significant to anyone else as it was to me. I woke up three times last night thinking about this.

MS. HANIGAN: Well, let me put it out to the subcommittee that was there last night. If I understand, Jim, you're requesting that we change the wording, and I am, second paragraph from the bottom, to say, "The subcommittee supports the Agency's direction to evaluate?"

DR. DENTON: Evaluate.

MS. HANIGAN: "The need for a campylobacter performance standard including," is that what you're recommending?

DR. DENTON: Yes.

MS. HANIGAN: Okay. Caroline, I guess --

MS. DEWAAL: Say that again. Sorry.

MS. HANIGAN: Okay. "The subcommittee supports the Agency's direction to evaluate the need for a campylobacter performance standard including evaluating methodology, completing the baseline study and initiating risk assessment," is what I've just penciled in here.

DR. DENTON: I think that's exactly what we're trying to do.

MS. DEWAAL: Including -- so, you don't change one, two, or three?

MS. HANIGAN: No, I take out the word "establish campylobacter."

MS. DEWAAL: And say, "Evaluate the need for."

MS. HANIGAN: For.

MS. DEWAAL: I'm just looking also at what Dr. Morse said. Yeah, he said, "Committee should" -- because he's kind of our real public health official on the subcommittee. And he said the Committee should support adding a performance standard, taking as a goal to help reduce illness due to this leading to foodborne pathogens.

You know, unfortunately, I think establishes a little closer to what his vision was. In terms of what the public health need is, let's see.

MS. HANIGAN: The one thing would be the recommendation that Jim's given us would be consistent then with the bottom paragraph where, "This committee is requesting the micro committee evaluate and recommend back to us."

MS. DEWAAL: Yeah, but we're asking for the options and the alternatives. So, we're essentially saying the Agency should take action to address this public health

problem.

DR. DENTON: Right.

MS. DEWAAL: And you're fundamentally changing to say they should just evaluate the need for it. I think there is a fundamental change that's moving away from kind of what the public health message the subcommittee was trying to communicate.

MR. CLINCHE: Could I just interject one thing? If you're talking about supporting what the Agency was doing, when Gerri made her presentation yesterday, this was what I was trying to remember. She said FSIS management is committed to evaluating the concept of a campylobacter performance standard.

I mean, if you're talking about supporting the Agency, but if you're talking just establishing, it might be two different things.

MS. DEWAAL: But there's a difference. You know, either way -- the NAC -- what we're asking the micro committee to do is to say -- if they do a performance standard, how should it be? Qualitative vs. Quantitative? And what are the options? I mean, what else could give us the same public health objective? And I'm just concerned that the message -- I mean, according to the Food Net Data is the top cause of foodborne disease.

Sorry. I'm rambling.

DR. WOTEKI: Might I make a suggestion for the Committee? Based on the discussion and also the note that you read from Dr. Morse, would the Committee support the idea of, in your first paragraph, stating the public health goal of reducing foodborne illnesses attributable to campylobacter? And then you're finding that I believe it is the first sentence that currently -- the FSIS data is incomplete to form the basis or to establish a performance standard. I believe that's what the first sentence says.

And then you support the achievement of the public health goal. You make some observations in the second and third points, and then the actions that you're recommending is in the last two paragraphs.

MS. DEWAAL: And how would that effect -- Dr. Woteki, how would that affect the -- evaluate the need for?

DR. WOTEKI: I'm going to leave that for you all to work out. I was just trying to suggest a way that you could address the public health goal. You could address Dr. Morse's concerns, and you could still keep essentially a very similar text to what you have drafted.

DR. DENTON: I agree with Cathy that the public health goal probably needs to be stated up front. That's where we're going with this whole issue. I don't think anybody disagrees with that.

MS. DEWAAL: I agree with that, too, and I think

it is missing. We were so into details that I think that statement -- Katie, the subcommittee supports the public health goal of reducing campylobacter -- illnesses linked to campylobacter in poultry. Katie, did you get it?

MS. HANIGAN: Well, this is what I'd wrote when Cathy was talking. I'll correct it, of course. "This subcommittee supports the public health goal of reducing foodborne illnesses caused by campylobacter." That's what I wrote while you were speaking.

MS. GLAVIN: That's good. And then the rest of this remains as written?

MS. HANIGAN: I don't know if they've decided that.

DR. HURLBERT: Caroline and Dr. Denton, if we say, "The Subcommittee supports the agency direction to evaluate campylobacter performance standard including, da-da-da without going into evaluate the need. We just say, "Evaluate based on these scientific criteria." Is that --

MS. HANIGAN: I agree.

DR. DENTON: I think that's consistent because what we're trying to do is allow the National Advisory Committee for Microbiological Criteria for Food to have open rein to evaluate with regard to standards, prevalence, quantitation or whatever they think is the best with regard to dealing with the issue.

MS. HANIGAN: Did I hear agreement from your, Caroline, on that?

MS. DEWAAL: Yes.

MS. GLAVIN: Let's hear it for everyone.

MS. HANIGAN: Okay. So, the second paragraph from the bottom now reads -- it's going to have "Action" above it. We're going to have the goal and then we've got conclusions, and then under "Actions" the first statement is: "The subcommittee supports the Agency's direction to evaluate a campylobacter performance standard, including (1) evaluating methodology, (2) completing the baseline study, (3) initiating the risk assessment." And then the bottom paragraph stays as written.

DR. DENTON: Yes.

MS. DEWAAL: That's good with me.

MS. HANIGAN: Okay. Now, it's opened to the rest of the subcommittee for -- and I'm assuming, Maggie, that you'll take the chairing at that point for the rest of --

MS. GLAVIN: Okay. The full Committee has not weighed in a whole lot on this. It's been mostly the subcommittee, but are you satisfied with where the subcommittee has come out? Nancy?

MS. DONLEY: I'd just like some clarification because I -- changing this word "establish" to "evaluate." Is it the intention of this subcommittee and the

Committee -- let's just throw it out to the whole Committee. Is it the intention to establish performance standards of some sort to deal with the campylobacter problem?

The Agency is -- I think the way that this has been changed is the status quo. We're already there. The Agency is already evaluating. Are we saying as a Committee, "We want to have something" -- the rubber meets -- its time for the rubber to meet the road here. Let's get something moving.

MS. GLAVIN: Collette?

MS. KASTER: I like the way we've changed it because I think it supports the objective of having the Microbiological Committee do some review first and get us some answers before we move to -- I'm getting mixed up on which way we were -- before we move to establishing, if we first evaluate. And then, perhaps at our next meeting, we can look at establishing once we have more information.

MS. DONLEY: I think there's going to be a lot of discussion frankly once it actually gets down to quantitative or qualitative and exactly what that is to be. But can we agree as a committee here that the time has come to say, "We need to have this?" We don't need to evaluate whether or not we should have it.

But we need to have campylobacter performance standards or we need to address this issue if it's not a

campylobacter performance standard, which I think the subcommittee is saying here is there's some other way to address the public health if the micro committee can come up with some other thing other than a campylobacter, which I'd be interested to know what that would be.

I just think we're wishy-washy. This thing is coming out wishy-washy. Do we as a committee want to say it's time to do something about it? We're just saying, "Let's continue to do as we're doing now." That's the sense I'm getting from this.

DR. HURLBERT: Nancy, I think one of the things we were coming from is in the presentation material, we were pulling up wording when we say we support the Agency's direction. And in the materials that we presented yesterday when they listed the direction, they talked about if FSIS management is committed to evaluating the concept of campylobacter performance standards. So, I think that's -- when we talked about supporting the Agency directive, we were pulling out of what was presented yesterday. Whether that's right or wrong, I don't know, but that's where we were coming from in supporting direction till we heard from the Advisory Committee.

MS. DONLEY: But our -- what comes out of this Committee is something that Dr. Woteki is going to be sitting around and digesting and Maggie Glavin, Tom Billy,

and it's going to go up to the Secretary of Agriculture eventually.

And we're not saying anything different now. If this Committee's recommendation is just to -- if this is what we're saying is just go continue along as usual, or are we saying let's light a fire here and get moving? And I'm saying I would like to -- I'm suggesting that we as a committee come out of this and say, "Let's light a fire and get this going." It's the number one public health threat and we're not doing a darn thing about it at this time.

So, let's get going on it. Let's speed things along a little. Let's do it correctly, which is what I think the subcommittee here did an excellent job of saying the correct way to do it would be, you know, go through these channels. But let's make a commitment. We're not making a commitment I think as a committee on this issue just yet. I'm not getting that sense.

MS. GLAVIN: Jim?

DR. DENTON: I believe that the Committee has already made the commitment to dealing with the issue. If we use the analogy of what took place in the establishment of salmonella performance standards, which are in place and apparently working as well as we could have ever hoped for, we had two pieces of the puzzle before we actually were able to go about this.

One, is we had a very reliable methodology for measuring. We had a completed baseline study with a very good assessment of where we were with regard to each of the industry's that had to meet this particular performance standard. Those two pieces of the puzzle are not in place. We were willing to move ahead with the assessment of the use of performance standards in the absence of risk assessment because that was done for salmonella before the risk assessment was complete.

I don't think that we have all the tools in place yet to be able to deal with this particular issue. We're still trying to come to some agreement with regard to the methodology that's going to be used. We don't have complete set of baseline information with regard to how we would even approach setting a performance standard.

I think that's where the advice of the National Advisory Committee for Microbiological Criteria is pivotal to this entire process. We can't establish good, sound policy with the best information that we can have in our hands to do this.

MS. GLAVIN: Caroline?

MS. DEWAAL: I actually -- I think that we're much closer to having a methodology that can address this. And what I think is -- the real question -- we actually do have baseline data. We have the same type of baseline data that

was used in setting the salmonella standard.

And one of the discussion pieces, Nancy, we had last night, was why the Agency hadn't compared their findings on how the plants were doing with the old baseline data, because the way the salmonella baseline was set was not on the right public health number, the infectious dose of salmonella. It was set on what was technologically achievable.

MS. DONLEY: Excuse me. Wasn't it set on what was actually out there saying that this is where we are. At the status quo today, this is where we are. We want to make sure that 80 percent of the plants can reach this.

MS. DEWAAL: Right. And that -- we are short one thing, but we are very close to having it. And that is the methodology.

The issues that the subcommittee looked at were issues of, you know, should we wait for a risk assessment? And there we said no. We shouldn't have to wait for that.

We discussed whether -- you know, should we put a technologically achievable in, which is what they did for salmonella pending finding out what an infectious dose might be, or finding out what the right qualitative number is.

So, we want to look at all those. We also -- Alice suggested there might be an indicator organism that might fit the bill and give us an indication of what

campylobacter was.

The key issue is that I think the Agency is moving on this. There is a lot of action happening in terms of these two new studies and in terms of the methodology. And we need to support that action. So, I think that's what the subcommittee did. We recognized the action is being taken and to support it.

I do think that the Secretary's addition this morning of a strong public health-oriented goal helps to address the problem that you've identified. I agree that that was a gap that we, the subcommittee, didn't say outright, "It is our goal to reduce illnesses -- foodborne illnesses from campylobacter." But I think that helps to really set the stage for the rest of the action recommendations.

Alice?

DR. HURLBERT: Just a note on the methodology and the protocol being used for the salmonella testing. You know, the Agency has gone back from the original protocol put out in the pathogen reduction and HACCP rule because of changes in the methodology. And I think that's what we're saying now with campylobacter. From the original baseline study, things are changing in some of the methodology with the way they're testing.

So, I think that's one reason why we can't hang

our hat on the original numbers because we're even changing some of the methodology that was used when we originally selected those baselines in '97.

MS. GLAVIN: Okay. My read of where Jim was, was not that he wasn't having the Committee's support -- and I don't want to put words in your mouth. I'm just trying to see if we can move this forward -- was not saying no, the Committee shouldn't actively support the Agency moving towards a baseline or -- I'm sorry, towards a performance standard, but that the Committee should support the Agency moving towards a performance standard or an alternative means of meeting the goal. And for example, an indicator organism.

If, in fact, we don't get a good method in the foreseeable future, are we just going to put everything on hold while we still tried -- I gather, getting a method has not been easy. Is that where you were?

DR. DENTON: That's essentially where I am.

MS. GLAVIN: Is there a way to explicitly put that in there?

MS. DEWAAL: No. This was hard work last night. This exact issue, Maggie, and I appreciate your efforts here, but I really -- I think we captured exactly that thought in the direction to the NACMCS, and I really at this point would object to further modifications on that first

statement.

MS. GLAVIN: Katie?

MS. HANIGAN: I have a very basic question. The micro committee meets May 25 and 26. Is that correct?

MS. GLAVIN: 26th through 28th.

MS. HANIGAN: Okay. So, this Committee is not scheduled again until November. And is that bylaws that says you can't meet again? Because I do appreciate Nancy's view. It seems like a long time.

MS. GLAVIN: Right. We have an extremely limited budget. We can, and we've done this once before I think fairly successfully do teleconferences. Our experience is that the teleconference is best if it is on a single subject. It just doesn't seem to work very well because this is a large group.

So, if you've got -- I think when we get into the discussion of what are the topics for the next meeting, one of the subtexts there ought to be, are there one or more individual topics that you feel can't wait that long? But the hard, cold fact is we've got money for two meetings a year. And that's all we've got, and we're not going to get more.

So, that's the issue. And so, we try to space them out so that we don't go a very long time without a meeting, but there's no magic to November.

MS. HANIGAN: Okay. Just one other comment. I think Caroline said it very well, and I just want to piggyback on what she said. We thought long and hard over this wording last night. I'm in favor of leaving it the way we have with the pencil changes that I've made for the Committee. And I really want to wait and see what the micro committee tells us. They are the microbiologists. They are the scientists.

MS. GLAVIN: Okay. Would you read how it now reads and we'll see everyone can agree to that?

MS. HANIGAN: Okay. Directly under the statement that says, "Developments in the campylobacter program," I have in bold, "The subcommittee supports the public health goal of reducing foodborne illnesses caused by campylobacter."

Then, I have titled the next section as "Conclusion." And there's been no change there. It says, "FSIS data is incomplete to conclude the value of campylobacter prevalence being used to establish a performance standard. But prevalence appears unlikely to be used."

"Risk assessment is in the initial planning stages to evaluate." And those three points stayed identical: farm to table, intervention and the infectious dose.

The statement saying, "It is noted that the

salmonella performance standard was established prior to risk assessment" is just as we agreed.

Next category was subtitled as "Actions." "The subcommittee supports the agency's direction to evaluate the need for a campylobacter performance standard including (1) --

MS. GLAVIN: Wait, wait, wait.

MS. DEWAAL: Evaluate a campylobacter performance standard, Alice's recommendation.

MS. HANIGAN: Evaluate -- okay. Let me repeat it. "The subcommittee supports the agency's direction to evaluate a campylobacter performance standard including evaluating methodology, completing the baseline study, initiating risk assessment." And I did not change the last paragraph at all.

MS. GLAVIN: Okay. Is the Committee --

DR. WOTEKI: There is one typo in the last paragraph, I might point out. In the next to the last line, "accomplishes" should be "accomplish."

MS. GLAVIN: Accomplish, right.

MS. HANIGAN: Okay.

DR. WOTEKI: Alternatives that accomplish the same public health objective.

MS. HANIGAN: Okay.

MS. GLAVIN: Is the Committee ready to move on?

Are you satisfied with this? You want further discussion?

MS. DONLEY: You know, I'm just one voice here, and I just feel that this evaluating is wishy-washy. That we should either leave it as "establish" or perhaps say "to identify a campylobacter performance standard including," but something that is more action-oriented, which is what this -- which I like the way you've set up these categories, and you're talking about an action here.

So, that's just -- I want to go on record saying that I disagree with what is -- if we keep the word "evaluate" here. I would just suggest leaving it as "establish" or "identify" a campylobacter performance standard.

MS. GLAVIN: Any further discussion?

MS. DEWAAL: I have one more question. And that is, I think the two action items should be from the subcommittee because we anticipate that we'll be getting information back from the micro committee. But does the goal -- should the goal be from the subcommittee or from the full committee for where it says, "The subcommittee supports the goal of reducing foodborne allose from campylobacter?" Do we want that as a full Committee goal?

MS. GLAVIN: Well, actually as we have these discussions, as things are amended by the full Committee and agreed to, we take them as Committee work. So, you know,

the wording can stay this way. But we assume that these are, at this point, Committee work.

Okay. That group did good. You must have been there till midnight. Okay. Since we have another group report, my suggestion is that we start our break a few minutes early and try to get back by about 20 after. And at this break, we have pictures of the Committee members. So, comb your hair, straighten your tie, and we're going to do the pictures back by this curtain. And Dr. Woteki is going to be part of the picture taking.

(Whereupon, a recess was taken.)

MS. KASTER: For clarification, there was one field execution task force. Can some -- I think, Katie, did you put that down?

MS. HANIGAN: I did.

MS. KASTER: Can you explain again what that is?

MS. HANIGAN: It's executing our field employees.

MS. GLAVIN: Guess we went through yesterday.

MS. KASTER: Yes. What that is, that is the -- I think it's the September 11 letter from Dale Allan to this Committee back in November. And it is a paper that was put together by AMI. And it's seven parts. The basis of the paper is the seven issues need to be addressed in order for HACCP to be fully effective and fully implemented in the field.

And if you want me to go through this seven pieces of that, I'll be glad to.

MS. GLAVIN: Do you need that?

MS. KASTER: No.

MS. GLAVIN: No. Collette's shaking her head no.

MS. KASTER: Those seven pieces are the field execution task force?

MS. GLAVIN: Yes.

MS. DEWAAL: I have a question. Can you hear me okay? I have a question. HACCP inspection models is on this list as though it's an optional part of our agenda. I thought part of the mandate of this Committee is to work on the inspection models. And the question goes a little more broadly. We haven't had an update during this meeting or a report on that project. It's an ongoing project. So, I just wanted some clarification.

MS. GLAVIN: Okay. I don't know that it's a mandate, but I think it's fair to say that whatever your ranking is, we're going to keep that one on your agenda because it's real important to us that this committee continue to be involved in that.

MS. DEWAAL: Okay. So, maybe it's not -- I just hope the Committee doesn't have to vote and then make sure everyone have that as a number one, because it should be --

MS. GLAVIN: What will happens is after -- you

know, Mike will do some consolidating for the discussion this afternoon. And after the discussion, we will come up with an agenda for the next meeting and on into the next year. But we really need your input as we develop that.

Inspection models, I would say for the next several years, are going to be a part of that. Depending on you know kind of where we are at any given time, it might be simply a briefing, or it might be bringing it back to one of the subcommittees for some advice and counsel. It sort of depends on where the project is at a given point in time.

MS. DEWAAL: And will someone brief us before the end of this meeting ends today?

MS. GLAVIN: We can do a real -- I can do a very broad-brush briefing. We should have put that on the agenda. It's a good question.

Okay. With that, we have a concept paper on inspection of all animal flesh foods, which is the Inter-Government Role Standing Committee. And Dan, you're the chair of that?

DR. LAFONTAINE: First, a comment. I'm normally known as the taskmaster, but I want to yield that honor to Katie. I think she's outstanding.

MS. DEWAAL: Cracks the whip.

DR. LAFONTAINE: The subcommittee had a very healthy wide-open discussion, and the way we approached this

thing is we realized that the original recommendation from the full Committee was very broad. That is, all animal flesh foods. So, what we did with acknowledgement to Loren and his concept paper, we took the major elements of his concept paper and tried to answer the key questions that he had put forth.

So, my thanks or the Committee's thanks, subcommittee's thanks to Loren. And also, before I forget, I want to also acknowledge the fine support from -- admin support from Gene Myers who's in that same group as Loren.

In front of you, you have the results of that. And I'll go through it and try to explain the key elements.

The Subcommittee on Intergovernmental Roles and Coordination gave consideration to all aspects of the subject concept paper. And first of all, there's already a typo. Insert the word "and" formulated after "paper" and before "formulated." "Consideration to all aspects of the subject concept paper and formulated the following broad guidelines for resolving the issue of what animals should be included in mandatory inspection." So, these subbullets are just that. They're broad guidelines or concepts on how we feel FSIS should proceed.

Subbullet 1, and there's a 1A and a 1B under poultry, we feel that a acceptable definition would be: "Any commercially slaughtered and/or processed birds for

human consumption unless exempted." And I'll explain the "unless exempted" part here in a moment. I want to acknowledge that it was back -- that language was lifted from the FSIS concept paper.

The next item -- major element or item we discussed was what meat items should be involved? What meat animals, rather, should be involved under mandatory inspection? And we struggled with this quite a bit to find the correct mix, and we come up with "any commercially slaughtered and/or processed mammals for human consumption unless exempt."

So, what I want to do is stop for a moment and expand on those two items real quick. By using the word "birds," we felt that that would capture anything that now or in the foreseeable future might be commercially raised and commercially slaughtered and processed for human consumption. The prime examples being quail, pheasants and ratite.

For meat, obviously, if you use the word "animal" as Loren pointed out, that's extremely broad to include fish and other lesser degree animals. By using the word "mammals," we include all the known other type of animals that are currently covered under voluntary inspection. Rabbits and your various exotic species that are farm-raised and commercially slaughtered such as reindeer, deer, elk, et

cetera.

If someone in the future would come up with another mammal that was considered acceptable for human consumption and commercially slaughtered and/or processed, it would be broad enough to cover that, also.

So, what I'd like to do now, Madam Chairman, is stop right there, because that's kind of a big ticket group, and present a discussion. Then, we can move on to the other subelements.

MS. GLAVIN: Can I ask if the Subcommittee considered resources in their deliberations? Resources and priorities?

MS. DONLEY: Maggie, I guess the short answer is no. Looked at it instead of -- really from also -- kind of with the idea of the agency's own five-year plan, if you will, of having risk-free food, and with the goal of public health and safety as being the issue here. And that we felt as a subcommittee that any food products or meat and poultry products, I should say, animal products, that were available to the public to consume. And to the public -- we did keep -- I don't mean to run into Dan's program here. We kept the custom-exempt category, but that is available for the public to purchase and consume should be under mandatory inspection.

MS. GLAVIN: Lee?

DR. JAN: I'd just like to maybe -- brings out the consideration particularly in light of the strategy of risk- free food, I think -- yes, risk-free food. By going to mammals, you know, obviously, insects are taken care of by themselves. Nobody's going to be slaughtering those. I guess you don't have to slaughter those. But there are other mammals -- I mean, flesh foods that are eaten besides mammals and they're commercially prepared. We mentioned one yesterday. It was fish, particularly farm-raised or commercially raised fish.

But there's others. Rattlesnakes. People eat rattlesnakes. And we've had health issues with that because it was simply FDA or a state would say, "It has to be licensed. Send in your fee, and we'll send you a license." And that's it. And so, a lot of these rattlesnakes are essentially hunted or a certain time of the year, particularly in Texas, they have rattlesnake roundups and they're hunted. So, lot of those could be used for food with no inspection, and salmonella is very high in those.

Alligators. That's a flesh food that's eaten. And it's quite popular in Louisiana and east Texas and maybe other places, but I know in those areas, it's quite popular. And those, there's no requirement for any inspection, the inspection as we think about for meat and poultry -- inspection as we think about paying a license fee and

therefore, you're approved source, yes, they may have those, but there's no on-site inspection.

So, those things -- if we're going to look at a risk free, look at it from the broad strategic goal of risk-free foods, then those at least should be considered.

It brings up the point of the resources. Well, that's a problem that we all have. And that's where I think HACCP can play a role in moving resources around. Once we have HACCP -- HACCP system if it's going to work the way the HACCP system was designed to work, it's going to continue inspection even when the inspector's not there, then that would give me a feeling that maybe the inspector doesn't have to be there every day. And maybe he can go and look at the HACCP plants at the alligator plant.

Personally, I don't really want to inspect anything I can't use a thermometer or temperature. The rattlesnakes and alligators being two examples. But I think from the perspective of a totally risk-free food, we should not just not consider those.

MS. GLAVIN: Caroline?

MS. DEWAAL: I appreciate all the hard work that the subcommittee did, and I'm just going to defer to them. But I have to enter this debate with wearing the hat of a consumer who consumes lots of different foods. And when I go back and look at outbreak data, what becomes clear is

meat and poultry products are not the only ones we're having outbreaks from.

Seafood, produce, eggs, juice dishes, juices, these are all contributing significantly to food poisoning. And I strongly support the issue of mandatory inspection, but I think at some point we need to start making some decisions about where those inspection resources should be. And they should be based on risk and on where we're actually seeing outbreaks. And meat and poultry will always have a lot of inspectors, but we need inspectors in these other areas of the food supply, as well.

And so, as the Committee looks at the issue of you know, we need more inspection for quails and pheasants and ratites and buffalo and many other products, which I generally agree. You need to be cognizant of the fact that all of the foods regulated by FDA do not have a level of inspection that even comes minutely close. I mean, we're talking average inspection frequencies of once every eight to ten years. Seafood is inspected at best once a year. And they're trying to get high risk -- all high-risk foods down from once every three to four years. And these are ready to eat products and they're just being inspected very infrequently.

So, I just -- we need to be aware that this system is very uneven in how we regulate food. And it is not

hazard-based today.

MS. GLAVIN: Mr. Mamminga?

MR. MAMMINGA: Mike.

MS. GLAVIN: Mike, thank you.

MR. MAMMINGA: Whenever you try to discuss what is supposed to be or what should be or what might be an amenable species, obviously, the first two things that hit the table is if we increase the list, how are we going to pay for it? And the second thing is, where do we stop?

Initially in the work that was done by our state directors associations, and Dr. Jan and Terry Burkhardt worked very hard on this. It seemed common sense to us at the time that what is so noble about a beef, pork, lamb, goat, equine and domestic poultry that warrants its mandatory inspection and the other species such as buffalo and rabbits and lowland gorillas and whatever else we might choose to eat are not subject to mandatory objection.

MS. FOREMAN: Talking about my cousins here.

MR. MAMMINGA: I knew you'd appreciate that. So, what we tried to do was not fix the world, but we tried to fix the part of it that we thought made some common sense to everyone. Obviously, many species of mammals are protected and can't be commercially raised or slaughtered for food anyway. However, in our programs, both state and federal, we are confronted with a significant number of buffalo,

members of certain subspecies of the deer family, rabbits on a daily basis. On a weekly basis, we have people that seek inspection and wonder why their species is not graced with mandatory status when others are.

So again, the resources part of it, as in all things, and you know, Maggie, we're going to have to redirect our resources this afternoon based on some thing happening. What we're trying to address here is those real light animals that we are seeing in significant numbers that are coming into the plants for inspection, and we simply want to -- and when you talk about baseline data, Caroline, on what problems there may be in the buffalo herds or the deer herds that are transmissible to people, things like e-coli 015787, we know that's a possibility. It is a possibility in buffalo. Certainly in any ruminate animal, I believe. Isn't that correct, Dr. LaFontaine?

So, we know that there are certainly potentials and we see these animals increasingly going through our slaughter houses. Again, the thought process behind this about talking about mammals, was talking about the species that we have seen and are seeing in growing numbers across the last number of years. We think it's time to reevaluate. Like cattle, sheep, swine, goats, equines and domestic poultry should forever stay as the only mandatory species considering what we know now.

And again, we knew that if we threw it open to fish and reptiles and bugs and worms and things, it would make it so great a burden just to establish protocols for inspection, that that would be unrealistic at this time. So again, at least my thought processes and what I tried to contribute to this was not to fix the world, but to adapt to what we are really seeing today that is really going out in human food channels in fairly significant numbers. And that's why we didn't make it all-inclusive.

And another reason for not making it all-inclusive was to know that we're going to all have to come up with resources to do this so that at least we can take the numbers that we have now for what we've been historically doing, either in the federal program or the state program for the last number of years, and at least we could project a number.

If we take all species, it would be impossible to project a number for that. If we take what we know we've been dealing with, at least we can come up with some realistic numbers and let the people that vote for appropriations and changes in acts, determine whether we're willing to fund that or not. So, that's kind of what the process that got us -- at least got me where I'm at.

MS. GLAVIN: Okay. I appreciate that. Other comments? Do you want to continue then?

DR. LAFONTAINE: Yes. There currently exists in the law in the Federal Meat Inspection Act, a provision for custom exempt. And let me briefly explain in my own words what that means. The essence of it is that an individual can bring an animal they own to a establishment that is under sanitary surveillance but not carcass by carcass, antimortem, postmortem, have it slaughtered in a sanitary environment and returned to them marked "Not for Sale."

The essence -- excuse me. The consensus of the subcommittee was to leave that untouched. And for what exists in the FMIA would be rolled over to the new definition of mandatory species. In other words, for all mammals.

In the Poultry Products Inspection Act, there is no similar language. And we felt that the same essence or the same language should be incorporated in the Poultry Act. And the same time as we do that, that we would strike the existing exemptions in the Poultry Act that provide exemptions, for example, of someone slaughtering up to 20,000 birds without any inspection for commercial use under certain conditions. We felt that part of it is obsolete and that we'll still have a level playing field for both industries and for the individually owned animals to have the same -- in essence, the same language on custom exempt in both laws.

So, that's the custom exempt part of the puzzle.

MS. GLAVIN: Any discussion on this? -- on that, please.

DR. LAFONTAINE: Food additives? We had one very vocal member on this issue. And we went with his recommendations, Mike. This might seem kind of odd to put food additives in the middle of this, but let me explain why. First, I'll read. "Food additives allowed under the Food, Drug and Cosmetic Act will be allowed for all amenable species."

The scenario we have now is that for certain exotics, the FDA does not allow the use of nitrites of any form. And I won't get into the why and whatever. But so that there was no misunderstanding, if eventually, the family of amenable species was expanded to include exotics such as deer, that they also -- the process slaughter houses and processors would be allowed to use any currently approved food additive in those species the same as the existing amenable species.

So, in one way you could say if they're made amenable by default, they -- you know, you're allowing nitrites to be used, but it's such a confusing and controversial issue, the subcommittee felt we should be -- come up on the net and say, "We want to make sure there's no misunderstanding on this issue."

MS. GLAVIN: Is there any discussion on that? Dr. Jan?

DR. LEE: I would -- I agree. I think nitrites are -- is an ingredient that's actually almost mandatory or if the food safety's really necessary for certain, meat products to be particularly shelf stable ready-to-eat products. Jerkies and those kind. And that is a high part of the nonamenable species that a lot of nonamenable species, jerky and sausage that cannot be shelf stable unless -- because you can't use nitrites.

What I would do instead of writing it the way it's written here, because I'm not clear -- it's my understanding that FDC does not allow the use of nitrites in any food. They only permit it in those that it's already been used for before they passed their law.

So, if you write it this way, it's my -- I think what you're saying is nothing changes. I would go and say what we wanted to say. Nitrites be used in all amenable species as we bring them up under or not even use the word "amenable." Nitrites to be allowed or to be permitted to be used in all meat products that are -- that is appropriate for. And that would again, be particularly the shelf stable products, ready-to-eat products.

So, I think the wording is -- I just don't think that this wording is going to get us anywhere. I also know

that FSIS can't tell FDA what to do, but it seems to me that there might be another MOU or some deals or maybe not deals, negotiations between the agencies. And obviously, the logic that FDA used in their Food, Drug, Cosmetic Act can be expanded to include other meat items. And the logic they use is there was no -- from the history of 25 years or so of use before they passed their law, there is no link to a disease process in humans from use.

And they can use that same logic for other species. It's not that beef and pork and some of these other species had some magical effect on the nitrites. It was if the nitrites were a risk, the nitrites were a risk. And if they're not a risk, they're not a risk.

So, it seems to me they could use that same logic. It seems to me that there's some evidence, and I talked to an individual -- I can't remember his name now -- I believe he was from Nebraska, when we would work on some of the HACCP plans. And his recollection of some data that they have already done demonstrated that there was not a risk, but people in charge at FDA didn't want to accept it.

So, it's political at that time. And I believe when we put political -- politics aside, we've been saying that all along, from a food safety issue, I think we need nitrites in all those products.

MS. GLAVIN: Caroline?

MS. DEWAAL: I think Lee Jan has outlined some important points that may actually suggest that perhaps this issue isn't right to be in this document. The whole issue of food additive approvals by FDA is highly technical and scientific. And I don't -- I'm not certain anyone on this Committee is really technically qualified to begin to address the issue of the safety of nitrites and their use in the different animal products.

Perhaps what Dr. Jan is saying is absolutely correct about why they're not allowed, but the reality is the decisions made on food additives are food safety decisions that have been made by the leading agency that considers those the questions of toxicology in the food supply. So, I would suggest that perhaps this issue be taken off and perhaps either sent back to the subcommittee for some further discussion on what should be done in this area, or perhaps -- and we -- I don't usually say this, but maybe we should send this to the National Advisory Committee for Micro because they might have some toxicologists that could help address this issue.

But I do not feel qualified. And I don't know if anyone here is a toxicologist who is skilled in this area, but I really don't feel qualified to have this particular provision in this statement.

MS. GLAVIN: Let's do Mike and then Carol.

MR. MAMMINGA: Well, first of all, my friend, Dr. Jan, we knew that no matter what language we came up with, you can always question the verbiage. We wanted to send a message. We also knew that FDA -- this is in the part of the Code of Federal Regulations that FDA deals with. And we knew that, and we knew that they would have to take an action, an action which they have even refused to discuss in any forum that I'm aware of after being petitioned many, many times by those people who raise animals that are not cattle, sheep, swine, goats, equines and domestic poultry. We knew all of that going in.

And so, this isn't language that we expect to be put in the C.F.R. This is a message to our Secretary of Agriculture and to the people at FDA saying again, "You're a veterinarian. What is the difference between a piece of buffalo meat and a piece of beef? And what does it take to determine which is which by the histopathologist a little bit more than just looking at it, smelling it or touching it?"

So again, the question came back to fairness. And what is so noble about a beef that is so unnoble about a buffalo or an ostrich in respect to a Rhode Island Red? So, what is so noble or unnoble?

And to our Caroline I would say, for the last 30 years, even after tremendous battles in the early '70s of

whether nitrites and nitrates should be permitted at all. It's been produced not just for color, not just as food additive, but for food safety. And I agree with you. We're not scientists.

But again, we're putting these products on the market by the billions of pounds in this country, and all I can say is when you consider the food safety concerns of a product that's ready to eat in an anaerobic environment that might be heat or temperature abused, the risks that we know today would seem to say that we should at least treat these products the same across the board. And again, we're not trying to fix the world.

We're not trying to say the nitrite is the greatest thing that ever was or that it should be used. We're just saying that if it is a necessity in certain products under our inspection, why shouldn't it be permitted in all products that are made under our inspection? That's all we're saying. And we're not writing language for the C.F.R. And we're not demanding that anybody do anything, but we'd like to make them aware that at least out of fairness and with food safety in mind, that these products all be treated the same.

MS. GLAVIN: Carol?

MS. FOREMAN: I swore that I would never say another word about this subject. I still got the scars from

the last time.

I think your point's actually a good one because of all the products that I'd -- because of what Lee said, when you're using these in jerkies and stuff like that, I think there is probably some risks there, much more so than in a lot of the products -- do open the possibility that with today's science, FDA will be forced to do -- of nitrate and -- nitrites, and that it's not safe.

That is a risk. And if it's one you're willing to live with, I suspect that I don't have any particular problem with this proposal because I think the products that would get covered under it are probably the ones where the cost-benefit ratio or the risk-benefit ratio of using nitrite is a lot higher than it is in some of the places where it's used.

MR. MAMMINGA: Could I respond?

MS. GLAVIN: Absolutely.

MR. MAMMINGA: I think that the industry is willing to defend its use scientifically. And I think they're up to the battle. And I rely on the scientists to give me good advice, whether they be from government or industry or academia or wherever. And if it is -- if it turns out to be a safety risk, then by golly, we ought to know about that. That ought to be on the table.

And if on the other hand, it will make our foods

that are in these kinds of packaging and prepared in certain ways safe, then we ought to include all such products under its use. That's my only thing.

MS. GLAVIN: Okay. Katie, and then Caroline.

MS. HANIGAN: I was just going to say I support the language that the subcommittee put on the paper and I just assume it would stand as written.

MS. GLAVIN: Caroline?

MS. DEWAAL: I still have concerns. The language as it's written is -- covers all food additives, not just nitrates. It seems to also exempt food additives used in amenable species from the FDA food additive approval process. It just says, "If it's been approved for one use, then it's approved for all amenable species." And that language is too broad.

What I would suggest is this. FDA has committed to speeding approvals for additives that are alleged to have a food safety impact. They've agreed to move those food additives to the front of the list. If the problem is that nitrites can't be used in these species, they're approved for other species. They're grandfathered in. And we want to see them used here. Why don't we just ask FDA to approve it in an expedited fashion for food safety reasons?

I appreciate that you said you don't -- you know, you want to make sure it's safe, and you want to rely on the

scientists to do that. I do, too. But I think that what you've got drafted here seems to circumvent that process instead of simply asking that it be expedited.

MS. FOREMAN: I join Caroline on that. Could we be more specific and make a reference to nitrites instead of food additives generally because I don't know what else is out there in that universe.

MR. MAMMINGA: Well, we also considered -- at least I considered in my talking that we're going -- that USDA and FDA are working right now as far as approved -- making reference to the C.F.R. that's under FDA for additives, food additives, et cetera, et cetera, et cetera.

MS. GLAVIN: Yes.

MR. MAMMINGA: Isn't that correct?

MS. GLAVIN: That's right.

MR. MAMMINGA: And I thought again, we're not writing specific language for them here. They'll have to write the language that they're willing to write for their regulations. And I didn't want to suppose -- this -- what we're asking here does not limit them to disregard it, to change it, to make it more agreeable. We're just trying to broach the subject that what's good for one should be good for all.

And they can write the rules to suit themselves. If they decide that nitrite -- sodium and potassium nitrate

and nitrite should only be permitted in amenable mammals and birds, then they can write it that way. That would be exactly what we were shooting for. And maybe we could have directed them a little more closely that way. But this is just a recommendation that they at least consider these issues, which includes of interest to me, is sodium and potassium nitrate and nitrite. It could be approved upon.

MS. GLAVIN: Dan?

DR. LAFONTAINE: Let me, as the chairman of the subcommittee, try to -- I don't mean to be grandstanding.

MS. GLAVIN: Well, you said you were going to try to get your reputation back.

DR. LAFONTAINE: I've lost it. I'll never get it back.

Here's what I suggest we do. Let me just talk in concept. We take this out of the main body of this document and add it as an add-on recommendation or a supplemental recommendation, and then we word it according to the consensus of the full Committee. Because first, it's obvious that it's sticking it in the middle of this major topic is awkward. And it clouds the bigger issue of mandatory inspection of what species.

So, our first recommendation of full Committee is that we take it out of the main body. We make it a supplemental recommendation to FSIS, and in the supplemental

recommendation in essence agree that -- I mean, states that the use of nitrates in amenable species be a key or priority topic in FSIS/FDA evaluation of food additives.

MS. GLAVIN: Reactions? Is the Committee ready to go with that? Could I ask you to do a little writing and get it to Mike for me, and he'll then have something to share with the Committee so that you can see how this has turned out?

DR. LAFONTAINE: I'll do that.

MS. GLAVIN: Okay.

DR. LAFONTAINE: Okay. Let's move on to four, legislation or regulation. FSIS, Loren, specifically in his paper said, "How should we approach this from a legislation/regulatory viewpoint?" And there's some typos here, but let me just read the sentence. "Recommend the legislative" -- rather than legislature approach -- "legislative approach to effect these changes be amendments to the PPIA" -- that's Poultry Product Inspection Act -- and the FMIA" -- the Federal Meat Inspection Act -- "(surgical approach)."

And then, as a follow-on, regulations would be changed accordingly. But obviously, the laws -- regulatory changes -- I mean, the legislative changes to the statutes would drive regulatory changes.

There were three options that were put forth. One

was completely rewrite the two laws. One was this. That is, amendments to the existing laws. And a third one was a separate law. This was the unanimous consensus of the four subcommittee members.

And I put the surgical approach. That was the verbiage used in the concept paper. That's what that means, "surgical approach."

MS. GLAVIN: Discussion?

MS. FOREMAN: I'd just remind the subcommittee that the making of law is a lot messier than the making of sausage.

DR. LAFONTAINE: We realize that.

MS. FOREMAN: This remark reminded us, and there's no such thing as surgical, but it's a good recommendation.

DR. LAFONTAINE: The fifth item -- I'll read it. "Inspection standards should be the same as current amenable species." In essence, what that means is the subcommittee was not going to get into how to inspect what when. As we consider HACCP-based inspection models, turning -- possibly turning certain things -- certain responsibilities over to industry, if it makes sense with the existing amenable species, and it would in turn could make sense for the add-ons.

And I'll add an editorial. The three million quail that are under state inspection in South Carolina are

young, uniform healthy animals would be the same as young broilers, for example. So, if we ever got that far, we could possibly use the same approach for those type of animals if the volume and the type of volume justifies it.

So, basically, we're saying is leave well enough alone. We've got existing standards and we're working on changing those. And so, anything that's added would be brought into that family for consideration.

MS. GLAVIN: Comments? Carol?

MS. FOREMAN: I apologize to everybody for being late this morning. You may have already gotten into a discussion of this earlier in your recommendations. Would you be willing to insert in there health-based/risk-based standards so that it really says that you should have risk-based standard for the inspection of these products just as we're developing for other products?

DR. LAFONTAINE: In other words, risk-based inspection standards?

MS. FOREMAN: Yes.

DR. LAFONTAINE: I don't have any problem with that.

MS. FOREMAN: I'm really saying the inspection standards should be risk-based for these as they are for others.

MS. GLAVIN: Could I just seek one clarification?

By the same as, I'm assuming you mean comparable, similar standards that you don't mean that we do exactly with quail what we do with young chickens necessarily, or do you? I'd just like that clarified. We have a bad history "on the same as."

MS. FOREMAN: Well, I was looking for -- that's why I was trying to get the risk-based in there so that they would be -- you'd do this based on --

DR. LAFONTAINE: We can accomplish the same thing if the rest of the committee agrees, is should be equivalent to.

MS. FOREMAN: I'm looking for that health risk in there so that -- if you determine there's not much of a risk, you have a level of inspection that is appropriate to a low risk, and if it's a high risk, you've got a level of inspection that's appropriate for that.

MS. GLAVIN: Do you have a suggestion to solve the problem?

DR. LEE: I would suggest something with that risk-based, but something -- inspection standards should be risk-based and appropriate to species.

MS. FOREMAN: That's fine.

MS. GLAVIN: Great. Terry?

MR. BURKHARDT: I want to ask the subcommittee when you discussed this issue and you consider moving from

voluntary to mandatory, presently those products that are all under voluntary inspection in state programs are allowed for interstate shipment. If this were to go to mandatory and we become mandatory species, did you discuss the possibility of whether interstate shipment of those products would be a factor at that point?

DR. LAFONTAINE: We did not discuss that but I did think about it. And you make certain assumptions, and the assumption I made was that interstate shipment of state inspected product will become a fact hopefully within the next year or two. So, hey, I personally went out on a limb, but you're right. If that failed and this passed, you would have a dilemma. That was an assumption that I made as I developed this.

MR. BURKHARDT: Because right now the market is well established for these voluntary products across state lines.

DR. LAFONTAINE: I want to go back to number 5 to make sure I got what Terry I guess -- inspection standards should be risk-based?

DR. JAN: And appropriate for species.

DR. LAFONTAINE: And appropriate for species.

DR. JAN: And appropriate for these species.

DR. LAFONTAINE: And appropriate for the species.

Okay. Let me go on if that part is solve, or

resolved, I should say.

Now, we threw this in -- and we're not bashful. We threw it in for political reasons. No. All kidding aside, we feel that -- the subcommittee felt these changes will be consistent with USDA's vision of a same state and federal inspection system.

And to embellish just a moment, what is currently happening and what will probably happen even more in the future if the interstate shipment issued is resolve and this becomes -- these species become amenable, that a great deal of this workload will end up with state programs, but that state and federal inspection agencies will have the same ground rules. So, it will be seamless. It won't be state laws for this and federal laws don't cover it and the big mess we have right now.

So, that's why we put that in. It would fit in with the vision of a seamless consistent system. Yes?

MS. FOREMAN: Could I ask that -- I'd like that a lot better if it said, "the changes" because you're recommended a bunch of changes before this "should be consistent with the USDA vision of a risk-based seamless federal, state and inspection system. I bet you'll see when we get around to discussing ours, I keep wanting to shoot for what's appropriate to protect public health and see everything through that lens.

DR. LAFONTAINE: The subcommittee -- let me read it back to see if the suggested wording captured it. "The subcommittee feels these changes should be consistent with the USDA vision of a risk-based seamless federal, state inspection system."

MS. FOREMAN: Yes. I would like that a lot better.

DR. LAFONTAINE: Anyone in the committee feel otherwise? Okay.

And then the final paragraph is we feel is a follow-up action that FSIS develop a revised or second edition concept paper incorporating these recommendations to be presented at the next meeting similar to the scenario we used for interstate shipment.

MS. GLAVIN: Okay. Let me ask you to expand, and it doesn't have to -- you don't have to change the recommendation but just talk a little bit about what you're looking for. We spent a fair amount of time trying to figure out what the heck you guys wanted in a concept paper. You know, are you looking for the Agency's kind of take on this? Are you looking for some more technical information? Are you looking for options on how to do this because you know, we can do any of the above but it's sort of silly for us to waste our time and then come back with something that may or may not meet what it is you're really looking for.

What do you mean when you ask us for this?

DR. LAFONTAINE: Let me try to answer that. The concept papers, the three versions that were used for the interstate shipment is what I'm talking about. There's an agreement on where we should proceed. So, that's what is the objectives? And then, how are we going to reach those objectives through actions, whether it be rulemaking or legislative changes? And then, what would be the essence or the content of those changes?

So, the full committee can see what language is going to be proposed or recommended to effect the end result or to accomplish the end result.

MS. GLAVIN: Well, if you're asking for the agency to write its position on these issues, that's one -- which is what we did in the interstate shipment. We wrote concept papers on our -- and it did evolve over the various versions -- our evolving position on the issue of interstate shipment. You know, whether the agency's position is going to come out the same as what you're recommending, I don't really know at this point.

I just need to be sure what it is you're asking for. Are you asking for what is at the point in time the agency's position on this subject, or are you asking for some options for you to consider further?

Again, we're able to do it a number of different

ways. I just need to know what we're being asked for.

MS. FOREMAN: It's my perception that there's some distance between the Advisory Committee and the agency on this particular issue. And again, I'm wondering if we might narrow that gap by getting -- and I'm asking you and the members of your subcommittee, Dan, on this. If we could get the agency to come back with the paper that first addresses what the health risks are from these uninspected species.

We've been going at it kind of on an economic basis. A gentleman yesterday was quite eloquent about that. But I'd feel better if we could go at it in terms of what are the health risks? And how can you address those so that we might end up with a proposal that is based on a health risk and doesn't have to go back and raise the issue of whether or not we're going to have bison-by-bison, continuous inspection if there is no health risk that justifies that. And I don't know now.

MS. GLAVIN: I guess, Carol, I just want to react to your opening of that, which is that there's a fair distance. I think it is fair to say that the agency and the committee are very much in sink on the objective. And that's no question.

My sense is that we have different senses of the priority of this in the scheme of moving to a risk-free food system. That's --

MS. FOREMAN: I certainly agree.

MS. GLAVIN: Loren, you have something to add?

MR. LANGE: Yes. If it's appropriate because -- I mean, if the recommendation to revise the concept paper is sort of agreed to, I figure there's an outside chance it might affect my life. Something like that.

But I was thinking last night as I sat in the parking lot having left my lights on and my battery was dead at 9:15, so I had an opportunity to think, too. And I was thinking one thing that as we move to the next paper, at least, even if it wasn't really providing a lot of data on like pathogen levels in these species, the next paper should at least capture -- you know, when Mr. Burkhardt asked for yesterday that the volume of these products that are currently inspected in states to document the types of inconsistencies we have such as if Iowa has mandatory inspection for deer, you know.

What are the species that are mandatorily inspected in different states? And to document the types of -- you know, Mike said last night the status quo creates a lot of headaches. So, at least without getting real specific on maybe sort of a risk assessment for which probably by the next meeting isn't possible, we can move the issue forward.

If we have four states represented here, is that

shortly after this meeting, the agency sort of could initiate at least a questionnaire out to the states to sort of ask for the information on what other mammals are now under voluntary mandatory inspection, how much, and what types of problems does it create for the states? At least that is the beginning of sort of I think moving the characterization of the problem forward.

MS. RIGGINS: You would have to get approval from OMB for that.

MS. GLAVIN: I was going to suggest if we move -- if people agree with what Loren is suggesting, we could have our state members send out a questionnaire to their fellow state members because they don't have to go through OMB.

Reactions to what Loren who -- who is right. There's a fair chance he will be your author.

Mike?

MR. MAMMINGA: It would seem very logical to take this to the step that Loren indicated, but in very short order, we're going to, once these things are fleshed out and numbers that are available are put on paper so that we can do some cost analysis of what it costs to provide this expanded service under a mandatory inspection, but in fairly short order after we have that, the agency's going to have to take a stand on it. Obviously, we have a limited amount of time to work on a number of pressing issues in this

committee if we're going to try to do our job.

And for me, if something's deceased, then we better move on to something else. And that's why we need to make our case in front of the agency, have some numbers, and then let's get the agency's stand on it because as with all of us that are ultimately governed by a political process, there are other ways that people can choose to try to get what they want other than through our personal approval of something.

So, I'd say in fairly short order if we can get you the data, I would like to know what the agency has to say about these things individually. I don't have to have them all, but what can we have? What are you willing to support? That would be important to me.

MS. GLAVIN: Is that a good way to go with the concept paper?

DR. LAFONTAINE: Let me summarize what I hear and Loren, what you hear. As one of the actions leading up to the next concept paper is through the state directors we would provide additional information -- background information on what's happening in the existing marketplace for all these species that are not currently amenable, and also, as a part of that, any knowledge we have of pathogens or risks from these animals. That's kind of a subset.

The concept paper, I guess I'm still not clear

what the consensus is. I'm saying -- I'm repeating partly what I said is it would be taking these broad guidelines and melding those in with the agency's thinking to see what would be a reasonable position and pathway to accomplish it. And if the agency comes up with -- well, I'll just stop right there.

MS. GLAVIN: Okay. Collette?

MS. KASTER: Maggie, back to your original question, which I think Dan was trying to hit on a little bit, which was what do we want in a concept paper? And maybe we're talking about two different types of papers because what Loren initially presented was a very nice menu for us to work off of what the options were. So, maybe we're no longer talking about a concept paper, but more of a position paper because we've described how that subcommittee, then the Committee and then the agency feels about this particular issue.

And so, I don't know if that's the right vernacular or not, but maybe some further definition of what concept paper is versus what we're trying to do might be necessary.

MS. GLAVIN: Okay. Katie?

MS. HANIGAN: I just wonder how the agency could present a paper to us without having the information back from the states first. I would think that would be a key

factor before you could develop a position.

MS. GLAVIN: I think that's probably right. Carol?

MS. FOREMAN: I really want to stick on this notion of having some indication of what the health risk is from these. If you come up with quail as we have or chickens where fewer than -- what is it? One percent have any disease, and none of those are transmissible -- virtually, none are transmissible to humans. I'd like to see a paper that puts extending inspection to that product in an appropriate context, rather than doing it because there's an economic equity issue involved.

So, if the paper can just start from the notion of we want to do this on a risk to human health basis and I presume that that relates both to the nature of the beast and the disease and to the number of them being slaughtered for human food, then I think we could come to a paper that would get to be almost irresistible in terms of taking some action.

MS. GLAVIN: Alice, you've been trying to jump in.

DR. HURLBERT: I think Carol said pretty much what I was going to say. You had mentioned earlier, Maggie, about prioritizing. And I think everybody realize there's resource issues with this. Maybe as the state association pull in their numbers, maybe there's some way that there

could be some priority based on public health risk. And then the agency could respond after that type of information is given to them with a priority list included.

MS. GLAVIN: Okay. In the interest of -- go ahead.

MS. DEWAAL: I'd just -- and maybe this has been said, but I think it's vital that we start having some cost figures associated with this because the public health data will be very beneficial, but a lot of the rationale behind this frankly is a level playing field for these competing species. And that's really an economic issue as well as a state resource issue. I think we really need to see numbers and start that priority setting that Alice was talking about.

MS. GLAVIN: Okay. Let me suggest the following if this meets with people's agreement. Dan, if you and Loren can work together to get some information on what is going on now as outlined by Loren from the states with obviously the request going from you guys to your colleagues. When we have that information, we will undertake to do a concept paper along the lines of our earlier interstate shipment concept paper. That is, laying out our current thinking on what the objectives are, what the issues are, and where we are at this point in moving towards that.

To the extent that we can include both cost and risk information, we will. Cost information is -- you know, we can probably calculate that. There's very, very little information -- very, very little data on risk. So, I don't want to promise you something that isn't going to be there.

Yes?

MR. MAMMINGA: Could I just say one last thing? I agree with all sorts of these good suggestions that have been made, but I want to sensitize you in one point. This is not just a state issue. Exotic animals are slaughtered under federal inspection in all the designated states including buffalo and servidae, the ratite family. This is not just something that comes from your state program cooperators. This is an issue that affects all 50 states, and those species in all 50 states. And the health risks address all 50 states.

So, as we look at this with the data that we can gather to make an educated decision on what we're willing to assume and not, let's just keep it as a national issue involving other species that are not currently amenable to the mandatory provisions. That's just --

MS. GLAVIN: Absolutely. I think the reason Loren's looking for some information from the states is I think that's a good place to start in terms of what's out there. Okay?

DR. WOTEKI: I'd also like, Maggie, to make a few comments. I think this conversation has been very interesting. And I'd like to remind the committee of something that I said yesterday in my opening comments. And that is, that you are advisory to the Secretary. And in the development of proposals such as this one, it's very valuable, both to the Secretary and to me to understand where the differences of opinion lie between the agency position and proposals, and those -- the views of the organizations and the constituencies that you represent.

In the development of the concept paper on the interstate shipment, that give and take that occurred at the subcommittees and in the Committee discussion really shaped the direction that that proposal took. And it was also very helpful to us that there was a position paper -- a concept paper that came forward that reflected all of those views, and also that was agreed on by the agency and by the Committee.

I don't think that that's necessarily going to happen every time. I mean, I could envision circumstances where the agency position and the Advisory Committee's position might be quite different. And that in itself is also helpful to me and to the Secretary to understand those situations.

So, as this concept paper is moving forward, I'd

like the approach that we came up with in the end for further development of the paper. And I think that these kinds of discussions, if you all keep in mind that your advice does go to the Secretary, that that will also be helpful in shaping the directions that we take on this, as well as other issues.

MS. GLAVIN: Okay. Dan, anything more from your committee? I think, you know, you may have lost a little bit in the race, but you're still in there.

DR. LAFONTAINE: I agree.

MS. GLAVIN: Let me ask. Bill Smith and Mary Clutshall are here. I gather this was added to the agenda a discussion on HACCP implementation in small plants. Did you -- they asked for this yesterday? This is a request from yesterday for an update on HACCP implementation in small plants.

MS. HANIGAN: Maggie?

MS. GLAVIN: Yes?

MS. HANIGAN: Just for clarification, we heard yesterday and correct me, the committee, if I'm wrong that the micro committee was doing some identifications of hazards for the very small plants, and the question came up once these hazards were identified, were they going to be mandatory CCPs? And clearly, we were told yesterday, no. And that there would be a packet of information sent to the

circuit supervisor. And that led to questions about would the very small plants get the same packet of information as well as the language? Would it go out under guidelines that prudent manufacturers would follow?

And that's when they said perhaps we needed to have Bill come over when we got into those type of questions.

MS. GLAVIN: Okay. And Kaye mentioned to me as she was leaving that the subcommittee of the micro committee that is working on that document has not yet produced a document. So --

MS. HANIGAN: Do you think they will by May?

MS. GLAVIN: I don't know. I have not been very close to that, but I think we are close approaching a time when a document is not going to be of an ease to anybody.

MS. RIGGINS: Could I add to that? Yesterday evening we had a discussion with Dr. Stringthal about what our appropriate response would be once the micro committee does, in fact, develop these risks. My understanding is that we would simply reproduce them. They would not go out under the agency's -- we would not add them or make them a part of any guidelines that are under the agency's heading.

That we would provide these as information to the very small plants, but not attribute ownership to the agency. That they would be scientifically based, based on

the micro committee's expertise and not be considered guidelines from the agency in that respect. I mean, I'm not sure what you were -- is that making sense?

MS. HANIGAN: No, that doesn't really make any sense. I mean, I guess my question is, if the micro committee is going to identify hazards and we -- you, I'm sorry, you, the agency, are going to put them in a packet is what we were told yesterday and send them to the circuit supervisor, we were clearly told yesterday they would not be mandatory CCPs, but we sit and struggle with -- you just said it's not guidance material. Then, what exactly is it that's going out?

MS. RIGGINS: What I'm saying is in order to do guidance material, we would have to go through a much more elaborate process. We'd have to go through rulemaking possibly. And to make them available to the small plant, the very small plants so that they can avail themselves of it, they can use that information is our current goal.

If we were to do something more, we would probably have to go through rulemaking or some other administrative process to make that happen. In the interests of getting the information the very small plants, that was one of the options that we discussed yesterday evening.

MS. GLAVIN: Why don't we let Bill and Mary make their presentation and see what the questions are after

that?

MR. SMITH: I think the best examples is something we've already done, and then we can go back. But let me say first, any guidance material that is sent out as Judy was saying or that's attached to anything that field operations sends out would be cleared through policy and then the national HACCP coordination effort, and then we would send it out.

Just recently, in fact, yesterday -- no, Monday. I'm sorry. We sent to all district managers a letter designing and instructing them on initiating the very small plant -- what we call the very small plant HACCP outreach program. And what that does -- what we have done is identify every very small plant under federal inspection in the country. And we know location, city, state.

And we also have identified the front line supervisor, whether it be an in-plant supervisory veterinary medical officer or what we call a multi-IP supervisor. That's one -- that's a supervisor that has responsibility for five or six plants in a geographical area and/or the circuit supervisor, which is one level up. And usually, they have responsibility depending on the size of the operation, anywhere from 20 to 70 plants.

What we have asked them to do is to begin and complete by July 1 making contact with each and every one of

these plants. On the federal level, there's about 3,300. And again, we're sharing this information with the states and all our materials so they can go through that process. And I believe Dr. Leis is coordinating that effort with the state programs.

And the first thing we will do is Mr. Billy sent out a letter on March 16. And in that letter, there was a number of things in there. One was a very small plant proposed timetable for HACCP implementation that laid out in calendar months, you know, "you should be doing your hazard analysis and getting your training done in this time period. And then you should be establishing CCPs by this time period." And we can share that with you.

And so, we're going -- we're in this contact with the front line supervisors. They'll ask if they have gotten Mr. Billy's letter and all the attachments because there's guidance in there and HACCP coordinators are also identified in there. And if they have not, we'll provide it.

We're also going to provide them a copy of the regulation 417. We will answer any technical questions as far as what's in the regulation. And then, they have been instructed -- given a list of the state coordinators and the state information and all the HACCP coordinators and the network that's under the national HACCP coordination team. And so, if they have questions about training or where to

get information, they can go there.

And then, we're also going to ask this front line supervisor in this one on one contact to identify their readiness at this point. So, in March to May, we think it's a good idea that the plants would be starting to think about getting HACCP training and understanding that process. And so, one of the things we'll be asking, do the plants -- are they aware of the requirements coming up including the implementation date?

And then, if they are, where? If they're aren't sure how to meet them, how do we get them information? We have a category where they may be aware, but they're not really interested in meeting them because that puts you in a different interaction. If they weren't aware of the requirements but now they are, they're going to put in a process to meet them. And then there's a category that they weren't aware of the requirements -- so, that gets you a start point.

Each one of those plants will be based under the category of a -- database, which will be tracked at the district office. And so, then the next timeline for advancing HACCP will be on or before August 1999 -- the plant should be in the process of performing their hazard analysis and listing their products, developing their flowchart, understanding their hazards. And so, again, we'd

have the front line supervisors go out and make an assessment based on those categories where the plants are.

If they don't, and again this would not be that you must. This is not a regulatory -- we're not taking any regulatory action if they don't have their hazard analysis done or they don't have their training done, but at least it allows us to track and provide them information where to go get, based on the listing of the state coordinators and the guidance material -- where they could go to get this information.

So, I would see here on the Advisory Committee on this hazard that that would be a guidance document like generic models or other things that periodically Mr. Billy -- and I'll let Mary Clutshall talk about that -- is sending out periodic letters just like he did on March 16. And those become attachments that "Here's another piece of guidance that is available to you to use in performing your hazard analysis." And so, we would hope that we can get those kind of things out there.

But that's how we plan to track this all the way up to January. Yes?

MS. HANIGAN: One very specific question. As they're moving through the timeline with the very small plants, will the circuit supervisor or the IIC, whichever it may be, if they clearly see that the plant -- although

they're trying, they are not doing it correctly. Are they going to try to give them guidance in July saying, "I see you're doing your flow diagram, but that's not exactly what we had in mind?" Because then, we get into who's writing the program and who's not.

And I have concerns because at the same time the plant has to have some feedback prior to January and let them go this whole six months doing it wrong. How is your agency going to address that with these real small people?

MS. CLUTSHALL: One of the things that we plan to do with the circuit supervisor outreach and as Bill said the tracking mechanism, is to make sure that we're aware of those folks, that although they're trying, just aren't getting it, so that we can steer them in the direction that they need to go.

We don't expect that the circuit supervisor will be, or the IIC or the multi-IPS supervisor will be the one that necessarily is given the most detailed information, but they will be leading these people to where they need to go so that they can get that information. And we are going to supply that type of material and information to these folks.

We expect that through the feedback system, which will be operating through headquarters and also through the HACCP coordination office, that as we go along, we will have pinpointed the folks that are fairly well on their way, seem

to have a good understanding. And therefore, we can focus our resources where they're most needed and we can be the most effective.

MS. DEWAAL: I have a question. I think for Judy on the -- it's the guidance. Is this --

MS. RIGGINS: The distinction I was trying to make is that we will make the document available. We will make 7,000 copies so that we're sure that we've got everyone a copy, but it won't be identified as FSIS guidance. It will be guidance from the micro committee who stand on their expertise, and that information is valuable to small -- very small producer, very small plants.

MS. DEWAAL: When we were doing seafood HACCP and I was working with FDA at that point as they were implementing, they produced something called, "The Hazards and Controls Guide," that we called the Bubba Guide because it was designed as kind of, you know, any fish processor could open it, find their species, figure out what the hazards were and then go to the control chart and figure out what the controls were. And it provided guidance both for the industry, these very small seafood processors and the agency, so that when the agency went in, they at least had a list that they could look at to see if the plants were complying.

Is that the level of communication in this

document, or is it going to be very high minded and scientific? I mean, we want it high minded and scientific, but we also want it capable of informing.

MS. RIGGINS: We don't know at this point. We don't know whether there will be -- you know, whether it will be a very academic scientific document or whether it will have practical steps that very small companies can follow. We just don't know what it will say at this point.

MS. DEWAAL: And the agency may want to have more of a role than just turning it over to the scientists because there is a communication element to this that -- I mean, the hazards are not that different between small plants that are producing the exact same product. And so, it is a uniform set of hazards that at least they need to consider and then they can put different controls in. But this isn't -- I just hope there's a good document that gives -- you know, a kind of Bubba Guide that gives the people out -- you know, the people who are really trying to implement this in their own plants.

MS. GLAVIN: We have an enormous amount of material out there. And Mary, I can't do it off the top of my head. My guess is you probably can do a pretty good job of spilling this off.

MS. CLUTSHALL: I was going to say, we have a number of things that we've already put there. We have a

general HACCP guidebook that we have designed all our guidance. When we first started putting together the guidebooks, the generic models, everything we put together, we put together with that very small producer in mind so that we have 13 HACCP generic models that have been out as draft for a number of years. We're getting ready to finalize a number of those.

We have the basic video on HACCP that is available to anyone. We have the SSOP documents that are available to anyone. We have the overall HACCP guidebook that is available to anyone. We have an implementation videotape that is available to anyone.

These are the kinds of things that we have already gotten out. As Bill mentioned, the Mr. Billy letter, what I call the Mr. Billy letter. Part of what was contained in there was not just the list of contacts and coordinators, but information about our office, the kind of things we do, the programs that we've undertaken, my personal phone number, my personal fax number.

MS. DEWAAL: Just bear with me for a moment. I mean, I'm a small turkey producer. Are there any -- okay. And I know a whole lot about turkeys, but I don't know the names of these long scientific things that might make people sick. I mean, is there a guide that I can go look up turkeys and see, oh, campylobacter, salmonella, here are

your control steps, you know, for me?

MS. CLUTSHALL: I would say that we do have that, but I think that at this point and Bill was trying to make that point is that we can tell you, you need to worry about campylobacter. You need to worry about salmonella, but when you talk about the very small producers, what our challenge is, is to not just say, "It's salmonella, it's campylobacter," but to say, "Do you understand what this means?" And when you talk about a Bubba Guide, that's where we're really trying to go.

And I think what Judy is saying is that we're more than willing to put that information out, and perhaps what you're asking from us might be that if indeed we do that under the auspices of one of our correspondences from the Administrator that we include some information and talking points, not only for our circuit supervisors to assure that people understand what they're reading, but that they understand where they can go to get some of the information. And that's what we're trying to accomplish through the outreach process.

DR. HURLBERT: The outreach and the way I understand the circuit supervisor is kind of the messenger here. Here's the materials. Here's where you go get help.

Now, there have been a lot of changes. Mary was talking about the Mr. Billy letter. We've had a couple of

Mr. Billy letters that have come out as we've worked our way through some of the hazards involved in our HACCP plans and our programs, which have resulted in reassessment of HACCP plans and that type thing.

Are the circuit supervisors relaying this information to the smaller processors that, you know, the agency reviewed this and they feel like that there should be a CCP other than it receiving? And to throw in one more question, that information if the agency continues in that direction really needs to get the very small guys, you know, as they're in this process right now.

If we just have circuit supervisors as kind of the outreach people, then when we get to something like that, you're asking them to go beyond and start going into hazard analysis. Has the circuit supervisors had training? Do they sit down and do a hazard analysis as part of a training course at any point?

MR. SMITH: Okay. A couple things. We have said, and it's not just the 200 circuit supervisors that are doing this. The front line, where we have multi-IPS, and we have just abouts. So, we have a workforce about 500 people that are going to be tracking this. So, it's where you don't have a multi-IPS supervisor or a circuit supervisor to get involved.

We are now in the process of identifying multi-IPS

supervisors that have not been trained. Right now we feel there's probably less than 30. And once they are -- so, they are getting priority to be trained very shortly.

They will talk about regulatory requirements. So, in our training package last year, we included the C.F.R.s that communicated the policies you just talked about. And so, that's part of the training, and they will be able to communicate regulatory requirements, whether it be what's in 417, or the C.F.R. that clarifies that, the ones on zero tolerance, multiple -- you know, one CCP. All those Federal Register Notices have been included in the training. And so, they'd be able to provide feedback from a regulatory perspective. And any other direction, they would be coming from the guidance sources.

DR. HURLBERT: But they have not had training in hazard analysis as sitting down and doing a hazard analysis?

MR. SMITH: No, and we don't -- other than with the circuit supervisor in the specialized training, but again, we see the guidance of where we send the people, too, for that guidance, where they'll get information on hazard analysis. We're not making them hazard analysis experts, no.

MS. GLAVIN: Let's do Dan and then Katie.

DR. LAFONTAINE: Bill, you kind of answered already, but I want to make sure and then I guess you can

formulate this is a recommendation -- personal recommendation. My question is this. The part 417.7 gives training requirements for industry folks. And it's broad, but specific enough that you can understand seven principles and how to develop a plan. That's the nuts and the bolts of what I call the technical part of HACCP.

My question is, what group or groups of FSIS supervisory individuals and front line individuals have actually had the equivalent of what's in the C.F.R.?

MR. SMITH: Basically, it's the group going through the expert -- it's much more than that, but the group going through the expert HACCP training because that gets into how I do a hazard analysis, those type things. And I believe there's about 30, 40 individuals and then Policy has a number of people that would more than meet that requirement.

We did not -- and I've said this numerous times. What we have trained our people on is determining compliance to the regulatory requirements of 417. And so, they need to be able to make determinations. Was a hazard analysis done? Critical control points set up on that? Frequencies established? Verification? All the requirements in the reg are there, and that's what the basic compliance checklists do.

If there's questions about science, we have

constantly instructed our people to call the Technical Center. The Technical Center then would give them feedback about whether they have a concern or not. If the Technical Center can't answer that, Policy and OPHS work with field operations to get an answer back.

So, that's why we feel that they can be in a verification mode. So, once you have those questions established about the science that's in the program, and again, reliance on the Technical Center and/or OPHS or Policy to help do that, then what they do is on an ongoing basis, verify they're carrying that out. And that's really what we train them to do.

DR. LAFONTAINE: Let me make a statement, and I realize this dialogue could go on, but I have to state it. For the small and especially the very small plants, there is a disconnect when the evaluator, i.e., the circuit supervisor or the ICC does not understand fully the technical aspects of what they're evaluating, i.e., how to do a hazard analysis, how to identify critical control points, how you actually determine critical limits and et cetera.

So, my point is that I still feel FSIS has a disconnect in that you're evaluating things you do not fully understand. I'll just leave it at that. I just state that for the public record.

MR. SMITH: Well, let me state also, though, whether you're very small or large or small, it's the plant's responsibility to understand those, because we can tell them that you have to be worried about stabilization, let's say. They don't understand why they need to be worried about that. Then, the problem lies with the plant, and we can tell them that you need to do this, this and this, but they'll never achieve a basic understanding of why they need to do it.

And so, that's been the problem all along, reliance on FSIS. "Tell me, Mr. Inspector or Dr. Veterinarian, what to do and I'll do it, and you'll have no problem from me." The problem becomes they don't know why they're doing it.

And so, when a deviation does occur, (1) they don't recognize the importance of it, because they don't know why they're doing it. And so, to them, it's no different than not filling out a record in some cases. I'm not telling you anything you don't know.

So, yes, our people and I think in our training, we do them a pretty good grounding in hazard analysis is what the plant goes through. Certainly, from establishment of a critical control point and we're at a critical limit monitoring verification, we do spend a lot of time on that. So, I don't -- but we have not taken them through any

decision tree process on hazards, and nor do I think that is our job.

So, I just want to make that very clear that really with this going to work, they have to have the basic understanding. And that's where we want to provide the resources, which is not the inspector, but all these support groups that the coordination group is leading to work them through that. And I think that's really important. And our people are there to tell them where the resources to get it. As far as regulations, they can share with them like cool down on roast beef, what that accomplishes because that's already published, and they can share that kind of information. But the plant really needs to understand why they're doing what they do.

MS. GLAVIN: Okay. Katie?

MS. HANIGAN: We don't have any very small plants coming on at Farmland. All our plants are on HACCP. And I'm really concerned for the small plants. And this is why. I am subject now daily to what I call drive-by regulations. And basically, we have various interpretations of regulations now out in the field by agency personnel that are in the same establishment. And we see a resistance for those folks to call the Technical Center when, in fact, the plant will call the Technical Center almost immediately for help.

And I would like to suggest that the agency consider putting on their Website their current thinking on some of these issues that are on hand. And I don't mean a big long paper on current thinking, but for instance when the performance standards on chilling were issued, and the directive 7110.3 was left out, even if there was somewhere on the FSIS Website that gave a one-paragraph current thinking so that everybody could read it and understand, plus have a contact. "If you have a question about the new chilling directive or performance standards, please call this person."

And you know, that may not help our smaller plants coming on. Maybe they don't have access to the Web. But there has to be a unified written communication back to the industry and your people in the field that we call all access, because what I'm feeling is that a lot of it depends on who in the Technical Center you talk to. And I'm not trying to -- they do an excellent job. A lot of it is how we present the information to the Technical Center.

But I'd like to see an expansion on the Website of just simple blips. "This is what the current thinking is on the chilling," or "this is what the 30-day letter meant to the small processors and how it can start rolling back into larger processors," and get away from what I'm calling this drive-by regulations that we're being subject to. It's a

serious matter, and I think it's going to snowball into these small, small processors and really cause trouble.

MS. GLAVIN: Okay. Collette?

MS. KASTER: Just to build on what Katie said, one other danger for the small processors is for the most part, they are isolated. With the exception of trade organizations or informal communication between plants, they don't have the luxury that Katie's describing of being able to see and compare differences. Therefore, they will take whatever is fed to them at whatever level, circuit, IIC, and that's their only link. And so, it is critical that that link be consistent from processor to processor.

MS. GLAVIN: Okay. And that is what we've attempted to do with the Tech Center being the place where concerns are brought. And you know, I think that has improved the level of consistency. It certainly hasn't completely solved the problem.

MR. SMITH: I think we can get at some of this and maybe when we make sure in the continuing following up letters from Mr. Billy to all establishments that they'll be talking about training in the upcoming one. Then, they'll be talking about establishing your hazard analysis according to that timeline. And therefore, they'll be some more in-depth direction and guidance that gets to some of this, or where you can get this information. If not, we can make

sure those things get in there or talking points for our people so our people can direct them to those types of things.

MS. HANIGAN: I just want to say that I fully support the Omaha technical group. I think they do an outstanding job. And I think they work a lot of long hours, and they try their best to answer questions. And I think a lot of it is how it's posed to them over the telephone, interpretation. But I think it's been one of the most solid things that the agency has done to try to bring consistency and a focal point. And I commend you for that.

MS. GLAVIN: Thank you, appreciate that. Nancy, did you have something?

MS. DONLEY: Really, I guess it's just more of an observation or if someone could -- if I'm making the wrong observation, I'd like to know about it.

It sounds to me like there's a wealth of information out there. And I know that over the past two years when this whole -- the whole HACCP implementation schedule was rolling out, there's been talk from the very beginning about the -- perceived that there was going to be a problem when it got to the very, very, very small plant level. And I have heard over the years trade associations saying, "We're doing this and this and this and this for people, for our members. And there's a big brother/little

brother program going on by companies."

It seems to me what I'm hearing is, you know, you can lead a horse to water, but you can't make him drink. And that there just seems to be that there's just some flat-out resistance on the part of some companies.

It's just an observation I'm making. And if I'm wrong, someone feel free to correct me. But it sounds to me like there's a lot of tools out there, but they're not being used.

MS. GLAVIN: Well, I think the concern the agency has with the very small plants is many of them don't belong to associations. Many of them are very isolated. Many of them are one and two people, you know, owner-operated operations. And so, if there's resistance, that's one thing. And that's what Bill was talking about getting -- trying to get a sense of what it is. But we just want to make sure that there's no one who simply hasn't heard or simply hasn't figured out where to go for help. And that's where we are. And certainly, I know that's where the states are also, since many of the very small plants are under their jurisdiction.

I'd like to suggest that we probably want to break for lunch. I don't want to cut off discussion if anyone has a burning issue, but we're due back here at 1:00 p.m. I'd appreciate people trying to be as close to that as possible.

I know sometimes it's a little hard to get something to eat and get back quite that quickly, but let's try hard to be back at 1:00 p.m. Thanks Bill and Mary.

(Whereupon, the hearing recessed to reconvene that same day, Thursday, May 6, 1999, at 1:00 p.m.)

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

1:00 p.m.

MS. GLAVIN: Let me quickly go over what is on the agenda for the afternoon. First of all, we have a briefing on the field automation information management project. At our last Advisory Committee meeting, Peter Kuhmerker came and did a little demo for people at the break, and members requested a briefing at this meeting. So, that's what we're having.

Then, the third of the work groups will report out at about 1:30. I thought after the 1:30 breakout report and just before the break, I would do the models briefing if that meets people's needs. And then we will discuss what issues the Committee would like to consider over the next year. Actually, next two years and set up our plans for the next meeting. At the end of all of that, we will have a period for public comment.

So, if that meets people's needs -- okay. Peter, I'll turn it over to you.

MR. KUHMERKER: Good afternoon. What I'd like to do and hopefully I won't bore the people from the state programs too much because they've heard probably much of this presentation before. But let me just go ahead and describe to you what the FAME project is and the status of the project and where we're going.

The first question I usually end up with is what is FAME? And I'll just give you the very simple answer. And that is really that every computer -- every plant gets covered by a computer, which means that whenever the federal inspector in charge of a plant is there with plant management, they have access to a computer.

So, if we're dealing with a large Perdue, we would have a desktop computer there. If we have a compliance officer, a circuit supervisor, a person on a patrol assignment, they would have notebook computer. So, at all times they have access to the computer and all the functions within that, and I'll go over those briefly that we have them. There's also a computer in the back that I brought so I can give a very quick demonstration to anyone if they'd like to see if afterwards.

A little bit of history on this. We first started out with several pilot projects with what used to be called International Programs and in one of our areas before we were reorganized. That was in 1993 and 1994. And that was the process of getting approval from OMB and doing all of our homework and requirements analyses.

In 1995, we got all of our documentation together, got the budget approvals and got our contracts in place. And then we started a five-year implementation, which runs FY '96 through FY 2000.

And it's a five-year implementation for several reasons. Partly the life expectancy of a computer in part, how much we thought we could get appropriated from Congress. And also, how much we could actually afford to take people out of the plants for training because we're talking a fairly huge population which I'll get into in a second.

So, we are on schedule now. We're in the fourth year of implementation. We'll be fully implemented by the end of FY 2000. At that point in time, we will have in excess of 5,000 people trained in the federal program and over 4,000 computers.

The first year we went by area. Areas disappeared with the reorganization. We went to a district-based implementation, and in FY '98, we adjusted our implementations so that we could deal with the large HACCP plants to make sure those were up first before the start of the final rule.

And then this year, in addition to doing our plant implementation with the federal program, we started with the state program, as well. And that's something that I'll spend a fair amount of time on as we get into the whole briefing.

So, we are doing the state programs. And very simply, whatever a federal inspector gets, a state inspector gets. They are getting everything that we provide to our

own people.

We will complete implementation for the federal program in FY 2000. Completion of the state programs will be dependent strictly upon funding availability from the states themselves. We have sufficient funding in order to do that, and that is being done under a cost sharing 50/50 basis.

The numbers are on the bottom of the sheets. I'm not doing overheads, because if I do overheads, you'll look at that and not listen to me. So, I'll just walk you through the handouts.

This year new changes that we are doing in the software in addition to where we're implementing, we've moved from HP Desk, which is a non-Y2K compliance system to Outlook and Exchange. We're going almost strictly Microsoft right now. We're moving to Office '97. We've gone out with electronic forms. We've put out over 100 electronic forms, everything from travel vouchers to leave slips for administrative purposes, to noncompliance records for HACCP plants.

So, we're just going through all the forms that we have. There are probably 600 some forms in the agency, and we're just going through in a sequential manner, finding those that are used the most often and replacing them as we can.

We've also continued to place a large emphasis on computer-based training. And I have several of the CDs out there on the side. If anyone is interested is getting some of the CDs, my e-mail address is on the front cover and you can just send me an e-mail message, and I'll send you a copy of the CDs that we do have.

In terms of our implementation and where we stand, this year we are completing four different districts. FY 2000, we'll go into the remaining districts that are listed on the sheet. It's pretty much the northeast and going off to the western states, Boulder and Montana, and up in that area.

Our state schedule, and I have to say that this has been a very pleasant surprise. We got started late on this in terms of getting the budget approvals and getting information out to the states. Of approximately 1,400 state inspectors, we are going to be training and automating just over 575 inspectors this year.

The states that -- we're doing 14 states. If you notice under the listing, "Full Implementation", those six states will be fully implemented. The ones that are listed as "Partial Implementation," we're not able to get sufficient funding this year in order to do their entire state program. So, they're doing part of the state program this year and the remainder in FY 2000. The remaining

states are listed for FY 2000.

We will be discussing with them during the next several months what their situation is and whether they'll be able to participate with us. I expect a vast majority of them will, but not all states.

One thing I will mention in terms of our funding. This is separate funding, and it is also what's called "No Year Funding." So, should a state not be able to participate in FY 2000 because they cannot obtain state funding to match our funds, our funds will not expire at the end of FY 2000, and we will be able to implement them say, in FY 2001 should they get additional money at that point in time.

So, we are moving along quite well in that. We actually had our first training class with the state employees at the end of March. And we're now running four classes per week intermingling state inspectors and federal inspectors. There's no differentiation.

Let me talk about why we're doing the state programs. For one thing, I believe it's cheaper for the agency to do that. Rather than pay 50 percent of 26 programs being developed, we're able to do -- extend out our current program. And they're no development costs because we've already sunk those costs in there. So, that's cheaper.

In addition, if you have 26 implementations, I can guarantee you that some of them will not be successful. That's just the fact of life. So, we feel it's a very low risk implementation. We've been doing this now -- it's our fourth year and feel that we can easily extend out what we're doing to the states.

In terms of a national implementation system, as I said, everything that a federal inspector has, a state inspector will have. The one thing that the state inspectors that will differentiate them is that they may have additional applications from the states. And we will be having a training session this July for IRM professionals from the state programs to come into Washington, and we will provide them training on how to incorporate their programs that they might have into our system. So, it will be a seamless program for their inspectors.

They will have the same e-mail. They will have the same data servers. They will be able to share data. Everything -- for example, with PBIS, federal inspectors will eventually be connecting directly into Washington with a server and entering their data directly into that system. Federal and state will be the same. So, the state inspectors will also be going ahead and entering the results along with the federal inspectors.

The states will be treated pretty much as a

district. So, they will have access to their data in its entirety. If they're a state inspector, they'll have access to the plants that they have responsibility for as would their circuit supervisors or equivalents, but no other state would have access to their data. So, there will be sufficient security in there so that no one is looking at their data except perhaps for some authorized people within the agency to monitor their state programs.

We've been fairly rigid, and I know Lee Jan can attest to that and several other states, in terms of saying there are certain requirements in participating in the program. We have a reasonably small staff and we are successful in implementing one program. We cannot administer 26 different programs, one for each state.

So, we've put limitation on how the program will work. They use our hardware. They use our software. They use our technical support. They attend our training, and they use our telecommunications. That's a hard and fast requirement. I cannot manage 26 programs and deal with all the requirements that might be involved with that. That means, though, that they are exactly like a federal inspector.

In addition to that, as I said, a state can add their own programs, whether it be state forms, whether it be a state that is standardized on Corel and WordPerfect, as

opposed to Microsoft Office, that certainly can be accommodated, in addition to having their own electronic mail system if they wish to have that, as well.

Let me talk about what is on the computer. As I mentioned, electronic mail. That is probably the number one useful activity that the inspectors make of the computers.

The second one is our technical references. We take all of our directives, C.F.R.s, regulations, manuals and place them on the computer. And all the information is indexed so they can simply go in and say, "Let me see all the references that include the word 'residue' that may be within 10 words of the word 'violative.'" And it'll bring up every document and highlight the words for you. Again, a state can add their state directives to that as well.

We have typical office automation tools, word processing, spreadsheets, which they make use of. Computer-based training is really something that we've emphasized quite a bit. I have a list of those at the end of this presentation.

On-line help. Help is there on every application so that they don't have to carry around books and manuals with them. The typical circuit supervisor use to keep a trunkful of regulations. Now, it's on the computer. There's no sense replacing the regulations with a bookful of computer manuals. So, we've got those on the computer as

well.

And various tools and utilities. Everything from a standard virus protection that you would have to a random number of generators. So, you can do certain random sampling.

The type of support that we have for HACCP, if I can take you to the last page. Computer-based training. All but two of the modules that inspectors receive in training on HACCP are being placed into computer-based training modules. The last six sets of those, we have data that I received today is going through final verification. And I expect those will go out for duplication probably within about two weeks.

Electronic technical references. All of the regulations that relate to HACCP as well as decision trees and the HACCP models. Automated noncompliance records. And then what we will be doing also and the most important thing and the timesaving factor for the agency and for the states will be we will be replacing the process of having district offices bill schedules, mailout schedules to inspectors, have inspectors fill out the schedules, return them back to the district office, have them entered in and then not have -- have limited access to the information.

We will have inspectors get their schedules electronically. They will enter in the results. They will

automatically get replicated back to Washington through a central service. From that point, that data will be replicated out to everyone who has the appropriate authority to see the data. So, that inspector's supervisor would see the data. The district manager would see the data. Washington headquarters and then back in the Tech Center in Omaha would get to look at that data. But another circuit supervisor without responsibility would not get to see it.

So, really what you'll be seeing are probably about 5,000 different subsets of the data disbursed throughout the country. And whenever any one inspector enters in information, that information automatically will get replicated throughout the country.

MS. HANIGAN: Question for you.

MR. KUHMERKER: Yes?

MS. HANIGAN: On the relief inspectors that come through the plants where you're talking about access to look at data, would they be permitted to look back through some of the data that pertains to an establishment that they're perhaps going to substitute in for two weeks to be looking at patterns, or how would that work?

MR. KUHMERKER: Every relief inspector has a computer because if they're relieving say, on a patrol assignment, that inspector may have taken the computer home with him, and then they need -- they won't have it available

to them the next day. So, relief inspectors have their computers.

When the relief inspector is given the assignment by essentially our resource management specialist in the district office, they would get what would be called a subscription right, which would allow them at that point in time to dial into the server in Washington and download probably about six months worth of data. So, they could have access to it that way. That would be any time that you have to cover an assignment or you rotate assignments, you would be able to get your data that way.

Let me touch briefly on the computer-based training and then go back open to questions.

I'd just like to very quickly list -- go through and describe the types of training that we have. We break them down into five different categories. Slaughter is one area of training. The poultry 904, red meat 904 D courses, those are slaughter courses that are given down in College Station to veterinarians. They've been moved to computer-based training.

The HACCP CDs. There is an introduction to HACCP, but this is the beginning, what you see here, of all of the HACCP modules that are provided in training for inspectors.

The reference library, that is simply a hodgepodge of miscellaneous applications which just aren't large enough

to fit into any one category.

Our workplace skills, we have "Avoiding Sexual Harassment." We will have other applications in there, as well. For example, I hope to have something say, like AIDS training.

The problem with training a field force is that you go through and you have a major emphasis on providing training. Everyone gets training one year, and the next inspector that gets hired doesn't get trained. So, that's really what we try to cover with this.

And then core skills, which are really the skills on how to use the computer, whether it be Windows 95, Excel, Word, Outlook 98 or electronic forms. Every inspector goes to training for four days, but after that initial training they do not return for training at any point in time.

So, we actually will train people in the field. We successfully moved people from a DOS-based word processor to a Windows-based word processor, now to Office 97. We've moved people from DOS to Windows 95. We've instituted electronic forms. All of those have been done with computer-based training. None of them have required inspectors to go back to College Station for training.

If I can talk quickly about the ones that will be available over the next six months, and several of these are more than imminent. Turkey osteomyelitis, that is actually

in production right now. The remaining ones on those are under development in the slaughter.

Every item under HACCP except for the last two, which are animal production food safety and microbiology, I actually received copies of them yesterday. They're getting final clearance through the Tech Center, and I expect those will go out for duplication this month. At that point in time, they will go out to every inspector.

The reference library, the second volume is currently being reproduced right now. Will go out to the field force.

Employee wellness, we have a beta version of that, so that'll probably go out right after the HACCP CDs.

And the in-plant life computer training is essentially is the -- as you think of cheat sheets, well, this is a computer-based cheat sheet for those applications that are on the computer that are sort of the minor applications. We'll provide them with little refreshers, and will also be used for all of our slaughter line people who will need access to a computer but we're not going to be sending down to training. So, that probably covers a population of about 1,500 to 2,000 people.

All told when we are done, we will have something on the order of 7,000 inspectors, 5,500 federal, 1,400 to 1,500 state inspectors using approximately 5,500 computers.

Every computer configured identically.

MS. GLAVIN: Are there questions or comments or clarifications for Peter?

DR. HURLBERT: Just real quick. This is really neat. The GS-7, the slaughter line people, they have access to the computer in the inspection office and they can, on days when they're not killing, they can sit down and go through some of the computer-based training modules?

MR. KUHMERKER: As of today, I've held very tight to a rule that if you haven't been trained, you don't use the computer. What this training will do, will teach them the very basics of how to use a computer, not how to do a fancy document, but how to just open a document, create a document, save it and print it, how to do a very simple search for electronic references and how to run computer-based training. So, yes, this last item here will train those people who are slaughter line inspectors how to use the computer.

DR. HURLBERT: That's great. And they'll have access to regulations and the whole works?

MR. KUHRMERKER: They'll have access to everything, yes.

DR. HURLBERT: That's super.

MR. KUHRMERKER: The one item they will not have access to is probably electronic mail.

DR. HURLBERT: Thank you.

MS. GLAVIN: Terry?

MR. BURKHARDT: Nothing but compliments from us, from the states. I think this is a very good example of how I would envision the state and federal working together with federal providing a lot of the guidance, the training, and some of the equipment, let's say, and the states administering the programs. So, I think this has worked real well, and my compliments to Peter and his staff. It's a super system.

MS. DEWAAL: Can I ask a question just to follow up on that? Are the states then -- they are applying the exact same standards? Because they're using this system, they're applying the exact same standards as the federal inspectors are, or do you have --

MR. KUHMERKER: If you're referring to inspection standards, that one I'm not going to answer.

MS. GLAVIN: The answer is yes. That has nothing to do with the computer. That's what the law says.

MS. DEWAAL: Right. But in terms -- there's not a separate -- there are not separate forms or anything else on there that the states --

MR. KUHMERKER: The states would have access to every federal form, plus because they would have probably separate administrative forms for the state programs. They

would not use a federal travel voucher. They have the opportunity to enter -- to create their own form if they place that within the system.

MS. DEWAAL: And what's going to happen when the millennium hits?

MR. KUHMERKER: They're all Y2K compliant, I hope.

MS. GLAVIN: Okay. Thank you very much, Peter.

MR. KUHMERKER: Thank you.

MS. GLAVIN: We are up to our third subcommittee report. This is the subcommittee that worked on two issues: the conceptual framework for producing food that is risk free and exemptions from federal inspection. And Carol, I believe you are the reporter on those.

MS. FOREMAN: I am. Mike's passing out our recommendations right now. We have found the way to have the smoothest best subcommittee meeting. All you have to do is reduce your committee membership to the point where you have a chair and a vice-chair to basically agree on everything, and you get to go home early.

I'm just waiting for everybody to have all of this. The committee, you can see our solidarity. Lee and I are even sitting next to each other here.

Let me take the inspection exemptions first. We tried to go back and do a little history in that. Our recommendation is basically that FSIS address the exemptions

within the context of the public health risk assessment and that the agency undertake an assessment of the health risk associated with exemptions, develop performance standards to address them, and then assign inspection resources where the risk is the highest and in a manner that insures compliance.

It's our assumption that that will lead the agency in the direction of investing more resources in raw products regardless of where they're produced, regardless of which exemption -- under which exemption they're being produced.

And Lee, would you like to add to that?

DR. JAN: I don't know that I have anything to add, maybe expand just a little bit. But thinking here now is that the exemptions that we have currently are based on things other than science or public health, at least that's our opinion, and we feel that the risks associated with producing meat are greatest at slaughter.

And the next area that they're at a high risk is when you're handling raw meat. And it doesn't matter whether you do that raw meat in a plant and you can put a mark of inspection on it or if you do in it in a retail store and you can sell it to the customer. The risks associated with that meat are very similar. And so, we feel that risk exemption based on who the producer is or who the customer is probably not very scientific.

And then, as we move to a meat product that's

cooked or ready to eat, it's been -- gone through the process where we have changed the risks, and the risk of that product are now much like the risk of any other food, such as cheese or milk or bread or biscuit or any of those kind of things. The risks are there, but the risks associated with meat are gone.

So, I think we feel like the need to look at where's the risk and then you know, either exempt some from inspection that aren't currently exempted or move them to another category or however you want to do it. But we just kind of left it broad for the agency would look at the risk and then assign resources rather than go through the exemption process.

MS. FOREMAN: And I think it's inherent in this that when the risk assessment comes back and says some of these products that are presently exempt are of a substantial public health risk, that then the agency may have to seek at a minimum, a regulatory change and probably a legislative change. But under those circumstances, there would be a base in public health for seeking those changes.

MS. GLAVIN: Okay. And that seemed to focus on products, but you also seemed to have considered the process exemptions, retail.

MS. FOREMAN: That's my fault. I used the terms interchangeably.

MS. GLAVIN: You were talking about both?

MS. FOREMAN: Yes, absolutely. And probably, we should clarify this by making it product/processes.

MS. GLAVIN: Okay. Comments and discussion from the group as a whole? Caroline?

MS. DEWAAL: I think this is a very good approach to deal with this issue because it really is based on analyzing the risks and putting resources where they're most needed. And I really think the subcommittee did a good job.

MS. FOREMAN: Maybe what we need is two-person subcommittees.

MS. GLAVIN: Nancy?

MS. DONLEY: I agree it's a very logical approach to addressing or finding out if there is a problem where the problems are, and where the largest problems are, I guess. I just want to ask -- it urges -- this document urges FSIS to create basically a risk assessment. Once that is completed, however, do we want to take this a step further and then say, "All right. If the one that's done then there should be the next step, which would be to eliminate some of these exemptions."

MS. FOREMAN: Yes. Obviously, what we went through there was, do the assessment develop performance standards and assign resources? In some cases, that will require a change to bring these products or processes under

the law. And we can certainly add that at this point if you want to. I guess we had thought let's see what the scope of the thing is and then decide what kind of legislative proposal you'd need in order to address it.

MS. DONLEY: I guess I just get concerned that we don't have -- that it just winds up in limbo in somewhere and that there's not a next step. So, I would like to see if we could add that step in.

MS. FOREMAN: Okay. That's fine by me. In fact, the place to put it might reasonably be after the phrase "develop performance standards to address them, then seek legal authority to take action." And finally, to assign. Thank you.

MS. GLAVIN: Dan?

DR. LAFONTAINE: First of all, I agree with the concept or the document. My question I guess is a very broad one. But we're talking about assessment of health risk. So, I guess first a statement. There was a very comprehensive document contract -- I mean, very comprehensive study, contract to the Research Institute Triangle that is available. It's still relatively current. It was done in the early '90s. That very excruciating detail lays out the risk for various types of manipulations of raw products, whether it be slicing, grinding, whatever.

So, I guess I wanted to make sure or hoping that

the agency and the folks around this table would acknowledge and say, "Well, maybe we're a long way down there, and let's put that back on the front burner, that particular study and see if we've got the information we need for answering that question."

MS. GLAVIN: Mike?

MR. MAMMINGA: When you look at risk at what goes on under the retail exemptions and you try to compare that to what we do in the inspected industry, and you look at what is usually customarily done at retail, you find that the only two processes that are specifically held away from the retail industry, which is exempt from inspection is retort canning and slaughter. Those two processes specifically. Otherwise, any other curing, cooking, smoking, stuffing, chopping, grinding, mixing from luau loaf to bologna can be made at retail.

Now, obviously, it can be only sold at retail, to household consumers. But the process goes on to the same friends and neighbors that buy product that bears the mark of inspection.

So, if you look at are current regulations on things like cooked roast beef, cooked beef products in general, the very specific partial quality control programs and controls that are necessary, you can seem to extrapolate from that that these same processes go on in unlimited

quantities at retail stores. And we might even assume that the same risks are there as what comes out of the plants that produce products under inspection. That's the first thing that you have to keep in mind when you're looking at what retail stores do being exempt from inspection.

And then secondly, you have to accept that when these exemptions were written, obviously it is just as you indicated in your first paragraph. It was by keeping the retail stores out of it, you would have less people against the passage of the Wholesome Meat Act and the Poultry Products Inspection Act because they wouldn't be effected by it. They would be exempt from it.

But when you talk about risk and what's produced at retail, if you look at what we're doing now in the federal and state establishments against these processes, which we know have been serious health problems, I would think it would be reasonable to assume that those same set of bad circumstances that cause human health problems would readily exist in the same sorts of facilities that produce these products at retail.

MS. FOREMAN: I absolutely agree with you. One of the things that we had in mind here was to try to put this statement in the form of a public health document, frankly, to get away from the equity issues. We're not going anywhere on the equity issues.

There may be some very substantial data, maybe enough data on which to make some specific recommendations already in the possession of the agency that requires some compilation. I don't think that we're going to make any progress on this issue until such a document exists and says this is how you improve the chances of protecting public health by doing these things. Then, I think you've got something that you can take to the President's Food Safety Council. You can take it to the Congress. You can take it to the public.

MR. MAMMINGA: The issue of what sort of processes can take place outside of the inspection at retail stores, those exemptions should have been looked at all along. And again, I think you've written this in such a way as we're not trying to fix the world today, but we've got to get this on the table so that we have some sort of an idea of what is necessary to do to protect the public health.

MS. FOREMAN: And incidentally, this might be a project that should come -- that the Secretary would want to ask be brought under the aegis of this working group in the President's Food Safety Council that's chaired by Cathy and Jane Haney, because it's clearly got some overlap with the FDA as well as with state agencies.

Until we have a document that says, "These are the public health issues," I don't know how we can advance this.

MS. DEWAAL: I just want to return back and I've stated my strong support for this, but also to one of the recommendations or one of the findings in the underlying seafood statement that was prepared by FSIS dealing with the food code, because simply because these entities aren't being inspected by FSIS or perhaps the state programs doesn't mean they're not being inspected. There are people who have the job in the state government to inspect restaurants and retail outlets.

And I was just wondering if any of our state representatives here could give us a report or maybe all of the state representatives on the adoption of the food code in their states?

MR. BURKHARDT: I can tell you in Wisconsin, we're in the process of adopting it. It's in the legislature right now. We're incorporating it into our statutes.

But the point of inspection at retail in regards to the things we're talking about are two different things. And I'm familiar with the inspection at retail, and it is for mainly sanitary operations. But in the things we're talking about here with the curing and smoking and the usage of nitrites and so forth, those things that are very closely monitored in official establishments, are not looked at in those other establishments. Just because they're inspected doesn't mean it's the same kind of control.

MS. DEWAAL: And are there modifications that need to be made to the food code? I mean, this issue of exemptions is not a new issue. It's been around as long as Rosemary, I think.

MS. FOREMAN: Well, Rosemary hasn't been around 1906.

MS. DEWAAL: Oh, well good. I mean, as long as -- she's been talking about it for a long time.

Anyway, but I'm just wondering there may be more than one way to -- excuse the expression -- "skin a cat". That's an awful expression.

MS. FOREMAN: An inspected cat.

MS. DEWAAL: Inspect a cat. That's better. And you know, are there modifications in the meantime knowing we're going to be working on exemptions for a long time? Is there a way that we could get the state inspection of retail establishments improved? Jim, how's Texas doing on the food code?

DR. DENTON: Well, Texas adopted the food code with some slight modifications.

MS. DEWAAL: Barehand contact perhaps?

DR. DENTON: They had big issue on barehand contact.

MS. DEWAAL: How's the warning label doing down there?

DR. DENTON: Which warning label are you talking about?

MS. DEWAAL: On shellfish and raw products? Consumer advisement?

DR. DENTON: I don't know on shellfish. I don't get into that. I don't know whether that done it or not.

MS. DEWAAL: Okay.

DR. DENTON: But I'll tell you the way that retail is inspected in Texas and I would just think a lot of states. The food code's adopted by the state. And then the actual inspection jurisdiction is pretty much done at the local level, local, city or county health departments, if they have one. And they have to use a code that's at least equal to the state code. So, then that automatically puts the food code in their hands. But they then handle their own budget and staffing and those type issues.

But until about -- I think it's four years ago, in Texas if a county or state didn't have a health or code enforcement organization, then there was no requirement, licensing or otherwise for retail establishments. So, there are a lot of rural areas and we found that a lot of restaurants were moving particularly along the interstates just outside of jurisdictions where they didn't have to by a license and nobody ever looked at them.

So, the legislature finally saw that, "Hey, that's

not right." They passed a law and said that in those areas where a local agency does not provide inspection, the state will. They authorized the program and they funded it through fees. So, the state got in the business of collecting fees. Basically, they didn't have any inspectors because they didn't have any money. So, they started sending out letters and said, "Now, you need to be licensed. Send us the money. We'll send you a license. And then we promise to send you -- provide inspection."

And that goal was -- the ideal goal would have been send an inspector out twice a year. But in reality, they were hoping to do it once a year.

The next legislative cycle, which in Texas is every two years, the legislature said, and this was after two years of collecting fees. The legislature said that, "Whatever your budget was last cycle is the same and you're not going to get an increase."

So, since there were no employees and no money expended, they were spending two years collecting funds so they could start posting positions and hiring positions. All the money they collected they couldn't get -- they couldn't spend.

So, now they have a program that is unfunded. It's mandated, but unfunded. There's a funding mechanism, but because of another cap, they can't get the money. So,

they're struggling with those issues.

So, basically, we have the code adopted. In the local areas that have local jurisdiction, it can be imposed and it gets inspected, but the rural areas I guess they're paying their license fees, but they're not getting the inspection yet. So, hopefully, one day they'll get -- well, they have a few people. They're not completely -- they did get a few people hired, but certainly not near enough to do it.

MS. DEWAAL: So, restaurants in rural Texas are probably uninspected?

DR. DENTON: For the most part.

MS. DEWAAL: Well, that's -- I'm glad you have a good code on the books, but it seems like that's not enough.

DR. DENTON: It's like anybody's issue, a funding issue.

MS. DEWAAL: Dan, anything in South Carolina?

DR. LAFONTAINE: Well, let me -- first of all, South Carolina has a code which is modeled after the food code, but it is not the food code. It was revised and updated three years ago.

There's an important point that hasn't been brought out yet. In addition to what I think Terry said that there are folks that are doing procedures with meat and poultry in the retail arena that are not -- procedures that

are not covered in the food code or are the volumes that are being produced are not your normal retail-type levels, there's another point, and that is this.

That we have these folks doing wholesaling of products that in our wisdom, that is the agency and the folks around this table bought into a final rule that says pathogen reduction HACCP systems. That means salmonella performance standards, and sanitation standard operating procedures that are industry executed and verified. You will have a HACCP system for all of your products.

None of that, to my knowledge, being implemented or applied to that part of the industry that deals with meat and poultry. So, I'm not talking about the equitable issue. I'm talking about food safety issues that we as a group has said are necessary tools to assure safe, wholesome food -- safe, wholesome meat and poultry.

So, my point is there are things that we're requiring the regulated industry that we deal with do that never see the light of day in those that have exemptions.

MS. DEWAAL: How about Ohio?

MR. MAMMINGA: Well, Iowa has adopted the model food code, and I work very closely with the state agency that's in charge of food inspection.

But to give you a couple of practical examples. In the model food code, if you are going to vacuum pack each

cooked ready meat product, you have to have a HACCP plan. And I've seen them because sometimes these places desire to come under our inspection so that they can sell their products outside the arena of the household consumer.

Some of them are quite lengthy and laborious and long, and I wonder who wrote them and who could possibly carry them out, although it isn't my business at that moment to do that, but they do have plans.

Another practical thing and the practical application of HACCP is you know it has to be your plan. It has to be plan specific, and it has to work. So, when you look at plans that were obviously written for some other facility, you wonder about the practical application of them at retail with annual or semiannual oversight.

And another thing is if cure products, cook, smoke and vacuum packaging, you have to be able to demonstrate that you're delivering the goodall (phonetic) nitrite at 120 parts per million. You can't imagine how many retail stores call me because they did not know how to figure in going parts per million of sodium nitrite if you pumped it, massaged it, soaked it, how it delivered. They did not know how to do the mathematical calculation and neither did their counterparts who were trying to enforce it. And it was no blame, in my mind, on any of them.

Nothing worse than give someone a task and not be

able to show them how to do it. And so, we figured parts per million on the phone many, many, many, many times because these places buy a recipe from a company. It says for this much and this much water. Do this with it, and there you go. But they do not know the mathematics of how to figure ingoing parts per million.

So, when you talked about analyzing risk and the level of risk and the level of oversight and how that all plays together, all I have to fall back on is my own experience. And I know that in big business and a lot of times in small business, you have to make sure that these people know what they're doing before you launch them out with a set of rules and regulations that look very good on paper and might be very adequate if they were properly carried out by industry and the government.

And that's where we kind of have a little bit of a concern on those of us in state meat inspection programs because we know how hard it is to teach, instruct and get everybody on both sides of the fence comfortable with knowing what they're supposed to do. And then we wonder about agencies who haven't been trained themselves or industries that haven't been trained themselves, and how does that play into a risk analysis when we say, should retail stores be able to make bologna at all under the current rules, regulations and structures? That's kind of

the crux of it.

MS. DEWAAL: Thank you.

MS. GLAVIN: Other comments or discussion on this one?

I'd just like to make one observation, which I think was reflected in the paper that was given yesterday. And that is that although there are establishments that are exempt from inspection, the meat and poultry is always subject to adulteration and misbranding provisions. The agency has authority all the way to the final consumer over adulteration and misbranding.

So, within the -- one of the things that's worth looking at is within the existing legislation, what kinds of things might be useful such as performance standards. We don't have inspection authority, but we do have authority to assure that that product is not adulterated or misbranded.

MS. FOREMAN: That's a good point. That was in the paper yesterday. In fact, we had a little discussions of it last night.

If you have a paper that starts to -- hate the word "prioritize" -- identify and list in terms of their potential risk, the issues that are here and come back to the Committee, then we'd have a way to say, "Well, we'd sure like you to pursue these. We recommend that you pursue these first because they're -- you're able to do it within

your existing authority. And somewhere down the line, you're going to have to seek additional authority to deal with this other problem."

And we all know we're going to have to deal with retail generally one of these days, because there may be authority do it, but there sure is shooting aren't any resources being assigned to it at the federal level.

MS. GLAVIN: It sounds like at the state and local level, too.

MS. FOREMAN: Well, I think they're complaining about the fact they've got to come along and kind of pick up behind.

MR. MAMMINGA: You know, when you're talking about problems, there is a provision in the Federal Act that allows the Secretary to designate an establishment for federal inspection. Did you know that? There is a provision in there. That if it were a state plant that were a problem or a retail store, you cannot bring to bear through the normal civil or administrative or legal proceedings, the Secretary can designate a place for federal inspection and tell them, "You are a federal establishment."

MS. FOREMAN: I'd forgotten about that.

MR. MAMMINGA: It's in there, isn't it, Carol?

MS. FOREMAN: Yes.

MR. MAMMINGA: That is another tool that as far as I know has never been used in 30 years.

MS. DEWAAL: Well, then here in this provision where we said seek legal authority, shouldn't we just say designate plants for inspection? Just an idea.

MS. FOREMAN: I'd forgotten about that, Mike. That's an interesting thought. Some of these might be big enough for the Secretary to actually think there was a reason if there were an indication that there's a real problem.

MR. MAMMINGA: There you go. I think the Secretary has authority to address that.

MS. GLAVIN: Dan?

DR. LAFONTAINE: I guess, and you don't have the answer now, but what I'm looking for is how does the -- you know, with this recommendation on the table, how does the agency -- what we be your thoughts on how to proceed from here as far as timeline, and can you chew it off? Give me some -- you know, the Committee can throw lots of good things at you, but if you've got a lot of things on your plate, so where does it fit in the pecking order? What's your thoughts?

MS. GLAVIN: We actually have a number of things going on in developmental stages that have a bearing on this. One of them is looking at performance standards for

meat and poultry products after they leave an inspected establishment. One of them is the in-distribution part of the models project, which is a piece of that. And I had another one, and now I've lost it.

Oh, I know. We have a advanced notice of proposed rulemaking we're working on dealing with what we fondly call OCP, other consumer protection issues, issues beyond the food safety, and the possibility of dealing with those more in the post inspected establishment arena then in the inspected establishment arena or doing some of that in that direction, which isn't quite on point here, but also builds into it.

So, those are the things that we have in developmental stage. You know, in terms of timing, I'm not going to be real helpful there. As you said, we've got a lot on our plate. Our first -- our highest priorities are one, completing HACCP implementation. That's absolute first. Two, completing the reg reform that we committed to at the time of HACCP of reducing or hopefully eliminating the command and control regulations and replacing those with performance standards.

As we do that, I think these performance standards in this area a real possibility to move forward with. It's a new area, so it's not something that we can just pull off the shelf and drop into the hopper. It requires a lot of

thinking. It's very helpful that we're getting the benefit of your thinking at this early stage of the kinds of things and the kinds of approaches you would advise us to take. So, I think that's very helpful.

But like I say, it's going to be this year or next year, but the work is ongoing. So, this kind of dialogue is extremely helpful even if we don't see a product at a date certain.

MS. FOREMAN: It might be worthwhile, Maggie, to have somebody take a look at that 1991 document and others that may exist just to see how much of a database there is there. And that might shorten the -- go ahead.

MS. RIGGINS: We do currently have underway a contract with RTR, and they are updating information that we originally received. Some of it will apply to this subject, but it's a -- I guess it's information that we're going to receive over a three-year period in phases. And so, some of it will be applicable to this fiscal year. We're making some headway, but it isn't -- we will not be able to piece it all together until we have adequate information to do a risk assessment.

MS. FOREMAN: One of the things we discussed last night but didn't get included in this document was that you've got another year and a half before HACCP is implemented in all of the federally inspected plants or even

-- I'm sorry. You've got about seven months before it starts to be implemented in that last group. I was thinking to the end of that first year of getting all of them under it.

I think it's hard to get the agency to think about great new chunks that ought to be brought under federal inspection until that's done. But where there are serious public health issues, seems to me that ought to get moved up on the list of priorities for once all the plants are under HACCP. Then, we ought to be going at those that create the risk -- high risk, get them there.

MS. GLAVIN: I would say that looking at the safety of product after it leaves an inspected establishment is very high on the priority list. That that's something that we are thinking real hard about.

MS. FOREMAN: So, and get your retail?

MS. GLAVIN: Pardon?

MS. FOREMAN: That would begin to go at the retail problems?

MS. GLAVIN: Well, it would begin to go at how meat and poultry products are handled and stored et cetera throughout the chain. That's a good question. I'm not sure how it impacts on the processing that goes on at retail. Little bit different. But again, that's part of handling a product after it leaves inspection. So, yes.

MS. FOREMAN: One of the things is that we've tried to stop thinking about this as an equity issue and start thinking about as a health issue. We need you to stop thinking of it as an equity issue and start thinking of it as a health issue, too.

MS. GLAVIN: I think we are. And thinking of what are existing legal authorities and how -- you know, Phil has done a very interesting thinking through of what the mark of inspection means and product continuing its eligibility to bear the mark of inspection and how that plays into things. So, that could get to -- if we set performance standards, clearly we would want those performance standards to be compatible with the food code when you get to retail. I mean, that would make -- seem to make a lot of sense. Obviously --

MS. FOREMAN: I hope it'll upgrade the food code a little bit.

MS. GLAVIN: Caroline?

MS. DEWAAL: I sat through a number of appropriations hearings this year where Catherine Woteki was asked very tough questions from members of Congress who seem to be very much against the concept of your inspectors going into retail stores.

MS. GLAVIN: Well, I think there's a lot of misunderstanding about what we are doing. And if you'll

indulge for me a minute, I'll give you a quick overview.

We've got -- first of all, as part of our models project, we've got a piece which is going to look at the use of our in-plant inspectors in the in-distribution mode. That is a very small piece because basically what we're going to have maybe 10 individuals in three different locations, because basically what we're looking at is the logistics of having employees who can move from in-plant to in-distribution.

They will be doing tasks that traditionally the agency has done. Tasks that have traditionally been done by compliance officers. And so, they will be looking at product in warehouses, for example. They will be doing plant compliance visits in warehouses and other locations. They will be doing recall effectiveness checks. They will be following up on consumer complaints. They will potentially be picking up samples at retail under our sampling programs.

But essentially, that is a very small -- let's look and see if it works, if we can manage employees in that way. Our longer term goal is to determine the need for and develop standards for product, for product retaining the mark of inspection. I mean, I can't imagine that we are ever going to -- first of all, we don't inspect warehouses. We don't inspect retail. We look at product, our product

in those situations.

Ideally, in my mind, the people who are going in and doing inspections of retail stores, that's really the resource that ought to be also looking at meat and poultry product in retail stores. That would be ideal.

And so, how the intersection between our employees looking at meat and poultry product and local and state employees who have jurisdiction over those entities, how that intersects is part of what we need to develop. I mean, I think the fear that was being expressed that there's going to be thousands of federal inspectors running around Giant Food, we might like to see that, but I don't think it's too realistic.

MS. DEWAAL: Well, I would recommend that you use people like Terry and Lee and Dan and Mike to educate members of Congress about perhaps the need for some of your inspectors to do that, because they seem to be under the impression that this would be a very bad idea. And I assume they're getting that from some of your sister agencies at state government. So, perhaps some education in the other direction would be helpful.

MS. RIGGINS: Another piece I should mention that contributes to the information that we have in this area is that we recently signed an MOU with FDA to exchange information on primarily conditions that we find in plants

and FDA finds in plants as we individually go about our business. As a part of that, there is a working group that is looking at what kinds of activities we can coordinate more efficiently than we are currently doing them now.

And we intend once we -- well, the way that we're going to go about is to do some case studies of cases of enforcement actions that have actually taken place, what we did in those instances, what FDA's role was in those instances, and then to learn from those.

And then we intend to work with states where we find that there were areas where we could have done a better job of communicating with the state to get the information to the state so that they could carry out their role and the agencies could have done a better job of communicating with each other to get the information, so that we can begin to build the relationships at the working level that need to happen in order to make this seamless system really work.

I mean, we talk at this level, but what happens on the ground makes a big difference. And if I know who I am supposed to talk to in the state and I know who I'm supposed to talk to at FDA, I will do a much better job when I'm actually under -- you know, experiencing a problem.

So, we've begun and we're getting off to a good start. So, that will also help us to do a better job in this area, too.

MS. FOREMAN: Are you -- I'm sorry. I was going to get into the next --

MS. GLAVIN: Okay. I think Terry had one more.

MR. BURKHARDT: Just a comment on this issue. I think what we're trying to say is that we would agree that we've identified some risks at the retail level that could be improved to help improve food safety.

And we're talking about seamless inspection and farm to table. There is an area that needs to be improved. The suggestion was to remove the exemption to get at it, but there may be other ways through more coordinated efforts with other agencies that we can accomplish the same thing, but there definitely is some improvement in that area that's needed from a public health standpoint.

MS. GLAVIN: Okay. Carol, you're ready to move on?

MS. FOREMAN: Yes. The Committee recommendations on the conceptual framework for risk-free meat, poultry and egg products. The staff gave us a document that invited comments on a long number of questions. And frankly, we didn't think that we were ready to begin that process right now. We think that the staff has to begin working through the various goals and objectives that it has listed.

But I think I made myself clear yesterday. I think this is a terrific idea. And so, we put together a

little recommendation here that commends the agency for taking this approach to addressing its mission and states our agreement that it's appropriate to assess what would be necessary to achieve complete safety.

Committee recognizes that as the agency's strategic plan and annual goals are developed, the state of technology law and budget will have an impact on the goal. But the best way to envision the system we desire is to begin with a statement of the most desirable goal and the steps needed to achieve it.

We're very eager to continue to work with the staff as they begin to develop the elements of this system.

Lee, do you want to --

MS. GLAVIN: I don't know if I'm doing something that Cathy did yesterday. I think it's also real important that you all stay tuned to what the President's Council on Food Safety Strategic Planning Group is doing.

MS. FOREMAN: It will make me happy if it is exactly the same thing as the conceptual framework here. Now, frankly, I cannot imagine the United States Food and Drug Administration coming up with a conceptual framework that says our goal is a risk-free food system because that's not the way they do business.

And I would urge -- you know, what I'd urge here individually is that Cathy should convert Jane Haney and

should convert your sister institution.

MS. GLAVIN: Okay. Dan, are you ready to move on? I sort of missed you on the last round.

DR. LAFONTAINE: Yes. I'd like to go back for a moment to the previous topic. And here's my thought or idea.

Recognizing the FSIS priorities on this whole issue, I recognize that and acknowledge that. However, I'm bound and determined not to let this thing fade in the sunset. And what I'm suggesting or asking is that possibly at the next meeting, it not be a topic for subcommittee deliberations, but that FSIS provide us a concise briefing on all of the things that you've got postplant. You alluded to three of them. I heard a new one from Judy on the RTI being looked at and an extension, and they're looking at three things in a three-year plan.

So, I don't want to grandstand, but we're your advisory committee, so we get bits and pieces in a coordinated briefing on what's out there and where you're at, would be much appreciated.

MS. RIGGINS: Yes, we can do that.

MS. DEWAAL: Could you also cover, though, the states? Because my sense is that you talked about what FDA is doing in the plants and what you're doing in the plants. But Dan, my sense is that a lot of states have a similar

bifurcated system where you guys may be looking at the meat and poultry plants, your state inspected plants, but you got someone else looking at retail stores and other entities.

And I think that would be -- you know, as we look at how to improve this system, it would help me to know what the whole system looks like, both at the federal and at the state level.

DR. LAFONTAINE: Well, I'm not against your recommendation. That may be more than they can chew off as far as --

MS. GLAVIN: At one point a few years ago AFDA was going to try and come up with a compendium, weren't they?

DR. LAFONTAINE: Who's that?

MS. GLAVIN: AFDA.

MS. DEWAAL: Association of Food and Drug.

MS. GLAVIN: Of what their responsibilities were state by state. And if they have done so and we can get our hands on it, we'd share it. It would be an enormous undertaking to put that together on our own.

MS. RIGGINS: We do have some information because for recalls, we do have a list of all of the functions within the states so that when we send our recall notifications, we know that in certain states, we send it to public health and in certain states, we send it to agriculture, and sometimes we send it to both.

MS. GLAVIN: And whatever we do, we get a complaint from somebody that didn't get it, so our list isn't all that good.

MS. RIGGINS: But to the extent that we have that information, we can certainly try to give you as much as we have.

MS. DEWAAL: That would be good.

MS. RIGGINS: It won't be 100 percent accurate but we'll give you what we have.

MS. DEWAAL: But to give us a vision that here's the system working at the federal level and then we've got to coordinate with these other agencies at the state level, and this is what they're supposed to be doing.

DR. LAFONTAINE: There's one other one that I want to make sure is -- or I suggest be included. And that is the whole business of the transportation issue that's -- you know, advance notice of rulemaking. It's in the works, work in progress and where are we at, and where are we going?

MS. RIGGINS: We can do that.

MS. GLAVIN: Okay. Carol, are you done?

MS. FOREMAN: I sure am. I think we may want to discuss this, but that's --

MS. GLAVIN: I think Nancy still has an issue.

MS. DONLEY: Actually, I'd just like a clarification because when we were handed the conceptual

framework for risk-free meat, poultry and egg products, I wrote a note on it "provide comments back by the end of the month."

I just want to find out what's happening with -- you know, are we submitting it to the Committee? Maybe it's a procedural questions.

MS. GLAVIN: Yes. If you could get those into Mike. We are in the process of -- we had a strategic plan that runs through I think 2001. It might be just 2000. And so, we're in the process of doing a new strategic plan which would run through 2005, 2006. And this is, you know, sort of the conceptual framework that we're starting with. So, your comments on it would be very helpful.

We had hoped to before this meeting do a phone conference on it, but getting the Committee named, et cetera, it took a little longer than we had anticipated. So, we weren't able to do that. So, yes, we would appreciate any further comments, suggestions, what have you that you might, but it is in that context that we have to update our strategic plan under the GPRA, which I'm not going to be able to -- where's Charlie? He was here.

Ken, what's GPRA stand for? Government Performance and Results Act. Thank you.

MS. RIGGINS: Our next step -- we've done the broad conceptual framework. Our next is to do the next

layer of the plan, which is to describe how those goals apply to meet poultry and egg products. And so, we are going to be undergoing that in the next few weeks. And then each area within FSIS, each deputy's area would do operational plans that are in since with those.

MS. DONLEY: This is such a -- I mean, it's an absolutely wonderful out of the box type of thinking by the agency. Are you going to do the same thing, and I don't know with your strategic plan if you even tie budget into --

MS. RIGGINS: Oh, yes --

MS. DONLEY: -- the planning. You do?

MS. RIGGINS: Yes.

MS. DONLEY: I hope you won't or maybe you have to be constrained by current budget numbers, but I would -- what would it actually cost to achieve a risk-free meat and poultry and egg society?

MS. GLAVIN: Since we don't know how to do it, we don't know what it would cost. But -- and this is certainly, you know, a result of having the person we have as administrator. I mean, he very much believes in getting way outside the box. And he calls it visioning the future. So, you envision the future that you want and then you -- instead of planning from today forward, which is very hard to do because you don't know -- you know, well, there's going to be budget constraints, and there's going to be

technological constraints, et cetera, that you go to the future and work back.

And it's kind of fun to do, actually. So, at some point because our budget must be based on our GPRA plan, at some point, you have to start getting down to some very specific -- these are the steps we're going to take, but you're taking those steps with an eye to ultimately getting to that vision of the future.

MS. HANIGAN: I have a question, please. The President's Council on Food Safety, has this risk-free concept been presented to them? And what was their response? And do we have a copy of it in our packet?

MS. GLAVIN: Of what?

MS. HANIGAN: The whole concept of risk-free food, has it been presented yet to the President's --

MS. GLAVIN: Well, the group that is working on strategic planning for the President's Council has just begun its work. It has seen this, yes. But it's very much in the beginning stages, still sort of organizing itself and you know, coming up with very broad objectives and moving from there. So, they don't have a response in that sense.

MS. HANIGAN: So, there's no documentation from them?

MS. GLAVIN: Not yet, no. Okay. Can we move on?

DR. DENTON: I have -- I think it's a comment and

a question. First, I think that the concept of a risk-free meat, poultry and egg product universe is a very, very noble goal. Philosophically, I think I can line up with that as a goal. But I have a question with regard to the perception that we're placing in front of the consuming product with regard to the use of the term "risk-free". Are we setting expectations that are so dramatic and so high that we are destined to fail from the outset?

MS. GLAVIN: I don't know. What do people think?

MS. FOREMAN: My view is that if we set our goals high and fail, that's better than setting them low and achieving them. Why not dream the future? You go along and you say to people, "This is where we want to go. Nope, we haven't gotten there yet." Sometimes the technology gets in the way. Sometimes the budget gets in the way. Sometimes human orneriness gets in the way, but we know where we want to go and we're trying to get there.

I think the public's very smart. I think they understand that, Jim. I do. I think you say to them, "We don't have all the answers, but we know where we want to go. And as we get the answers, we'll move in that direction, or we'll look for the answers that'll help us move in that direction."

I think government has been too slow to set noble goals. Think about the period -- you're old enough. Think

about the period between the end of World War II and 1952. Look at the things that this country did. Started the Federal Highway System, started school lunch program, started the Federal Housing program, did thousands -- hundreds of things that we're still living with today because built kind of on a domestic Marshall Plan notion, because we had the enthusiasm, and we knew that we needed to take the resources that we built up during World War II and put them to domestic use.

So, we had creativity and we have enthusiasm, and we had planned the energy to move ahead. I'd like to see us start a new century with that kind of energy and enthusiasm.

And you know, there are a lot of problems in the world we can't solve. We can come a lot closer to solving this one than we have.

DR. DENTON: I don't disagree with the fact that we can come a lot closer to solving this. I think that's the reason why we're all here is because we believe we can. I just think in terms of how our society is today with regard to how they accept risk. I would love to have one part of my life, doesn't matter what it is, that would be risk free.

As I look at it in problematic terms, I don't think it's there in any part of how we live. I think that if we can frame this in the context of a goal, a philosophy,

then I think we're absolutely on solid ground. But we have a tendency to want to depend on our government to provide things that we, as government, have indicated that we can provide for. And the statement that we can or that we desire to provide a risk-free food supply with regard to meat, poultry and eggs almost implies that that is going to be something that we can do.

MS. FOREMAN: Well, I just want -- let me -- I think one of the brilliant parts about this conceptual framework is that it assumes and states several times that it is seamless, and that it's not just the Federal Government, but it includes everything all the way down to me when I go home and cook for myself. And that's what I think -- that's how you want to think. You want to think of something where we all play a role in making this happen.

DR. DENTON: I think that's how we have to frame it, yes.

MS. FOREMAN: Well, and the paper does.

DR. DENTON: Right.

MS. FOREMAN: The paper does. It says that.

DR. DENTON: Okay.

MS. GLAVIN: Caroline, you've been trying to get in for awhile.

MS. DEWAAL: Thank you. I want to approach answering you in a little bit different way and basically

say, like it or not, consumers think their food is pretty much risk-free. They really believe that to the point where a whole job in our consumer education is to teach them where the risks are.

But people -- you know, and when I think about this, I look at the recall data from an outbreak from Schwann's ice cream where tens of thousands of people got sick from salmonella. And they had very exact evidence on who had received the contaminated products. And they got information to all those consumers, and consumers who were told specifically they had contaminated product and continued to eat it.

Because the hurdle -- the hurdle is so high to get consumers to believe that the food is going to make them sick, that it's just very hard to get this message through. People think that if they are sold food in a restaurant, if they get food at a grocery store and bring it home and put it in their refrigerator, that it's safe. That it's safe to serve their family because they couldn't eat otherwise.

So, like it or not, people already think that food is pretty much risk-free. And we have a huge job of consumer education to help them understand their role in accomplishing that objective. But I think getting the Government up to speed so they understand that this is a job that's their responsibility.

And I reminded of the FSIS' response following the Jack-in-the-Box outbreak where I went to a public meeting where a representative of FSIS said, "That meat met our Federal guidelines." It was essentially fully -- it fully met our requirements.

Well, gosh, their requirements weren't good enough. I mean, when that outbreak occurred, they clearly did not have requirements to consider and contemplated the risk of bacteria in those products. And they're moving forward, but I think that this conceptual framework is an important step and a recognition that consumers are ahead of the Government here and the Government is doing the right thing in trying to catch up.

MS. FOREMAN: I had a small question following on Katie's. It's my understanding that FSIS responded last year to the NAS document that you wrote a letter over to the National Academy of Sciences after that document came out. Is that right?

MS. GLAVIN: No. The President's Food Safety Council did a response.

MS. FOREMAN: But was there not an earlier response between the time that the NAS report was issued and the Food Safety Council was set up in which the agency responded to some of the recommendations in the -- if there is, I'd like to have a copy of it. And if there wasn't,

okay.

MS. GLAVIN: I don't remember that there was. Obviously, we were developing things for the Council. I don't remember that we developed them, but I'll make sure that's right. If we did, it's obviously available. But I think we just did pieces to go into the Council's response. That's my memory.

MS. FOREMAN: Well, think back to the time between the point where the NAS report was issued and the Council was set up.

MS. GLAVIN: Okay.

MS. FOREMAN: There were several months there.

MS. RIGGINS: I know that Cathy Woteki gave several speeches where she addressed concerns that she had about the NAS report, but I don't remember the agency actually writing any --

MS. GLAVIN: It's easy enough to find out.

MS. FOREMAN: I'd like the most detailed explication of your reaction to that report that you have. If it's Cathy's speech, that's fine.

MS. GLAVIN: Okay.

MS. FOREMAN: Thanks.

MS. GLAVIN: Let me -- Nancy?

MS. DONLEY: When I first got involved in the whole food safety issue, I had first taken a lot of the only

term I can use frankly is I took a lot of abuse by -- direct and implied abuse by industry, by Government that I had screwed up somehow that my son was dead because of something that I did wrong because the food -- that there is no such thing as a hundred percent guarantee, and "You consumers are ridiculous in even thinking of such a thing."

I think -- and my response back was, "You know what? There is no such thing as a hundred percent guarantee, but we can and should be doing as an industry as a government, as a society, a lot more than we are doing now."

I think if the agency is going to put in quotes, the meat, poultry and eggs you eat are risk free, that the Government better be ready to deliver. And it can't be it's risk-free if you cook it right, if the restaurant and food handlers cook it right and deliver it to your family right. You can't -- you can educate and educate and educate and until you change behavior, people are going to get sick and die.

I would like nothing, nothing, nothing, nothing better. It's my wish before I die that this could be -- that we could all say this and really mean it and deliver, but we can't. And I am scared to death that Staph is going to grow and grow and grow and grow and grow to millions and millions and millions of people because they're going to buy

this and they're going to get sick and they're going to die.

I think this is has to be given a lot of serious, serious, serious consideration. And that because at the bottom line, and it is not acceptable that if it's still going to be dependent on the consumers that if they're assuming that everything else has been done and it's risk-free when they receive it and that they have to assume all responsibility and liability, that's not acceptable.

MS. GLAVIN: Okay. Thank you. As Carol pointed out in the document, it definitely -- and I understand your point very well, and it's very nicely made. That this is not about blaming the consumer, but the consumer does have a responsibility. And one of the agency's responsibilities, one of the responsibilities that we see in aiming for the food you eat is risk-free, is making sure that consumers have the knowledge and the ability to do the right thing.

And you know, maybe that's time temperature indicators on product. Maybe it's -- I don't know. Maybe it's embedded chips that show you when your hamburger is cooked the right away. I mean, you know, who knows what it is? But it has -- it really -- in coming with this, and believe me, this went through a lot -- it sounds so sample, but it went through a lot of versions.

The reason it's stated the food you eat is because it's not the food you buy, because that's not good enough.

You could buy an absolutely sterile piece of product, send it home with your teenager who doesn't have a clue what to do with it, and you know, that teenager gets sick. So, it's got to be all the way to where you eat it.

MS. DONLEY: And I'll save my -- I will definitely submit comments on this, but it's just again, is that's a huge -- that's a huge task. And goals -- when I went to school, I was taught that goals should be measurable and achievable. And you know, I could go into my neighborhood grocery store and I will hear four or five different languages being spoken in the parking lot. Unless we have an educational campaign that can reach to each and every segment of society and then the illiterate also, we just -- it's just -- that would be the most expensive campaign possible to produce safe food, is to try to put it all in the hands of the consumers and educate the consumers.

MS. GLAVIN: Okay. Is it all right if we move on? We're running over and we have added a briefing by yours truly on the models project.

Okay. I will do it before the break, because that'll keep it short because I know everybody wants a break.

We started the model -- first of all, the models project is a project that we've undertaken to explore better ways to inspect the slaughter of healthy young animals in a

HACCP environment. We recognize that plants are implementing HACCP and that to some extent on the slaughter line, FSIS decides what the critical control points are and controls them under our current inspection system.

So, we wanted to look at how we could in a HACCP environment improve that. And we're looking initially at healthy young animals because one, they have probably the lowest level of risk. Two, they are the largest portion of what is slaughtered in this country. And three, because they are uniform, we felt we could come up with systems that dealt with them and covered a large range of products. So, we're not at all dealing here with anything other than healthy young animals and their slaughter.

We started this back in the summer of 1997. We did a Federal Register Notice which gave a general description of what it was we were trying to achieve. We sought volunteer plants to participate in this project. And we also did a paper on diseases and conditions that are seen in these animals and made a cut at which of those diseases and conditions had food safety implications and which had other consumer protection implications when sometimes they were both. So, we did a first cut at that for comment.

We had a meeting that summer, I believe it was in July, to discuss all of this, to talk about what our plans were. Following that, in the summer of 1998, we had a

second meeting, because at this point we had a number of volunteer plants, and we wanted to revisit with the public where we were. Our thinking had evolved. We had gotten comments on the earlier documents, and we had a plan of how to proceed. So, we laid that out during the 1998 summer meeting. I think that was also July.

Shortly after that meeting in the fall, we began baseline data collection in the five volunteer plants. And that was two pork, one turkey and two broiler plants that volunteered. These are all HACCP plants, by the way. That's one of the requirements for being in the models.

We began baseline data collection in the fall. And that included micro data, that is salmonella and generic e-coli data, and it also included organoleptic data. We had a contractor, the infamous RTI Institute, we keep coming back to them, collect the data for us so that it would be arms-length. It also enables the data to be blinded when it comes to us blinded by source.

And they went into plants. They gathered e-coli data and salmonella data. And they also hired for each plant a veterinarian who was familiar with meat and poultry inspection who sampled carcasses that had been passed by our inspectors. They also actually looked at condemned carcasses.

And the idea was to get a baseline of what was

achieved both organoleptically and microbiologically by our current inspection system. So, it was to take our current inspection system and say, "This is what we achieved."

In November of 1998, we had a third meeting and reviewed the baseline data. Went over in a great deal of detail how the data was collected and then what we had found. At that point, we were essentially ready to begin the actual models phase. And in the models phase, it is our intention to make changes in how we inspect the slaughter of those animals. To have plants -- the volunteer plants, first of all, will include food safety concerns on the slaughter line in their HACCP plant, which they don't have right now.

Secondly, they will have what we're calling a process control plan, which will address the other concerns, the other consumer protection concerns that would not be in a HACCP plan because they're not food safety. They would develop these plans and would have the charge and the ability to determine how best to meet at least the achievements that were met during the baseline.

In other words, how best to meet all of the regulatory requirements which remain in place and how best to meet or exceed the micro levels that were come up with during the baseline and the organoleptic inspection levels that were achieved during the baseline. That is our

intention during the actual models phase.

During January and February, we met with our bargaining unit to bargain on implementation and impact of these changes since obviously, we're changing the inspectors job or changing grades. We're doing a number of things. And so, the bargaining unit has an interest in this.

We had two sessions of bargaining. And we have reached impasse with our bargaining unit. The issue is before -- and I probably have the wrong -- what I will call the Federal Impasse's Panel. It has a nice fancy name and I apologize. I don't have it down straight.

That panel actually will be hearing this case I believe it's the week after next. It might be next week, but I think it's the week after next.

We expect that -- and this is in their hands now, but we would expect to have a decision some time this summer from them. So, at which point, assuming that our position more or less prevails before the panel, that we would be in a position to begin announcing jobs in these model locations, these five locations, filling those jobs and training our employees in what we would have -- the ones who are selected in what we would have them do. So, that means that we're not going to actually get into actual models most likely until some time in the fall of next year.

In the meantime, we now have an additional roughly

15 plants that have volunteered. And we are beginning the process of doing baseline data in those plants since that does not have a bargaining unit impact, the collection of the baseline. We don't have to go to impact bargaining there. So, we're moving ahead to gather baseline data in roughly 15 additional plants.

So, that's the status of the project. I know that's a real quick overview, so let me just see who I've confused how badly.

DR. LAFONTAINE: I have to be first on this.

MS. GLAVIN: Okay.

DR. LAFONTAINE: My question is -- my understanding is that the original contractual arrangement with RTI expired in the meantime.

MS. GLAVIN: That's right.

DR. LAFONTAINE: And there was a bidding process, a request for proposal, whatever the right word is.

MS. GLAVIN: Right.

DR. LAFONTAINE: Out on the street.

MS. GLAVIN: Right. And I believe we -- have we completed that contracting process? We have completed that contracting process.

DR. LAFONTAINE: Has it been announced yet?

MS. GLAVIN: I don't know, but --

MS. RIGGINS: I don't believe it's been announced,

but --

MS. GLAVIN: But we have selected a contractor and we'll be -- you know, so, we're set on that.

DR. LAFONTAINE: Okay. And that contract, whoever it is, would be the conduit for both the additional baseline and if you get to go ahead --

MS. GLAVIN: Yes, yes.

DR. LAFONTAINE: You have the ability to go ahead.

MS. GLAVIN: The contract provides for both baseline work and models work.

Yes, Collette?

MS. KASTER: Just to clarify, did you mean fall of 1999 or fall of 2000?

MS. GLAVIN: No, fall of 1999. Caroline?

MS. DEWAAL: Just a question for clarification. You have statutory authority to engage in experiments. Is it true, though, that -- it sounds like in every plant where an inspector's job is impacted, you have to go to the bargaining unit. I mean --

MS. GLAVIN: That's -- well, in addition to the meat and poultry laws, we also are required to obey other laws of the land, which includes the Federal labor laws. And under the Federal labor laws, we have a contract with our organized employees in plants, our inspection employees in plants. And there are certain processes that we are

required by law to follow. And that's what we're doing. We're working through that process. And it at times appears very tedious, but it's a very normal process that one goes through.

MS. DEWAAL: If you were doing an experiment in just one plant, would you have to go to the bargaining unit?

MS. GLAVIN: Yes.

MS. DEWAAL: So, anytime one inspector's job is effected, you have to go through this?

MS. GLAVIN: Well, I'm not a labor relations specialist, but I think in general, the answer is yes, if we were changing the terms and conditions of employment.

MS. DEWAAL: For one person?

MS. GLAVIN: I don't know the answer to that. That wouldn't do us much good in terms of getting data.

DR. LAFONTAINE: There's a second -- well, correct me if I'm wrong. I believe there's a second related labor issue. And that is the suit that this concept violates their interpretation of the law that says that Government employees have to do the inspection. Is that entering into this picture as far as delaying it?

MS. GLAVIN: Thank you for bringing that up. There is also -- the AFGE has filed suit against the Department on a number of issues, which include what you just said. That this particular design, the design of this

product would not meet the requirements of the Meat and Poultry Act for the inspection of animals at slaughter.

That suit is in district court in the District of Columbia. We had oral arguments back maybe a month and a half ago. And there were new filings, I believe, this week.

MS. RIGGINS: Yesterday.

MS. GLAVIN: Yesterday? So, that's sort of moving along. One of the legal issues in that suit is rightness. And so, until we actually start a model, is the case right? So, you know, our conjecture is that's why the judge is not moving. That he could rule on rightness, or he could just wait until it was right.

Yes?

DR. HURLBERT: Real quick because I know everybody wants to go on break. I think the model project is excellent. I think the way you've gone about doing it with the baselines and the whole works has been good.

And to kind of piggyback on the carcass by carcass, it's my understanding that what you're impasse group is not related to the lawsuit itself, but it's related to the inspector jobs, the inspector --

MS. GLAVIN: Yes, yes. One is -- the lawsuit has to do with whether we are properly carrying our responsibilities under the law. The other one has to do with our rights and obligations and the union's rights and

obligations under the contract we have with them in terms of how they work, what work we given them, how we assign it, how they take breaks, what the grade levels are, et cetera, et cetera.

DR. HURLBERT: But the union has negotiated to some point on this?

MS. GLAVIN: On the impact?

DR. HURLBERT: Yes.

MS. GLAVIN: Yes. We have two negotiating sessions. I think they were two weeks each, or I could be wrong on that, in the late January, February period. And we reached impasse. We had a mediator who declared us to be at impasse. And we went jointly to the authority and asked for them to address it. And that's what's going on now. And as I said, I think it's the week after next that we're scheduled for oral hearings -- three days of oral hearings on that. But that's the labor issue.

But it doesn't really have anything to do with whether this is legal or not.

DR. HURLBERT: Has the agency made the decision that once the labor issues are resolved, then they will not wait for the court case?

MS. GLAVIN: Yes. We'll move forward. Make it right or whatever they -- yes.

Okay. People want to -- see, I was smart. I got

out right before the break. Break time.

Can we be back at 3:15?

(Whereupon, a recess was taken.)

MS. GLAVIN: Okay. Our next agenda item is to go over the issues for the Committee for the next two years. And let me just talk a little bit about what it is we're doing here.

We're looking for a list of issues in some sort of rough priority order that the Committee believes they would like to make a contribution on some time in the next two years. The way that is used is once we get that, at the end of each meeting, we have a discussion about the plans for the next meeting. We look at the list that is produced by this process and decide if there are things on that that we want to address at the next meeting.

Sometimes -- you know, obviously, over the course of two years, things change. Our sense of what's real important right now might not be the same six months or a year from now. So, things come and go.

And then, the agency in putting together an agenda considers the Committee's discussion at the prior meeting. It considers this list, and it considers issues that the agency wants input on even if it isn't on the list.

And so, that's what we're looking for now. So, you know, this is an important list because to some extent

it sets the agenda for the next two years. On the other hand, I don't think it warrants agonizing over because a lot of things will happen over the next two years to add or subtract from this list. But it will give us a sense of what we've got.

All of the Committee members, you know, we came up with a list of things. And all of the Committee members ranked their first, second, third, fourth and fifth priority including adding things that they could rank. And we have with us Nelson Clinche who's going to tell you what he did with these, so that what he gave you makes some sense in terms of how he came up with these two lists of ranks.

Nelson?

MR. CLINCHE: Thank you. We looked at the information that you ranked on your tally sheets several different ways. The two methods that we have presented on single sheets provide the most separation between some of the issues as far as giving them a ranking, which is why we chose them. I thought I'd just briefly go through what the two different methods are that are presented here.

The top one labeled, "Weighting All Issues," gave a weight to each member's response based on whether they're ranked at a one, two, three, four or five. For example, on the tally sheets that I believe were passed out to all of you, the top one on one of the pages says "HACCP Inspection

Models." And under the number five, it's says two. Two people ranked it as a five. One person ranked it as a four. One person ranked it as a two.

Since two people ranked it as a five, 10 points were allotted from there. Four points were allotted from the one person that ranked it a four, and one -- and two points from the person that ranked it a two, for a total of 16.

All of the issues were tallied up this way. And looking at this other sheet, you can see that the HACCP inspection models ranked third out of all the issues with 16 points, doing it that way.

The bottom method was similar, except the only columns we looked at were the number of people that ranked it either a five or a four. Using the same example, two times five is four, plus one times four is four, giving a total of 14. And again, all of the issues were ranked that way. And you can see the 14 ranks it second among all the issues that way.

On the right-hand side of that page, the points for each issue are listed. And in the bottom set of rankings, the number in parentheses is the ranking from the method up above.

One minor typo in the top one. The fourth and fifth issues had the same number of points. So, it is

really not a number four and number five. They're both number four, essentially.

Any questions?

MS. DEWAAL: I have a question for clarification. I just like checked off HACCP Inspection Models because you had said they're already on the agenda. So, I mean, that's really not a new issue. It would have frankly been my first choice -- my number five because it's so vital to --

MS. GLAVIN: Well, we'll have to eliminate all Caroline's votes. She apparently did it wrong.

MS. DEWAAL: But I mean, isn't that a given? I mean, isn't the issue really not that one, but -- I just --

MS. GLAVIN: You just wanted an extra vote.

MS. DEWAAL: You know, we're going to do that.

MS. GLAVIN: Okay. Well, is it a general consensus that the HACCP-based inspection models is a given on our list? Okay. We've got one.

MS. DEWAAL: Thank you.

MS. GLAVIN: Other questions?

MS. HANIGAN: I have one other question on agenda, if you will. When are we going to decide, and maybe I'm ahead of it here, but when are we going to decide if based on what the micro committee brings back to us on campylobacter one, if we're having a teleconference or two, if we just stick it on the November agenda? Because based

on this, it's nowhere.

MS. GLAVIN: Good question. Well, and that's one of the reasons for having a second agenda item, which is what are we going to next meeting?

I spoke to Kaye before she left and she wasn't able to predict whether the Committee would actually get us something as a result of their meeting in the next couple of weeks, or whether it would take them longer than that. So, once she comes back from that meeting, we'll have to get back in touch with you and let you know either we've got something, here it is. And in that case, maybe we want to schedule a teleconference on it. Or they anticipate getting us something by -- okay. But it's hard to predict at this point.

MS. HANIGAN: Can I ask you one more question on that? So, has Micro been working on the campy issue for six months, since November, or is the May meeting the first go at it?

MS. GLAVIN: I think it's the first go -- it's certainly the first go at this particular request. Whether they've been working at it in other ways, I simply don't know. I'm sorry.

MS. HANIGAN: Okay.

MS. GLAVIN: Mike?

MR. MAMMINGA: If there are other givens,

obviously, FSIS can -- there's no question that you can put things before us. We've already identified inspection modules. Why don't you tell us the other ones that you anticipate you would put before us and then let us discuss from what remains how we prioritize those other issues?

If there are other obvious issues on here, we might as well hear what they are.

MS. GLAVIN: And it's a fair question. I'm not sure I'm going to answer it very well. That one's a real obvious one that comes to mind right away as an ongoing thing.

DR. LAFONTAINE: Well, I think the initial list was that -- or the first part of that list was FSIS generated.

MS. GLAVIN: It was FSIS generated, but that was generated really to kind of get people thinking. It was some issues -- you know, we didn't rank them in any order. So, you know, not necessarily.

It's more likely that as things go -- well, another thing that will certainly at some point bring back to this Committee is the strategic plan. We have in the past when we -- when our budget is public in January, do a briefing on that. We had at the last meeting a very good presentation from Eileen Kennedy on ARSCSREES research efforts. And I would anticipate asking her to come back and

do an update on that at some point.

The models is the one that we want some work on. The others are more in the nature of informative briefings.

Well, certainly as we get a little further on in our thinking on performance standards for product beyond the inspected establishment, that would certainly be a substantive one I would want to bring back to the Committee. But I guess right now what I want is what do you all -- what are your best advice on what you think could be most useful on? Caroline?

MS. DEWAAL: I'll dive in a little bit. I have two issues that are on this list that I just want to make comments on. One is the risk-based inspection and its effect upon current policy and daily inspections shows up one on both these lists. So, I think clearly there's a lot of consensus among the Committee that that's a very important issue. So, I'd just note that.

The second thing --

MS. GLAVIN: Can I -- go ahead.

MS. DEWAAL: The second issue I want to raise again -- you'll be able to tell which one was mine. I noted that there were three sampling issues on this list. And of course, on mine, I decide just to lump them all together and give them the same ranking. And I notice only one of them shows up here, but that may be because we so divided the

question on statistical sampling that different people voted for it.

I would like to suggest to the Committee that we may want to consider on your ranking issues tally sheet which starts with improving information flow, it's the one that says, "Examine FSIS Statistical Sampling Program. What is the agency's expertise which shows up on these lists?" Then, there's "Should there be an independent review of the adequacy of new statistical sampling protocols before new statistical sampling protocols are instituted?" And then there was a peer review of statistical information.

Those three to me seem to be asking a very similar question. And perhaps all of those could be linked -- grouped as one question. The agency's approach to statistical sampling, and is it adequate? I mean, I would really suggest that we group those together as one thing.

Does anyone --

MS. DONLEY: I did the same thing. I circled them all and put them together.

MR. CLINCHE: I was going to say, I couldn't tell yours because there was someone else that did say do the same thing.

MS. GLAVIN: I guess what is it that you want to do about the agency's -- you want to make recommendations to the agency on how it designs its statistical sampling? I'm

not clear what it is you're asking for.

MS. DEWAAL: Well, I'm not -- first of all, I didn't author any of these, so I'll just give you my off the cuff approach. But we've been troubled that the statistical sampling protocols that are used, for example, in the inspection models haven't been fully peer reviewed, because none of the people in my community have much in the way of statistics background. We'd like to -- and we also have experience with FSIS in the past saying -- feeling like they weren't handling statistics properly. That we were trying to get the agency to get some of their statistical work peer reviewed. But there are clearly other concerns that were expressed by others.

MS. GLAVIN: Carol, can you shed some light on this subject?

MS. FOREMAN: Well, let me follow up on what Caroline said. The agency is in the process of making a shift that goes from command and control to a very heavy reliance on statistical sampling. Statistical sampling is a beauty that viewed different through the eyes of the beholders.

There's a lot of debate about the quality of FSIS's work on this in the past. We have been very critical of it. In order to be absolutely sure and competent and be able to go forth and endorse the future, we need some work

with the agency to be assured that the statistical sampling quality is good enough to make us comfortable with this shift.

And you can -- I think the statement is -- the suggestion there is a good one. Can't we roll these together and find some way to delve into this?

MS. GLAVIN: What I'd like to do is take what Caroline said and what you just said and put some people to work coming up with some options for how to bring that to the Committee and shape it. So, come back to you with that between meetings with some options, because I'm sort of struggling being a non-statistician myself -- sort of struggling with exactly how we do this. But I heard your concerns. So, can we --

MS. FOREMAN: Yes. I think that's a good idea. And if you could come up with a paper and distribute it before the next meeting, it might be possible to either say, "Gee, we'd like to go into one part of that in more detail at the November meeting." Or we may want to suggest to you that you handle it in some way other than the Meat and Poultry Inspection Advisory Committee.

MS. GLAVIN: Let's give it some thought.

MS. FOREMAN: Thank you.

MS. GLAVIN: I'd also like to ask if you don't mind. Since risk-base inspection and its effect upon the

current policy of daily inspection is first on those, can we get some clarity on what that one means?

Are you the author of that?

DR. LAFONTAINE: Yes.

MS. GLAVIN: Perfect.

DR. LAFONTAINE: That's not why I had my hand up, but yes, I proposed this. Very simply, when you look at risk, and you look at resources, the utilization of the resources should be risk-based.

You have in existence at least for -- well, you have in existence a system, PBIS, that is performance based inspection system. It gives you good data on the performance of individual plants. Everything from HACCP implementation to some economic task still, but it's been redesigned, reconfigured for HACCP, SSOPs, you name it. But it's not being used.

And what I mean by that it's being used for review purposes, but it's not being used to make decisions on looking at or using the performance of plants and deciding the frequency that those individual plants need to be visited. The agency is saying, "Go every place every day and get it done somehow." And some days, you can't get it done because you don't have enough time and resources.

So, that's really where I'm coming from is take that system and any other that you might have, and for the

folks that are doing a good job, continue to visit them randomly, unannounced, different times of the day, twice a day one day and maybe not for a few days, and get out of this, to me, craziness of trying to go every place every day just because they have a grant of inspection.

So, that's one piece of this pie, and that's why I asked to be put on.

MS. GLAVIN: Okay. One of the things that might be useful is to have a briefing on the PBIS system. The PBIS system, and I'm going to get over my head real fast here. But the PBIS system does provide information on plant performance. I mean, it is one measure of plant performance. Obviously, there are others.

It also is capable and is used for when there are shortages deciding what task will be dropped or postponed. So, it has some risk rankings within it. It either has or could easily have the ability to switch frequency of inspection, but right now it's written with the rules that the frequency of individual task will vary depending on findings, but always within the context of a daily inspection.

So, I think it would be useful to start with a good briefing on what the system is capable of doing and what it currently does. Is that what --

DR. LAFONTAINE: I agree. And there's an

important part I forgot. And that is the whole -- the reason I'm putting it on there is not necessarily to figure out a way to skip plants, but rather to put assets where they're needed for problem situations in problem plants in problem issues. And if an inspector feels -- if the program feels that they need someone there "x" hours -- extra hours in a problem plant, they're not driven to drive down the road to go to the next plant. It's not -- it's based on an arbitrary daily criteria, as opposed to anything resembling risk.

MS. GLAVIN: Well, you know, I do have to say that it is the agency's position that we are not interested at this point in time in looking at moving away from daily inspection. But I think the context of how do we best focus our resources is one that we would -- so, let us give you the briefing on the PBIS system.

MS. DEWAAL: One of the things I think the agency needs to grapple with is the fact that both the National Academy of Sciences and the GAO have come out and suggested that carcass by carcass inspection is no longer needed. And in a sense, I see this as a -- I think Dan's -- the focus on the PBIS system is good, but I also see this is an opportunity for the agency to -- or for us really, to be able to say that carcass by carcass inspection, particularly in the red meat area is hazard-based, is a risk-based

inspection program, and to come out with something that responds to these statements.

So, that is another way just in putting together the position paper on this. Another thing you should focus on that there has been criticism.

MS. GLAVIN: Well, I haven't yet agreed to do a position paper. I'm going to lay on you all that you need to decide what you want us to prepare for the next meeting. And there's a limit. You know, I'm going to say, "Stop." And you're going to have to give me some rankings.

MS. DEWAAL: Well, this is over two years.

MS. GLAVIN: This is about the 17th paper I've heard about today. I'm starting to worry. Okay.

DR. LAFONTAINE: Maggie, let me answer your question. As a first piece of the pie, this is ranked number one. So, if you could work on the agendas, so be it. And the piece of the pie that I think has the most need for a look see, is the processing part and the patrol part, the patrol/processing part and its relationship to PBIS.

So, a briefing on PBIS and an explanation of your philosophy on daily versus less than daily would be a starting point.

MS. GLAVIN: Okay. Collette?

MS. KASTER: An additional thing to think about is, a dose of reality into the situation is there is in many

circuits a staffing shortage. And that is something that we should bear in mind as we look at how we allot responsibilities, too, because there's some struggling to get available people for the tasks that are assigned at present.

MS. GLAVIN: Katie?

MS. HANIGAN: I'm going to move us on to another agenda topic. Is that okay?

MS. GLAVIN: Absolutely.

MS. HANIGAN: Working off of what Caroline did, I'm looking here at number two, FSIS Uniformity For the HACCP Audits review the company's plans. And then even when we looked down under the other weights, those three are rated two, three and four.

And I guess when I look at those Maggie, were three-quarters or two-thirds of the way, if you want to say it that way, into HACCP? We've got the small plants coming in in January. I think it's key that we look at uniformity. Make sure that what we've got based on HACCP in the field is uniform. If we're going to have audits by FSIS of the HACCP programs to insure consumer safety, whatever the reasons are for them, they need to be carried out in such a manner that they're uniform, that they're worthwhile.

I think those there items tie together fairly well. And I just want to throw out to the group. We're

putting a lot of weight in here on these company HACCP programs, and yet we've heard at the table and through other public meetings that some plants have many CCPs. Some don't have many CCPs, et cetera, et cetera.

There's got to be some way of tying this stuff all together. It's probably a huge topic to put on an agenda, but it needs to be addressed.

MS. GLAVIN: Well, that's certainly something we can address. I'm going to take off the word "audits" and call it reviews, because my friends from OIG will come and beat up on me if they think we're doing audits.

MS. HANIGAN: Okay.

MS. GLAVIN: But it has always been our intention to go into plants with expert teams to look at the adequacy of the plan both in design and in execution. And we have the beginning of a methodology for doing that. So, I think by the next meeting, we'd be in a position to lay that methodology out and get some advice on it.

We're also sharing that methodology with FDA and getting their advice on it. And somebody else -- oh, we're sharing it with our friends in OIG who are about to start an audit of HACCP.

MS. HANIGAN: I think that ties well, because that may be the first piece to uniformity, too, that we're driving for.

MR. MAMMINGA: And just to put something in your mind and not give you anything more to do, but from the state program perspective on this particular issue, everything that she just said, there will come a day somewhere between now and the possibility of interstate commence when each one of your state cooperative programs are going to be in the situation of having worked with the industry they regulate on all of these issues regarding HACCP. And then, we'll be working with FSIS on whether we met their expectations of the implementation of HACCP.

And so, as these schemes come together for uniformity, it's absolutely positively critical that you work with the state programs outside of a crisis situation, not when interstate commerce is on the line, not when the "equal to" status is on the line, but as this is developed so that we're really all partners in this as we go forward. You leave us in the dark, and then you're going to have 26 programs that you're going think about me taking over, and you won't want to do that.

So, this is just something. I see Dr. Liese out there and know the work that he and I and all of us try to do to keep this going. He's got to be the linchpin in this for us. He's got to keep us -- he's got to know what's going on to keep us in the game.

MS. GLAVIN: Good point. Thank you. Dan?

DR. LAFONTAINE: Switch gears again. First of all, on the HACCP inspection models, an editorial should be HACCP-based inspection models. That's the term you've been using all along.

MS. GLAVIN: Right.

DR. LAFONTAINE: Which is a more accurate term.

MS. GLAVIN: Right.

DR. LAFONTAINE: And then, this morning you asked that I defer my recommendation related to this till this afternoon. And what I'm talking about is I recommend that at our next meeting, we do have as a topic HACCP-based inspection models and at least that part that deals with -- and I'll read this: "Minimum qualifications for industry personnel in HACCP-based inspection models project."

MS. GLAVIN: Okay.

DR. LAFONTAINE: Because tying that with what you said earlier, you hope to break the logjam and be able to start actual pilots this fall. So, it's a topic that needs to come forward.

MS. GLAVIN: Okay. Is there sort of a general consensus from the Committee that that ought to be on the fall meeting?

MS. DEWAAL: When we also talked about the Australian proposal and you know, and you could come in as part of that discussion and talk about what the Australians

did in that area, as well.

DR. HURLBERT: Yes. I brought up this morning that I thought it would be good to either have a paper on the Australians, what their qualifications were and you said it was on their Website, as well as maybe bring in some of the guys that are in the model plants now and kind of see where they were headed with training their people, as well. Kind of get a briefing from them if that's possible.

DR. LAFONTAINE: Mike, I have the Website if you need it for that, where to find that, the Australian Meat Safety Enhancement Act. Peter was here earlier.

MS. GLAVIN: I was going to say, Peter was here, but I don't see him now.

Okay. What I'm hearing so far we have as issues for the foreseeable future, risk-based inspection and its effect on current policy of daily inspection.

MS. FOREMAN: Maggie, can I just amend that in order to have some clarity? Why don't you say risk-based inspection and its impact on daily processing inspections? So, you don't have to go through the slaughter argument every time.

MS. GLAVIN: Right. Thank you. The HACCP-based inspection models, a combination one of uniformity and HACCP review/audits, a combination one on the statistical programs the agency uses, and then the one Dan just mentioned we'll

try to pony up for the next meeting. I forgot what it is. Oh, yes, the qualification. With respect to the models, particularly, the qualifications of industry people. Okay.

MS. HANIGAN: How will we know what we're going to do on the campylobacter? I know I keep throwing that back to you, but --

MS. GLAVIN: Yes, and I'm not sure. We need to get an answer back from the micro committee -- either an answer -- either what they give us or a date. And Mike, can you when we have that, make sure everybody gets it? And if it's a date, then -- well, I guess either way, we need to sort of at that point think about and maybe Mike can sort of poll you all -- how you want to proceed at that point.

MS. HANIGAN: I realize that that have not seen what my subcommittee put together last night. I understand that completely, but I guess what I'm looking for after that meeting is whatever they talked about in regard to campylobacter at that meeting. I mean, if they put out anything, I'd like to have a copy of it so that we know what at least was discussed, if it was lengthy or not.

MS. GLAVIN: Okay.

MS. DEWAAL: Well, the other thing is that committee appears to meet far more frequently than ours. I think they have three to four meetings a year. And so, it seems like given they have one at the end of this month,

they may have another one. We really need them to come back to us with something at the latest at the November meeting, and hopefully before that.

MS. GLAVIN: We can push them.

MS. DEWAAL: Okay, thank you.

MR. BURKHARDT: Will we also get update on the current issues that we talked about today regarding the exemption? Any progress there or in regard to the flesh species inspection? Updates on those issues?

MS. GLAVIN: We can put that on the list.

MR. BURKHARDT: I think just kind of an update of what we've previously done would be good to go over.

DR. LAFONTAINE: On the mandatory inspection, Loren and I will be working hopefully to have information that can be presented on that topic. And part of our recommendation was to bring that back at the next meeting or have a new concept paper. So, yes.

MS. DEWAAL: You can have Mike writing the concept papers.

MS. GLAVIN: Okay. Well, I guess over the course of the day we would need to provide that paper assuming that we can get enough information to do it. And I would expect with these four stalwart state people, we'll get the information we need to do it.

Are there other things that --

MS. HANIGAN: I do believe that you folks agreed on the qualifications that you're also going to tell us what the current qualifications were of your agency people that held those jobs now underneath those HACCP-based inspection models. We wanted to know what those qualifications were.

MS. GLAVIN: Okay. Or background. Okay. You know, there are a few items here that still -- that we haven't put on. We've seemed to have covered most of them. The consideration of new food safety technology, is that one that people want?

MS. DEWAAL: I think the issues there, Maggie, are that approvals of new technologies are taking a huge amount of time between the FDA approvals, USDA approvals and then in some cases they have to be pilot tested. There have been issues around whether the unions support the pilot tests or not and how that impacts it. So, I think there are a lot of -- if we're relying on new technologies to make meat and poultry a whole lot safer, there's a few multiple hurdles on the road to getting that done.

So, I think that's the issue. And it's clearly one that if we have time to discuss, we should discuss it.

MS. GLAVIN: Mike is reminding me that we also talked about trying to do a briefing on the things we're doing or we have in the pipeline, and sort of where they are on the retail in-distribution. Then, what states do during

recalls. And we said we would try to find that, but I think transportation could be added to that one. But we're not sure we'll be able to get our hands on much of that.

Okay. I think that gives us a good list to work with as we do agendas over the next two years. Are there -- well, no, let's keep on. For the next meeting, we've got one agenda that I think we're all pretty much in agreement on. And that is an update on the models with the particular emphasis on this question of qualifications of employees doing tasks.

Is that right? Okay. And obviously, they'll be some update briefings. Are there other things that people today know that -- well, quite possibly the campy, that would be on. I'm hearing that that's a high priority if we've got and haven't dealt with it ahead of time. Okay.

And Mike, can you tell us where and when the next meeting is?

MR. MICCHELLI: Yes. The next meeting is November here.

MS. GLAVIN: Oh, two to four.

MR. MICCHELLI: Now, one thing I don't think we have any remaining issues. Normally, we meet on a Tuesday for two hours. The subcommittees meet before the Wednesday. Sometimes we do that. If there's issues that are going to continue work on, and I don't think we have any of those

now. I think we completed all our issues that we had on our agenda. So, we won't have a Tuesday meeting. And so, it would be a Wednesday and Thursday. So, those would be the dates?

MS. FOREMAN: Three and four?

MR. MICCHELLI: Yes. Actually, it's three and four. It would be three and four.

MS. HANIGAN: Could I make one request? Could we please have all materials and presentations ahead of time because --

MS. GLAVIN: Yes. And I want to tell you we promise this every time and we promise it again. We really do do our best, but our track record is terrible.

MS. HANIGAN: Because between Gerri and Jeanne they wow with you with enough information. It's like whoa! You know.

MS. GLAVIN: So, it's working?

MS. HANIGAN: There you go.

MS. GLAVIN: I do apologize. We will try to do better.

MR. MICCHELLI: Just to make sure I was clear, the third and the fourth.

MS. GLAVIN: Okay. Are there any issues that before we open the floor to public comment that Committee members want to raise either for future consideration?

Anything you want to say about the things we've already discussed? Anything that you had a brilliant insight on during the break?

MS. DEWAAL: Thank you, guys, very much. You did a great job. Mike and Cheryl did a great job, and I'm tremendously pleased with our new subcommittee, especially the woman who cracks the whip over there. She's very good.

MS. GLAVIN: Okay, thank you. My open problem with having the next meeting here is every time I get lost. I only live like five miles from here.

MS. FOREMAN: Don't complain. We'll be back on the Scott Circle.

MS. GLAVIN: Oh, I like Scott Circle. I can walk there. Yes?

MS. DONLEY: If I could just ask almost like a procedural for November's meeting. The two topics that we talked about that the campy, and well, the HACCP-based inspection models and qualifications of industry personnel, were you looking at that as perhaps being just a whole committee discussion, or are you just breaking that down again? If so, your subcommittee's going to be swamped.

MS. GLAVIN: Well, we can move them around, and we've done that before. I mean, the titles of the subcommittees are a bit of a fiction. I mean, we sort of have -- to some extent sent things to the appropriate

subcommittee, but when one subcommittee has two or three big items for a meeting, we've sometimes moved them. So, we can do that.

My sense is that the subcommittee system works rather well. That you know, it gets a lot of work done in a very short time, and then can bring it to the full Committee for discussion. So, I'm inclined to stay with that process. But you're right. I don't think we could both those -- well, let me ask the other people. Should we put both of those topics with the same committee? Is that too much to put with one committee?

MS. HANIGAN: The only suggestion that I would have, we've already canceled two to four on Tuesday, November 2. The other members here are probably just me, but if you want to have a full Committee meeting separate to talk about campy, I suggest we do it the afternoon of the second, depending clearly on what comes out of the micro committee and if or not we had a teleconference and this, that and the other thing.

MS. GLAVIN: So, we'll keep that open as a possibility. If you will keep your calendars open. Great idea.

MS. DEWAAL: The other thing is or the training piece could be done that Tuesday, as well. I mean, other one of those.

MS. GLAVIN: That's good.

MR. MICCHELLI: I have just one administrative detail. Those of you that have a lot of things that you don't want to carry back, we do have mailing pouches back in the registration area. You're more than welcome to fill those pouches, put just your name and address on there and we'll have them mailed to you.

Also, on your travel expenses, if you have any questions, Yolanda Kennedy would have loved to -- Lopez. She was recently married. Yolanda Lopez would love to help you, but she was ill this week and was unable to be here. So, just give her a call on the phone and she'll help you with your travel expenses. Thank you.

MS. GLAVIN: Okay. We have two individuals who signed up to make a statement. The first is Dale Hensel. And I apologize if I've pronounced your name wrong, but I'll blame it on your handwriting.

MR. HENSEL: Yes, my name is Dale Hansel. I'm President of the National Bison Association from Denver, Colorado.

I'd like to first of all thank all of you for allowing me to speak today and think you're doing a wonderful job taking care of the -- trying to get this food safety issue settled.

I've been raising bison for over 20 years. And

during that time, I've seen an awful lot of changes. When I started, there were about 50,000 bison in this country, and they were mostly in private herds -- I mean, public herds. Today, there are a quarter million and they're mostly in private herds.

At the present rate of growth, there'll be -- in 30 years, there'll be as many bison as there were in the late '1800s when there were 50 million. And that may or may not happen, but we haven't killed any female bison other than colts for the last 15 years.

Last year there were between 28 and 30 million pounds of boxed bison meat that was sold to the public. And each year that will go up 20 percent.

Now, I notice you were talking about checking records of alternative livestock is being slaughtered. That would be very hard to find because USDA is not required to keep track of the slaughter of bison. So, many times bison in the USDA plan is included with beef. And Tom Billy and I have spoke about that, and he's trying to get that rectified in the record-keeping process. Elk and other alternative livestock I'm sure is in the same situation.

Bison ranching and farming has become one of the bright spots of American agriculture. Bison has adapted to our environment, and it's more environmental friendly. Bison is an environmental friendly browser.

Many beef producers in the Northern Plains are switching to bison because it fits what they need. After the blizzards of two years ago, it was very evident. All those that raised bison lost no animals. What happened was the storms packed the snow. The bison walked over the top of the fences after the storm, but in the meantime, the cattle were all lying dead. Makes a lot of people think that this might be a better product for our country.

So, what I'm trying to say is that this animal is not going to go away. And you're going to have to deal with it in inspection. And it's going to become more and more and more prominent.

Bison are raised without hormonal use. And to my knowledge, no one that I know of is using any type of antibiotics in their feeding programs.

So, for those reasons it's currently a big demand for the product in this country.

Now, the reason I'm here, let's talk about inspection and sometimes the lack thereof inspection. The first point I'd like to make is bison meat must come under our USDA mandatory inspection process. This product becomes more widely produced and marketed. Contaminated, uninspected meat could so easily be sold to the unexpecting public.

Consumers think that everything sold in stores and

restaurants comes under an inspection process. Sometimes it doesn't. Most producers understand the importance of inspection, but occasionally someone doesn't, especially when there's a cost involved.

This issue must be addressed to guarantee that the public is consuming the safest foods possible. I would assume that this Committee and the USDA would want to close these inspection loopholes to solve that problem.

To have bison meat USDA inspected costs the producer $37 an hour. That price was recently raised from $32 an hour.

The second point I'd like to make is that state inspected product must be given the same interstate freedom as federally inspected products. If that is not done, implementation of a mandatory federal system would put many meat purveyors out of business who presently ship interstate.

Our industry depends heavily on state plants to process our animals. And I feel that this is an emergency situation from my discussions with several of those in the state departments. If there inspection system doesn't survive financially, once they're dead, they'll never be restarted again. A lot of states have already dropped state inspection. I think it's very important for all small producers of different types of livestock coming on line.

Our industry also depends heavily on very small federal and small federal inspected plants. Many large plants will not inspect bison because it would disrupt their high volume process. Many state and small federal plants adapted their operations to accommodate bison. And it's a big factor in keeping a lot of small plants in business.

Meat inspection laws vary from state to state. Some require inspection and some don't. In some states, bison comes under Department of Ag. In some states, it comes under fish and game. Some states allow or require use of sodium nitrite, and some states and FDA, ban the use of it.

Nitrites are so necessary for the safety of sausage and cold cut products. That's one of the very big loopholes, and I've worked on this for many years. USDA -- I mean, FDA presently is in the study project that's been going on, and it should end this year. It's been a five-year study of the safety of nitrites. I don't know how many of you are familiar with that or not, but we've been following it because the minute that study is finished, we want to find out the outcome, so maybe we can get included in bison. But that's just for your information.

Some states requiring inspection provide free inspection. And the bordering states that have to do with federal inspection, the feel have to pay. So, it causes a

problem. For example, in South Dakota, the free inspection. North Dakota and Colorado, the inspection -- so, they can ship the product cheaper, because that $40 -- $37 an hour adds up, and it adds to the cost of the product. So, it causes some unfair trade practices.

I'm also a member of the United States Animal Health Association. And I'm on the Tuberculosis Committee. And I don't know if you're aware, but that committee at our last meeting presented -- passed a resolution requesting USDA to place alternative livestock under mandatory surveillance inspection. What precipitated this was tuberculosis in surveida.

In 1983, we had tuberculosis in bison. Now, that was caught at an early stage because of surveillance inspection. Now, if surveida and bison don't go through surveillance inspection, that disease could spread very widely, and that's also a human safety matter. So, for that reason, those animals need to go under mandatory inspection.

We were able to clean up the TB very quickly in bison because it was caught under surveillance. But if those had not been inspected, the disease would have spread much farther.

Last evening I sat in on the Government role committee, and I must say whoever chose that committee has to be commended because you did a very -- you have some very

knowledgeable people and you're doing a very good job.

And to end this, I hope that the powers that be will implement your recommendations. Everything I've heard here for two days I'm very impressed. I just hope that the people that you talk to listen to what you said because we need this food safety more than anything.

Thank you very much. If there's any questions, I'd be glad to answer it.

MS. GLAVIN: Okay. Thank you, Mr. Hansel. Appreciate it. Appreciate your being here.

The second and last person to sign up is Stan Emerling.

MR. EMERLING: Thank you, Maggie, and thank the Committee. I thank the Committee for the opportunity. I also want to commend you for what I thought and feel is a very excellent two days discussions on a lot of the issues. I think you really address the points. It was excellent going back and forth.

I have just a couple things that I noted as I listened to what some of the commentary. First, I would like to follow up on some of the reports that Jim Denton and Nancy Donley made with respect to the risk-free meat, poultry and egg food concept paper.

You know, that's a goal that is really similar. It's a motherhood issue, and it's pretty hard to argue with.

But as I've always thought and have been told, a goal should be achievable, incredible and if people would have a perception that they can't be achieved, they may tend to ignore them or they may be lulled into some sense of complacency that everything is better than what it is.

I also worry about, as we do in fund-raising, we put those thermometers up and we put 100 percent as our goal, and suddenly we start looking at the risks in food safety, and we got a red line at 50. And the next year it moves up to 60 or to 80 percent of that goal. And whether or not maybe we'll be sending a message to people that our food safety efforts aren't as good as they should be. And yet, at the same time, I think we're doing a wonderful job of moving towards what would be perfection if we could ever reach it.

So, I just would ask you to consider is you look at that how you address it, how you call it and what you name it.

I'm also pleased with the fact you're looking at risk assessment with respect to exemptions and to the inspection of all animal foods. I think that's a really good way to go. I commend you for that. I only hope, though, that if you do find some risks in there that FSIS went on record in its paper that it didn't intend to do anything about changing exemptions or anything this year. I

would hope that if in case that risk assessment is done and you find it worthy, that you don't let that stand in the way of moving forward with it.

With respect to the HACCP models where you're talking about the inspection models and possibly processing, I said this almost I guess at every meeting where I've had a chance to say it because someone said to me if I don't keep it repeating it, it may be forgotten. So, I'll say it again.

I would hope you would look at the possibilities of 24 hour a day, seven day a week operations without overtime being part of what would be a true implementation of the HACCP concept. So, when you get to that, if you would consider that as a possibility, I would appreciate it.

I would also, and I have some concerns about relying too much as you move into the restaurant section or the consumer section with respect to the food code because it hasn't been adopted in all the states. It isn't adopted in entirety.

And in this '99 food code, they also put in a requirement which I hope will be addressed and will change it on the non-impact intact issue, which I hope you will do risk assessment on as well. But they've now asked for warning labels to be attached to menus and -- or table tents and things, which I think preempts some of the authority of

FSIS. But I think as you get into this, you need to be taking a look at as whether a sister agency is not doing something that is incompatible with what we need to have under meat and poultry.

I think that ends some of the comments that I saw as I listened to what you said. I was impressed with what went on here, and I thank you, and good luck in all your endeavors.

MS. GLAVIN: Thank you, Stan.

MS. FOREMAN: Maggie, I have a question for Stan. Stan, come back.

MR. EMERLING: I don't want to get out of the --

MS. GLAVIN: No, I didn't ask you to cross the line.

MS. FOREMAN: You're in the 10-second zone there, Stan.

I want to point out that the document on risk free is referred to as a conceptual framework. On the first page of it, it is described as the FSIS vision. Then, when you get into it, there are several rather specific goals. Goal 1, establish a national research and new technology infrastructure to insure adequate scientific support, so on and so forth.

So, I think it's important in discussing the risk free, that we understand that's not a goal. That's a

vision. I would suggest to you that it's a very appropriate vision that one has of where we might get if we achieve the specific goals. And I think the goals that the agency has set forth are quite reasonable. They may be changed. I'm sure they will be changed. But they are much more -- they're harder, more specific, more detailed and the objectives under each one and the means to the objectives even more so.

So, I'd argue with you a little bit about whether or not it's an appropriate vision.

MR. EMERLING: Well, and I -- you know, I don't really want to argue with you about it because I understand what you're saying about the vision, but I also listened to what Caroline said about people -- and I think it's true -- really believe the food is safe. So, that when you start to draw and maybe it's just the use of words. Maybe it's -- I was trying to think if I could think of something better than risk -- you know, eliminating risk or whatever the way would be.

But I think we don't want to undercut the credibility we have. We don't want to make people maybe even in foreign countries think that the food we export to them may not be safe. We need to improve it. We need to do better. I don't think anyone --

MS. FOREMAN: I want us to live up to the vision

that the public already has.

MR. EMERLING: Well, I'm for that. I'm trying to give you some thoughts about how I would -- I wonder how people perceive it. You may be understanding it better. They aren't going to hear all those words that are in there, so that's the only reason I raised it.

MS. GLAVIN: Thank you. There's no one else signed up. I gather there's one other person who wants to make a statement.

Could you come up and identify yourself, please?

MR. NORTON: I'm Dick Norton, microbiologist. I'm consulting with a company that's working on a new antibacterial solution.

I was 32 years a microbiologist in the Food and Drug Administration.

MS. GLAVIN: Can you get a little closer? People can't hear you. It's not picking up.

MR. NORTON: For 32 years, I was a microbiologist in the Food and Drug. I've been squirming a little bit in the last few days. I think a fish out of water here. But really, the two agencies have a lot of common problems and a lot of common solutions and needs.

The food supply in this country is really good. I mean, we don't acquire a foodborne illness one in 10,000 meals. When you stop to think about it, it's 99.99 percent

risk-free. What we're working at here today and the last two days is that other last little bit because it's serious.

And one thing that came up and has come up before is this business of the housewife cooking meat. As a microbiologist, I worked in sterile areas and worked with companies designing sterile manufacturing facilities and so forth. I know that the average housewife can't bring that meet into an airline, into a laminator flowhood with a HEPA filter. And she can't scrub down her ceiling and her floor and her walls every day with potent bactericides. She can't dress in sterile gown with a sterile cap and goggles and sterile face gear and sterile booties. And she can't refrain from touching the refrigerator or the onions of whatever.

It's not an either or. It's not you work on getting the pathogens out of the meat or you cook it. Once you bring them into the house, it's an unsafe situation. You could cook it and maybe you can -- that will helpful in some cases. But it's an unsafe situation. So, it's really a serious business to work on keeping the pathogen levels down, those that result in human illness.

Too long days ago when we started all this, Tom Billy started off by trying to emphasize how important research is to what he was thinking. I could really sympathize with that from all the years of trying to handle

food and drug-type products and not having all the facts. And so, we're really driven to do the research first.

With the Food and Drug, it's usually been the other way around. Usually, we're starting with clean, sterile materials, and we just have to keep them from getting contaminated. With the meat products, they already have the pathogens in to start with. The problem is removing them.

The key in this whole process is the anti-bacterial solutions that you apply to eliminate the pathogens. So, it's a very important part of the research. When I was listening to Tom Billy, I was trying to hope that people would focus their attention on that particular aspect.

Last year we -- thanks to FSIS, we were able to report some recent research at the symposium last July, 10 months ago. And the adequacy of these solutions were vastly better than the phosphates and the chlorine oxides that was being reported in the same symposium. And it was so much better, several logs, that we knew we couldn't pass the "Are you crazy test?"

I mean, this was two strangers from a company they never heard of coming to a meeting with big industry making their sophisticated reports. But we came anyhow. And since then, we've continued to work on this. And the other

studies have shown that that first study is in about the right range.

One of the more recent studies that we've done or that was done out of Clay Center, the agriculture research center in Nebraska, they put known pathogens on beef squares and treated them and they followed this through. And they used e-coli and salmonella and listeria, which again, they tried to use campy and they didn't do it, which is unfortunate, but that study needs to be done. But anyhow, it was complete elimination.

And one of the interesting things is that it was still active five to seven days after application. So, there may be some things that we can investigate about food spoilage outside of the plant before it gets to the table.

Anyhow, it's a new paradigm. There may be other companies with other compounds that can do the same thing, but it's at the nub of what we're trying to do to cut down on the pathogens.

So, we feel that this is very urgent. It should take some sort of priority.

We had a hard time getting cooperation from different companies. We have some now and we have studies going on. But it really should be other industry groups and other companies that are pursuing these applications. You can't just do one study on a solution and call it a solution

because each production line and each product is different, and there's a lot of engineering to apply this in each situation. So, we need the cooperation of the industry.

We had the study that we wanted to be done with the campy. He was very interested in doing the study, but when it came down to doing it and we had the money, he didn't have enough graduate students. They were already doing other projects that we thought weren't near as urgent. And he didn't want to bother with all the paperwork. He had as much paperwork in getting funding as he could handle.

So, it's like, "Well, we'll do it next year." Well, this is important now.

So, my urging would if there could be some prioritization as to the research and get things started.

MS. GLAVIN: Okay. Thank you very much. Thank you for attending. Anything else from the Committee? Yes, Lee.

DR. JAN: I'd like to make a comment based on Mr. Hensen's comments or he brought out I thought a very good point. We've gone back to the HACCP-based inspection model and in qualifications of plant personnel. He mentioned the surveillance -- slaughter surveillance for TB in the bison where the same principle would apply to slaughter surveillance for diseases in livestock. And from a farm to table perspective, we, in the slaughter industry, have to do

whatever we can to go back down to insure a continued healthy population, and slaughter surveillance is part of it.

So, with that, I think the sorting has to be done by qualified people that can make clinical diagnoses appropriate to some -- that may lead to a quarantine of an infected herd or whatever to maintain a healthy population. So, I think that in this HACCP-based model program, although the initial protocol didn't require any specific training, that should be addressed and required that there's at least oversight of a qualified person to make those diagnoses.

MS. GLAVIN: Okay. Thank you. All right. I thank you for your hard work and your good spirits despite some of the rough handling you got from your chairpersons. Thank you. We'll meet again in November, but we'll be in touch.

(Whereupon, at 4:20 p.m., the hearing concluded.)

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May 6, 1999
Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 221 through 440, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by Sharon Bellamy, 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.

5/12/99
Date

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Name and Signature of Transcriber
Heritage Reporting Corporation

5/12/99
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