UNITED STATES
DEPARTMENT OF AGRICULTURE

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

Pages: 246 through 387

Place: Washington, D.C.

Date: June 6, 2001

HERITAGE REPORTING CORPORATION
Official Reporters
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Washington, D.C. 20005-4018
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INSPECTION MEETING.)

Columbia I & II
Holiday Inn Capitol
550 C Street, S.W.
Washington, D.C.

Wednesday,
June 6, 2001

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

SPEAKERS:

MARGARET O'K. GLAVIN, Moderator
MICHAEL MAMMINGA
DANIEL LAFONTAINE
BRENDA HOLBROOK
NOREEN HYNES
DON SMART

PARTICIPANTS:

JOHN NEAL
LEE JAN
MARTY HOLMES
IRENE LEECH
TRICIA STOLFA
ALICE JOHNSON
KAYE WACHSMUTH
SANDRA ESKIN
PHIL DERFLER
CAROL TUCKER FOREMAN
COLLETTE SCHULTZ KASTER
ELSA MURANO
VICKI LEVINE

PARTICIPANTS (Continued):

JUDY RIGGINS
MICHAEL GOVRO
CATHERINE LOGUE

P R O C E E D I N G S

(8:35 a.m.)

MS. GLAVIN: Good morning. I know you all worked into the evening last night, but it looks like most of you made it back for the morning session. You did in a few of your members, it looks like.

This morning's session is given over to reports out by the subcommittees on their work of last evening. There is no even way to break up three reports, so we're going to do one report and have an early break, and then have the second two reports prior to lunch. I've been asked by some of the committee chairs to do a slight switch in the order in which these come, and so I am going to ask Dan LaFontaine to go first before the break; then immediately after the break we'll leave Mike there as is currently scheduled, and then Dale will finish up in the third slot at about 11 o'clock. If that meets with all the members' approval, then so be it.

Then this afternoon after lunch we will have a briefing from the Micro Committee. This is something we have made a bit of a tradition; we like to keep the two committees in sync with one another in terms of what they are working on, what their issues are; and this committee has on a number of occasions referred things to the Micro Committee. So Brenda Holbrook will be coming over this afternoon to do that. Following that we have a briefing from Noreen Hynes, who is an epidemiologist -- who is

still on our staff? Noreen is in the Public Health Service and is about to get a new billet, so we're not sure exactly when that's going to happen. Unfortunately we will be losing her, but apparently not quite yet. And Noreen is going to talk about how the agency has begun to use epidemiology as a tool in our work, and bring that to you. I know there is a short paper in your briefing book on that.

Following that we have Don Smart from our Tech Service Center in Omaha to talk about a new correlation strategy that has begun this spring using the Tech Service staff to go into a district at a time to correlate our inspectors, and also to determine what kind of assistance might be needed by plants in that particular district. Following that -- that is all of the stuff that we are trying to cram into people's heads -- we will have a discussion of plans for the next meeting and any remaining issues.

I know that one or two of you will be leaving at the lunch break because of other commitments, so I would ask if you are not going to be here until that discussion on plans for the next meeting, if you have some issues, that you get them to Charlie or to one of your fellow committee members to get those on the table as we have that discussion. And then as yesterday, we will end with any public comments that people are interested in making. I have to up-front apologize that

at lunchtime I have to go to a meeting. I would expect to be back by no later than 2:30 and I apologize for that. The problem with not being out of town is that you can get called back, and that is what happened to me last evening, and again at lunch time, but I will come back as quickly as possible, and certainly be here for the discussions of the next meeting. I may miss some or all of the first two briefings, but I'll get back as soon as I can.

In my absence Phil Derfler, who is the head of our policy area -- he is our Deputy Administrator for Policy -- will be chairing. Tom Billy may join us this morning. He was due in last night from Rome, I think is where he was. Paris? The OIE meeting was going on. He was due in last night. I have not spoken to him so I'm not sure that he actually got in, but if he did he was hoping to come over this morning. He was particularly interested in the subcommittee briefings, so he was hoping to get here for that. So he may join us if we are lucky.

So with that, I would like to ask Dan to make the report -- if you are the reporter for your committee -- to make the report out on the committee that considered federal, state, and local government relations.

MR. LAFONTAINE: Thank you, Maggie. Dan Lafontaine, South Carolina. I was asked to chair this

particular subcommittee and the subject was -- the issue we covered was federal, state, and local government relations.

First of all, before I get into the substance of the report, thanks to the other committee members. Four out of our five who were designated for this committee were able to attend -- I think we had a good, open, healthy discussion, which is noteworthy and encouraging. And also to the FSIS staff, both the folks that interfaced with us, Ralph Stafco, Bill Lees, Dan Potillo, and of course the staff behind the scenes that helped do the recording and produce this report.

The way we approached this, we set aside a period of time to do some brainstorming to look at thoughts or ideas that may not have been brought to the table previously as far as this area of federal, state, and local government relations. And then after approximately a half hour, we said, what do we feel of all of this array should be the agency's priorities, realizing that you can't be everything to everyone. So using that mandate, you might say, we put various items on the board, and then took a vote among the four subcommittee members, and ranked them or prioritized them. So the report that you have in front of you, which shows 1 through 6, is prioritized based upon the committee's vote.

With that I'll progress through the report, and if any of the subcommittee members need to embellish on their particular area of interest, why we'll provide them an opportunity to do that, and then, of course, the full committee can comment or question any of us on the items.

First of all, our lead-in paragraph, "the committee commends FSIS for its continuing efforts in assuring that meat and poultry food safety procedures are being implemented farm to table; and to assist FSIS in directing the federal, state, and local government relations area we recommend the following priorities be established."

Number 1 is to continue a strong, proactive FSIS state meat and poultry inspection cooperative agreements for the small and very small plants. And of course, when requested by states that are currently called designated states, to support efforts on the part of those states to establish additional cooperative agreements. And I use the recent examples of Minnesota, Missouri and, I believe, North Dakota. So that was our number one priority. It kind of fits in a category of continue to do well the things that you are already doing well.

The next item I kind of categorized as communication. Throughout the whole subcommittee discussion, the communication issue kept coming up and up, over and over in different venues, both in

brainstorming and when we got into prioritizing. So this paragraph that I'm about to read here is a summary of our thoughts. And as I already said, it kind of popped up to what we think should be the number two priority. In cooperation with the FDA, USDA, we feel, should produce and maintain a document that describes what agencies perform what functions in the area of food regulations and education. And this document should be as detailed as possible, actually listing names and contact information of personnel involved all the way down to the local level, where applicable.

To add a sentence or two on to that, what kept coming up is there are folks in all of the states, and of course, the federal government's presence out at the state and local level, but it is very difficult to find those folks so that people can get in contact with the right organization and get answers or get help. So the committee feels that someone needs to take the lead and do the hard work to get a comprehensive list. It came up that there are those types of lists that various organizations have worked on, but someone we feel at the federal level, that is FSIS, needs to take the lead of course in coordination or cooperation with the FDA.

Still on communications; to continue with and expand the current public food safety outreach initiatives, that came across strong in numerous peoples' comments. And this next sentence is kind of a

potpourri but, you know, these efforts should evaluate the various methods of disseminating this information, use wherever possible the most effective, the web, publications, other organizations such as AFTO and IFT. Physicians, as you -- a good example that was brought out yesterday with the AMA -- schools, food safety task force, extension offices, public contact. So we realize that that is a very broad-brush comment, but the point is use all the communication methods you can to continue your food safety outreach initiatives. So that one kind of has two parts to it, one is a nitty-gritty recommendation on a type of information to make available, and the other is a more general comment.

The third item, I kind of categorized as meat and poultry processing food safety training. This particular recommendation ties in with what already is being worked on by the federal, state, and local relations staff; and that is provide some updated meat and poultry food safety processing training for state and local food regulatory agencies. And we are aware of the previous satellite training that FDA and FSIS and AFTO did, and I personally viewed a lot of those and I thought they were quite good. So take that maybe as your basis, and refresh it, and go at it again in coordination with AFTO. And once again explore multiple ways to deliver the content: face-to-face, trainee-to-trainer seminars, distance learning through modules delivered by satellite

and/or the web, and of course partner with related agencies to include the FDA, cooperative extension, state agriculture and health departments, as well as representatives of key consumer organizations. So, once again, reach out as you are and try to provide that food safety expertise that is inherent within FSIS in the particular area of meat and poultry, and provide assistance to the folks that don't do that on a routine basis -- that is, the meat and poultry food safety.

This fourth one is to do with the HRI retail exemption. And this first sentence is rather blunt: Remove the HRI retail exemption.

MS. GLAVIN: Can you explain what you mean by that? It's a little unclear.

MR. LAFONTAINE: To delete it, to discontinue it. I need to say for you, and also for Mr. Derfler, I did not bring this up.

(Laughter.)

That is the honest-to-goodness truth. They both know this is one of my favorite topics -- but I certainly support it. But before I go on, we also realized that this particular exemption is codified in the law, the basic exemption, not the dollar value, so it is not an easy fix even if you attempt it, but the subcommittee did feel strongly about it.

Let me elaborate: In discussing gaps that exist in the meat and poultry products entering commerce, it is

of concern to the subcommittee that many retail establishments sell inspection exemption meat products to food service establishments. This exemption was first developed -- the one that was developed played a role in many outlying communities but has long since lost its usefulness. Federal, state inspection, HACCP systems, and SSOP programs should be in place for all establishments that are selling meat and poultry products to hotel restaurants and institutions. That is the acronym HRI -- that is what that means. Lack of inspection for processing, distribution, especially returned goods at these locations is a gap in the inspection system that should be closed.

Number five, state-level task force: Encourage and continue to support the development and continuation of food safety task force at the state level. These should involve federal, state, and local agencies, and include consumer representatives. Encourage these groups to develop agendas that meet the needs in each state. Networking and sharing experiences and resources are typical activities. For those who aren't familiar, I should mention that this is an initiative nationwide that is actually in place in many states. And to a certain extent, FDA monies are available to support this for those states that want to apply for the grant. So this is not a new thing, but speaking from personal experience, in my state it has turned out to be an

excellent support or idea in improving food safety within our state and local system. But the full committee -- also the State of Oregon was present at our subcommittee, and he likewise spoke highly of that state-level task force effort.

And then finally, number six, continue with the current efforts to standardize laboratory food safety testing procedures, methodologies, management of the database of those results, and the reporting of those results or the sharing of those results at the federal, state, and local level.

So those were the six items we chose to put on the table and to prioritize. First, are there any comments from any of the other subcommittee members to embellish on our report?

MS. LEECH: Irene Leech from Virginia. I'd just like to add one thing. As we were discussing the communication, we need to remember that all consumers don't have access to the high-tech things at this point. So just doing something on the web doesn't solve all the problems of communicating with the public. So, yes, we need to use those things and so forth, but we also need to remain cognizant that there are some folks that are going to need some other methodologies. Plus, we need to do things in multiple ways; people got to hear it more than once to do it.

MS. GLAVIN: Thank you.

MR. LAFONTAINE: Dr. Jan, you had a question?

MR. JAN: This is Lee Jan. I didn't have necessarily a question, but I did notice something in communication that I think is a good idea. Of course I know FSIS didn't have anything to do with it, but I think it brings awareness up. And the other night when I got in to the hotel and turned on the TV and there was a program on, and it happened to be when somebody sent somebody out for an egg-salad sandwich and they went all over town and three hours later brought it back and they got sick. So these little subtle messages like that are good. And if there is any way that we could encourage that type of media where people aren't looking for a health message but get it, I think that is a good idea and I think I said that before.

But I also wanted to agree or put in another vote for removing the HRI retail exemption and would recommend considering at least looking at or modifying the retail exemption all across the board, because the retail exemption I think once was put in was the idea that the consumer can go into a store and make a determination on the sanitation. But we've gone beyond that with HACCP. And the consumer can't go into a retail store and determine whether or not kill-step temperatures were reached, cool-down temperatures were appropriate, or any of these things that HACCP is designed to control. And I made a perfect example, or brought one out that

happened in Texas, where HACCP -- a plant could not validate the safety of their product through the HACCP process and chose to stop producing it under inspection but continued to sell it retail. Well, those kinds of things -- a customer that comes in to buy it at a retail store has no way to make a decision on their own.

I know these exemptions are written in law, but those laws, I don't think, were etched in stone, so I know they can be changed. But it is difficult because we saw how difficult when we tried to get Senate Bill 1988 passed and that didn't happen. I think that one was etched in stone, but other ones are not. So I just wanted to give a kind of other vote on looking at exemptions and removing some of those that can't be controlled with the current standard for safety.

MR. HOLMES: Marty Holmes, North American Meat Processors Association. I was also reminded this morning by Stan Emerling that the Research Triangle Institute report also found that as a gap in the inspection system too, if I recall from their report.

MS. GLAVIN: Other discussions on this subcommittee's report? Other comments or questions about where they are going? Okay, then what I would like to do is go to the second presentation. Contrary to my earlier statements, we were so expeditious on the first one, and asked Mike Mamminga to report on the industry petition

for proposed changes to the HACCP final rule, and agency current thinking on that petition.

MR. MAMMINGA: Well, we were really given quite a long and broad subject. In our handouts, we actually had three documents. And that is the issue paper that we received regarding this that was presented to us yesterday morning; we also had the FSIS current-thinking document, and then we have the petition itself. And with the time allotted last night we could have spent it all cross-referring those three documents, et cetera. So we went through and picked out from our discussions yesterday, or from the discussions that we heard, three issues, if you will, from this petition, and the agency response, and we tried to give them some fairly careful thinking and discussion. And we were given three questions by FSIS to respond to or to provide information about.

And the first question was, what is the committee's reaction to the agency's thinking? And after going through our discussions and the comments that followed, we thought that we basically agreed with the agency's thinking. And then I would like to go to A, and this is going from the documents. We talked a lot about prerequisite programs, that prerequisite programs are essential in forming a HACCP plan. And that industry, if they are going to have a plan that will stand on a good base and go through all its points, you have to have

prerequisite programs; and that the agency and those of us who work with the agency and do this line of work should have recognized this when the regulation was created. And perhaps we even thought that some of the criticism that has been leveled by OIT, for example, at the agency on prerequisite programs and other things, may have been with the thought that the agency should recognize prerequisite programs.

In order to make the prerequisite programs work with the agency thinking, obviously the prerequisite programs are going to have to be defined. What do you mean by prerequisite programs if they are going to work into this system of HACCP as we as regulators look at it? We felt that prerequisite programs should enhance critical control points, and that the prerequisite programs, as the agency indicated, should be in a separate section of the regulations because those of us who regulate know that we have to have some legal authority to demand to see records, and to look at them, and that sort of thing.

We agreed that the prerequisite programs should be voluntary. If there are plants who do not have prerequisite programs or do not want to share them, do not want to make them a part of their overall HACCP plan as they present it to the government, well, then I guess, they shouldn't have to. But if they are willing to do what we agreed with the agency, that they are going to

have to provide proper documentation, something that will document the activity in those prerequisite programs. We drew upon an example of when you talk about how prerequisite programs might work in a HACCP plan to enhance a CCP. We drew from the Food Processors Institute book called *HACCP: A Systematic Approach to Food Safety*, which for many of us who have been involved in HACCP training is kind of the cornerstone of that training for industry in how they are supposed to develop a HACCP plan.

An example of a prerequisite program might be as illustrated here. It says: "For example, many establishments have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and the loss of production. That would be an SOP. During the development of a HACCP plan, the HACCP team may decide that certain maintenance procedures, along with the calibration of the oven's temperature, should be included in the plan as verification activities. This would further ensure that all food in the oven is cooked to the minimum internal temperature that is necessary for food safety and which would be a critical control point for thermal processing."

So by having an SOP that documents this maintenance as including and going on to the calibration of thermometers and the critical control point and the critical limit, and the monitoring of the same, this all

works together to provide a better picture of food safety than without that SOP for equipment maintenance. So that was our thinking along that line.

We looked at the issue of "may" versus "reasonably likely" in the petition. And if I may for a second read from the petition, it says: "The rule's definition of food safety hazard is inconsistent with the definition of hazard provided by the Micro Committee. Currently the rule defines a food safety hazard as any biological chemical or physical property that may cause food to be unsafe for human consumption. The Micro Committee, however, developed a tighter, more appropriate definition of hazard in its 1997 report. Specifically, the Micro Committee defines a hazard as "a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control." They went on to say that this definition will facilitate development of HACCP plans that focus on food safety, while encouraging firms to utilize prerequisite programs.

The agency resisted or did not agree with that thinking. We thought about it from the attitude of what does "may" say versus what does "reasonably likely" say. I'll tell you personally, I'm not good at this, but the committee did a very good job of discussing it out. And the consensus was that as indicated under B, there is a difference that "may" denotes a more sensitive standard. The agency looked at it from another perspective. We

looked at it from the perspective that "may" denotes a more sensitive standard than "reasonably likely."

You can use those two words or phrases in different sentences, but there was a concern that it is still possible to lose consumer confidence, the public's confidence in HACCP, with the criticism that has been leveled at it, and that if there was an inference that "reasonably likely" was easier than "may," that that would erode that confidence. Certainly from industry's viewpoint, training is needed for us in the government on what is meant in the proper interpretation of "may." From a regulator standpoint I commented that if there is an art to what we do as regulators, it is to exercise good judgment and have a consistent definition that we all agree upon, if possible, for the use of these kinds of terms.

The third thing that we talked about had to with the industry petition on when things are shipped or when they entered commerce as far as at what point is the company done with it; and when can the regulators make a determination, if the product has, in fact, met its critical control points, is it ready to be shipped? Is it ready to be sold? Pat Stofa mentioned yesterday during our briefing the word "produced." We took that word "produced" and, as indicated under C, we feel that "produced" is the proper term. Produced comes after preshipment review, and I think that is absolutely,

positively critical that we all understand that the product is not produced by the company until after preshipment review.

Because if that is the definition and if that is the case, then the following part of that sentence is undoubtedly my fault; it kind of came out as a jumble as we were completing this. But if in fact "produced" occurs after preshipment review, then there should be no problem for a company that has limited refrigerated storage space and had taken, perhaps, their own company listeria test, to move that product to cold storage while they are awaiting the results from the test and thus awaiting the completion of their preshipment review. But there should be no question that that is a perfectly normal function.

I don't know if I've explained that properly. We can discuss it some more, but "produced" following preshipment review allows, we felt, the flexibility necessary for companies to move their products and hold them pending completion of tests or completion of their preshipment review, when the product then would be up for our scrutiny as having met its critical control points and really being out there in a not mix-branded or a not-adulterated state. But "produced" was a key word and it's a very excellent word that was put out to us yesterday.

There was some confusion. I think this may be something that occurs throughout industry and their relationship with government on that point. Can we take this truckload of frankfurters that we have not completed our own testing on, can we move them ten miles down the road into a cold storage house while we await testing? And the use of the word "shipped" puts a limitation on that. It sounds like it has gone away. Maintaining that plant control or company control through preshipment review, and then the product is produced.

Those are the three issues that we spent our time deliberating in the time that we had available. There may be other issues -- we recognize that -- in this petition and in the agency's response that may be burning for other people, but this is what we had the time to do. We concluded the second question, are there additional factors or concerns that should be considered by the agency in developing its response to the petition. Obviously, we offered none. We really didn't have a lot of time to consider that, but nothing came to mind as we finished our deliberations.

On the third question, are there additional areas of concern about which the agency should develop guidance and instructional material to continue the success of HACCP implementation? Obviously, improved training. In fact, I think we came up with training, training, training. It's like how do you get to Carnegie

Hall? Practice, practice, practice. And the guideposts for our success is to properly train -- when we want to talk about "may" versus "reasonably," when we want to talk about "produced" versus "shipped" -- our people, those of us who do this have got to know exactly what we mean.

FSIS and my program should try not to judge too narrowly. That is a common pitfall for us in government. We tend to get tunnel vision and it gets narrower and narrower as we try not to make mistakes. On the other hand, we should have checks and balances in place to offset that. And training, training, training helps that.

Last, and this was a very important issue that we discussed and it came down to a single sentence, "to encourage the development and adoption of technology," especially to eliminate subjective judgments. But those new technologies should be searched out and widely distributed, if we can. And I'd sure offer the subcommittee time to fill in the blanks with what I have missed.

MS. GLAVIN: Okay. In the absence of anything more from the subcommittee, Marty.

MR. HOLMES: Marty Holmes, North American Meat Processors Association. Maybe it's semantics or maybe I'm a little bit confused here. In the interpretation of "may" versus "reasonably likely," you're using the word

"may" as denoting a more sensitive standard, whereas in my mind, I'm thinking that "may" is a broader -- so help me understand that a little bit.

MR. MAMMINGA: Marty, I'll be honest with you. It's a little hard for me to understand. But I had to listen and kind of draw upon the feelings from -- you know, "we" listened -- it wasn't me, we all listened to each
other, but there was a feeling that if you say, this food "may" be contaminated with something, well a "may" the committee felt, some more strongly than others, felt that "may" denoted something -- it is broad, but by being broad it gives you more latitude to say, yes, it may be there, versus "reasonably likely," which -- well --

MR. HOLMES: I see "may" as being, hey, it could be anything, and "reasonably likely" as being fewer things, and so the term "sensitive" makes me think fewer. So my concern is, number one, to make sure I understand what the subcommittee is saying, but more importantly or just as importantly, is that FSIS and those who were not in the subcommittee and are going to be looking at these papers understand what's being said here. If we're not clear -- if you and I are having trouble interpreting what's actually being said and we were actually here --

MR. MAMMINGA: Understood. Let me offer my best shot at it. If this doesn't help, you're going to have to get somebody smarter than me, Marty. But the way

I look at it is, if you pick up a handful of raw ground beef and stick it in your mouth and eat it, you may get E. coli 0157:H7. If you want to look at the statistics and roll the dice, could you say it's "reasonably likely" to -- well, it might not be reasonably likely depending on the time of year, the place you're in, where you got the ground beef, where it came from. It may not be reasonably likely to get that. But you may get it. And so "may" gives you the empowerment, then, to address it, even if it might not be statistically "reasonably likely." That's the best I can do.

MR. HOLMES: Would it be more clear if this said that "may" denotes a broader standard?

MS. STOLFA: The subcommittee used the term "higher" until it was replaced by "sensitive."

MR. NEAL: John Neal, Arkansas. Marty, the point in contention -- we're in agreement with this, you and I. At the same time I saw FSIS's side of it. I didn't totally agree with it. We came to a point of contention. His example is very good, but I know our position on it would have been that "may" can entail anything. A meteor "may" come down. The roof "may" cave in. "Reasonably likely" is more conducive in the long run to -- we came to a consensus, and I understand their point, but at the same time "reasonably likely" is more definite.

The consensus of the agency, what we took -- and correct me if I'm wrong, Mike -- is that they felt that it would be contradictory to their original statement on this -- and let me finish here and I'll let you respond --that it wouldn't work well in their system to say "reasonably likely." The point was brought up that if someone saw this, "reasonably likely" would be a scary term. I personally don't think that the public sees "reasonably likely." They don't look at your hazard analysis very much. Pat may disagree or agree; we talked about it last night. I'd lean a little bit more toward "reasonably likely," but "may" is the agency's stand on it and they're not very begrudging on it.

MR. HOLMES: I appreciate that. I certainly would be in favor of "reasonably likely," too, but that's not really even my issue this morning, debating between "may" or "reasonably likely." It's just, "may," if I'm not here, or even if I am here, "may" denotes -- when you say higher standard -- I guess "may" is a more encompassing -- anything. When it's more encompassing, it's -- when I think of "sensitive," I think of more narrow. And "more encompassing" is broad. Maybe it's just semantics here, but if I'm not in this meeting and having this discussion -- I understand where you're going in terms of saying, sensitive means that it's sensitive in that it's going to catch more things. But when I

think of sensitive, I'm wanting to get rid of the excess and get down to what's actually there. So "less sensitive" would be --

MR. NEAL: Right, and it's hard when you're making a hazard analysis to use the term "may." That was our point last night.

MR. HOLMES: I understand what is actually being said, but I don't -- at least in my mind, semantically, this is not saying -- and I'm not debating the "may" or "reasonably likely" issue,I'm just saying if we're going to define "may," it's not -- it is not more sensitive, it is less sensitive. It is actually broader and encompassing more things, not less things.

MR. MAMMINGA: I agree with you, Marty, and I think that's exactly what was being said.

MR. HOLMES: If we're going to put this document out, I think it needs to be elaborated on. That's my opinion and I'll shut up now.

MS. STOLFA: Carol was the principal spokesperson on that issue and she is not here this morning. And if you want to revise the report, you might want Carol's input on it.

MS. WACHSMUTH: "Sensitive" would be more appropriate in the statistical sense. It's the difference between specificity and sensitivity, and in that case, this would be more sensitive versus what you're saying -- more specific.

MR. HOLMES: Not being a microbiologist, I will yield.

MS. GLAVIN: Dan, and then Alice, and then Sandra.

MR. LAFONTAINE: Dan Lafontaine, South Carolina. I want to throw a dissenting vote -- or a dissenting view, I should say. Notwithstanding FSIS's position, I disagree with the continued use of "may" for determining food safety hazards. Let me tell you why I say that. I have had the pleasure, you might say, of teaching approximately 15 HACCP courses now, International HACCP Alliance accredited courses, along with some of my colleagues. And when you get into hazard analysis, the thing that happens every time is they get off on the deep end and start making everything a food safety hazard.

They don't even know about the word "may" versus "reasonably likely." They just start looking at everything that can possibly happen and end up with a lot of, at that point, control points, not necessarily critical control points. The only way that you can get them out of the quagmire is to go back to the Micro Committee's definition and say, now, you need to take your plant and your system and all your variables and look at what is reasonably likely to occur in your situation. Sharpen your pencil and narrow it down to those big-ticket items, those food safety hazards that

you absolutely have to identify and bring under control on a continuous, no-excuses basis.

My point in that whole little scenario is that as long as you continue to buy into the "may" and make it across the board that anything that could possibly be a food safety hazard be included, you are missing the point of the true intent of HACCP, of identifying those things that are reasonably likely to occur, and to concentrate on those and make them fail-safe.

I wanted to throw in my personal opinion. It may or may not change any minds, but that's the experience I have.

MS. GLAVIN: Okay. Alice.

MS. JOHNSON: Alice Johnson, National Food Processors. I guess it's no surprise that I agree with Marty and Dr. Lafontaine. But I'm not sure that we are going to be able to resolve the differences with "may" and "reasonably likely to occur" in this committee. I know that the agency has several initiatives that are in place right now looking at HACCP implementation and some of the concerns with HACCP implementation through, I think, the district correlations that are going out. I wonder if it would be appropriate for the committee, instead of focusing on the definition, to make the recommendation that the agency consider this and look at some of the difficulties when they're doing their district reviews -- if there was a problem with this, if

there was a misinterpretation -- and try to come up with some understanding and include that in part of the discussion when they go to look at some of the petition issues.

Also, I know that some other agencies, FDA, has implemented HACCP and is on the verge of implementing HACCP in the juice rule. And they've changed the definition in that area, and I think Pat told us yesterday that the agency did intend to look at what FDA was doing and see some of the issues there too, to benchmark that.

So I would like to ask the full committee if we would maybe want to make a recommendation that the agency look at this "may" and "reasonably likely to occur" through their reviews and through the experiences of other agencies and determine if it's truly an interpretation problem, which obviously it is since we're all having this whole discussion -- and approach this in that way.

MS. GLAVIN: I've got Sandra next, and then John. And I would ask the committee members to respond to Alice's suggestion, since she is asking for, as I understand it, a change in what the committee report -- or maybe an addition to the committee report. Was it an addition or a change?

MS. JOHNSON: Either way you want to look at it. They have nothing under 2), but I think the

committee did a good job to get through this issue. I know this was a tough issue to discuss in two hours because I think the industry and the agency have been discussing it for about ten years, now. It may go in as addition to number 2, or however the committee feels appropriate.

MS. GLAVIN: Okay, so I would like some responses to that. Sandra?

MS. ESKIN: I have two questions, one for the subcommittee and one for FSIS. Again, on this issue of "may" versus "reasonably likely," did the subcommittee come down in terms of one or the other, as far as a recommendation goes? Because at the very top of the paper it says that you basically agree with the agency's thinking. And if I remember correctly in the issue paper, the agency said at this point they are not planning on changing any of the definitions -- unless I'm mischaracterizing it. Was there consensus on which way you all were leaning?

MR. MAMMINGA: I think as a subcommittee we ended up agreeing with the rule as written, where it says "may cause." Now, considering that we've had the same discussions here as we had last night, you know, if you notice under B, where we say there is a difference and "may" denotes -- I almost -- you know, to say "sensitive," I knew that would be a keyword last night when we put it in there. But the second thing is the

training needed to properly interpret "may." And I would offer to you that in my opinion, that "may" or "reasonably likely" are both going to fall -- or any other words that you could come up with to describe what you are trying to accomplish -- all would be subject to some person somewhere deciding, it is or it isn't.

MS. ESKIN: No, that always happens, obviously. That's just -- language.

MR. MAMMINGA: And I am sensitive to Dr. Lafontaine and his comments because I agree that a hazard analysis should be done by a company based on their specific company and their specific processes. And one size does not fit all in hazard analysis. I think again, trying to speak for Carol Foreman, which is kind of unique -- we've known each other a long, long time and we're not always on the same side of issues, but it was her feeling, representing the consumers, as Pat indicated, that the broadness of "may" allows the government to step in when a one-size-fits-all doesn't work, perhaps.

MS. ESKIN: I understand. Again, I just want to make sure I understand that as between the two, obviously understanding all the issues of interpretation, the subcommittee's recommendation at this point was to support the agency's thinking at this point, which is to stay with "may."

MR. MAMMINGA: And that's where our first comment that we basically agree -- basically, but with all those discussions that we've had today.

MS. ESKIN: The question I have for the agency is -- again in your presentation you mentioned the Micro Committee's definition of "reasonably likely." In the preamble to the HACCP rule, did the agency address this issue in any specificity saying, here's our definition, and here is how it relates to the micro standard, and here's why we picked the language that we did?

MS. STOLFA: No, we didn't address that in the preamble to the final.

MS. ESKIN: But you're likely to address it if, again, you come out with a proposal?

MS. STOLFA: We will certainly address it in any proposal that is subsequent to --

MR. DERFLER: I understand that the Micro Committee's recommendation was made in 1997. The final rule was done in 1996.

MS. STOLFA: Well, that's a good reason why you didn't address it.

MR. NEAL: In response to Alice's statement down here, I believe that that is a good recommendation. I think that the FSIS should take a good hard look at that terminology right there. To sum up what Dan said earlier, we have been trained as plants and HACCP coordinators to use the term "likely to occur." When I

walk through our facility I use "is this likely to occur" when I first begin this. And I still do it. Is there something here likely to occur -- you know, most likely to occur? And that's the way we are related, that's the way we're taught. And that's the way the plants were developed. And when we get this far down the line, it is hard to change our thinking to "may." We did basically agree. As I said a moment ago, we agreed that "may" is a nice, broad term, but in the same way the argument went last night, those on the opposing side, several that were on the "may" side -- we felt that it's the agency's belief in having control, and it's hard after all these years to lose that control. At the same time, we're supposed to be self-monitoring, and that's what we're doing. We're developing the HACCP. We don't get any approval with the final HACCP from anybody, but we approve it ourselves. We develop it. We sign it. And it goes in form, and as long as FSIS is in tune with it, they come along and check our records and everything is fine.

But still we don't get any final approval from the agency, and that's why "likely to occur" is more -- I think it became an issue of, what does the public feel. Well, the public has a right, they can look at my HACCP plan anytime that they want, and I'll be happy to explain it to them. They don't really come in and say, what does that mean, "likely to occur" or it "may occur." That

really isn't sensitive, it's not out in the public every day. So that was the answer to that. And I agree with Alice that we should take a hard look.

MS. STOLFA: I'm sorry that Carol isn't here. Carol's point was that public confidence in HACCP is still a fragile situation. And a front-page headline on the *Washington Post* that the administration rolls back or loosens the HACCP standard was not actually something that was in anybody's interest. And those were her exact words. When she was talking about "may," she was actually referring to the statutory basis of our regulation, not to language in the regulation. As I say, that was the point that Carol made last night -- eloquently, much better than I could do.

MR. NEAL: She made some good points. I mean, I agree with her. I just didn't want to make you mad.

MS. GLAVIN: Dan? Are you finished? I didn't mean to cut you off.

MR. LAFONTAINE: To switch gears slightly and talk about training. The subcommittee -- you know, under 3, you've got: Improve training. And I wanted to give my personal opinion and embellish on that.

The agency back in '96 or '97 chose for whatever your reasons were, for your workforce, for the supervisors and inspectors who were involved with HACCP, to not provide a full technical HACCP course -- rather, what I call the regulatory aspects of HACCP. I have

stated numerous times before, and I want to state it again, I think that was a huge mistake, and a continuing mistake.

Let me digress for a moment. In South Carolina, we periodically teach a HACCP course and we invite our FSIS colleagues to attend. We've got a wonderful working relationship with the Raleigh district. Over the last year we've had approximately 10 circuit supervisors and three compliance officers go through our three-day course. And I'm not trying to grandstand, but the comment is simply, we needed this two or three years ago. We needed the full, technical explanation of how our HACCP plants should be developed and implemented, and with that we feel that we can do our job better as regulators.

I realize that you have done some of this subsequently, with some of your senior staff. But at least for those decision makers, circuit supervisors and inspectors in charge, I seriously think you're missing the boat if you don't figure out a way to get them up to par with the industry on what the technical aspects of HACCP preparation and implementation are.

I'll leave it at that, thank you.

MR. HOLMES: Marty Holmes, North American Meat Processors. Although my initial discussion started on the term "sensitive" being in here, I do want to kind of reiterate what Dan Lafontaine said. Although I was not

in the subcommittee, and I appreciate the work you did, I do respectfully disagree. Of course, realize too that I am a signer of the petition. So I certainly think that "reasonably likely" makes more sense than "may" and would be better not only from a training standpoint -- and I respect Pat's statement that there's the agency, and the inspection force would have some difficulty in getting that term understood and so forth.

That being said, I think that I certainly agree with Alice's point of view that maybe under number 2 we need to add a sentence that says to the effect that the agency should take a look as they do these district correlations and see what kinds of problems that has represented for the agency and the industry.

I am curious, though, and I appreciate Irene's comment here to me on a side note that possibly, could we add a sentence or maybe even a term here that may denote a more statistically sensitive standard?

MS. WACHSMUTH: I was giving you a statistical definition of sensitivity versus specificity, just to help.

MR. HOLMES: I'm just curious if we can add some elaboration. I will hush and wait to see what happens.

MS. GLAVIN: Alice I have next. And there was someone else over there.

MS. JOHNSON: Alice Johnson, National Food Processors. I just want to respond to the comment that in the subcommittee discussions there was concern that if the agency made any changes that it would appear that there was a lack of confidence in HACCP. And nobody knows public perception, I mean, it's a difficult thing to predict, but I would like to put on the record that I don't know that you could say that changing the standard as asked in the petition would erode public confidence, when actually what you're doing is updating based on the 1997 -- as Phil said, the rule had not been written in -- the 1997 Advisory Committee report. So I don't know that if you can reference a group of experts like that, that that should be considered an erosion of public confidence or maybe just an upgrading based on the latest thinking.

MR. MAMMINGA: While we've been talking about these concerns, these very valid concerns, Alice has been working on some language. We were whispering back and forth, so just to throw something on the table to perhaps address Marty's concerns and the rest of us with these sorts language challenges, under 2, where we have offered nothing in our original report, how about making a statement that the agency should address the request in the petition regarding hazard definitions after reviewing implementation issues identified in district correlations, and experiences of others agencies in

implementing HACCP, such as FDA. Can we fix that, Marty? Does that sound okay?

MS. ESKIN: I would only suggest -- Carol is not here for health reasons. She will be here later, and I think maybe that language should be -- she should be included in that discussion in fairness, if any change is made in the subcommittee's report. I mean, she will be here, I think, soon.

MR. MAMMINGA: Oh, sure.

MS. GLAVIN: Here's my suggestion. We can, since you've done the drafting -- my plan was to ask you to do a draft proposal, we can get that -- tell me if I'm lying -- we can get copies made of that redraft, we can take a break and come back, have everybody have it in front of them. We're talking about a very precise kind of language here, so I think it would be important for everyone to have it in front of them and go from there. Is that acceptable to the committee?

Alice has one more point.

MS. JOHNSON: Maggie, I notice that there is -- I don't know what happened to that committee last night, but I notice that there is another committee member, or subcommittee member, who's not here, either. So that's probably not very fair. So maybe we wait till everybody is --

MS. GLAVIN: What did that committee do -- what did you do to that --

MS. JOHNSON: Whatever they ate --

(Laughter.)

MS. GLAVIN: The tough ones are here. I can see the weak have fallen by the wayside.

Irene?

MS. LEECH: The other thing that we probably have still got out there is that I think there's a lot of disagreement about the sensitive word. And if there is something that we can do to address what that really means. Once you discuss it, I think we understand, but I think there is probably a perception problem that if we leave that unaddressed, there will be problems down the road.

MS. GLAVIN: Okay, well, I have a reproposal then, that Mike get that language to the staff here and they get it out and that you also during the break consider the question of "sensitive" and the potential need to clarify that. And we'll bring that all back to the full committee after the break. If we are still missing three of the subcommittee members at that point, I would ask Dale, if you would be willing to go ahead with your report and bring this up at the very end of the discussion, before lunch.

Is that acceptable? If anybody knows where our missing committee members are, you can try and rouse them back to the meeting. Thanks.

Let's have a break for -- my watch says about 10 of 10, so can we be back at 10:20?

(Whereupon a break was taken until 10:22 a.m.)

MS. GLAVIN: Okay, I'd like to get us back together. We had the suggestion on the table that we wait for some of the missing subcommittee members to arrive before continuing this discussion, and I see that two of the three have, and I understand that Charles may not be joining us at all, that he is unwell. I'm not going to wait any longer for Charles, if that meets with the subcommittee's agreement.

Is that acceptable to the subcommittee? The proposal is that we have two of the three missing members and that -- I am hearing that Charles is not well and so I'm proposing that we don't wait any longer for Charles, if that's okay with the chair?

MR. MAMMINGA: It is with me. Thank you for raising the question.

MS. GLAVIN: Oh, wait. So we have, I understand, we have a redraft -- do people have copies? Have we gotten copies out?

All right. Can I ask you, Mike, to walk us through what changes have been made and see if we have any further discussion, or whether people are ready to go with the subcommittee's work.

MR. MAMMINGA: Thank you. If you'd please look at your draft number 2, and looking under B,

"Interpretation of `may'" versus `reasonably likely,'" we have offered to rewrite that "there is a difference" and that "training is needed to properly interpret `may.'" Under number 2, under C, "Are there additional factors or concerns that should be considered by the agency in developing its response to the petition," we have some draft language that the agency should address the request in the petition regarding hazard definition after reviewing implementation issues identified in district correlations, and experiences of other agencies implementing HACCP, such as FDA.

Now, I will tell you that two of our committee members arrived during our break and have read these changes and would like to offer to the committee their opinions and proposals for perhaps different language on those. So if it would be all right, I -- Carol or Elsa, either one of you -- they both have opinions, maybe we could let them offer them now.

MS. FOREMAN: I'll start. On B, we think it would be better -- since you have dropped the first line about the definition of "may" and since the agency has said it in its working paper, we don't think it's necessary to repeat it here. Dropping that line is okay. But if you drop that line, you really should drop the line in addition: "There is a difference and training is needed to properly interpret `may.'" "May" and "reasonably likely" are legal definitions, and if we're

not going to have some discussion about that, then it may be misleading to have this line in here about training. We haven't said anything about the difference, but we've left the line with the difference --

MS. GLAVIN: So you're proposal is to drop it completely?

MS. FOREMAN: My proposal would be -- if you see our first line up there, we basically -- it ends with "we basically agree," and B would read: "with the agency's interpretation of `may' versus `reasonably likely.' And then we wouldn't say anything else about it.

MR. HOLMES: Marty Holmes, North American Meat Processors. Carol, I understand what you're saying. However, from the discussion earlier this morning, I think that basically, at least my understanding of the discussion this morning, the subcommittee did not necessarily basically agree with the entire agency's thinking on the industry's petition. And that was why there was even the B issue at all. If you basically agree in its entirety, then you wouldn't even have a B statement at all. So with that being said, there are enough differences on "may" versus "reasonably likely" that -- maybe just say there is a difference, period. Regarding the interpretation of "may" versus "reasonably likely," there is a difference.

MS. FOREMAN: Look. Let me go back because you weren't in the subcommittee. Our general number 1 is -- the question was, what is the committee's reaction to the agency's thinking? Then there were separate parts under that in the agency's paper. One was about prerequisite programs, another one was about the interpretation of "may," a third was about "produced" versus -- about "enters commerce."

We agreed in each case with the agency's thinking. So under number 1, it says: "We basically agree with the fact that FSIS needs to define prerequisites with the agency's interpretation of "may" and with their decision to go with "produced" versus "entered commerce."

I will strongly argue that we need to stick with the interpretation of "may" versus "reasonably likely." It was, I think, a strong feeling in the subcommittee, and if you want to have more discussion of it here, I'm glad to have more discussion of it here. It basically says that in this instance the agency will take a standard that is more protective rather than a standard that is less protective. That's the standard that the agency is following now, and that's why the industry petitioned to change it. I don't think that the industry or the administration or this committee wants to be on record and publicly identified as saying it is okay for USDA to take a less protective standard for meat and poultry than it has right now.

Now, if you want to do that, we can have a vote and I'll just vote against it.

MR. HOLMES: I'm all for having a vote. However, I don't know that I agree, Carol. I wish I had been in the subcommittee because I would have liked to have had my two cents there, but I think these recommendations are not necessarily from the subcommittee, they have to be from the committee as a whole. My feeling is that you actually watered down HACCP by saying we're going to look at all these things that "may" occur. If we looked at all that is "reasonably likely," we'd focus our energies, our efforts and our resources towards the things that are really, truly food safety concerns.

I think the agency, even if there was any public concern over what you're saying, is lessening HACCP in your opinion. If you look at the National Advisory Committee, you look at what FDA -- the juice rule, and defend it from the standpoint that we are actually going to spend our time and effort on legitimate food safety concerns, as opposed to anything in the world that might occur, I don't know that I would have trouble being able to defend that.

MS. FOREMAN: I understand, but you are also talking about, and the petition advocates, changing a legal standard. And the legal standard now is the more protective one that is possible under the law. The law

says that you can act against a problem if there is an added substance, if it *may* be injurious to health or, in the case of a naturally occurring substance, if it is ordinarily going to cause harm to health.

The agency chose, in making the HACCP standard, to write the standard on the more stringent one in the law, on the more protective one in the law: "may." If we recommend changing this or if the agency backs off as the industry has petitioned, you are not talking about those things that have nothing to do with food safety in the plant; you're talking about saying that you will not have the agency have the power to take action against salmonella unless it can prove that the salmonella level will cause illness ordinarily in every person or in most of the people who come into contact with it.

I don't think the committee wants to be in the position of saying that USDA should have a lower standard. FDA does have a lower standard in this regard. They chose not to take the most protective standard. I think they're wrong. I think GAO indicates that when GAO now points out that FDA-regulated products are responsible for 80 percent of the foodborne illness. Part of the reason that USDA's products are now causing less illness is because we have a better, more rigorous system.

The Advisory Committee on Criteria is a scientific committee, it is not a legal committee. I

think when it used that language, it did not intend to be establishing a legal guideline. This committee is a policy committee, not a scientific committee, and if we use that it will be taken as the legal standard. And It will be less rigorous. And finally, on the FDA thing, of course, I don't get any FDA products that say, inspected and approved, United States Government, or inspected for safety, United States Government. I think that does require a higher standard.

MS. GLAVIN: Okay. I have Sandra and then Alice.

Sandra?

MS. ESKIN: Sandra Eskin. I just wanted to respond to your point, Marty, about this morning's discussion because I do know that in two instances I asked directly what the subcommittee's basic consensus was on "may" versus "reasonably likely." And twice I heard, I think, the response that, between the two, the consensus right now is "may."

MS. GLAVIN: Okay. Alice?

MS. JOHNSON: Alice Johnson, National Food Processors. I just want to be sure that it's understood that the industry petition was to try to make the HACCP rule more consistent with the 1997 advisory committee. And I know there is a disagreement with some of the committee's recommendations, but the industry supports

that and does not feel like it's a loosening up of any type of standards.

I don't think that we are going to be able to reach some sort of resolution on this thing. I know as full committee that I cannot support saying we basically agree with the interpretation of "may" versus "reasonably likely." I heard Phil say this morning that the reason why there was no discussion of this in the original HACCP rule was because the 1997 paper wasn't finalized and the rule was written in 1996. So I understand why there was no consideration by the agency.

Carol, instead of saying we basically -- you want to say we basically agree with the interpretation of "may" versus "reasonably likely"? Is that correct?

MS. FOREMAN: That was the subcommittee's position.

MS. JOHNSON: But you don't think that underneath, "there is a difference, and training is needed to properly interpret `may'" is appropriate?

MS. FOREMAN: No, because "may" and "reasonably likely" are, in this instance, legal policy terms. I think that they require a standard and that we have a standard. It's the salmonella standard, it's the E. coli requirements.

I think that the training, if it followed some further interpretation of that first line, Alice, would be okay. But by knocking that line out, the training

kind of hangs out there without much to hang it on. But I know what you want, I think. I think you want inspectors not to be looking at the quality of the gravel in the parking lot. Hey, don't laugh, I had a plant close down over that when I was at USDA.

So I understand and I'm sympathetic. You want people to be looking for the food safety, and if we change this to, you know, we need training in the interpretation of HACCP as a food safety program, that would be okay with me. But I don't know what the sentence means when it's just hanging out there.

MS. GLAVIN: I have Collette, and I took that pause as you were finished. Was that correct?

MS. FOREMAN: I was just thirsty.

MS. GLAVIN: Collette and then Elsa.

MS. KASTER: Collette Kaster. Carol kind of went there at the end of her comments, and I appreciate that. But I would just like to say as somebody who doesn't live in Washington and isn't a lawyer and has to do this stuff with inspectors at different plants every day, that the interpretation of these legal terms -- which I agree that they are, and I also concede that it's possible that the Micro Committee may not have considered the legality of the difference between these terms -- but these interpretations are so broad, and we have to use them when we come up with hazard analysis, that we really

need some kind of training or help out in the field to make sure that these are applied uniformly and fairly.

MS. GLAVIN: Okay. Elsa?

MS. MURANO: Elsa Murano, Texas A & M. I have a couple of comments to make that might help us a little bit. If you use "reasonably likely," there is a lot of interpretation that is needed to know what is reasonably likely. And there is a concern from the subcommittee that that would require something that inspectors are not prepared to do and would require a tremendous amount of education and training. Not only that but, besides the idea that the word "may" is legal, I think we are missing or misinterpreting "may" by thinking "might." And I'm not an English scholar, but "might" means possible; "may" means reasonably possible.

I think if we don't equate "might" with "may" and we just know that "may" is a reasonable possibility -- and I think that's what the legal definition probably means. Not that an asteroid is going to fall on this building, that *might* happen. But to say that it *may* happen, I think common sense tells us that there is a certain amount of unreasonableness to that. So I'd just like to offer that from the subcommittee's point of view. We feel that to change to "reasonably likely" even though that is scientifically desirable -- to leave it as "may" is not going to hinder plants from developing good HACCP

plans, because that is exactly what they've been doing up to now.

And then secondly, perhaps what we should do in terms of addressing, Marty, your issue here as far as format, number 1 saying "What is the committee's reaction to the agency's thinking." We basically agree and then we have all the parts. Perhaps what we should say under B is, we should say that the committee feels that "may" is the proper term and we should have a statement that says exactly that. Just like in C, we say exactly that: We feel that "produced" is the proper term.

And the last comment I had -- because I know that once I stop, I'll never get that mike again --

(Laughter.)

-- point number 2, based on what I just said, then, what we'd like to do is have the language of point number 2, then, say that the agency should review implementation issues identified by their inspectors, because I think there's a lot of value in what the inspectors have to say. I know that when I do some teaching out at the FSIS training center in College Station on different kinds of micro issues and topics, the inspectors are a wealth of information in terms of their life experiences doing what they do best. And I don't know, maybe this is naive, because maybe you all already get input from them regarding that. But if not, this would be a good place for us to encourage the agency

to seek and review issues that are identified by their inspectors regarding anything at all having to do with the implementation of HACCP and the rule in general. Thank you.

MS. GLAVIN: I have Michael and then John.

MR. GOVRO: Michael Govro, Oregon Department of Agriculture. I just need a little clarification on the purpose of this committee and what we are attempting to accomplish here. It seems like we're into an area where it's unlikely that the different interest groups represented here are likely to reach an agreement. It's reasonably not likely to.

(Laughter.)

And I'm wondering if it's incumbent on this committee to actually come up with a single recommendation or if we can just agree to disagree on this issue.

MS. GLAVIN: I'd like to make sure that everyone has had an opportunity to put their opinions on the table, but I am moving towards suggesting that we simply for 1-B indicate that the committee did not arrive at a consensus on this issue. That's absolutely acceptable. And that's certainly what I'm hearing, that there is not a consensus on this issue from the committee. But before going there -- I guess John was the next hand, and if there's anyone else. And then I'll just ask whether you agree with that -- and Marty.

MR. NEAL: This is in conjunction, John Neal, this is in conjunction with what Elsa said, she put it very well. At the same time she speaks of a review and that review has been done. Inspectors have come through small plants, large plants, and they have already reviewed the records; they've done it several times. I am not sure how many times, Marty, in the plants in the area you serve, but they have reviewed this. I'll go back to what I said earlier, is that we still need a part of this as training for the simple reasons we are trained to look at something like it is likely to occur. We have a conflict between the HACCP training that we went to, we spent good money to train our personnel, and it was very informative, and we feel it is working, we are all comfortable with it now, and we feel stronger in our companies.

I feel stronger about our business, too, about sanitation. Even though we were clean before I think we are better now at it, and I think industry general consensus is that they are, too. I think it comes down to what I said earlier. It is a matter of control. If you have a good plant, we are doing a good job. We are getting used to HACCP; in fact, we are comfortable with it. We are doing a good job. "Reasonably likely" is the way we are trained. It may say "may," but that is not the way we were trained. We've got conflicting sides there. We're being taught HACCP, the inspectors are

being taught HACCP, and it says "reasonably likely" to occur.

MS. FOREMAN: I keep thinking that we might get closer together on this if we could differentiate between a legal standard and what clearly is some problem that is occurring on the ground in the plants.

Would Marty or somebody, John, give me an example of a case wherein an inspector you think acted too broadly as a result of the word "may" and this has been the operative word of course ever since HACCP started. Can you give me an example of why you think on the ground it should be different?

MR. HOLMES: I guess I would just lend that many times when an inspector looks at a hazard analysis, they may ask of things, what about this -- and I can't give you a specific example of an item -- but why did you not consider this, this, and this in your hazard analysis because they may occur. They may have nothing to do with food safety. Or they may say, well, that is covered in a prerequisite program or something along those lines. So "reasonably likely" is more conducive to HACCP and true food safety hazards. Now I'm not a microbiologist here. Certainly anybody else who could think of suggestions to --

MS. FOREMAN: I think the problem is that the industry has asked the agency to go to a standard that legally is less protective of public health. And I think

that we could probably agree about the problems on the ground, and that we probably can't agree if the goal of this, or the effect -- and I'm sure it would be the effect -- is to back off to a less protective standard when it comes to public health because you don't want to do that, and we sure don't.

MR. HOLMES: And I certainly concur with you. We're not interested in producing food that is unsafe. That is not the objective here at all. But my point that I wanted to make, and I thought you were going to say -- the reason I yielded to you first is I thought you were going to tell me that the consensus of the subcommittee was to adopt "may."

So my point is that I wanted to look back at the agency's thinking paper. I want to call your attention to page 7. It says, "for these reasons the agency cannot respond positively to these parts of the petition at this time." By saying we basically agree in sentence number one, we are basically agreeing that the agency doesn't have the ability to respond positively at this time, meaning that they could possibly be in favor of some of them at a future date. And so, as long as we understand, at least from my point of view, by saying we basically agree, we are saying that we basically agree that the agency is not in a position at this time to support that part of the industry's petition.

MS. FOREMAN: I'll buy that.

MS. GLAVIN: Lee?

MR. JAN: Lee Jan. I just wanted to give an example to Carol or anyone else that has that concern about where an inspector may have acted too broadly. And example could be a grinding operation where they say that the grinder may rub against the side of the grinder and produce metal physical hazards, but that's not reasonably likely to happen if the equipment is properly maintained. Or another instance may be where oils from bearings would drip into the product, and again that may happen, but it is not reasonably likely to happen if the equipment is properly maintained.

I think that could then move us back to the prerequisites. If you have prerequisites and can lean on the prerequisites, then I would be more comfortable in going with the "may." We did consider it, but rather than having a critical control point, because if you identify a hazard that may occur, then you must control that hazard, and without prerequisites then we must put it in as a critical control point that needs to be monitored. So if we can go to the prerequisite and get that ability to control some of these hazards that may occur, but are not reasonably likely to occur, then I think the "may" term wouldn't be quite so difficult to deal with.

MS. FOREMAN: Maggie, could I? Lee, that is really a very helpful comment. And of course we did

consider it within exactly that context, having just finished discussing the prerequisite, and agreeing with the agency there, but saying that they need to define prerequisite programs more tightly.

MS. GLAVIN: Marty has put on the table a suggestion that B, and I am a little bit putting words in your mouth, Marty, so I know you will feel free to jump in -- that B read that we basically agree that the agency cannot respond positively to this part of this petition at this time.

MS. FOREMAN: If we can get an agreement that, I'd certainly go with it.

MS. GLAVIN: Okay, so the committee is not opining on whether "may" or "reasonably likely" is the appropriate standard, but agreeing that the agency is not in a position to respond positively at this time to that particular issue. Is that acceptable?

MS. JOHNSON: Maggie, are you saying that -- and I think Dr. Moran had mentioned it too, the recommendation that the agency should come back at some point --

MS. GLAVIN: Okay, we haven't gotten to that one yet. Do we need to get to that before we can close this one?

MS. JOHNSON: I hate to make a recommendation that we don't ever revisit this based on the information you learn through some of your district correlations.

There may be a need to go back and look at this. Carol, does that work? If we just take out FDA? I hate to say that we won't readdress this because there may be some issues that come up that we can identify during the correlations.

MS. GLAVIN: Okay, so what I'd like to do is keep Marty's suggestion on the table, which is that the committee basically agrees that the agency cannot respond positively to this part of the petition at this time for B. With that on the table, can we move to the second change that Mike outlined? The one that Alice is talking about under number two? Are there comments on that?

MS. FOREMAN: I consulted with Elsa, and our original suggestion was re-writing that re-write to say the agency should address implementation issues identified by their inspectors. How about saying implementation issues identified by the industry and inspectors?

MS. JOHNSON: Don, maybe you can address some of this: In the district correlations, -- Alice, I'm sorry -- do they not talk to and work with the inspector and look at the industry documentation so that that is both part of the correlations that you are working with?

MS. GLAVIN: For committee members who don't know, this is Don Smart from our Tech Services Center.

MR. SMART: That is exactly correct, and that is something I will be going over this afternoon. It gives us a good vehicle to cover these types of issues.

MS. GLAVIN: So the proposal is that the industry should address information --

MS. FOREMAN: Implementation issues --

MS. GLAVIN: -- implementation issues identified by the agency --

MS. FOREMAN: No, by the industry and the inspectors.

MS. GLAVIN: Inspectors or agency? By the agency and by industry. Now, with that, do we have agreement with the earlier suggestion on B from Marty? Do you all know what we've got? Now, this is important because we get back and we don't know what we've agreed on.

Let me try this, and what I'm going to ask is for the staff to put this into a typed form and we will re-circulate it just so everyone goes home with a piece that says the same thing. I believe what has come out is that B would now read, "the committee basically agrees" -- and I'm going to page 7 of the agency paper -- "that the agency cannot respond positively to this part of the petition at this time." Got that? I don't see anybody flagging, so I think we're on a roll here.

And number two would now read, replacing the current number two, "the agency should address

implementation issues identified by the agency and by industry." I had changed "their inspectors" to "agency" because of the work the Tech Center is doing. Is that acceptable?

MS. FOREMAN: Just for the record, I believe that Elsa was trying to go to this beyond the ground issues that have been focused on both from the industry side and from her experience in training. Although I understand, the record at least ought to show -- or the agency, including those on the ground -- some language. It would be okay with me if the record simply indicates that that was what we were talking about.

MS. GLAVIN: Okay, let me try again and make sure that we've got it. "The agency should address implementation issues identified by the agency including inspectors, and by the industry." If you'll bear with me, I just want to make sure that we've got this because it is important to have the wording the way you want it. Okay. Thank you --

MS. FOREMAN: Maggie?

MS. GLAVIN: Yes?

MS. FOREMAN: I just wanted to thank the committee for holding off to have this discussion after the break. I appreciate very much your accommodating my need to go for physical therapy this morning. Thank you.

MS. GLAVIN: Mike, have we addressed number three?

MR. MAMMINGA: We have read it, and we have not had any discussion, that I recall, about that point. So we might ask if there is some.

MS. GLAVIN: Number three, are we comfortable with that?

MR. NEAL: One of the main key points of this right here, and it goes along with everything we've just done -- this will only take a moment -- the FSIS should not try to judge too narrowly. And it goes along with the statement you just made about the agency review and everything and what the tendency is. And if the book says go one way, especially with different inspectors, their determinations are a little bit different sometimes, they have a tendency to judge very narrowly.

When they take a look and do their reviews, they need to go with the fact that it is written up as "may," but they also need to go "reasonably likely." They can use that. It can stay as "may" at this point. It is going to. But they could use "reasonably likely" in their thinking when they make a review, so they won't stay real narrow on their visions of what we're doing here.

MS. GLAVIN: Are you suggesting a change to the wording here?

MR. NEAL: No, leave what's there in there. But that needs to be -- but basically that should apply to the whole policy.

MS. GLAVIN: Okay.

MS. FOREMAN: I would like to, if I may, say one word about that last line there, if we are to the last line.

MS. GLAVIN: Sure.

MS. FOREMAN: And this is something that just comes back to me every time I sit through one of these meetings or have any interaction with the program. So much of what is contentious here is contentious because the judgments aren't necessarily subjective because we don't have adequate technology for the inspectors to make objective judgments. So, once again, I make my plea to the agency, and I assure you I have made it everywhere else I can; we've got to have those objective measurements, the chemical tests, the whole range of mechanical tests that can be applied to say it doesn't make any difference which inspector applies this test, it either passes or it fails. And then we could stop having these meetings. Thank you.

MS. GLAVIN: I think we are ready to move to Dale's report? Is that right? Good job. Subcommittee number two. Okay, three? Thank you.

MR. MORSE: A revised copy is being passed out. While that is being done, first, on behalf of the committee I want to express our thanks to Sandra Eskin, who worked overtime last night to sort of type together

some of our comments. And that is what is being passed out now.

Our group was standing committee number one and the issue was emerging egg and egg products strategy. I think at first we thought it was a mission impossible. I say that because we were somewhat asked to comment on implementation of a proposed rule that we haven't seen yet. So it was difficult to make recommendations on how it should be implemented when we weren't sure what it was going to say.

The second point is that we also were aware that FDA is simultaneously proposing its own rule, and that because of the complicated nature of both FDA and USDA agencies' oversight of various levels of egg production, from breeding chickens which are under USDA to egg laying on a farm, which is under FDA, back to processing plants that are under USDA, and then transportation under FDA, wholesale under both, retail under FDA, and restaurants and institutions, FDA quite often implemented by state and local health departments.

We felt that it was difficult that both rules needed to be considered simultaneously, in terms of their implementation. So with those caveats, in discussing point number one, which was what comments or suggestions does the committee have based on its members' experience with HACCP on the implementation of the proposed FSIS egg food safety plan. I think the consensus was that we

could really comment on the development of the proposal. It is difficult to talk about the implementation until we saw it. So it is as FSIS develops and implements it, what sort of things should they consider. And those are the first six principles.

The first point was that the committee felt that in implementing the proposed HACCP system for eggs and egg products that it should take into consideration the experience and lessons learned from the development and implementation of other HACCP systems, such as, for example, the meat and poultry products and FDA's juice HACCP system. The concept was to learn what didn't work and try to avoid some of those pitfalls as you go forward.

The second point, and this may now be redundant with point three which we added this morning to try and clarify, but now in retrospect I think point two may be covered by point one and three now that we clarified. Point two was that FSIS should specifically request comments in its egg HACCP proposal and issues identified in the implementation of existing HACCP systems, which now I thought was redundant with number one, because that was looking at existing systems. So I think number two the committee -- can we drop now that we've added number three, which was probably a clarification of two?

I'm going to go to number three. In our briefings last night we learned that some of the packers

have quality assurance systems, and that some of the egg processors that handle eggs that might be going for pasteurization, already have some existing HACCP systems that they have developed themselves. Or they have some kind of quality assurance, so point three was that FSIS in developing its rule should request comments on the effectiveness of existing programs utilized by egg packers and processors in developing its egg HACCP regulations. So I guess what I am saying is that the committee can comment. So I think one and three cover two, and two is now redundant.

Point four, the FSIS proposed that egg HACCP regulations should follow HACCP principles outlined in 1997 by the National Advisory Committee on Microbiologic Criteria for Food. I guess there was a discussion that this should be science and risk based.

Point number five, FSIS should work with industry to train industry members and regulators on both the scientific and regulatory components of the egg HACCP system. I think the feeling was that it would be better to get input from industry upfront in terms of what would work best and in terms of training its members.

And point number six, there was discussion about whether the regulations should be phased in by size of operation and we thought that that would probably be a good idea, but there was discussion that there should be no blanket exemptions. Blanket exemptions are discussed

in relation to some of the smaller flocks that which might be sending their eggs for packing. The feeling was that -- I guess there is an exemption now for flocks smaller than 3,000, and the feeling was that there should not be a blanket exemption upfront, that they could pose some risk, so that exemption should not be used.

Do you want to add any comments or clarification? Or shall I go through the next two?

MS. GLAVIN: Let's pause and see. Are committee members clear with where we are going?

MR. MORSE: So the first thing I am suggesting is that two if now redundant with one and three, so we can remove that.

MS. GLAVIN: Sounds like people are following.

MR. MORSE: The second question we were asked to address was what is the best way to achieve interaction and communication with federal, state, and local agencies involved in egg food safety. Part of this initial discussion was about -- there was overall discussion again for the point, the need to work closely with FDA on its rule-making as well, so there is, as much as possible, uniformity between rules that are being developed by FDA and USDA. That said, the feeling was that FSIS should take advantage of a number of existing forms and approaches to communicate. A number of those are listed. Townhall meetings' feeling that they should carry information to where the egg establishments are,

and should use land grant universities' extension agents, shell egg surveillance program information, trade associations and shows. And that there should be a joint training program for agency personnel and industry. That would be valuable.

On the next page, I want to emphasize in this regard, one -- this relates back to the need for coordination between FSIS and FDA in the development and implementation of their egg safety regulations. It is important that they're viewed at the same time and commented on to try to remove potential disparities between two sets of regulations. Two, that it was important to have effective communications between headquarters and the field. Part of this is again so that there is uniform interpretation of rules. Three, uniform application of federal requirements by federal personnel. Four, consistent implementation of requirements from state to state. So these points were added to try to reduce the amount of disparities between different locations and agencies. Are there additions by the committee?

MS. GLAVIN: Any discussion or questions by committee member?

MS. MURANO: Elsa Murano, Texas A & M. I just wanted to get clarification on point number five of your first question. Can you explain a little bit more what you guys had in mind in terms of the training that the

industry and regulators would engage in terms of FSIS working with industry. What did you guys envision with that?

MR. MORSE: I'll defer to someone else.

MS. JOHNSON: We talked in the subcommittee about the joint training on the scientific issues, and that there may be a need to look at regulatory training separately; but that for on the basic science of it to have industry and agency people trained together. That is what we were recommending. We helped write that one and it didn't come out quite right. We were talking about the joint training on the scientific areas with industry and agency people.

MS. MURANO: I guess I would like to suggest maybe that you kind of change the phrasing to say exactly what you just said now, Alice because I think that is important.

MR. MORSE: Do we have the suggested modification wording? Oh, we'll have that in a minute.

MS. GLAVIN: I'm waiting for her to stop writing. Did you get the suggested wording down? Can you repeat it?

MS. JOHNSON: I was trying to remember what I said. FSIS should consider joint training on scientific concept with industry and agency. Sandra? Collette? Anybody got anything better for the wording on that one?

MS. ESKIN: I have the original language here, is that going to help? This principle says, "educate and train on science aspect as well as regulatory component, joint training between industry and regulators when possible."

MS. JOHNSON: Sandra was nice enough to take this home and type it up for the group last night.

MS. GLAVIN: Sandra, could you make sure that the staff gets that wording?

MS. KASTER: Maggie, I have a question. Under number three we say uniform application of federal requirements by federal personnel, and then we go on and say consistent implementation of requirements from state to state. Was that where we were getting at the fact that some of this is going to be done contractually, and especially the relationship between FSIS and FDA, and that we wanted that to happen uniformly? It might just be me, but I don't understand exactly what we are trying to say by uniform application of federal requirements by federal personnel.

MR. MORSE: The other committee members may want to comment. My understanding was that number three was addressing within the application of the rule within the agency. So there would be uniformity in the central office, and in the field in various regions. Number four was addressing where other agencies might be involved. So one was within the federal system and the second was

implementation where other agencies might be involved, such as at the local level where states --

MS. GLAVIN: Let me ask Lee for his point, and if you need to come back, we will.

MR. JAN: I just wanted to kind of say what I remember in the discussions regarding this. We talked about the federal program being contracted out to states, which is the case in many instances at this time where there is some type of program; and so we wanted to make sure there was some kind of a review process or some way to assure consistency that every state is applying or implementing or enforcing the same regulations in a similar manner. And from that came where FSIS inspectors are doing that in different states, that that is also consistent from state to state, even though it is carried out by the same agency, because we know that there is different area heads, and so we wanted to have consistency there. That is where those two points are kind of coming in.

MS. GLAVIN: Does that clarify it for the committee? Hold just a second, I want to get back to Collette and see if her --

MS. KASTER: I think Lee verbalized what we were trying to say. And maybe it is me, but I just don't read that in points three and four, so --

MS. GLAVIN: Well, maybe you can work on a rewrite while we hear from Dan.

MR. LAFONTAINE: I have a question that relates to this directly and I need to know the agency's thinking. We are talking about a regulation here, not a law, I realize that. My question is will this apply only to interstate shipment of egg products and shell eggs? Or will this also apply to producers who ship only intrastate? Because that is real key in this whole issue when you start talking about the very small, which the committee has basically bought into that it has to apply across the board. And if you haven't thought about it, then you really need to dig into it, because it gets into the whole implementation issue and how it actually happens once you put it on the street.

MS. GLAVIN: Judy is saying that the FD&C Act applies only to interstate and unfortunately without looking at it, none of us can be absolutely sure whether EPIA -- there we go -- Vicki, you need to come to a microphone. Does EPIA apply only interstate?

MS. LEVINE: It applies intrastate as well as interstate.

MS. GLAVIN: Okay, so--

MR. LAFONTAINE: So the Egg Products Inspection Act applies intrastate as well as interstate.

MS. LEVINE: Yes.

MS. GLAVIN: You can go to the bank on what Vicki says on that. Okay. Where are we on your recommendation there, Dan?

MR. LAFONTAINE: I wasn't really making a recommendation, it more of a query that as this whole thing evolves that that is a very key point on how the regulation is written. You know, we talk about contracts with states, or combinations thereof, and how are you going to put this work force together to effectively implement it? If you've got, to start with, a big loophole, if they only ship intrastate then you've immediately got a tremendous confusion factor in the industry and with regulators on who really falls under this. So it was only an opportune time to clarify that. That is the only reason I brought it up.

MS. GLAVIN: And clearly it is important that the proposed rules in this area be exquisitely clear as to what is covered because of the differences in the laws. Lee and Collette, do you have a proposal on re-writing that one section?

MR. JAN: We'll give it a try.

MS. GLAVIN: First, would you clarify for me what we are re-writing?

MR. JAN: This is under question two on page 2, and it's after the bullets. It talks about the subcommittee also noted the importance of one, two, three, and four. And we are going to re-write three and four. Three will continue with "the uniform application of federal requirements by federal personnel," and we will add to that, "where FSIS provides the regulatory

oversight." And four, "consistent implementation requirements from state to state through an established, periodic review of the state programs."

MS. GLAVIN: Did all of the committee members get that proposed change, and if so, is that the sense of the committee, where you want to go?

A PARTICIPANT: Can you repeat number four, please?

MR. JAN: "The consistent implementation of requirements from state to state through an established, periodic review of state programs."

MS. GLAVIN: John has a question.

MR. NEAL: I may be wrong on my number. How many states are MPI certified, 23?

MS. GLAVIN: Meat and poultry?

MR. NEAL: Yes.

MS. GLAVIN: I think it is 27 at the moment.

MR. NEAL: Is it 28? I wasn't sure.

MS. GLAVIN: It has been going up the last few years, but I'm sure Dan's right. Twenty-eight.

MR. JAN: Basically, they will come under these federal standards, regardless, and they will have to --

MS. GLAVIN: Well, these are eggs, so that is not necessarily the same as those that are under meat and poultry or have meat and poultry programs. Judy, do you know how many have egg programs?

MS. RIGGINS: Thirty-seven, I believe -- it's about 37 states right now.

MS. GLAVIN: I'm going to repeat that since I have your microphone. Judy says that 37 states have egg programs.

MR. JAN: They just told me that it doesn't come under this, anyway. I just figured it might fall under it. Excuse me, just ignorance.

MS. RIGGINS: But these requirements would cover all 50 states, though, because in those states that don't have egg programs, we would then provide the inspectors to do the verifications. So it would apply across all 50 states.

MS. GLAVIN: Yes?

MS. ESKIN: If we're done with this point, before we go on to the third point or conclude, I was going to read the revised language, Elsa, that you had requested on that bullet. On the first question, number five, I went back to the original language and plugged it in and here's what it sounds like. "FSIS should work with industry to educate and train industry members and regulators on the scientific aspects as well as the regulatory components of the egg HACCP system. Joint training of industry and regulators should be conducted whenever possible." Is that all right?

MS. GLAVIN: Elsa?

MS. MURANO: I guess I'd like to encourage the agency that it consider doing the training on the scientific aspects like Alice was saying, jointly -- not leave it as whenever possible because that is one of those iffy words, just like "may" and all that and we don't want to go there.

And I know from my experience in doing HACCP training in other countries, for instance, in Argentina is a good example, inspectors and industry people get trained in workshops together -- and I cannot tell you the value of that -- on the scientific aspects of HACCP. So I would like to make it stronger than just "whenever possible."

MS. ESKIN: It looks like the original language was stronger. It's just again, I don't know the people -- who worked on this particular principle.

MS. GLAVIN: Dan?

MR. LAFONTAINE: I want to strongly back up what Elsa said. We did the same thing in South Carolina with our part of the industry who regulate, and it has paid tremendous benefits because you start off with a common understanding. I would recommend making that the plan and not saying just if possible. In other words, eliminating if possible, and make that your action plan to do it together and work out a way to do it.

MS. ESKIN: Simply take out "whenever possible"?

MR. MORSE: That would make it consistent with number two, page 1 of the last bullet, where we get the joint training program for agency personnel and industry.

MS. GLAVIN: Do people want Sandra to read it again as further modified, or are you okay with it? And you will provide that to the staff? Great. Lee?

MR. JAN: I'd like to just make one comment regarding that. I agree with both Dan and Elsa that joint training is beneficial. We did that in Texas as well. But I think we need to be careful that we don't mandate that industry attend these trainings because if you do, how are you going to get them to come. What are you going to hold over their heads? We made it available, but actually had a very small segment of the industry actually attend. That was their choice. We made it widely available. So if we make it mandatory you may have trouble getting them in, unless that is the only training available. But I certainly support that joint training. I think that is very beneficial.

MS. GLAVIN: Are there comments or questions on this subcommittee's report? One more section -- I'm sorry. I'm apologize. I'm getting hungry.

(Laughter.)

MR. MORSE: The third question for the committee was in which areas of the egg food safety plan should FSIS concentrate its limited resources. And the committee listed several different options. The first

point, in terms of priorities, "the FSIS should focus its limited resources on developing the regulatory structure for an egg HACCP system."

The second sentence -- I may ask the committee for some modification, now reading it, it says that it should then contract with state regulators who would enforce the standards and other regulatory requirements developed by FSIS. And from the previous discussion, it looks like 28 states, I guess there are state systems, but it may not always be the case. This maybe should be modified somewhat. It doesn't sound like all the states do this, right? So the first principle, the first sentence, the general principle is that the focus should be on regulatory structure, and then how that is carried out in some states. I'll ask for some wording while I continue to talk.

The second point was that some portion of federal resources should be used to evaluate on a periodic basis the effectiveness of state contractors' enforcement activities. And the third was that some portion of federal resources should also be used to educate all stakeholders -- producers, packers, processors, retailers, and consumers -- on its egg HACCP system. Throughout the discussion by the committee some general principles or emphasis, this was sort of like apple pie so it wasn't put in, but felt that FSIS should use sound science, public health importance, a risk-

based approach, uniform standards, and education and training. But those just re-emphasize what is probably already known.

Other committee comments? I guess I am asking for some transition in the second sentence for the first one. Or maybe there isn't a transition needed. Dan?

MR. LAFONTAINE: As far as your comments, Dale, about only 28 states having MPI programs, I think every state has regulatory structure for various items, rather than it be only 28 currently have meat and poultry inspection programs or a combination thereof. So I guess my point is, the question is limited resources. And the most effective way to use limited resources is a 50-50 funding or some type of a contracting out, so I don't think the fact that there is only 28 that have MPI programs is a limiting factor. It still may be that some states cannot buy into it and FSIS has to assume the whole mission. I guess I am saying that in that second sentence it should then -- contract with state regulators to the extent possible or put in some word that encourages to go in that direction to the maximum extent possible. And then realizing that it may not work out in all 50 states.

MR. MORSE: So if we just add to the extent possible.

MR. MAMMINGA: I heard a little apples and oranges in that discussion because when we talk about the

MPI programs, that is not what we're talking about here. We're talking about 37 states that have some sort of an egg program now and they are not necessarily in the MPI programs or even in the departments of agriculture or departments of health.

We are talking about existing states that have some sort of an egg surveillance program now. Isn't that correct when we talk about state regulators?

MS. GLAVIN: What I am hearing is that the subcommittee is recommending that in any state where a state regulatory body is capable of carrying out this program, the federal government should contract with that body. I don't know that it necessarily has to be an existing today body. A state could choose when this goes into effect to set up a body, or to have another body that is in existence take care of it. Is that the sense of the subcommittee?

MR. JAN: I agree.

MR. MAMMINGA: I was hearing MPI programs and that doesn't necessarily apply.

MS. GLAVIN: Yes, I see your confusion.

MR. MORSE: So it seems like the wording "to the extent possible" would cover that unless --

MS. GLAVIN: Would that cover it? Okay. If there is a state body willing and able to take this on, USDA should contract with that state body. If there is not, USDA would do -- okay, Lee?

MR. JAN: One thing that just came up real briefly. I'd like to just pose a question to FSIS whether it would be in those states that perhaps choose not to take this project or hire staff to do this project, would it be appropriate or even allowed for the federal government to contract with an independent contractor in that state to carry out the provisions of the regulations? And there is precedent for that at least at the local levels where a private firm provides FDA-type inspections for restaurants and retail establishments for cities. So I don't know if the federal can contract that way or not.

MS. GLAVIN: We have not done so, I don't know the answer as to whether legally we could choose to do so, but we have never done so. At least so far, I haven't heard that that is where the committee is going. So that is just a question. At this point the committee position is contracting with states and it is not going past that.

MR. MORSE: There was some discussion on the last point about the need to try to address the farm setting, but that currently isn't under FSIS's responsibility. But that just reinforces the need to have close interactions and discussions as FDA develops its rule. And that they basically need to be brought out together, rather than independently so that they can be viewed side by side.

MS. GLAVIN: Dan?

MR. LAFONTAINE: Administrative suggestion is that now that all of the three subcommittees have reported and we feel we have the refinements -- I assume that after lunch we'll get a final version -- and to make enough copies for the general public so our colleagues in the back here can see exactly what we come up with.

MS. GLAVIN: Right. Yes. I think we can commit to that. Yes. So after lunch at your place will be the versions that have been worked out this morning at each place and they will also be on the table -- for people in the audience, they'll be on the table outside the meeting room after lunch.

Any further discussion on the subcommittee issues at this point? Well, we are going to get an early lunch today. I ask you to be back promptly at 1 o'clock for a briefing on the Micro Committee work, an update on the Micro Committee work. So don't let the extra 15 minutes go to your head.

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(Whereupon, at 11:43 a.m. the meeting in the above-entitled matter was recessed, to reconvene at 1:00 p.m. this same day, Wednesday, June 6, 2001.)

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

MR. DERFLER: We're going to get started now. Maggie Glavin, as she said before lunch, is going to be at a meeting, and she asked me to lead the meeting until she gets back, which will probably be about 2:30.

During lunch the revised versions of subgroup number 2 and subgroup number 1's papers were handed out. I believe they reflect where we wound up. If anybody wants to take a quick look or has any changes, any suggestions -- well, I don't want to go back and reopen it. We're going to take it that this is what everybody agreed to unless we hear otherwise. Having said that, the first briefing after lunch is by Brenda Holbrook, who is going to summarize the latest dealings of the National Advisory Committee for Microbiological Criteria for Foods.

As Maggie said before lunch, we try to keep both advisory committees in contact with each other. It so happens that we actually had that advisory committee here in the beginning of May. And so I would like to ask Ms. Holbrook to provide us with a report.

MS. HOLBROOK: Is my microphone working? Can you hear me? Welcome all, as Phil just mentioned I'm going to be speaking on the activities of the National Advisory Committee on Microbiological Criteria for Foods.

Our advisory committee was formed in 1988 by the secretary of USDA and the secretary of HHS on the

recommendation of two external organizations; the National Academy of Sciences recommended that such a committee be formed to achieve some sort of an interagency approach to food safety. And then it was also recommended by the U.S. House of Representative's Committee on Appropriations for 1988. We have five supporting agencies: FSIS is one; the Food and Drug Administration of HHS; the Department of Defense; the National Oceanic and Atmospheric Administration of the Department of Commerce; and the Centers for Disease Control and Prevention, which is also from HHS.

Our main purposes are to advise the member agencies that we've just described. Our committee focuses on science, not policy. And we also try to maintain a liaison and communication with this committee to coordinate with you on scientific matters.

The existing committee was rechartered on September 6, 2000, and the charter will hold for two years. As we constituted this committee this time, we tried to enhance our capabilities in risk assessment, predictive microbiology, and statistical analysis. We also paid close attention to our balance with respect to industry members, consumer members, and academic members to bring their respective perspectives to our committee. We have a total of 28 members at this time. We are aware of and try to create a diverse population of our

committee with respect to minorities, women, and persons with disability.

As Phil just mentioned, we held our first meeting of this new committee on May 7, 2001. We wanted to have an agenda for you at your places, but I'm not sure they were actually handed out. I do have an overhead that shows what our agenda looked like.

We had major items of salmonella performance standards in green, and then at the bottom of the screen you see our E. coli 0157:H7 in blade-tenderized nonintact beef was our other main issue. I think you have at your places congressional language that sort of further describes the charge to our committee. And I'll read just briefly from it. The copy that you have in front of you might be a little difficult to read.

"The congressional committee would like our committee to produce a report, including recommendations to the secretary, to be prepared by the National Advisory Committee on Microbiological Criteria for Foods regarding microbiological performance standards, including the role of such standards as a means of assuring meat and poultry product safety, as well as such other considerations as the committee deems appropriate. These activities should in no way delay the implementation of HACCP inspection or other food safety activities." So that was the general charge that we received from Congress.

Now, also at your places I think we've handed out the specific questions that we presented to our committee per that congressional language. The first one you should see is the salmonella performance standards set of questions and then the blade-tenderized E. coli 157:H7 questions. Our members were also encouraged to attend the follow-on public meeting on the proposed rule for performance standards for ready-to-eat foods as a means of introducing them to the general topic of performance standard questions once the specifics of the salmonella standards work was completed. I think we have some handouts of those questions.

These go on at length here for two pages, so let me just summarize in more general terms what the committee was asked to do. They were asked to review the role of microbiological performance standards in general as a means of improving and ensuring meat and poultry product safety. Furthermore, they were also asked to review and evaluate the FSIS salmonella performance standards, specifically in what they've accomplished to date. And on the performance standards questions, let me just say that FSIS would like technical input on the use of indicator organisms in lieu of a specific pathogen like salmonella.

The agency wants to know whether it is both scientifically appropriate and wise from a public health standpoint to incorporate regional and seasonal

variations into performance standards. They also asked for technical input on how quantitative baseline prevalence data should best be used to develop and modify performance standards. And finally, what are the key considerations that should be factored in when using risk assessments to develop performance standards? So that is a different way of saying what you've got on your handout.

I think we will move to the next text slide. We have formed subcommittees to address these two issues that were submitted by FSIS as well as some other questions that I will get to in a minute. Questions that come from the other member agencies. We hope that the subcommittees that we were formed will talk about and resolve the FSIS questions. We hope that they both can meet twice over the summer months. And we hope that by our next plenary session in September that the committee will have had a chance through the subcommittees to come to some conclusion on those questions.

So these other questions on subcommittees are as follows. While we decided that we would take the broad question of microbiological performance standards and break it into two if not three general categories, the first one being questions related to meat and poultry specifically, primarily an FSIS issue. Seafood, which is not dedicated to any one particular agency but seems to be of interest primarily to FDA and NOAA. And then we

are reserving another slot for another question that may come up so that we can hold a place for another subcommittee on a different question of performance standards. We also have a subcommittee on the blade tenderization/E. coli 0157:H7 question, which is of interest, of course, to FSIS and also to FDA through their work with the food code.

The third issue we have on the table is criteria for refrigerated shelf-life based on safety. We also have another question about CODEX for the committee that we hope will be a short one. There is a document that has already been prepared that would -- that is coming up for review on CODEX, I think in October. I would like the committee review that quickly and then come to some conclusions about that.

And the final one is hot holding temperatures, of interest to FDA, FSIS, and the Department of Defense. So that is basically what we plan to tackle while we are in session for this term. Our next plenary session is planned for late September.

MR. DERFLER: Thank you, Brenda. Anybody have any questions about what you just heard about the other advisory committee?

MS. LOGUE: Hi, Catherine Logue, North Dakota State University. Just a couple of questions for you regarding emerging pathogens or looking at any of the newer ones of concern -- I'm thinking here of

campylobacter -- does the committee have any proposals to look at that at a future time?

MS. HOLBROOK: I am going to refer that question to Dr. Wachsmuth, who is sitting across the table.

MS. WACHSMUTH: The committee was asked once by this committee to look at campylobacter in terms of generating a performance standard similar to what we have for salmonella. And the committee did consider that and concluded that we did not have enough data for them to draw any sort of scientific judgment on that. At the time we proposed a baseline study within FSIS and we were already doing one, so we have concluded both a baseline study with our traditional methods, and now a baseline study with the new method, and at the same time we collected those samples, we collected salmonella and generic E. coli samples. So we have a tremendous amount of data we are trying to pull together now.

It will take a little bit of time to analyze. And it has taken, of course, a year to get a baseline for each. We hope to have -- I don't know if it will be by the end of this year or not, but we hope to have data that we can take back to the Micro Committee so they can consider this question in more detail. Our first shot at it was that it would probably have to be something like a quantitative standard, if that were to be the case.

MS. LOGUE: My second question is regarding Listeria monocytogenes in terms of ready-to-eat products and where the committee stands on that at the moment.

MS. HOLBROOK: I'm sorry, I couldn't hear the end of your question.

MS. LOGUE: I'm interested in knowing where the committee would stand on the likes of Listeria monocytogenes on ready-to-eat meats and such products and what is happening with that.

MS. HOLBROOK: There are a couple of different things that the committee has done. They were some of the primary reviewers and contributors to the large risk assessment, risk ranking, that FDA had the lead on that we also participated in. So they were involved all the way along in the development of that. They will probably also consider listeria in ready-to-eat foods under the performance standards at a time in the future. Our first agency decision was to have them look at salmonella in HACCP as the first performance standard because that is very big, and I think that is one of the things that our mandate was suggesting, even though it is not stated. Then we will take our other performance standards, any that involve micro criteria to the committee, so that will involve listeria and FSIS ready-to-eat products.

MS. LOGUE: Thank you.

MS. HOLBROOK: Any other questions?

MS. FOREMAN: What is your time frame on these first couple of questions?

MS. HOLBROOK: The first two, the one on the performance standards on salmonella and the blade-tenderized?

MS. FOREMAN: Yes.

MS. HOLBROOK: We formed the subcommittees and they will be meeting over the summer. And we have asked to have a product from each subcommittee to be presented to the full committee at our next plenary sessions at the end of September. And then the full committee will have a chance to review and react to what the subcommittees have produced.

MS. FOREMAN: Do you expect to have some sort of full committee report before the end of the year?

MS. HOLBROOK: I would assume so, yes.

MR. DERFLER: Any other questions? Okay, thank you again.

Next we are going to hear from Noreen Hynes, who is the deputy director of the Human Health Services Division of our office of public health and science. And she is going to give us an introduction and overview of field epidemiology. As most of you are aware, we recently requested recalls of potentially adulterated meat and poultry products, based in part on information gained through field epidemiology investigations.

The presentation will provide some insight into those investigations and/or actions. Our policies and practices are evolving in this area, and we present this as the start of a public process. We expect to hold a series of public meetings beginning this summer to expand this discussion, listen to comments from all interested parties, and help us to formulate firm policy and procedures in this area. This is an issue we will likely be asking you to consider at a future meeting.

MS. HYNES: Hi, it's a pleasure to be here today, and because I've heard a few mumblings or comments, no, this is not a uniform of the United States Navy, it is the uniform of the United States Public Health Service, a uniformed but not military service of the United States. And I am here at FSIS under a special arrangement with the Office of the Surgeon General of the United States, working at FSIS.

Today, I should note for everyone who is here, to remind everyone that there is a briefing paper in your binders, behind tab 10, which will essentially cover the items that are included in this briefing.

What I would like to do today is just very briefly discuss applied epidemiology as a public health tool that is used in general in public health agencies whether they are purely public health agencies or public health regulatory agencies, such as FSIS or the Food and Drug Administration. And then I'd like to discuss more

specifically the role of applied epidemiology in the timely identification of hazards, particularly foodborne hazards, and how it is used to bring about the appropriate and timely institution of public health actions that protect us, the consumer.

How I'd like to approach this today, very briefly, is to put applied epidemiology in the perspective of epidemiology in general; talk about some of the unique aspects of applied epidemiology, which is also called field epidemiology -- and certainly in my description you'll understand why that's another name for it; the importance of cross-jurisdictional collaboration on such investigations between federal, local, and state health and agriculture departments; some of the unique challenges that are presented when doing such field investigations; and a few examples of field epidemiology in action.

But first, in general, to give everyone sort of a background, understanding that there are people in this room who are highly trained epidemiologists and others who are public health professionals for many years, so this will be old hat, but for many others this may not be so, I'd like to discuss very briefly the concern of epidemiology in general and then how this applies and how applied epidemiology relates in general to epidemiology.

Epidemiology in general really is concerned with the frequency and types of illnesses and injuries

and how they're distributed in populations. Very often you'll hear epidemiologists talking about the important aspects of time, place, and person, which help put whatever the illnesses or outbreaks or injuries are in perspective. And epidemiology also looks for risk factors that influence the distribution of time, place, and person that one sees in epidemiology.

The whole approach to epidemiology really is twofold. There are the detailed, prospectively designed studies that often take a long time to come up with and to institute, to carry out and analyze. And then there are these applied epidemiological investigations, also known as field epidemiology, and they really are similar and yet there are some very, very distinct aspects to the latter.

So I would like to begin first, before we get into the nitty-gritty of applied epidemiology or field epidemiology, just to briefly discuss how epidemiology is used to inform important public health actions and decisions. And I'm going to use, for this example, hepatitis A virus infections in the United States. Now, as many of you know, some part of these infections actually can be food borne, usually due to the fact that you have an infected food handler who contaminates food and then it gets served to individuals and then they are part of a foodborne hepatitis outbreak, although there are many others modes as you see here, modes of

transmission which are only important here to demonstrate what epidemiology does to inform public health decisions.

Here is a global distribution of hepatitis A virus infections in the United States. If you look at the legend on the bottom, this tells you that whether or not a particular area is designated as high, intermediate, low, or very low in terms of this map, has to do with the prevalence of antibodies in the population to hepatitis A, meaning how many people in the population in general or the prevalence of people who have antibodies which would suggest they've seen the infection in the past. According to this particular graphic that comes to us from WHO, it suggests that the United States is a very low prevalence country, although some of the definitions that are used would suggest perhaps it is not. It might be intermediate.

Through epidemiological study and looking at the distribution of time, place, and person, this is how these particular subsets in the population are identified as high, moderate, low, and very low. If you'll take a look at the moderate and low, for moderate, it's person-to-person spread through waterborne outbreaks, which tend not to be the case in the United States; and low, it tends to be person-to-person foodborne and waterborne outbreaks with young people, young adults being the peak of infection although, as you'll see, the United States

probably is moderate because late childhood is part of the pattern here as well.

So in the classic time, place, and person of epidemiology, this particular graphic shows the time, 1983 through 1993; the place, the United States; and the characteristics of person, which in this case are age-specific rates of antibodies in the population. So according to this, you can see that over time, at least most recently, the highest rates have been reported in the 5- to 14-year-old age group, and the lowest in the 40 plus age group, so that would mean many people in this room, although I'm sure not all.

Another way of looking at the person part of this -- okay, we still have the same time and are still the same place, but another way to look at the person is to look in the context of the acquisition of their infection. So in this case, as you can see, personal contact is highest in terms of the percentage of all cases reported, with again the Y axis being different this time than the last -- the last was cases per 100,000, and this is percent of all cases. Looking at this you would see, for instance, that there was something going on in the United States in 1985 through about 1989 that made drug users a higher proportion of hepatitis A cases.

Now, from all of the types of epidemiological studies that have been ongoing and have been undertaken

regarding the hepatitis A virus, there are certain observations that were made: that many cases in the United States occur in the context of a community-wide outbreak and that within the context of those outbreaks, one, no risk factor is identified for most of the outbreaks that occur. But when there is a risk factor identified, the highest risk rates are in 5 to 14 year olds, and children serve as a very important reservoir of infection in these outbreaks. But additionally, the epidemiologic studies have shown that persons who are not involved in outbreaks who are also at high risk for hepatitis A infection are travelers, homosexual men or men who have sex with men, and injection drug users.

Based upon these data, and data similar to these, the recommendation was put forward that hepatitis A vaccine should be an early childhood immunization, and that by immunizing young, young children, you then prevent the peak that you see in the 5 to 14 year olds, et cetera. Additionally, HIV-infected persons, those gay men who even are not HIV infected are recommended to get this vaccine, along with injection drug users and travelers. This is a public health decision that was made and a public health action taken.

As a result of this, for instance, the United States Peace Crops immunizes routinely now all of its volunteers upon arrival in country, within 72 hours of arrival, with hepatitis A vaccine if they have not

previously received it. After two years, essentially, hepatitis A is no longer seen in any Peace Corps volunteers who've served in over 90 countries worldwide. So this gives you an idea of how epidemiology has been used to inform very important public health decisions that have had important public health impacts.

So what about these detailed, prospectively designed studies that are part of epidemiology? The important aspects of those are that they're detailed and they're designed before you are actually going to carry out the study. When they are at large and because humans are involved, an institutional review board process is necessary to make sure there is nothing unethical in the way the study is going to be carried out. It is very time intensive from the planning, the protocol development, the IRB, the implementation, the analysis, the written reports, and this entire process often, if the study is of an infectious agent, takes at least a few years to carry out from start to finish.

Using that same list I gave you before that helped determine that hepatitis A vaccine should be a childhood immunization in the United States and also offered to these other high risk groups, let's take this aspect that for outbreaks in communities, no risk factor is identified for most cases. Taking this particular issue, the state of Utah decided to do an investigation along with the University of Utah, to do a serologic and

descriptive epidemiological study to see if they could identify what the risk factors were for these particular individuals. They specifically wanted to look at the role of household contacts and food handlers and foodbornes in the role of hepatitis A vaccine. Their study, which took between two and a half and three years from start to finish, found that hepatitis A virus among children is very common, but often unrecognized, and that these children are very important sources of transmission within homes and outside of homes as they travel to play with other children, and they actually accounted for 13 of 18 clusters in over 300 cases that were looked at in this study, and that transmission from commercial food establishments is uncommon. So this was an additional study to look at how further to inform this public health issue, again, taking between two and three years from start to finish, to complete.

So what about this applied or field epidemiology? Now, this is really a subspecialty within epidemiology and it's applied in specific and unique circumstances. One, it's when the problem is unexpected or acute, when an immediate response is needed to protect the public's health. And also, the epidemiologist must travel to and work in the field to solve the problem -- hence the other moniker for this being field epidemiology. And also and very importantly, the extent of the investigation is limited. The overriding

imperative is timely action. And so, what's enough data? Just enough to make the decision that you need to make.

The unique aspects are that the acute problem defines, really, an imperative to protect the public's health. This public health imperative drives the entire investigation beyond what a prospectively designed, long-term epidemiological study may do; it goes beyond the collecting and the analyzing. The actual taking action to protect the consumer, in this case from foodborne illness, is an integral part of the investigation.

What's important, as well, is that often these types of investigations begin with descriptive epidemiology, going in and saying, what's the time, the place, and the person, who's sick, when were they sick, and where were they sick, before you ever get to the how did they get sick and what's the risk for them becoming ill.

These types of study require vigorous ongoing analysis while you're undertaking them, so that you have just enough -- you have to know when there is just enough to take the action to protect the public's health. So, for instance, action can be taken, and has been taken, when the link is only hypothesized and before any formal case control study of risk factors is undertaken. For example, five cases of E. coli 0157:H7 in which there are two hospitalizations and one death from HUS, in which all of those individuals name the same product, bought at the

same place, in an approximate same time period -- public health action has been taken to protect the public's health with withdrawal of a product from retail shelves to protect the consumer's health.

Then also, action can also be taken on the outcome of an epidemiological field study that demonstrates a strong link between the illness and a food without a product isolate. Without a product isolate? There are some very important reasons why that would be so. And I'll go into those as this develops more.

Collaborations for such investigations are really key. In almost all cases, these investigations begin at a local or state health department who actually identifies that there is an outbreak, begins the investigation, and often carries out the entire investigation and identifies risk factors including food and even particular brands of food. State and local health departments alone or in collaboration with federal agencies then also may conduct the investigation with people from CDC or FSIS or FDA actually going on site to assist in the investigation.

There are some unique challenges when you do a field investigation that all epidemiologists know are potential constraints, one of those being that the data that you use often is not data collected with doing an epi study in mind. So if you're going to go into grocery store A, I can assure you they did not collect their

grinding records for ground beef because they knew you, as an epidemiologist, were going to come and look at them. So that's something to be considered.

Also, at times there are very small numbers, and when you want to do one of these comparative studies for risk, to identify risk factors such as a case control study, having only two or three cases sometimes puts statistical limitations on the inferences you can make.

And then this issue of how could you do an epidemiological study and come up with these links and then you would have a public health action taken and there would be no product isolate. One of the realities of life is that the horse is often out of the barn. What I mean by that is that often the outbreak comes to the attention of public health officials when the outbreak is on the wane, and by the time you have done everything necessary to identify the risk factors et cetera, sometimes there is not any product left. It has already gone to consumers and been consumed. And that doesn't mean the outbreak is over. It could be that you just cannot retrieve product. So that's a very important issue. It takes a while for the outbreak to be identified, and then it's propagating along, but also maybe trailing off at the time when the actual investigation is undertaken and ultimately completed.

Additionally, when you go to do these, particularly when you want to do the study for risk factors, you may in fact have fear on the part of the persons who are ill. They're afraid that medical confidentiality will be breached when they have to share information about their illness with the Health Department, a branch of the government, because they don't necessarily believe that I'm from the government and I'm here to help you. And also, similarly, establishments where implicated food products have been manufactured may also be reticent to participate because participation would potentially mean the threat of litigation.

There are also other factors that just have to do with, some people just don't want to be questioned for any reason, whether you're from the government or not, and many others that I could probably talk to you about.

What do these epidemiologists do when they do these field studies? Well, first an outbreak has to be identified, and so you identify an outbreak if it's above what you would usually expect to see. And often it can be as little as -- for some diseases, as little as one case and for others, maybe two or three. For cases like influenza it has to go above a baseline that's calculated often statistically, using models.

The case interviews go on in which a broad food history is taken to find out what people have consumed

over the past X number of days or weeks. A broad environmental exposure history is taken, particularly when there are agents that could be food borne or could be transmitted in other ways, and identification of common food suppliers in the process of this case interview. Additionally, there will be laboratory investigations to see. For instance, if there's an outbreak of diarrhea, well, what is the diarrhea from? You then want to match them up, so if you have 15 cases of diarrhea and it turns out that three are salmonella and four are E. coli and two are you can't figure it out, well then, it isn't necessarily an outbreak. But should you have 15 cases of all the same thing that are PFGE matched, then you begin to become concerned and then you want to know, was some common link between all of them.

And then a case control study, remembering that a public health action may have already been taken, depending upon the severity of what the outbreak is. So the more severe the outcomes of the illness, the more likely there is to be a public health action taken earlier to attempt to abrogate the outbreak, particularly when there are severe illnesses, hospitalizations, but especially deaths.

And then the comprehensive environmental investigation can go on and this can be in a grocery store, for example, can be actually in a plant itself.

And then, of course, part of this process is to take a public health action.

Now I want to give a few examples that may come closer to the heart of the people on this particular advisory committee. This was a large outbreak of Listeria monocytogenes that was linked to small-diameter sausages and deli meats that occurred between 1998 and 1999, with 101 cases and 15 deaths that occurred over a period of time from August of 1998 through February of 1999.

As you can see, the fatal cases are interspersed throughout. Over half of these were perinatal deaths. What is not shown here, if you look at the date 7-19, you can put a very large circle there, and at that time at the implicated establishment there was a very, very large construction project that went on in a particular area near the small-diameter sausage region of the plant.

Subsequently the outbreak took off in several weeks, and then if you see the top peak of this outbreak on the graphic, it has no deaths; the highest peak there is 9 cases. It was during this week that the establishment voluntarily recalled small-diameter sausages and deli meats that they made. And in one incubation time, approximately six weeks for listeria, the outbreak was essentially over.

Okay, that public health action in this case was in fact the voluntary removal from commerce and people's refrigerators of this particular product.

Now, to give you another example of what can go on in terms of epidemiological investigations, there was in fact a positive product isolate for the last outbreak that I showed and it did molecularly match the isolates from the patients as well. Here was another outbreak of E. coli 0157:H7 linked to dried, cured salami. And in this very short period of time, over about a one-month to one-and-a-half-month period, 20 cases of laboratory-confirmed diarrhea due to 0157 were reported in which there were three hospitalizations out of the 30 cases, and one of the three hospitalized persons developed hemolitic uremic syndrome.

Brand A of dried, cured salami was named by all those who were interviewed, even before a case control study was done. And based on this information alone, this product was voluntarily withdrawn from retail. Subsequent to this, the case control study was carried out and an isolate was found, but the public health action had already been taken to ensure that no more consumers became ill.

And finally, this is preliminary data -- all of the data has not yet been forthcoming from CDC -- this was a more recent outbreak of listeria in which ten states were involved, that went from May through December

of 2000. Again, this particular outbreak investigation, through a case control study, identified sliced deli turkey meat as the vehicle of the outbreak, which was -- all of these 30 cases of PFGE matched. In further investigation of the potential sources of the outbreak, a particular establishment was identified and the environmental investigation in that particular establishment supported that in fact they were the actor in this particular outbreak.

However, and subsequent to this -- and there were, I believe, seven deaths, four of which were perinatal, related to this outbreak -- the establishment voluntarily recalled product. There was not at the time of that recall any product isolate identified that was in commerce at that time.

What I have just briefly tried to give you a sense of is that applied epidemiology is not the same pristine, long-term, lots-of-time-planning type of epidemiology, but it's public health epidemiology to protect the public's health. Whereas the more detailed, prospectively designed studies aim at the bull's-eye on a target, applied epidemiology's goal is to hit the target and get as close to that bull's-eye as it can, understanding that the imperative is protecting the public's health.

I've tried to impress upon you, if at all possible, the unique aspects of applied epidemiology, in

that you don't always have the best data; it hasn't been collected with you in mind, necessarily, although the case control studies are, but a lot of the environmental data that we use is not; that without excellent cross-jurisdictional collaboration with state and local health departments and agriculture departments, we all could not do our jobs. I hope that you see now that there are some unique challenges that we deal with when we go into the field and do these investigations, often when the "horse is out of the barn."

Finally, I hope that some of the examples that I've shown you today will give you some sense of when this particular type of epidemiology is appropriate and, in fact, has a very salutary effect upon the public's health.

If you have any questions, I'm happy to entertain them.

MS. WACHSMUTH: Noreen, I'd just like to make one point, and correct me if I'm wrong on anything, but I think the three examples, all three examples you showed of the foodborne outbreaks, we did eventually have an impact product positive with the analyte -- in all three. The first outbreak, it was January after that recall in whatever -- November. There was finally an isolate in a PFGE match. And I think one of the things that --

MS. HYNES: But the third example that I gave, there was never an in-commerce, a current in-commerce

isolate. There was an isolate, but at the time of the public health action, there was not a --

MS. WACHSMUTH: Correct, that's my point. Although eventually we had these isolates from impact products that did go into commerce, I think there will be times when we might want to take that public health action -- we don't have the isolate, it may not come three months down the line. But that's what we probably need to consider today.

MS. HYNES: Correct.

MR. LAFONTAINE: Dan Lafontaine from South Carolina. Just for information, I've got a couple of follow-on questions. I realize that, as you said, these potential outbreaks are first usually reported at the state and local level. And I'm not trying to be one up on you, but I didn't hear you mention PulseNet, which is becoming increasingly important.

MS. HYNES: Yes, as a matter of fact that's a very, very good point.

MR. LAFONTAINE: Which makes a local problem many times, obviously, a national problem. But the question I have for you or FSIS is, as these situations develop and FSIS has its, I'll call it, recall group, who's in charge. Who's making the decisions on who does the field epidemiology? Because I always hear, well, they called in CDC at a certain point or whatever, so I'm trying to get a feel for the mechanics of this. I think

it's important for all of us to know how -- what is the system, in other words?

MS. HYNES: Let me give you an example of the most recent listeriosis outbreak in which 10 states -- it was a multistate outbreak which included at least 10 states. Actually, one state noted that they had an increase, and then also PulseNet, which is the molecular typing surveillance system that's run by CDC, but most state health departments either directly participate or in collaboration with a nearby state collaborate, as well as the FDA and FSIS.

An increase in a cluster of PFGE-matched human isolates of listeria, which was a unique pattern that had not really been previously seen, was identified. The states in question then participated with CDC in a case control study to identify risk factors for this particular what appeared to be PFGE-matched numbers of human isolates. Upon the identification of process, a statistically significant association with processed deli turkey meat, then this cluster of PFGEs became officially an outbreak because now there was an epidemiologic link to the PFGE pattern, which in an of itself alone does not say it's an outbreak, it's a cluster of the same pattern.

Subsequently, a particular establishment by further investigation was epidemiologically linked to potentially be the actor. And then, although the first part of the epidemiological investigation was carried out

by the state health departments in collaboration with CDC, the other part of the epidemiological investigation was carried out by the Human Health Sciences Division of the Food Safety and Inspection Service, in collaboration with CDC and the states.

MR. LAFONTAINE: Run that last statement by me again.

MS. HYNES: The in-plant and part of the environmental in-plant investigation was carried out by the Division of Human Health Sciences in the Office of Public Health and Science at FSIS -- i.e., the group I work for.

MR. DERFLER: If I could elaborate on that just a little bit, once we get in plant, there's a different set of issues that are sometimes presented: for example, access to the plant's records and protecting the confidentiality of the plant's records -- something that we're prepared to do; something that CDC is sometimes *not* prepared to do. And so that is why there is a lot of discussion back and forth between the two agencies. But those factors come into play as you work through an investigation of this type.

MR. LAFONTAINE: Let me make a follow-up comment and question and kind of dig underneath the rug, as you say. So what I hear you saying is that as would normally happen with a food outbreak, state and local health departments are doing their thing and at a certain

point CDC gets involved or gets invited because it's apparent that it's beyond
their -- either beyond their capability and/or it's multistate.

MS. HYNES: The usual way that it works is, when it's a multistate event, CDC works in collaboration with those state and local health departments to conduct, as you would see here, a case control study. It's in collaboration. FSIS was a part of all the conference calls, or many of the conference calls that went on during that stage, in anticipation that there was a probability that a food product regulated by FSIS may be implicated. And then when that implication was made for issues such as what Phil has brought up, then the in-plant part of the investigation was carried out by FSIS.

MR. LAFONTAINE: Well -- I'm sorry, let me just finish. Now I want to jump to the in-plant part and I don't intend for it to be a loaded question but I'm just trying to get an honest -- my understanding of what I read -- and it may not have been accurate -- is that in the Michigan case, the listeria outbreak in '88 and '89, the CDC was actually in the plant as a part of the evaluation. Is that correct?

MS. HYNES: CDC was in the plant for that investigation. I was not part of FSIS at that time.

MS. WACHSMUTH: Actually, CDC went into the plant with one of our epidemiologists.

MR. LAFONTAINE: As a state program person, you know, God forbid, I may get involved in one of these and I want to know who's going to be available and who's playing what role. That's why I'm asking all these detailed questions.

MS. HYNES: I think your question is an excellent one, and as I've had to very often explain to my nonpublic health colleagues -- but you are a public health person, so I think you'll understand this -- that every outbreak is quite different, and it's almost like every patient is different. Every outbreak is different. And the local variables, and even national variables, differ with each one. And so the complement of professionals that you will put together to complete the investigation often is very outbreak specific. So if it's a small state with a very small epidemiology department, it may be CDC that has the lead on the ground from the beginning of the investigation because there is not the capacity at that time because of other competing demands on the state health department.

But many state health departments, almost -- and actually most foodborne investigations really don't come to CDC's attention to come and help with, so to speak. Most state health departments do their own.

MS. WACHSMUTH: There may be an important thing -- sorry to interrupt -- Noreen knows and I know, but CDC has to be invited. Even if you have a multistate

outbreak, CDC does not just go. Even when there was Jack-in-the-Box, those were individual state investigations, and the states are not always inclined to invite CDC. That's why it is very variable, as Noreen said, from outbreak to outbreak.

MR. LAFONTAINE: One final comment. I was just interested in that part, but also FSIS's thought process on the in-plant part of this, which is what I was really leading up to, is who and how gets -- who gets involved and when, in the plant part of the investigation.

MS. HYNES: Before I answer that, you, certainly, coming from South Carolina, I think, would realize that many state ag departments, particularly those in agreement with FSIS, actually do their own in-plant investigations when there's an outbreak, and health departments often do go into establishments. So again, I need to really impress upon everyone that every outbreak is unique and the team that you make up to address it has to be designed at that time.

When there are human illnesses involved and a particular establishment has been identified and there is need for an in-plant environmental investigation, that would be the Human Health Sciences Division of -- the Office of Public Health and Science would be a participant in that. As Phil has alluded to, there might be other issues, regulatory issues, etc., that would include other personnel from other parts of FSIS who

would actually be present in the plant, but their role would be different from the epidemiologist's role, because the epidemiologist's role is to determine whether or not the link is plausible that has been identified.

MR. GOVRO: Michael Govro, Oregon Department of Agriculture. I just want to comment that Dan's question emphasizes the importance of the issue that we brought up this morning, which is to delineate who does what where. I think that's extremely important in this case. And I have another question, but I'll defer that if we want to stay on this subject for a minute.

MS. JOHNSON: Alice Johnson, National Food Processors. Thank you for the presentation. This was very informative.

From reports from some of the establishments involved, when FSIS, the team is there, things work very smoothly. I think there has been a lot of concern in some of the plants in that CDC shows up on the doorstep first and asks for specific records; or it's even my understanding that they ask to go in and do some sampling. And I hope that FSIS and CDC and the other agencies, local or state agencies that are involved, can do as good a coordination as possible on this, because as you know, when it gets to this point, everybody is a little jumpy anyway.

MS. HYNES: Yes.

MS. JOHNSON: So I think that any type of agreement that can be reached -- and if there is a formal method of putting the team together and what happens here, here and here -- and I know it may be very specific to the individual situation, but I think that would help relieve some of the stress on the plant and allow for more information to be available when the team gets there, without having to run down records, because in some cases the records may not be readily available. And if the establishment understands that the team is coming and on their way, they can get these records and get information available that may actually speed up the whole process. So I would encourage the agency to do that.

MS. HYNES: I think that your point is a very good one, to make sure that everyone talks to each other. And I think that certainly Dr. Wachsmuth would tell you that one of the reasons for creating the Human Health Sciences Division was to get a team of epidemiologists who in fact know CDC and FDA and have worked with them previously and are in with states as well, to be sure that we all do try to sing from the same sheet of music and that these run as smoothly as possible, understanding that they are emotional for the consumer, they are emotional for the implicated establishment, and they are emotional for the team that has to investigate it all as well.

MS. JOHNSON: I'm sure the team may get jerked out in a way that is not that easy, either. I would encourage information sharing as soon as information is obtained. I know in some of these situations the facilities have felt that they didn't receive all the information upfront that may have helped them to make some decisions. Thank you.

MS. HYNES: Anyone else?

MR. GOVRO: It is kind of a change of subject, if anybody has another -- I'll go ahead and ask. What kind of progress is being made on the identification of viral agents from foods?

MS. HYNES: Actually, CDC is in the process of creating sort of a colici net. And also PulseNet does anticipate bringing viral pathogens on board in the future, although in my discussions with them they do not know when they will bring viral pathogens on board in PulseNet.

MR. GOVRO: My question is specifically the ability to identify viral agents such as Norwalk-like viruses from foods. It is my understanding that we're not very good at that yet --

MS. HYNES: There is a pilot project right now that includes, I believe, ten state health departments/ag departments in which they are specifically PCRing et cetera. And it is in the pilot phase right now. And Dale, you can correct me if I am wrong on that. Are

there not about ten states that are participating in this pilot project?

MR. MORSE: I don't know the exact number, but there has been tremendous progress made in the testing of humans. As people are probably aware, most foodborne outbreaks are presumed viral and previously were undiagnosed at least in terms of confirmation. Recently CDC looked at 229 outbreaks, and approximately 90 percent of those they were able to show with the new viral testing that they were related to Norwalk-like coliciviruses on the human side. They still need to do more progress on the food side, as Noreen mentioned, because there are other things in food that you have to get rid of, so it is a little more complicated. But progress is being made there as well.

There have been some outbreaks that the CDC has actually been able to -- I believe there were some clam and oyster-related outbreaks -- were able to actually trace it back to the water, the part of the bay where the clams came from with genetic sequencing. So progress is being made on the viral side as well.

MR. DERFLER: Any more questions? Thank you very much. I think it was an excellent presentation as well, and it provides a lot of insight into what we've been doing lately.

The next presentation is going to be made by Don Smart from our Technical Service Center. Yesterday I

believe you heard a presentation on next steps, FSIS next steps, and the two goals of next steps, which I think you've heard twice, are to try and help us do our jobs better, and also to help plants do their jobs better. One of the ways that we're tying to effect this is through what Mr. Smart is now about to talk about.

MR. SMART: While we're getting set up here, I'd like to also say what an excellent presentation. And I'm a little jealous because I don't have a real fancy uniform to wear up here, and if I wore the last one that I had available it would involve shoulder pads and a helmet.

I'm very pleased to be here today with such an illustrious group of individuals. Some of you I have had long-standing relationships with and have been very pleased with that. Others, I am just meeting today. I see that she has left -- Carol Tucker Foreman -- I was going to make a comment about being glad to actually see her in person, I've heard her voice so many times. She was essentially in charge when I came on board in 19--.

Anyway, as Phil said, I am Don Smart, Director of the Review Division at the Technical Service Center. Talking about the subject that I am here to talk about today, one of the first things that we addressed was the history, the stigma attached to the word "review" and the review staff which used to be Lawrence, Kansas. During reorganization we moved to Omaha, Nebraska. And when we

were in the developmental stages of this process we decided that there weren't a whole lot of people that had really fond recollections of review, so maybe it would be better if we approached things from a different way, and part of that approach was changing the name. So we have changed the name of the domestic review staff to the Food Safety Systems Correlation Team.

I'll try to run through this presentation pretty quickly because in earlier conversation it seemed like maybe you guys had maybe read through your hymnal here, either that or you were aware of some of what we are doing. So I think you might have some questions, so I'll try to go through this fairly rapidly to give you time for questions.

The purpose of the Food Safety Systems Correlation is to enhance and improve the effectiveness of inspection verification activities and assist the establishments in improving their food safety systems. It is kind of a dual-pronged approach, that while we are in the field we anticipate being able to provide benefit to both.

The way we start before we go to a district is we have a planning and preparation group for each district activity, and we select a random selection of plants within the district, numbering 10 percent of the plants or a minimum of 40 depending on the population of the district.

As I said, they are randomly selected from the entire population of each circuit so that we have a fairly equal number in each circuit. We do not include plants that have had an IDV -- I presume all of you know what IDV is --you don't? -- okay, in-depth verification review, which is a very rigorous process that we have teams go out and do. If you have had an IDV in the last year as a plant or you are scheduled to have one, then you're automatically out of our list.

Before visiting the plants for the on-site visit, the planning and preparation group will gather all of the information they can on the plants. We have access in Omaha to up-to-date PBIS information, enforcement information; we contact the district offices, we use all the tools at our disposal to give us a handle on what we might see when we go into these establishments. For instance, looking at PBIS data, we would probably raise an eyebrow at establishments that had no NRs documented for the last six months. Even though we know there are some really good plants out there, we question whether there are any perfect ones. We would be delighted to find one.

On the other hand, we would also look very closely at establishment results that showed a huge number of NRs; we would look to see what was causing that and whether that was an accurate portrayal of what is going on in the plant. Once we do all of our preparation

work in Omaha and assemble our group that is going to go to the district, then we travel to the district office with the work group and meet with the district manager, the deputy district manager, the ADME, the entire district office staff, and the circuit supervisors. We walk through the entire process, we go through the paperwork that we are going to use in the plants, and we describe everything that we are going to be doing while we are out in the establishments, and give them the opportunity to ask questions upfront in that environment before we get to the plant.

The Food Safety Systems Correlation Team, once we arrive at the plant, consists of our TSC staff person, the circuit supervisor, and in-plant inspection personnel. In most cases that is the inspector-in-charge, and on some occasions it could include other district office personnel that come along as observers.

When we arrive at the plant we want to be sure the plant officials know who we are and why we are there. So we hold and entrance meeting with the establishment officials and we go over exactly why we're there, what we're doing, what types of questions we are going to be asking, what we're going to examine while we're there.

We emphasize to those establishment officials, many of which have a history with our group and know what previous reviews have been like, that this is unlike what they've experienced before, that it will not be a

comprehensive review in that we will not be issuing plant specific reports that identify a laundry list of deficiencies within their plant.

Again, here we emphasize that our purpose is not to create a laundry list but to observe food safety systems in operation, and inspection application to that environment. The one proviso that we have is that during our plant visit if we do observe adulterated product being shipped or produced, that we would expect the normal action to be taken, which would be to control the product.

We try to make the environment in the plant such that all of the establishment officials and inspection officials feel very comfortable with the process and participate fully. We want maximum interaction. We do not want to the inspectors or the plant people to feel that we are in a got-you mode. We are just in there to gather information and provide assistance while we are on site.

Each visit to the plants in the district that we go to involves two component. We look at the records associated with the items that we have selected for that plant to examine, and we go out into the plant and watch that part of the system in operation. We don't do all of the component of food safety systems and inspection checks in each plant. We pre-select a minimum of three component to look at from a list that we have, which

should show up here; it includes SSOPs, hazard analysis, CCP determination, critical limits, and procedures for reassessment record keeping, monitoring, and verification.

In the entire population of the district and the checklist that we use, we strive to maintain an equal balance among all eight of these checklist items, so we use each one approximately the same amount of time. At the conclusion of the plant visit, the team will get together with plant management, if they haven't been involved every step of the way anyway, for an exit conference and talk to them about our observations and what we have noticed from their food safety systems that they have in place. And we ask them if they have any concerns or things that they would like to see addressed, and the follow-up correlation activities that I'll get to in a minute.

We again emphasize that the purpose of the visit is to gather information on the range of practices of inspection personnel in the industry, and not to create that laundry list, a plant-specific report. And one of the reasons for that is that individual plant information does not provide sufficient data to represent the range of practices within a district.

Once we bring back all the information back to Omaha, we work with our analysts at the TFC to develop a written report that describes the range of practices

observed within a district. And we use a lot of that information to develop correlation activities, which is the second phase of the food safety systems correlation process. After all of the in-plant data gathering is completed and we assess all that data, we determine what major points are at the fringes of the range of activities that I talked about earlier. The ones that are either obviously not meeting regulatory requirements or application of regulatory requirements or inspection procedures. And then the ones that are in the gray, fuzzy area edges. And we develop correlation materials and activates based on those fringe areas and those outside the edge to go back to the districts to have correlation activities on those items.

We have completed the in-plant portion of one district; our pilot district was Boulder, Colorado. We received some very positive feedback from inspection personnel and industry officials on the process. They felt that it was very open and they were very pleased that they were included in the process and were able to point out items of concern that they had, and issues that they thought we should correlate on.

The Boulder office did an excellent job of scheduling some correlation sessions, which will begin next Monday. All GS-8s and above in the entire Boulder district will be involved in a full-day correlation session over a two-week period, two days next week and

then all of the following week; and then we will have nighttime industry sessions in Boulder, Albuquerque, Phoenix, and Salt Lake City.

Shortly thereafter, the following week we will begin our second district in Atlanta, Georgia, and we will follow up that activity with correlation sessions in the Atlanta district that will include inspection and industry representatives.

We are in our infancy in this process. We do want to include any concerns that any of you might have, because I know that at least most of you have been involved in the meat and poultry inspection aspect of the industry for a long time and we value your input. Any questions?

MR. GOVRO: Michael Govro from Oregon. You lost me just a little bit there at the end with a couple of terms that I am not familiar with. And those were what are correlation materials and activities?

MR. SMART: I didn't explain that, did I? We have developed Powerpoint presentations to guide our TSC staff members through a correlation session. We could conceivably have hand-out materials that focus on specific points. We might bring up a certain part of the regulations that we think needs further guidance or a reiterance of the guidance that was given that -- of all of the changes that we've had over the last three or four years, that maybe that point didn't stick as well as it

should. We have a full range of materials that we have available. If we find an overriding point somewhere that we think that we are seeing in every district -- that we need better clarification -- then we would work through the policy staff to maybe have something reissued like reminder notices or clarifications.

MR. GOVRO: So would this be where you would address issues such as the interpretation of a phrase like "reasonably likely to occur"?

MR. SMART: Absolutely.

MS. JOHNSON: Alice Johnson, National Food Processors. I think it is great that you are sharing the training material with the industry, because I think industry can learn as well as FSIS. I know that the Tech Center -- the people who are going out and doing the correlations have gone through a lot of training, as opposed to what the normal in-plant or district person. Would you explain a little bit about the type of training they've received?

MR. SMART: Every Tech Center employee has essentially had a baptism of fire since we had phase one of implementation. A number of the people involved sat on the HACCP hotline day after day, week after week, month after month during implementation. So far, everybody that we've included on this effort has also gone through follow-up HACCP training and has attended what we originally called advanced HACCP training at

College Station, but it is now retitled advanced concepts in risk and analysis, which has some heavy-duty science components to it and risk analysis, and epidemiology, microbiology, statistics, and a large portion of them are responsible on a day-to-day basis for questions that come in on the Tech Center email account. Where we are receiving literally thousands of questions each year from inspectors, supervisors, industry officials, state officials, foreign government officials. We've got a huge amount of data available. So we've been living and breathing it every day without having to deal with what inspectors have to deal with in the field trying to get that in the plant.

MR. LAFONTAINE: Dan LaFontaine, South Carolina. First just a comment and then a question. For those in the audience who aren't aware, Mr. Smart's staff also do the reviews of the state programs. I believe it is different groups of people but they both work for you, is that right?

MR. SMART: They are derived from the same group on the domestic staff, although for the food safety systems correlation, we use all the resources of the Tech Center, so we have review, processing, and slaughter people that have already worked on this process.

MR. LAFONTAINE: My question is -- I just went through a state review, it was still called a review at that point and was a very thorough look-see. The

approach was somewhat similar to what you describe, although this is new and different. So my bottom-line question is, is this the same system we are eventually going to use for the states or is it premature to answer that question?

MR. SMART: There is a gentleman sitting right behind you who can probably address that better. Currently we have a mandate to review -- have comprehensive reviews of the state program, so I don't expect that is going to change, although the way we conduct business we can vary as long as we meet the criteria. I would like to say that a lot of what went into this was based on some successes that we had working with the state programs, and Mike Mamminga was the one who got the ball rolling. He volunteered time and time again for us to come over and practice in Iowa, because he was close by, and he felt that any interaction that we had outside of the state review system would be very beneficial. I believe we gained a lot from it at the Tech Center. And Mike has indicated that he and his staff gained a lot from it, too.

After he shared information with some of the other state programs we've gone to four or five other states outside of the review activity and conducted some correlation-type activities with the state programs.

MR. JAN: First question I would have is, you say you finished Boulder and you moved to another

district. Is Boulder done or is this going to be an ongoing process that you will do these food safety reviews annually or every three years or something?

MR. SMART: If we fulfill the mandate from Dr. Mina, we will be up to our eyeballs in activity, and it will not stop. Presuming that we get through the 17 districts on schedule, I fully expect that we will start right in again and just keep right on going because there will always be a need to bring us closer and closer together.

MR. JAN: My next question would be, if I understand when you finish a district and put the data together, you develop or create a correlation program specific to address some of the weaknesses that you have identified in that particular district. Can the state program inspectors be invited -- or at least a staff equivalent level -- you said GS-8 and I'm not sure why that -- if that is supervisors or what level that is -- but is it possible to get state inspection personnel to benefit from these correlations and, one step further, when the staff does the reviews of state programs -- currently those are done once every four years or maybe every year -- but whatever it is, rather than just saying how you handle the deficiency can you develop correlations for the states to help work on their problems if there are some deficiencies that could be correlated on?

MR. SMART: We very definitely have provided assistance to the states as I mentioned, with Mike and some of the other states, on correlation activities and we will continue to do that as resources allow. The reason I said GS-8s and above, those are our individuals that have offline HACCP responsibilities, and Dr. Mina indicated that he wanted every inspector who had offline HACCP responsibilities to go through these correlation sessions.

For Boulder, we do have -- during the Salt Lake City, I notice that we scheduled State of Utah employees are included in that, and I am almost certain that I am not going out on a limb to say that when we do Dallas if you want to have people there and you work with our district office, as long as we have a facility that is big enough that we would welcome that.

MR. DERFLER: I would like to second that because one of the things that we do OPPDE is after we issue a directive and people in the plants have had an opportunity to work with it for a while, we conduct a survey to try and see how well it is working and how well they understand it. One of the decisions that we made fairly recently is that we want to contact state people to see their take on it as well. So I think that is perfectly consistent with what Don just said. The basic principle is going to underlie what we do. Any other questions? I want to thank you, Don, for your

presentation. We're going to take a short break now, because I'm not sure how much more we will have after the break. So if we take a 15-minute break and then reconvene, and hopefully Maggie will be here by then.

(Off the record.)

MS. GLAVIN: I'd like to recognize that our administrator has come by to at least have a short time with you. You are moving so expeditiously through the agenda that he is not going to have much time with you. But I would particularly urge the new members on the committee to introduce themselves to Tom as we have the opportunity, and say a few words with him -- and certainly the old ones are welcome to, also -- the experienced members of the committee.

My understanding is that we are up to the discussion on any remaining issues that the committee as a whole or any members of the committee would like to put on the table for discussion. Tom, I didn't have the chance to tell you that subcommittees did yeomen's work last night, and the committee has put forward, based on the subcommittee's work, some recommendations and advice in the three areas -- the emerging egg strategy, the industry petition on HACCP, and the federal, state and local government relations. Real hard work last night and again this morning bringing it to the full committee.

Anything that any committee member would like to have discussed or talked about? Questions?

MR. HOLMES: Maggie, I've got something real quick. There was something that was brought up yesterday morning about Chris Church and his group maybe looking to see if there was possibly a list of legislative issues that may be pertaining to food safety. I don't remember exactly what we were asking, but there was something in that regard.

MS. GLAVIN: The question was whether there was a bill introduced on interstate shipment this year. And this answer is no, there is nothing introduced on the Hill at this point on interstate shipment. I don't think we got a copy of the full list of any food safety things. That is certainly something we can share with the members. If you like it, we can get it sent out to you. That changes day by day, but we can send you one and you can look at it, and see what is there. But there wasn't anything on interstate shipment at this point, and I think that was the one that we were asked to check on. Dan, you are the one that asked -- you know, it was additional species, that was it. And there was not anything on that on our list.

MR. LAFONTAINE: I mentioned this to some of the staff earlier, but I wanted to mention it to everyone. A recommendation for the next meeting would be to have a briefing on what you're doing on your lab system. You've recently taken Pat McCaskey and put him over all the labs to standardize, make them state-of-the-

art, to make them stand tall; not that they weren't before, but I think it would be beneficial to me and others to know what is going on behind the scenes of the FSIS lab system. Because it is so integral to everything we do, whether it be foodborne outbreaks, or pathogen reduction, pathology, residues -- the whole business. A good thorough briefing on what you do and where you're headed would be my recommendation.

MS. GLAVIN: That is absolutely a good segue into the final piece of our agenda, which is plans for the next meeting. It is really helpful for you all to provide us suggestions and as we get closer to the next meeting, which will be next fall under current plans, we look at what issues are at an appropriate point that we would most benefit from your advice and counsel, either on briefings or on issues. That is a good subject for a briefing, so thank you for that suggestion. Sandra?

MS. ESKIN: I agree with the suggestion that Dan just made, and I also think that Marty's comment about legislation -- that might be a good thing to do either again between the meetings or at the next meeting, to brief us on sort of what is out there in terms of legislation affecting food safety. I also think it would be worthwhile, certainly for me, I know we did discuss very generally new technology, but if there was a possibility of getting briefed on the number of new processes, rinses, whatever that are out there and are

being developed to help reduce or eliminate microbial contamination, that would practically be useful so we a sense of what is out there.

I also think that since by that time hopefully the comment period would close for the listeria proposed rule, that it might be useful to discuss. Obviously some groups represented here filed comments, but just to get a sense of what is out there in terms of -- to the degree that FSIS can discuss it -- what is the status?

And finally I think it would be useful to get a briefing from CDC just on the trends in foodborne illness outbreaks at that point in the fall. What type of data collection they are doing, what they are seeing, and how it compares with the last period of time.

MS. GLAVIN: Now those I am hearing as suggestions for briefings?

MS. ESKIN: Right.

MS. GLAVIN: Okay. Catherine?

MS. LOGUE: One of the ones that might be considering as well I think is keeping up-to-date with the National Advisory Committee for Microbiological Criteria. If they would have some kind of briefing again for us on how far they've got with their end of things, so that we are kind of running parallel. That would be nice.

MS. GLAVIN: Okay. Alice?

MS. JOHNSON: I know that Phil mentioned that they were doing the agency surveying, doing a lot of surveys to follow up on directives, and he said that they had either just completed or were in the process of just starting on the ready-to-eat testing directive, so I think it would be interesting to hear something from that group. And I think that may be the same group that several years ago started the review of HACCP over several years, it was a several-year process --

MS. GLAVIN: The evaluation?

MS. JOHNSON: Yes, and I haven't heard anything about that over the last few years, and I just wondered where that is going and what is happening with that. It would also be cool if Don's group has anything that they want to share because they should have completed a few more districts by then. What you're finding in some of that information would be helpful.

MS. GLAVIN: These are all good ideas. We really have tried to maintain a balance between briefings and substantive work. And I assume that you approve of that balance, but maybe you want to comment on that also.

MR. JAN: One of the issues that I would like to see us attack in one of the future sessions, if not next but sometime down the road, and I think we had it up before but it has never gotten anywhere that I can tell, and that is the issue of exemptions. I think the last time we talked about exemptions it led to exempt species

and we explored that quite well, but there are products that are exempted just by the kind of products they are. We may even want to look at retail exemption, and some of that I know is under statutory -- but we already mentioned in this meeting about eliminating HRI, but I think we need to look at certain products. Why are some products exempted and why are some not? Maybe look at those reasons again and get some kind of a clear definition of what is exempted, and have some standard by which they are exempted.

MS. GLAVIN: You are proposing that as an issue to discuss?

MR. JAN: An issue to discuss, I think. I'd like to see that.

MS. GLAVIN: Okay. John?

MR. NEAL: I would like to continue -- it doesn't have to be an issue, but the update every time on the new technology, especially for the smaller plants; how they'll be adapted, as we spoke of earlier. And anything that might help small plants adapt some of the technology, maybe like pasteurization, but they can't afford the big equipment. Anything new comes along, just a briefing each time.

MS. GLAVIN: Okay. Thank you. Irene?

MS. LEECH: I'd like to comment on the format and say that I think it is good to have a mixture of issues and briefings, and I think it would be a mistake

to go to just briefings. I think the way you've laid it out and spread them is a good way to do that, so that we aren't just -- you can sit but for so long -- I think you all had a well laid-out agenda. And that worked very well.

MS. GLAVIN: Thank you. Thank you. Lee?

MR. JAN: I've got one other area that has sort of been tossed about but I think FSIS has been trying to develop a policy and has not gotten there yet, and maybe if we put it on as a briefing or as a goal for next time, and that would be how to look at Internet sales of meat and poultry products, and what is the FSIS's position and policy on that.

MS. JOHNSON: Since Charles is not here to bring this up again, and it is one of my issues a lot. On the inclusion in the HIMP project of different classes. We talked a little bit about the breeder issue during the HIMP briefing, and I just wonder if maybe -- we're told that it is a policy decision that was made some time ago, and maybe it would advisable to let this committee look at it and see if in the light of the performance standards, if there needs to be revision to the policy.

MS. GLAVIN: How is Charles? Is he okay? Has anybody heard from him?

MS. JOHNSON: He looked bad at lunchtime and he was on his way back to the valley.

MS. GLAVIN: Other ideas, suggestions? Obviously Charlie and his staff are available at any time to receive your comments and feedback. I really do urge you to use that. Things that worked; things that didn't work, that sort of thing. Even some of the mundane things like hotel accommodations -- since we don't stay in them we have no way of knowing whether they are adequate or not. Charlie will not take it ill if you give him feedback, positive or negative, on how the meeting ran for you, what worked, how your accommodations were and that sort of thing. Dale?

MR. MORSE: Just a suggestion for future topics on irradiation because it seems like it is going to become and important issue in the future. Just what impact is that going to have potentially? Are people using it? Just some background information on it.

MS. GLAVIN: Okay. Anything else? Before we turn to public comment -- Do we have anyone signed up for public comment? -- let me ask is there anyone in the audience who not having signed up would like to make a comment at this time to the committee? Okay, then I would like to personally thank the committee for really hard, good work, and for starting to come together as a working group. I think that you have done really wonderfully in that regard. I thank you for coming, and for those of you who stayed until the bitter end, thank you very much.

MS. JOHNSON: I think we need to thank Sonja and Charlie's -- all the people who worked so hard to put this thing together.

(Applause.)

MS. GLAVIN: Absolutely.

(Whereupon, at 3:06 p.m. the meeting in the above-entitled matter was concluded.)

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National Advisory Committee - Meat and Poultry
Name of Hearing or Event

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Docket No.

Washington, D.C.
Place of Hearing

June 6, 2001
Date of Hearing

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