UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE:	X	HELD JUNE 3, 2004
	X	8:30 A.M.
NATIONAL ADVISORY	X	HILTON ALEXANDRIA OLD TOWN
COMMITTEE ON MEAT AND	X	1767 KING STREET
POULTRY INSPECTION	X	ALEXANDRIA, VIRGINIA
MEETING	X	

VOLUME V OF V
GENERAL SESSION

APPEARANCES:

ON BEHALF OF THE UNITED STATES DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE:

DR. BARBARA J. MASTERS, Acting Administrator

MS. MARY K. CUTSHALL, Director
Strategic Initiatives, Partnerships and Outreach

MR. ROBERT TYNAN, Deputy Director
Strategic Initiatives, Partnerships and Outreach

DR. MERLE PIERSON, Deputy Secretary for Food Safety

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Recall Management Staff, Office of Field Operations

MR. CHARLES WILLIAMS
Office of Policy, Program, and Employee Development

DR. GERRI RANSOM, Executive Secretary
National Advisory Committee on Microbiological Criteria for Foods

DR. CAROL MACZKA, Assistant Administrator
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APPEARANCES (Cont.):

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Inspection and Enforcement Initiatives

MR. DAVID GOLDMAN, Director
Human Health Sciences Division

MR. BILL SMITH, Assistant Administrator
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MR. RON HICKS
Office of Program Evaluation, Enforcement and Review

MS. KAREN STUCK, Assistant Administrator
Office of International Affairs

ALSO PRESENT:

DR. LEE JAN, Director
Texas Meat and Poultry Inspection Program
Texas Department of Health

DR. DAVID CARPENTER, Associate Professor
Department of Medical Microbiology Immunology
Southern Illinois University School of Medicine

DR. CATHERINE LOGUE
North Dakota State University

DR. GLADYS BAYSE
Department of Chemistry, Spelman College

DR. JAMES DENTON
University of Arkansas

DR. JILL HOLLINGSWORTH, Vice President, Food Safety Food Marketing Institute

DR. ALICE JOHNSON
National Turkey Federation
MR. KEVIN ELFERING, Director
Dairy Food and Meat Inspection Program
Minnesota Department of Agriculture;
Instructor, University of Minnesota
Center for Animal Health and Food Safety

APPEARANCES (Cont.):

ALSO PRESENT:

MS. DEANNA BALDWIN
Maryland Department of Agriculture

MR. MICHAEL GOVRO
Food Safety Division
Oregon Department of Agriculture

MR. MICHAEL KOWALCYK, Chapter President
Dane County Chapter of Safe Tables Our Priority
Madison, Wisconsin

MR. MARK SCHAD
Schad Meats, Incorporated, Ohio

MR. CHARLES LINK
Cargill Meat Solutions, Cargill Value-Added Meats

MS. SANDRA ESKIN
American Association of Retired Persons
Maryland

MR. DARIN DETWILER, Educator
Best High School, Kirkland, Washington

MR. BERNIE SHIRE
American Association of Meat Processors

DR. JOSEPH HARRIS
Southwest Meat Association, Texas

MR. BRYCE QUICK

MR. TONY CORSO

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I N D E X

VOLUME V:

P R O C E E D I N G S

9:35 a.m.

MR. TYNAN: Let's get started. I think we have ample time to do all the work we need to do, but just to be

sure, I know some of you have earlier flights, and if we get done early you'll be able to make the arrangements.

With that, this morning's agenda starts at 8:30 with a little bit of a recap, I'm going to turn it over to Dr. Masters to kind of revisit a little bit of what we did yesterday, and then we can get into the discussions of the individual sub-committee reports based on the issues from yesterday.

Dr. Masters.

DR. MASTERS: Thanks, and I'm just going to sit here and keep it informal this morning. You should have -- the Committee should have at their place this morning a copy of the training chart that I mentioned yesterday that I would share with you, and I wanted to make sure that you saw that, bring it to your attention.

We're very proud of what we have accomplished this year. We have a lot of work yet to do, I don't want anyone to walk away thinking, "Whew, we're done with that," this was our uphill push, we do have a lot of work to do yet in the area of training, but we have done just a yeoman's job in getting that started.

If you have any particular questions on that, we'd be glad to answer those, but I think that demonstrates a good-faith effort in getting our folks trained, and a lot of work yet to do to get everyone trained, but I do think we have a good story to tell and I wanted to make sure folks

could see that, so that you could see that we are starting to make some progress in the area of training, and I want folks to understand that this is -- trying to get folks back where we need to be, or back to ground zero, as I stay, and the only place worse than not being at ground zero is being less than ground zero, so if we can get folks back to ground zero, then we can continue to move forward, which is where we'd like to go. Once we get all this accomplished, then I see us moving forward to do more advanced food-safety training, continuing education, those sorts of things.

So this is the basic training that we need to accomplish, which we're at least four years behind on, our entering veterinary public health officers and our entering food inspectors, we're going back four years in both categories to pick up folks that have not been trained, because we've been that far behind in our training.

So a lot of work yet to do, but I think we are starting to make some significant progress. So glad to answer any questions on that.

From our recap, I would say that -- I heard from a lot of you yesterday that this format for this particular meeting seems to have worked reasonably well, so my compliments to the folks that worked to put this meeting together. It sounds like there's a couple of suggestions, to make some -- even a little bit more improvement to it, but I think they did make a lot of improvements from some meetings

in the past, and I also want to compliment them for getting the materials out well in advance, because that obviously facilitates the meeting.

So I did hear a lot of positive feedback in that regard, and I walked around to each of the sub-committees as you were working on your questions and I found it most interesting, as I always do, that each of you were posing them and going through them in a very different fashion, so as you were working in your own little group, I'll let you know that each little group was working in a very different fashion than your own, but each group was working, one was very diligently working from a document that had been pre-drafted as a starting point, and one had flip charts going, and the other one was in very vocal deliberations, so it was interesting to see the dynamics and the different way of approaching, but it sounded like each group was putting a lot of thought to it, and again, the questions that we'll be hearing back on this morning are listeria, our Interim Final Rule, are we asking the right questions of ourselves, what additional questions do we need to be asking, we'll be hearing from the group and some recommendations on our adulterant policy and whether or not we should be considering holding product as a matter of policy when we take a test for an adulterant and what particular implications that might have for small and very small plants, and we'll also be hearing back from the sub-committee on whether or not we

should be requiring food-security plans, and if so, what they should contain.

So we're very anxious to hear these recommendations, and more than anything I just want to thank the sub-committees, because regardless of their approach, everyone was engaged, it was very evident that everyone brought a lot of work ethic to this committee and a lot of hard effort and a lot of hard work went into these recommendations, and I do appreciate the time and the commitment that everyone gave, so I want to say thank you up front and I'll look forward to hearing the input that we hear today. So thank you very much.

MR. TYNAN: Thank you, Dr. Masters. All right, I think with that we could begin our sub-committee reports. I believe the first sub-committee was Dr. Denton, related to the listeria monocytogenes. I am also going to apologize in advance for my secretarial and administrative skills, but I'm going to try and do the editing as we go along. So let's give it a whirl.

DR. DENTON: Thank you, Robert. Before we get into the discussions, I would like to recognize our committee and thank them for their efforts: Sandra Eskin, Kevin Elfering, Deanna Baldwin, and Charles Link. We had a lot of good open dialogue in this process, fairly strongly-held opinions on a lot of different things, but it was a fun process to work through as we think about what we need to be doing.

Now, obviously we're never satisfied with exactly where we are with regard to language, we've already made some changes this morning, but we'll get to that as we walk down through here.

We basically took a look at the overall Interim Rule and made some general comments up front, then we took each of those teams and tried to address those in a fashion that would allow us then to have some structure to the report.

We commend FSIS for their overall approach of issuing an Interim Final Rule and conducting an assessment of the effectiveness through a team approach. There is some concern on the part of our sub-committee that 18 months may not be a sufficient time frame to fully evaluate the Rule, with everything that's included in this process.

We also feel that FSIS should consider outstanding issues, such as the listeria retail study that's to be conducted by the National Alliance for Food Safety and Security, before finalizing the Rule. Realizing that not having as much data as we would like to have, I don't think we ever have as much as we would like to have, but knowing that this one is coming, I think it would be a good situation to be in, to try to recognize that information and incorporate that into the deliberation with regard to the Rule.

Although the Committee recognizes that FSIS has

some restrictions on including team members outside the Agency, several of the areas that these FSIS teams are evaluating fall within the jurisdiction of other federal, state, and local agencies. We feel that FSIS should ensure that recommendations from the Conference for Food Protection, FDA, AFDO, the National Alliance for Food Safety, and this Committee, among others, should be included in the assessment, or at least considered in the assessments, as FSIS moves forward.

Moving then down to the Economic Impact Team, the Committee recommends that the Team focus on differences among small, very small, and large plants and assess economic impact on very small versus large plants. For example: Has the Rule caused companies to go out of business or relinquish their grant of inspection.

In addition to the variables included in the Economic Impact Team discussion, the Team should consider other variables, such as product types and frequency of production within those plants.

The Labeling and Consumer Education Team, the Committee recommends that FSIS conduct focus groups and other consumer testing to assess various types of informational labeling, including safe-handling statements, statements addressing particular risk to vulnerable populations for products susceptible to LM contamination, and consider the National Advisory Committee for Microbiological Criteria for

Food recommendations on safety-based date labeling.

There is some debate among our team with regard to whether or not we should use the term "sell by" labeling, but we think that either of those would convey the issue that we're dealing with, the safety-based portion of that.

The focus groups are necessary to more closely assess consumers' response to labeling, and here's some of our first editorial correction: since consumer testing shows that consumers are frequently confused regarding various label statements, rather than just referring to the one industry study, there are several studies out there that show that there is some confusion.

In addition, the Committee endorses FSIS educational initiatives other than labeling to educate consumers. For example, FSIS working with health professionals to disseminate information is very effective.

UNIDENTIFIED FEMALE: Is Robert going to be able to make all those changes?

DR. DENTON: Yeah, I've got these on paper here, that will help you just a bit.

MR. TYNAN: Okay.

DR. DENTON: The training team indicates it is evaluating the effectiveness of Lm training and the verification and accountability measures pertaining to the training. Currently there is a perception that EIAOs and CSOs understand the Lm rule, while CSIs may not. As part of

their evaluation, the Team should review whether the training is equally effective for these three groups and whether the accountability measures are adequate to ensure that those who participate in the training achieve some mastery of the subject.

Under Team D, the Sampling Verification, the FSIS' Lm verification testing is a critical aspect of the implementation of the Rule. FSIS' verification activities will include determining whether establishments are following the correct sampling and testing procedures in compliance with the Rule.

Our sub-committee felt that FSIS should focus on assessment of the three alternatives for risk mitigations to evaluate their effectiveness. Through this process, FSIS can determine whether the assumptions on product risk made in the FDA/USDA quantitative assessment are accurate.

Under Item E, Small Plant Guidance Team, we feel fairly strongly, at least two of our team members felt fairly strongly, that very small plants face special challenges in implementing new requirements. FSIS should include universities in disseminating guidance information to the small plants. Representatives of District Offices should be involved to help deliver messages to industry through timely training. FSIS should use available technology to help train FSIS personnel and industry personnel by using remote broadcast and videotapes of the broadcast, with distribution

to the small plants, as a means of assisting in that process.

Under Retail Team, Item F, the Committee recognizes FSIS' expertise in many areas of the manufacturing of meat and poultry products. However, FSIS does not have the same knowledge of retail operations. Other groups, such as FDA, AFDO, state and local agencies, have experience in operations of retail facilities and should be included in the retail portions of the assessment. This can be accomplished by interviewing the subject experts to fully address all concerns related to potential contamination of product further processed at these retail facilities.

Under Item G, Public Health Team, the Committee believes that it is appropriate that FSIS is evaluating public health data to evaluate the effectiveness of the Rule. As with salmonella, FSIS should conduct molecular sub-typing and attempt to correlate positive product with actual cases of foodborne illness.

The final item being the "Next Steps," we believe that the steps as outlined are appropriate, FSIS should publish the report of the assessment and, based on the findings of the assessment -- and here's another editorial change -- and the public comments, FSIS should make any necessary and appropriate changes to the Rule.

With that, I will ask my team, our team, if there are any items that we may have overlooked, before we open the floor for general discussion.

DR. JOHNSON: A couple of questions. That's good work in a couple of hours (chuckles). The one area, on the small and very small plants and the idea of the video broadcast and getting the videotapes to the very small plants, was there any sense or discussion among your group as to whether or not those are actually utilized by the small and very small plants, whether or not -- certainly it's something that's doable.

DR. DENTON: Uh-huh.

DR. MASTERS: Was there any sense among your group whether or not that was something the very small plants would take the time to do, whether that's useful, was there any discussion on that?

DR. DENTON: I'm going to ask Kevin to respond to that, because as I understood it, they're not as easily accessed via the web and other mechanisms of technologically-assisted things, but -- Kevin.

MR. ELFERING: Yes. Kevin Elfering. I think one of the things that -- what we've been doing is, is at the university -- the University of Minnesota has been kind of coordinating what we call Just in Time training, so whenever there's a new directive, we have remote broadcasts, where we have subject experts, microbiologists, somebody from the district office come in and discuss the new directive and how some of these small plants can comply with all the requirements of the directives.

We make a videotape of that, we videotape that, and we distribute it to those small plants -- or any plants, for that matter -- that weren't able to see the remote broadcast.

One of the things, I think, that we found is, is that not all of these plants have the capabilities that we all are lucky to have, not all of them have internet capability; putting information on CD-ROMs, they probably don't even have a computer. So we feel that everybody has a video player and -- you know, we have had some success with people viewing the videotapes, but you never -- it's pretty difficult to measure the value of what they receive from reviewing it, but one of the things that we've done, then, is have the inspector talk to the plant operators, to make sure that they understand, and we have had some success with doing it like that. But, you know, there again, to do that on a widespread basis is not as easy.

DR. MASTERS: I think most of you are aware we're doing the teaching workshops, our workshops on E. coli, our -- the SIPL [phonetic] office, that's putting those on, is -- part of their follow-up that they're asking is: how can we best reach the small and very small plants, in general, so they're looking for ideas of how to reach these folks, so I was just curious if you had had experience where folks actually take the video and watch it, because while we'd like to think they watch it, my question is: are they watching it; and even if they are, is it effective; and what length of

time are they willing to watch a video, and I just was wondering if you had any experience with that.

Dr. Jan?

DR. JAN: Lee Jan, Texas Department of Health. About those videos -- and you've provided those, particularly some of the other workshops, and we've tried to use those to help train our supervisory staff, that can carry on down, and then take those videos and use those as a tool for smaller local groups, where perhaps you can get two or three plants together and answer questions and have small town-hall meetings, or something on that nature, and I think the information is useful, but the method of presentation or method of filming makes them very ineffective in that the camera is focused on a speaker while the visual aid for the audience is slides, and so the slides -- I mean the people in the audience are really getting more out of it, because they can enhance the points, and it would be more effective if they were created so that the camera is focused on the Power Point presentations, and I think that would enhance it, because it gets very dry and boring and people start falling asleep if you just watch somebody, you know, monotone -- many times monotone reading or talking about some subjects that are pretty complex, people start getting lost, but if they could have a visual aid and see some of those critical points, I think it would stick better and would be a better tool.

That's the only way I would say enhance them, but I would like to see the Agency continue to videotape these presentations so that it can be carried on down.

DR. MASTERS: Okay. Talk to me a little bit about -- on your recommendation on focus groups and other consumer testing, talk to me a little bit about what you meant by "other consumer testing."

DR. DENTON: There may be other approaches besides focus groups that help you identify the types of content and types of labeling issues that need to be addressed in those particular things, we just didn't want to restrict it to just the one, one approach.

DR. MASTERS: Okay. Ms. Eskin.

MS. ESKIN: Yeah, just to enhance that. I mean, you've got a whole range of possibilities. I know the most resource-intensive is like a mall intercept study, when you've got actual label statements and you have consumers actually respond to them, you can -- and, again, part of -- sometimes you obviously use both, where you do an initial focus group to sort of focus on and determine the certain label statements you want to have tested. You can do telephone surveys, but again, that's not always useful because you really want to get a consumer's reaction in a comparable setting to a supermarket.

So, again, focus groups are useful, but they also have limited value, if you really want to get down to: okay,

we have a sense of what people respond to or don't like, but: what's the most effective.

DR. MASTERS: Did you all talk any about internet surveys or surveys on the computer at all?

DR. DENTON: No.

MS. ESKIN: No. I mean, my own understanding, obviously it's being used more and more, but for certain populations, for example older people, you may not get the same amount of concentration of internet use that you would for younger respondents.

DR. MASTERS: Thank you. Dr. Hollingsworth.

DR. HOLLINGSWORTH: Jill Hollingsworth, Food Marketing Institute. On this labeling one, I was wondering if the group discussed at all an issue that was raised prior to our breakouts, and that was: if you label selected products as having had additional treatments or in some way being different, given that the standard is that there will be no listeria but you're labeling some products as having something different than that or appearing to be different, did you discuss at all that idea of: how do you avoid saying one product is safer than another, was that brought up at all in your discussions?

MS. BALDWIN: We did talk about that, and we didn't feel that incentive labeling was effective at all. The kind of labeling we were talking about would be more a positive statement (inaudible). In the risk assessment it showed that

refrigeration at certain temperatures and a use-by date could be effective in reducing, so we were looking at it as more: what positive statements could be made.

So instead of a complete safe-handling statement, it may something like "refrigerate at 41 degrees or below and use by," give a time frame that's based on what the other committee comes up with as safety dates.

DR. MASTERS: Thank you.

MS. ESKIN: I was going to just amplify what Deanna just said. I mean, I think the point we wanted to make mostly is that you have to look at the whole range of labeling, and you're right, you know, there's a group of label statements that were identified in the Interim Final Rule, and experience to date has demonstrated that perhaps they don't -- those statements don't meet the desired goal and that there may be other ways. Again, there's so many ways, as we all know, to express the ultimate message you want to do.

So I think the answer is: I think we want to look at a whole range of issues, including incentive labels. Obviously industry has done some surveys and has shown that they don't quite do what would have been hoped. There may be other ways to phrase it, whether you call it incentive labeling or not, there are messages to give to the normal populations, there's general factual information about the product, there's information that tells the consumer what he

or she can do to make sure the product is safe as possible. There's so many options. I think they all need to be considered.

DR. MASTERS: Okay, good. Dr. Johnson.

DR. JOHNSON: You're talking about the -- kind of a modified safe handling, or would you say it is like the safe handling that -- where FDA said the refrigeration, the whole product, the --

MS. ESKIN: Yeah. Well, one -- like the safe-handling statements that are out there right now, in general, are saying that, you know, it has to be cooked early and it has to be refrigerated. We were talking about a more modified safe-handling statement, that would just state something as "to maintain food safety, refrigerate at 41 degrees or below," and not get into the cooking because it may not be applicable to that product.

DR. MASTERS: Thank you. Mr. Elfering.

MR. ELFERING: I was just going to back up on what you were talking about with the internet surveys and -- I just have a question: Does the (inaudible) Mobile -- do they do any type of surveys?

UNIDENTIFIED FEMALE: They don't, but that's an idea, isn't it.

MR. ELFERING: Well, I mean, that might be an opportunity, you know, to have them do some surveys --

DR. MASTERS: Say, "We've been talking to a

contractor" but -- see, maybe I need to look at my contractor. Good idea. We've been hitting a lot of elementary schools lately, so we'll still not hit the older population, but --

UNIDENTIFIED FEMALE: We'll get there eventually.

DR. MASTERS: But no, that's a good idea, thank you. Other comments, questions for this group? Dr. Johnson.

DR. JOHNSON: Sandra probably knows this better than I do, but we've been doing -- I'm pretty impressed with the internet surveys, but you can actually go in and target, but you're saying even if you target the older-age bracket you won't get as much response, is that --

MS. ESKIN: I don't -- I can't say I have the substantiation to support that. That's my -- that's what I've heard, but again, as time goes on, internet concentration, you know, use is increasing. So it's just something to keep in mind. And for that matter, there may be other vulnerable populations that you don't address, I mean maybe you're talking about people who have English as a second language, they may be totally internet-savvy, but you may miss certain segments. Again, the whole idea of a survey is you try to get a representative sample of the population. You know, with a phone survey you take a thousand, generally, and there's all these parameters.

So I think it's certainly to be considered, and my understanding is it's being used more and more, it's a very

cost-effective way. We have to just be careful that you're getting a representative survey.

DR. MASTERS: Dr. Jan.

DR. JAN: Lee Jan, Texas Department of Health. In the Economic Impact Team, their statement made about determining the economic impact of the Rule, an example was given: as a company's going out of business or relinquishing their grant of inspection, and I think, talking about surveys, it may be a good idea to FSIS to develop a survey that would go out to all establishments when they give up a grant, just to say -- kind of like an exit survey, "Tell us," you know, "is there a reason that you went out of business? -- so that we can improve our service," and then make that type of survey -- those questions -- once it's determined: what are the most effective questions, make that available to state programs, because they handle more of the small plants, and I think there's a lot of -- it's very likely that a lot of plants will go out of business with this rule or other rules, but it would be good to know rather than make those assumptions, and I think a survey's a good way to go.

And I have another comment, on -- or question, and I don't really know that this would be to the Team, it's something FSIS may want to consider, under the Sampling Verification Team, and the Team may want to look at, I wonder if taking one sample per lot is really sufficient and what level of confidence does a negative result have when one

sample that's taken is negative, that the rest of the lot is truly negative, and should it -- should there be -- when a lot is selected for sampling, have enough samples collected that would have a 95-percent level that if it's negative, or that group of samples is negative, that the lot is proven negative, rather than hit and miss.

Now, I know that'd be more costly, but it may be a tradeoff, to have less lots sampled, but when they're sampled, get a better view of really what's going on.

DR. MASTERS: And I can clarify at this point that our thinking on follow-up verification of corrective actions is where the Agency is targeting -- looking at taking more samples from a lot of product, so that if in our random verification we found a positive, the plant takes their corrective actions and we do follow-up verification, we have already begun taking multiple samples from a lot for that purpose, of saying, "Hey, you've had a positive, you've done your corrective actions, we want to be certain that that problem is corrected," so we've begun that, and I certainly appreciate your comment, and certainly something we can take as a comment, but I do want to clarify that the Agency has begun that thought process on verifying corrective actions. Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk. A couple questions for the sub-committee, I guess with respect to the Economic Impact Team. In the Interim Final Rule there is a

cost-benefit analysis and it does look at impacts on smaller plants. In your recommendations are you thinking that you would want additional cost-benefit analysis to be done, with an additional focus on smaller plants, or is it -- or are you looking for additional information as far as, as someone mentioned, surveys? I don't know if those cost-benefit analysis numbers were considered.

(Pause.)

MR. ELFERING: You want me to answer that?

UNIDENTIFIED MALE: Yeah.

MR. ELFERING: I think what we're mainly looking at is, is if we're going to be looking at economic impact, what was -- what is the true economic impact on the -- on all plants. For example, based on the volume of product that they produce, what is the economic impact of the implementation of this rule, which may correlate, you know, who is actually being impacted most, is it the large industry, the medium-size industry, or the very small plants.

DR. JOHNSON: I think that Dr. Denton has it in his revisions over here, but one thing I want to be sure that the Committee, if they feel appropriate, that comes out in the report, that the information from these teams is published and made public and there's enough time given to review that and include it in the comments for the rule.

I know there's a lot of information-gathering here and it may take a while to get something published and

through the Federal Register, but I think it's very important that we have all these pieces to review when we are making comments on the Interim Rule, and I think you have that, the very last statement.

DR. JAN: Public comment (inaudible.)

DR. JOHNSON: Yeah. Thank you.

(Pause.)

MR. TYNAN: I apologize, in case you're wondering why I'm fooling around with the computer, it seems to be locked, so I can't do anything with the document, either to fix it, so we're -- we've got another disk, and hopefully this will do it.

(Pause.)

MR. TYNAN: In the interests of trying to get this document finished, I know there's some edits that we have to make on it, but generally, if there's consensus with the group that the document as we talked about it and as the changes we needed to make, if there -- were there additional changes, Jim?

DR. DENTON: It looks like that's it.

MR. TYNAN: All right. Then could I suggest that we take a break a little bit early, allow me to set up another computer, so that we can actually work on these documents as we go along. I'll try and edit this one and get us back together in probably about ten or fifteen minutes. I apologize for the inconvenience. I thought a simple Word

document would be easy.

DR. MASTERS: Nothing's simple, get over that [phonetic].

(Off the record and reconvened.)

MR. TYNAN: We can get started again. We are experiencing difficulty not only with the first disk but with the other two disks as well.

MS. ESKIN: Probably (inaudible).

MR. TYNAN: I'm sorry?

MS. ESKIN: Probably (inaudible) or something (inaudible).

MR. TYNAN: Well, one of the gentlemen suggested he had the military in here on another meeting and they couldn't change their disks either, it was a security issue. I don't know if discussing these reports comes under the heading of national security, but it certainly does come under, in one case, the food security.

We'll just have to -- if I can apologize again, I didn't anticipate that with a Word document we'd be experiencing this difficulty. Somehow these became read-only files last night on the three computers that we had, and I'm not sure how that happened, but evidently they're all locked. The hotel assures us it's not their computer.

So what I would propose to do is I'll display for the report for each of the sub-groups such as they are. For those edits that have to be made, perhaps the sub-committee

chairperson can talk through where they want to make some changes, you perhaps can pen and ink some in, and what I'll do is I'll take the material back to the office, and if we have to, we'll retype the reports and send them out to the sub-committees and the full committee to look at, to be sure that we capture them correctly.

So that will take a few days, I know it delays the process a little bit, but it's unavoidable at this point. So if we could go with that kind of a plan, I'll display the reports up there and I'll give Jim an opportunity to talk through, again, some of the edits he wanted to make, and then we'll go to Sub-Committee 2 and Sub-Committee 3, do the same process, and, as I say, after the meeting we'll make the appropriate edits and send it out to everybody. Is that agreeable?

DR. DENTON: Yes.

MR. TYNAN: Okay. Thank you. All right, Jim, did you want to --

(Pause.)

DR. DENTON: Thanks, Robert. The first edit that we had is under B, Labeling Team, at the point where we're in the statement -- I guess it's the very first one, where the National Advisory Committee recommendations on safety-based -- right now it says "safely," should be "safety," the following statement: "The focus groups are necessary to more closely assess consumers' response to labeling," we delete

"as an industry survey showed" and substitute the language "since consumer testing shows that consumers are frequently confused regarding various labeling statements."

The following statement, "In addition, the Committee endorses," we delete "reviewed and approved of," so that it now reads, "In addition, the Committee endorses FSIS," we delete "means," insert "education initiatives other than labeling to educate consumers."

Under Retail Team, F, in the second statement, where it reads, "Other groups, such as FDA, AFDO, state and local agencies have experienced in the operation of retail facilities" and "should be included," rather than "must."

Under Public Health Team, the Committee -- we strike "feels" and insert "believe that it is appropriate," et cetera.

And in the "Next Steps," the final statement, we insert after "based on the findings in the assessment": "and the public comments," "FSIS should make any necessary and appropriate changes to the Rule."

DR. JOHNSON: Sandra and I were talking about this during the break. Is there some way that we could actually put, in the "Next Steps" -- you've got "and comments," but put, you know, "documents published, comments to be" -- "have adequate time to review comments for inclusion in comments on the Rule"? Sandra, you were talking about maybe some wording?

MS. ESKIN: Yeah. Maybe one way to address what Alice mentioned is to say "FSIS should publish the report of the assessment and provide sufficient opportunity for public comments," and then you can say, "Based on their findings and the comments, FSIS should make any necessary and appropriate changes to the Rule."

DR. DENTON: I think that's appropriate.

DR. JOHNSON: Thank you.

MR. TYNAN: Other comments or changes that the Committee would propose to make to Sub-Committee Report Number 1? Dr. Hollingsworth.

DR. HOLLINGSWORTH: Jill Hollingsworth, destroyer of microphones, Food Marketing Institute.

(Laughter.)

DR. HOLLINGSWORTH: I hadn't thought about this earlier, but I would be curious to know if FSIS has defined their use of the term "retail," because I know FDA has a number of documents out where they go to great lengths to identify what they mean by that term. Does it include hospitals? does it include certain institutions? does it include nursing homes? does it include restaurants? when you're talking about retail do you mean convenience stores?

Many of those facilities also slice, handle, re-serve, open from its original container and rehandle product, and I'm wondering if you have defined what you intend to include in your term "retail."

MR. WILLIAMS: It's my understanding that we have that type of definition of "retail," but we have been relying on a traditional understanding of what retail operations are. I think that suggestion might be worth considering.

DR. HOLLINGSWORTH: So you're using -- by a "traditional," you're talking about a -- what would be a grocery store or supermarket, not a delicatessen?

MR. WILLIAMS: Well, we tend to just look at what traditional retail operations are, simple cutting and grinding, small-scale sausage-making, and that kind of thing, but we haven't really spelled out what the parameters are in the manner that you are suggesting.

DR. HOLLINGSWORTH: Okay. Thank you. We'd be happy to discuss that with you (chuckles).

MR. WILLIAMS: Fine.

MR. TYNAN: Any other comments on Sub-Committee Report Number 1?

(No response.)

MR. TYNAN: Do we have any opposition to accepting the report as it's written, any opposing viewpoints?

(No response.)

MR. TYNAN: Can I assume that we're good to go with Committee Number 1?

DR. DENTON: Yes.

MR. TYNAN: Perfect. All right, thank you, Dr. Denton, and the Sub-Committee, for doing all that hard

work.

DR. DENTON: You're welcome.

MR. TYNAN: Now what I'm going to do is try and get this file off and find another file, and the way the technology and the microphones are going, maybe that won't happen. I have faith, I have the highest expectations. Let's see which ones we have here.

(Pause.)

MR. TYNAN: Okay, Dr. Johnson will proceed with Sub-Committee Number 2, and that related to the mark of inspection or test-and-hold.

DR. JOHNSON: Our group addressed what's behind Tab 5, "Applying the mark of inspection to product tested for an adulterant," and we of course need to thank the group, I think we had good discussion and a lot of fun. Darin, David, Lee, Catherine, John the transcriber, Wanda, the flip-chart person, Jennifer, who helped us with our disk here, and of course Charlie, and then we also had some very good input from the folks that were listening in on the side, Bernie Shire, Tony all provided us some good input and some good information, and Dr. Masters actually went and made some phone calls and got us some additional numbers based on some of the questions that we had.

Our questions, if you can look at the back of Tab 5, "What is the Sub-Committee's view on the issue? How would such a policy impact industry, particularly small and

very small plants? Are there ways that FSIS could mitigate these problems?", we of course decided to change the order of the questions because we couldn't figure out how we wanted to address Question 1, so we put it at the end, and I think as we worked through the Questions 2 and 3 as they are listed on the sheet, we kind of came around to what we thought should be appropriate for the first question.

The issue, "Should FSIS delay a decision on granting the mark of inspection to product that has been tested for the presence of an adulterant until it has received the results of testing," Question 1, "How would such a policy impact industry, particularly small and very small plants?", we did -- after sleeping on this last night, we did have one change in which we took bullet "Some plants may not be able to meet their consumers' expectations," we moved that to be the first bullet, so the document now reads:

"Some plants may not be able to meet their customers' expectation. Mandating the policy may significantly impact small and very small plants by affecting the critical cash flow of the plant and the livelihood of the employees."

Dr. Jan brought up that, you know, there are some small plants that they have to get something out the door, you know, their customer down the road wants fresh-ground product, they have to get it out the door that day in order to be able to afford to get more trim to grind, that it's a

day-by-day existence.

The next bullet reads: "It may impact public health if plants change to a different level of inspection, e.g., retail exemption status on a permanent basis, in order to avoid test-and-hold."

Then the last bullet should read: "The Agency should encourage these plants to operate under inspection," and I know Bernie brought up that a lot of the smaller companies believe that in order to get out of some of the issues with FSIS inspection, that they can go into a retail exempt status and that would change the level of inspection that they're getting.

Anybody want to comment on that? Dr. Jan? From the group first.

DR. HOLLINGSWORTH: I do.

DR. JOHNSON: From the group first, okay?

DR. HOLLINGSWORTH: Yeah, I know.

(Laughter.)

DR. JOHNSON: Okay, calm, calm. Dr. Jan, anybody from the group want to comment on that?

(No response.)

DR. JOHNSON: Okay. Jill, let's get through all the questions, then we'll get you.

DR. HOLLINGSWORTH: Okay, that's fine, yeah.

DR. JOHNSON: Question Number 2: "Are there ways that FSIS could mitigate these problems?": "The Agency

encourages the education of small and very small plants." The first bullet we've changed to read "plan, hold, and/or encourage information meetings, such as the Saturday seminars that you've done on listeria and you're doing on O157:H7, and I think you've done some on BSE, we all felt like that was very good exchange of information, kind of the whole roundtable approach where the producers can ask questions and feel comfortable in -- I thought particularly with the listeria, that it was very good interaction and what all the questions were compiled and then, you know, you could go back and, as all the different seminars were conducted, you could look at all the questions.

We think that might be very useful for particularly the small and very small plants to understand what the whole process is about and to understand the implications of releasing product.

The next bullet should read: "Encourage plants to develop a plan of action to deal with difficulties that test-and-hold presents before products are selected for testing, such as networking with other companies in the area to fill customers' orders, partner with an alternate supplier," so that if you are grinding and you have a test pulled, then in order to meet an order that day you could stop and use a different trim from a different supplier, also issues on sanitation and cleanup and working through some of the -- just education on the basic processing and some of the

interventions that are available on some of these pathogens.

"This action will serve to help the ease with which small and very small plants can deal with the issues of cash flow and customer demand."

We did do a lot of discussion on that. A lot of the very small plants in particular, they are producing product that they will carry to a store, a restaurant that afternoon, and I think that we did a really quick review of some of the recalls and it would appear that you have about two-thirds of the folks tested -- we were basing this on listeria, two-thirds of the tests resulted in product being held, and the other remaining one-third, it was usually a small amount of product that was actually being recalled, and there was -- we made the assumption that that was because the very small or small plants had to get that out to meet customer orders in order to stay in business.

"FSIS inspectors should be trained and expected to express the importance of holding product when notifying plant management of planned testing." We recognize that the inspectors are told they should notify facilities when they're going to test, and we think in some of these small and very small facilities notification as early as possible would be useful and we don't think that that would sacrifice any of the information the Agency gets from the randomness.

We also felt like that the inspectors should emphasize the importance of holding and the consequences of

not holding product should the test result come back --.

"When possible, FSIS should adopt and employ new methods of testing that reduce the holding time, such as rapid testing, real-time technology, molecular assays, et cetera. FSIS should work in cooperation with researchers and companies in the development and evaluation of rapid testing technologies."

Catherine, do you want to add anything on that one?

DR. LOGUE: I only wanted to say that -- were we just looking at ways to make this a faster process and a faster exercise, you know, we talked about this idea yesterday, that the time frame can be five days or so, but there's a lot of newer techniques out there, and technologies, and there's no reason why FSIS shouldn't start to partner with these kind of companies or institutions that are doing this kind of work.

I mean, you're going to have the samples coming in all the time, so why not, you know, get these methods up and running. A lot of them are AOAC-validated already. It would cut down on the holding time, which, again, would be an ease for these smaller businesses and smaller plants.

MR. TYNAN: I just want to remind everybody, if you could, for purposes of the transcriber, I was chastised this morning, we're not speaking loudly enough or acknowledging ourselves, so if you could introduce yourself and your affiliation so the transcriber can get that down for us, that

would be great.

DR. LOGUE: Catherine Logue, North Dakota State.

MR. TYNAN: We want to be sure your words of wisdom are properly recorded.

DR. JOHNSON: Alice Johnson, Turkey Federation. Our next point is -- and this is something that Dr. Jan brought up, that I thought was very good, and I think we saw it discussed a little bit in the first group, with getting information out to the small and very small.

FSIS should provide a summary for plants on directives and responsibility and create a plant update, similar to the constituent updates issued by the Agency, but the updates to the plants should be simple bullets, "tell us what we need to do," and be made available in various languages. There may be some thought that the constituent update provides that information, but I think that there's a lot of confusion and it -- the update says, "Okay, the directive or the notice is out there," but sometimes the directive and notice can be very confusing.

So there's a thought: if we could make it simple, get it to the guys, say, "Here's exactly what you need to do, that that would be useful."

In the issue --

DR. JAN: Before we go there, can I just make a comment or two about --

DR. JOHNSON: Please.

DR. JAN: Lee Jan, Texas Department of Health. Related to Question 2, and we've got these bullets, but some of the things I'd just kind of like to maybe bring out and clarify a little bit. When we talked about early notification for testing, I don't think it was ever our intent to say small plants should get earlier notification, but they should be notified in time to make those decisions, but sometimes they can't make a --

I mean, we can't say, "We're going to test you next week," I think everybody would say that's not fair, and small plants, they're in the same business, they need to have the same notification that "today we're going to take a sample" or something of that nature, but I think it's really important for FSIS representatives, be it the CSI, be it -- if there'd be like a plant update newsletter or some kind of ongoing information, (inaudible) groups and things, to really stress to these establishments that when you're selected for sampling, you have an opportunity to hold your product, but if that impacts your business such that you can't sell production that day because your business is that small, then work out some of these other details ahead of time.

That's what we're trying to talk about in that one bullet, is: have contingency plans, whether it's purchasing that product at fresh -- if it's a fresh product, for example, purchasing it from a competitor and then selling it, so that you can meet your customer demand, whether -- if you

can afford -- some can, some can't -- afford to have their raw materials for two batches, some of them actually -- and I mean it's not many, but there are some that actually buy the materials and some of it may go to Sam's and -- bypass through product and make that into their product, whatever that happens to be, sell it that evening, and then on the way home or on the way to work the next day they use that money to buy again and they don't have any holding.

So -- but those are what we're -- those are the kind of things that we're talking about, is: work with these small plants so they understand the ramifications of being selected for sampling and what'll happen if they go ahead and ship and the product -- I mean the sample comes back positive.

So that's really what we want to talk about, but I didn't want the Committee and the people here to think that we were saying: we're going to give small plants -- or we're recommending giving small plants more time or longer advance notice, because I think we want to know what are the plant producing all the time, whether they're being tested or not.

So I think that's really what I wanted to point out, that we weren't trying to give them special favors. Okay, that's all I --

DR. JOHNSON: On our issue paper it also talked about residue testing, and we had a pretty good discussion on residue, and recognizing that there's basically two types of

testing: the surveillance testing that goes on, and then the suspect: if you see lesions, injection lesions, or something to make you think that there's an issue.

We don't believe that there's a need to consider any kind of change on the current residue policy. It's our understanding that if there are lesions, that the carcasses are held, surveillance testing -- I go back to the poultry, surveillance testing now on poultry, it would be very hard to try to hold flocks until tests come back. So we looked at that is: if you have for-cause reason to hold a carcass, then that's a little different than the surveillance issue.

We go back to Question Number 1 now, "What is the Sub-Committee's view on this issue," and somebody said, "Well, this is different than what we usually come out with." There were varying opinions as to what needs to be done, as to whether it needs to be mandated or we should consider it to be a voluntary program. It was, though -- there was agreement that the impact on the small and very small would be significant.

On estimates from the 2003 data on recall, in information provided by Dr. Masters, it looked like approximately two-thirds of the plants already hold product that's to be tested; however, very small and small plants should consider the impact of not holding test product and the possible mitigation strategies to facilitate the voluntary holding of the product. FSIS should be proactively

involved in enhancing current understanding of the ability of plants to hold.

Again, do the small and very small really understand the impact, are they, you know, flipping a coin as to say, "Well, maybe we won't have an issue," and if in fact they truly understand and look through what alternatives may be to holding product, would that increase their ability to hold.

Comments, Darin, from the sub-group, Darin, David, Catherine, Lee, any additional --?

MR. DETWILER: Darin Detwiler, educator. I guess one of the things that was pointed out was that the -- one of the biggest fears was that if there was something that did come back, that was not held, the ramifications in terms of the public reaction to that and that diminishing of confidence in the product.

MR. TYNAN: Other comments from the group on the sub-committee report?

DR. HOLLINGSWORTH: Am I recognized?

MR. TYNAN: I apologize. Dr. Hollingsworth.

DR. HOLLINGSWORTH: I have to announce who I am. Jill Hollingsworth, Food Marketing Institute. I have several questions, but also a comment, and I want to start off with my comment, because it's the thing that concerns me the most, and that is: the second bullet under Question 1 on the paper, a couple things, I think, for the record need to be

clarified.

First of all, there often, I think, is a misunderstanding about the concept of retail exemption. Retails are not exempt from anything that USDA enforces regarding adulteration. The terminology is misleading. Actually retailers are under USDA, FDA, state, and local jurisdictions, so oftentimes they have multiple statutes and requirements that they have to meet, they're not exempt from any kind of a food-safety situation.

The idea that if you're retail you can avoid test-and-hold: actually, retailers favor test-and-hold, it's to their advantage not to have to recall product once they've sold it to their customers. In the past FSIS has had numerous discussions with the retailers and we've written comments on the fact that retailers should be given an opportunity to test and hold.

In the past, most of the testing at retail has been done without any pre-notification. By the time the inspector comes to take a sample, the product has already been out in the consumer shelf to be purchased, product has been sold. Even if they stop producing at that point in time, product's already been sold, and they can't get it back, so they are in a potential recall mode every time a sample is taken.

We have tried to improve that situation in the new E. coli directive, for example, it does say that an effort will be made to give pre-notification, but without an

assurance of pre-notification, retailers always have to live with the possibility of a recall every time a sample is taken, unless they knew a day ahead of time and could have alternative supplies if need available. So I think the idea of avoiding test-and-hold is a misunderstanding on the part of the retail.

The other thing is that one cannot just change their business, if a person wants to be a retailer, there are certain requirements that they have to meet, that is based in part on the volume of their sales and the percent of their sales that go to household consumers, and so it's not just a matter of designating "I want to be a retailer," "I want to be a processor," it's not a choice, it's based on your -- the kind of business you operate.

The other point too is: strictly looking at E. coli, in the new directive retailers are not exempt from testing. If product has already been subject to testing at a federal plant because it's already ground product, then it is not again subject to testing at retail, but any product that is ground from boneless beef, muscle cuts, or trim is subject to testing. So retailers will continue to be tested. Hopefully we will get a day's notice so that we can do test-and-hold.

I guess my last concern is: I have to really question what was the meaning of the impact to public health by going to a different level of inspection. I'm concerned

that that is implying that retailers under state, local, and federal inspection have a lesser degree of protection of the public health than if they are under FSIS inspection, and I would have to question: what did the committee -- the sub-committee mean by that statement and can they back it up.

DR. JOHNSON: First of all I'll ask Dr. Masters to give us clarification on retail exemption, we were talking about this coming in, and I know we talked about it a little bit last night. Retail exemption is based on -- is it 50,000 -- what's the volume?

DR. MASTERS: I don't have the volume in my head, we'll see if somebody can get that number for us quickly.

DR. JOHNSON: Could you explain a little bit about the retail exemption status for going from a processing facility to selling directly.

DR. MASTERS: Right. We've got -- we'll have somebody go get the numbers for us, but as Dr. Hollings-worth was saying, when we talk about a retail exemption, the only thing that a retail exemption is exempt from is the actual inspection, they are not exempt from the adulteration provisions of our inspection acts, the Federal Meat Inspection Act or the Poultry Products Inspection Act. Similar to a customs-exempt facility, they're only exempt from inspection, they're not exempt from the adulteration provisions. It is the inspection component they're exempt from, not the adulteration provisions. The poundage -- it

has to do with the poundage, and we'll get somebody to get that back for us quickly.

DR. JAN: Lee Jan, Texas Department --

DR. HOLLINGSWORTH: Excuse me just a minute, I was waiting, if I could get an answer, though, to my question, about: what was the -- what is the thing about the impact to public health?

DR. JAN: That's what I was going to talk about.

DR. HOLLINGSWORTH: I'm sorry. Thank you.

DR. JAN: Lee Jan, Texas Department of Health. What we were thinking, our train of thought regarding this impact on public health, is that if an inspected establishment currently is slicing deli products to deliver to, say, a -- either into a package format to be sold at retail or is slicing deli meats to take to a restaurant that's going to make sandwiches out of it, that -- under this Lm rule, that establishment must apply or must address, specifically address listeria monocytogenes control, and in most cases these are going to have to go under alternative 3, which means that they'll be testing their contact surfaces for listeria organizations or listeria monocytogenes on a specified frequency, depending on the size of the plant, but if they wanted to avoid that type of cost, they may be able to go and change their process and no longer sell to restaurants but sell directly to -- make their own sandwiches and avoid having to do contact surface testing, their product

would not be subject to FSIS random sampling. It would still be subject to any testing that FDA may do, and, you know, we do agree that they are exempt from the provisions -- or they're not exempt from adulterating a product -- or selling an adulterated product, but the levels of assurances are lowered because those processes that FSIS believes improves the safety or assures that product is safe are no longer mandated, and that's where we're coming from.

MR. TYNAN: Mr. Kowalcyk.

MR. KOWALCYK: Michael Kowalcyk, from Safe Tables Our Priority. Under Question 2, ways FSIS can mitigate those problems where smaller plants would be unable to hold product because of logistical problems, was there any discussion about, given the fact that a facility cannot hold that tested lot -- would there be any required documentation above and beyond what is done normally?

My concern is, if you do get a positive read on that test, the ability to go further down the chain to the retail level to get that product back as efficiently as possible, was there any discussion about requiring documentation that says: yes, tests were taken on this lot and this lot was shipped on this day, so that way, six days later, on an E. coli test, if you have a confirmed positive, knowing that a lot of this might already be consumed and out there in commerce, you could pull as much back as you could if you needed to issue a recall.

Was that discussed?

DR. JOHNSON: We did not discuss that. We talked about the whole recall issue and the impact of a recall, and I think with the latest recall directive that's been published and the effectiveness check, it's my understanding this documentation is already in place and that the recall committee would require that type of information to be submitted once the test results are back and a recall is requested.

DR. MASTERS: Barb Masters, FSIS, and I would clarify: the recall group that actually -- the recall officer and the district would require that documentation at the presumptive phase, so if this plant tested, came back presumptive, they would start gathering that documentation even before it confirmed.

But your point's well-taken, that maybe we need to look at -- if we're at the point of product being tested, that there's a heightened awareness at that particular stage, but it would be required at the presumptive stage. Good point.

MR. TYNAN: Mr. Schad.

MR. SCHAD: Mark Schad, Schad Meats. I wanted to back up with Dr. Jan said here. As a small processor, I have to deal with this, and I'll tell you, this is a challenge, to hold this product when you are tested, but for me it was: once I realized all the ramifications, not only food-safety

ramifications but legal ramifications, it's a no-brainer, and I think the trade associations do bear some responsibility to better educate the small processor, and sometimes I'm a little surprised that small processors don't hold their product, but I do think it's because they don't fully realize all the ramifications. So I just wanted to put that down for the record.

MR. TYNAN: Mr. Govro.

MR. GOVRO: Yes. I just have a question concerning the retail exemption and the definitions of "retail" and "wholesale." It's a subject that we struggle with in some other areas, in determining whether farms are selling retail or wholesale, particularly in two areas:

One, when sales are made over the counter to other businesses and in quantities that are questionably of retail size, if you have a retail counter and the restaurant down the street comes in and buys ten pounds of turkey, beef, and ham each day and takes it down to use at their restaurant, is that a wholesale sale or a retail sale; and then also the question of some of the club-type stores, such as Costco, where there is membership and when you get a certain type of membership based on the fact that you're a business you get to shop at certain hours, then are those wholesale or retail sales; and I know that some of those retailers have sort of wanted to sort of play both sides of that fence and not be considered wholesale, and I just wondered how you looked at

that, at USDA.

DR. MASTERS: And I'll wait till Mr. Williams gets back, with some of the information, but again, it's an issue that is struggled with even within the -- within the Agency, and again, you're correct in that -- particularly with the clubs, wanting to be on both sides of the fence, but the Agency does have their definition, and the one issue -- the first issue's easier for me to answer, for the plant that -- the outlet that's calling itself retail, that's selling the smaller amounts.

When we get a situation such as that, that we believe they're defining theirselves in one way but perhaps acting in another, we would have a program investigator go in to look to see, are they calling themselves one thing but in fact functioning as something else, where they go look at documents, records, to see: is there a pattern, is there a trend, et cetera, can they really in fact document they're doing what their business says they're doing. So we could handle those on a case-by-case basis.

The bigger outfits have been clarified, we have worked through those as an agency, most of those have been worked through, and most of those are currently -- and correct me if I'm wrong, Dr. Hollingsworth. Most of those are currently wholesale, right, the bigger -- the clubs?

DR. HOLLINGSWORTH: Most of them are retail.

DR. MASTERS: Retail, okay.

DR. HOLLINGSWORTH: But that's because of the pass-through.

DR. MASTERS: The pass-through, okay.

DR. JOHNSON: Let me ask the sub-committee, on our -- which would now be our third bullet on your paper, it's the second bullet, based on the statements that Dr. Jan made, could we change that bullet to read something like "Level of assurances on process control may be altered if a plant elects to no longer be under FSIS inspection"? I think that would address Jill's question -- Jill's concerns. I'll ask the sub-committee before we put it to the full committee.

MR. TYNAN: Dr. Johnson, you're referring to Bullet Number 2, "It may impact"?

DR. JOHNSON: Yeah.

MR. TYNAN: Okay.

DR. MASTERS: What's the wording again, Alice?

DR. JOHNSON: Well, I was hoping somebody would take the wording and go with it a little bit. What I have right now is: "Level of assurances on process control may be altered if plant elects to no longer be under FSIS inspection."

DR. HOLLINGSWORTH: Versus state inspection?

DR. JOHNSON: I was going to put "e.g., retail exemption," da da da, as an example of -- or should we put "daily inspection"? Dr. Jan, I'm looking for help here.

DR. JAN: Well, maybe inspection under the federal

Wholesome Meat Act and Poultry Products Inspection Act, and then that would be whether it's state inspection or it's federal inspection, it wouldn't make any difference, it's still under the Meat Act, and what's where the requirement comes in for these --

DR. JOHNSON: Daily inspection.

DR. JAN: Right.

DR. JOHNSON: All right, "Level of assurances on process control may be altered if plant elects to no longer be under inspections as provided by meat and poultry statutes." Sub-committee?

DR. JAN: Good to me.

DR. JOHNSON: Dr. Jan, is that --

DR. JAN: I'm okay, yeah.

DR. JOHNSON: Catherine?

DR. LOGUE: It's okay, yeah, that's fine.

DR. JOHNSON: David?

DR. CARPENTER: (Inaudible.)

DR. JOHNSON: Okay. Open it up to the full group. Jill, does that address your concern?

DR. HOLLINGSWORTH: Not really. "Levels of assurance," tell me how -- what it would read.

DR. JOHNSON: "Level of assurance on process control may be altered if plant elects to no longer be under inspection as provided by the meat and poultry statutes."

DR. HOLLINGSWORTH: I assume in that case you're

referring only to listeria? Would that be true for other pathogens, for E. coli testing? I don't think it applies.

DR. JOHNSON: Was it just listeria you were referring to?

DR. JAN: Right. I was -- this is Lee Jan. I was referring -- or speaking to listeria, but there are also -- for grinders of beef, they have to have specific -- address specifically E. coli O157:H7 in their HACCP plans, and at this point retailers, it's my understanding, do not -- are not required to have a HACCP plan.

So the concerns are going to be: the requirements on that inspected establishment are more stringent than they are on a retail establishment, any way you look at it. They just don't have the HACCP plan. Now, if they had the HACCP and required to address E. coli O157:H7, then I would say then there's not a differences, you know, those differences ought to be recognized.

DR. HOLLINGSWORTH: I think if it focuses strictly on processing, then that would be -- it clarifies it better, I think. I'm sorry, Jill Hollingsworth, FMI.

DR. JAN: I agree that we're not talking about levels of sanitation or those things, because retailers have a responsibility to meet the levels of sanitation in a particular product from adulteration, but we're talking about -- the big difference is in the requirements for the process, processing that product.

DR. JOHNSON: Alternate wording suggested? We don't like "Level of assurances on process control"?

DR. HOLLINGSWORTH: I like that better, yeah.

DR. JOHNSON: Okay. "Level of assurances on process control may be altered if plant elects to no longer be under inspection as provided by meat and poultry statutes." Okay.

MR. TYNAN: Mr. Elfering, comment or question?

MR. ELFERING: Kevin Elfering, Minnesota Department of Ag. I was kind of hoping to try to piece all this together a little bit by maybe giving a bit of an example.

A retailer can sell single-ingredient product up to a certain dollar volume to hotels, institutions, and restaurants, so we have an establishment that's a very small plant, under FSIS inspection, and when the last E. coli directive came out, not this recent one, the last one, where they were required to consider E. coli as a hazard reasonably likely to occur, this particular plant only does about $40,000 in sales to one restaurant, of ground beef. They had been producing that under federal inspection.

Because of the new directive, they chose to produce that under retail exemption, under their dollar limit, which is about $50,000 a year. It goes up every year a little bit.

His question to me was, "Is that really what the Agency wants, do they want me to produce this product without

the benefit of federal inspection, without the benefit of a HACCP plan, and really kind of circumvent the issues by going under this exemption?"

And that's what they have the ability of being able to do, and I think maybe -- I wasn't on this committee, but maybe -- that's probably what you're looking at, is: there are options for these operators to produce product not under inspection, which would not be subjected to testing by FSIS.

If an FSIS inspector comes in and they say, "This is not inspected product," they're not going to test it. Now, they have the ability to test it, as a retail product, but I would say that they're not going to.

So that might be the issue at hand.

DR. HOLLINGSWORTH: Jill Hollingsworth, FMI. I would agree. I think, though -- and we'll have to go back and look at the statute, but my understanding is: it is not just the dollar amount, it's also a percent, 25 percent must -- or 75 percent must be to household consumers. So if a hundred percent of their production, regardless of the dollar amount, is going for restaurants, then they are not exempt.

MR. ELFERING: This is Kevin Elfering again. The only thing is, is these very small plants do have retail sales too, and it would be nearly impossible, just by their recordkeeping that these plants have, is -- to determine what the percentage would be.

So I would say that in most cases their retail

sales exceed their wholesale accounts. So I would look at it as the dollar volume. There is the two of them, but it's the dollar volume that really is the driving issue. And, again, the dollar volume is even difficult to be able to prove. You've got restaurants that may come in at some of these small plants and buy 20 pounds of ground beef in a day, there's very little records kept on some of those, of actually who that product went to. So even the dollar sales would be difficult to prove, that they've exceeded the $50,000 in annual sales.

DR. JOHNSON: And I think that we need to work through the wording, but from what I hear from Kevin and from some of Bernie's experiences, that this happens and it may be an issue that we need to consider as we look at changing policy.

Kevin, is that safe to say, that this type of -- changing your customer profile, do you have examples that it does happen based on some of the E. coli policies that have come out?

MR. ELFERING: It will, but only on single-ingredient product.

DR. JOHNSON: Okay.

MR. ELFERING: They're not exempted if they're -- for example, if they're making a meatloaf mix and using pork and beef, that's not exempted, those are not -- that's not a single-ingredient product. So it really would only apply, in

most cases, only to ground beef, or ground pork, something like that.

So how often that would happen? I would say that these would be the exceptions, but it does -- there's always that capability of being able to produce product under exemption.

DR. HOLLINGSWORTH: Jill Hollingsworth, FMI again. I guess, though, it seems to me we may be getting a little off track here, where we're off on defining the retail exemption and whether that's a good exemption and how that might make a company look at their business.

The interesting point here is that the retails would prefer test-and-hold, and there seems to be a push here that if processors are made to test and hold, then they will opt to be retailers. Interestingly, the retailers prefer test-and-hold. So they may be going to a business operation that in fact is doing and requesting the very thing they're trying to avoid. So I'm a little confused about that approach and how that plays into the whole -- I mean, if the issue here is test-and-hold, I'm confused about how that's going that direction.

DR. JOHNSON: And I think one thing we also -- as Jill said, we may be getting off a little bit, we have to remember this focus is on small and very small, so -- and in order to get through this, because I think we need to address Mark's comment about the education, because we have focused a

lot on FSIS providing that information.

"Level of assurance on process control may be altered if plant elects to no longer be under inspection as provided by statutes." Is that --

DR. HOLLINGSWORTH: Well, I guess my question would be: But is it understood that if they alter their level of inspection, they will be then opting into a requirement or a request to have test-and-hold? I'm not sure you're achieving your goal.

DR. MASTERS: This is Barb Masters, FSIS. Let me ask this, Dr. Hollingsworth. Is it fair to say in the education portion -- what I think I hear you suggesting, and I certainly have heard it from you, coming into the Agency, is that in the education competent of this, is that part of the education should be that education of the very small plants would be that the retail side of the house is pushing for test-and-hold, so at least these very small companies are aware that the retail-side-of-the-house position is that test-and-hold is the preferred method?

DR. HOLLINGSWORTH: Yes.

DR. MASTERS: So maybe there needs to be some kind of bullet to the education component of this.

DR. JOHNSON: We can actually put where the Agency should encourage these plants to operate under inspection or -- and maybe we can put that --

DR. MASTERS: An awareness of the -- I'm trying to

-- I'm not trying to put words in your mouth, but I --

DR. JOHNSON: Sounds good [phonetic].

(Laughter.)

DR. MASTERS: -- would not argue with Dr. Hollingsworth clearly that it is the desire of the retail industry --

DR. JOHNSON: And provide awareness --

DR. MASTERS: -- which is why the E. coli directive was written as it was, that they also -- you know, it is their desire to hold the product when it is tested at retail, so --

DR. JOHNSON: And provide awareness of retail industry's desire --

DR. HOLLINGSWORTH: -- not to have to do recalls, that's their desire.

(Laughter.)

DR. JOHNSON: Objective: to limit recall.

DR. HOLLINGSWORTH: And to protect their customers.

DR. MASTERS: Through test-and-hold. I mean, if we're trying to educate the very small plant, I think it's clear that to limit recall would be through test-and-hold. I'm not sure the very small plant would understand, if we said the retailers' goal is to limit recalls, I'm not sure that that would speak to a very small plant, as to what that means.

DR. JOHNSON: Okay, "The Agency should encourage

these plants to operate under inspection and provide awareness of retail industry's objections" --

DR. HOLLINGSWORTH: "Objectives."

DR. JOHNSON: Objectives, sorry. -- "objectives to test" --

DR. HOLLINGSWORTH: -- "to protect the public by minimizing recalls."

DR. JOHNSON: -- "to test and hold product."

DR. HOLLINGSWORTH: -- "to protect the public."

DR. JAN: Could I ask one question. This is Lee Jan. I just wondered to what extent the retail industry is asking that, is that the large companies or does that -- does that include -- are all the small mom and pops, that are doing retail, wanting to have that product held once it's tested, are they pushing for that, or is this just -- it doesn't seem that that's what we see in real life, when you go out there, mom and pop, they don't have the capacity, whether they're retail or whether they're under inspection, many times, to hold the product, and I don't know that they're on the same bandwagon as your institute is.

DR. HOLLINGSWORTH: Well, certainly we can't speak for every retailer, and I think that just like with small processing plants, you have the same situation with small retailers. The thing that the retailers have specifically said, though, is they see the value in pre-notification, and that -- well, that was going to be my next question, was:

Was there a discussion, and should we focus on the fact that pre-notification is really necessary if you're going to have an effective test-and-hold program, and as part of the test-and-hold problem or concern, that there is not always sufficient pre-notification, and I guess that lends itself to the next question: does pre-notification in any way bias the sample.

Our general feeling is it doesn't, if you have the product you have the product, whether you know the inspector's coming to take a sample, you can't change the product, you're not doing anything to alter it. I don't see that, personally, as biasing the sample, but I think that you'll never have even the option for voluntary test-and-hold unless there is sufficient pre-notification, and that, to me, is one of the issues that needs to be addressed.

DR. JOHNSON: And I think we -- we did discuss the pre-notification issue, and Charlie brought out that in the Directive, on the plant side, the inspector is required to notify, although we've heard cases when somebody's on patrol and they walk in the very end of the day and say, "Oh, yeah, I've got to do this," and we were trying to address that in -- with "FSIS inspectors should be trained and expected to express the importance of holding product when notifying plant management of planned testing," but we maybe need to be sure that we talk about appropriate timely notification.

And I do want to add to what Dr. Jan and

Dr. Hollingsworth were just talking about, it's the same whether it's a retailer or a plant: if we see that two-thirds of the industry generally will test -- will hold product that's being tested, then we still get back to: it's the small and very small folks, whether they're retail-exempt or whether they're under inspection, either state or federal inspection, it's still the issue that: the impact would be on the small and very small.

I think all of the industry and the retailers support a voluntary test-and-hold program because we don't like recalls, we don't -- you know, we believe that that's in the best interests of our customers and improving public health, but at the same time, we have to deal with these small and very small and help through education on what -- the objectives that they need to think about in order to be able to test and hold.

So we probably should come down, sub-committee, and put some wording changes, "FSIS inspectors should be sure to provide adequate notification"? And I think we have that -- I thought -- we talked about it somewhere, but I don't know that we -- but we'll make it --

MR. SCHAD: Alice -- Mark Schad, Schad Meats -- on that pre-notification, I just had a thought here on that. Maybe that's not really the key issue. To me the key issue is: is that sample representative of a lot that's going to verify the process, and whether or not you get notification

or not, I'm not sure that's the central issue on this.

DR. JOHNSON: Well, I know in our group we talked about: if there were -- if the issue with the small and very small plants are "I have to get this product out the door by 2 o'clock," then if I know that they're going to do a sample today, then I can have an alternate source of materials to grind, so that they come in and do a sample, I'm running my process the same as I would whether I'm grinding my trim or Dr. Denton's trim, and that -- then if they're testing my -- the trim they got from me, that they could stop, take appropriate sanitary measures, and go to the other trim, without the fear of having to -- you know, they would have some assurances that they could hold that and they could still meet their orders. That was one of the keys in the notification portion of this, so that they could have -- or they could talk to one of their other companies down the road, so "Hey, guys, I'm being sampled today, I'm going to hold product, could you help run some product for me so I can make this order?"

MR. SCHAD: But I was just thinking that if we want to encourage small plants to hold the product, you know, can the Agency or the in-house inspector work -- if he's confident that it's the same process, every batch is the same process, does he have to -- is notification really -- pre-notification, is that really a central issue, can you say, "Well, I'll take it today, or another day that's more

convenient for you, so you can hold that product, because based on your records and based on me being here and checking your process, I'm confident" --

(Tape malfunctioned.)

UNIDENTIFIED MALE: Isn't technology wonderful.

UNIDENTIFIED MALE: Absolutely.

DR. JOHNSON: Yeah. Mark, the whole -- the whole issue of notification was so that -- and even in the retailer issue, it would still give them the opportunity to be --

MR. SCHAD: I'm not disagreeing with you, I'm just trying to --

DR. JOHNSON: Yeah, try to enhance our --

MR. SCHAD: -- point out: how would you get more small plants to hold product?

DR. JOHNSON: If we could come up with some good wording, that would be great. Hint, hint, hint.

DR. HOLLINGSWORTH: (Inaudible.) Jill Hollingsworth, FMI. In response to Mark: I agree, Mark. I think that part of the difficulty or the challenge in this comes from: is it a verification sample of a process or is it a lot-representative sample, and that's kind of the issue, and I think the way the Agency looks at it, at least from where I understand it, is that it is a verification sample of a process but it still represents the condition of the lot and therefore it becomes a lot pass/fail test.

So long as it is perceived as a lot pass/fail test,

even if it is verifying a process, we're going to be into this concern about: if it's positive, then you're in a recall mode if you've released it.

I guess some alternatives to that would be to look at -- can samples be designated strictly process verification versus lot pass/fail? I don't know if that's an option, but that would address the issue that you've raised, and I think it's a good point, it's verification versus --

DR. JOHNSON: We did discuss this with Charlie last night, and, you know, he made it clear, at least to me, that this was a verification of the process, and, you know, that they had followed the recommendations of NAS and the International Micro Groups in looking at verification and not a lot release, because they statistically can't do that type of sampling, but the issue becomes, for the Agency, as everybody knows, if you're doing a verification sampling and it's adulterant, then action has to be taken.

But I think the words from the Agency are: it is verification and -- of a process and not a release -- lot release.

MR. SCHAD: The words I hear are "monitoring" and "surveillance."

DR. MASTERS: This is Barb Masters, FSIS, and it's clearly a verification of the process; however, I'll clarify: on E. coli O157:H7, certainly we've learned a lot more about the organism in the last couple of years, we no longer

(inaudible) with the new directive, we're looking at recognizing the companies are going to need to go back, are they able to identify source material, so that's where notification does come into play, because if you're using the same source material for grinding, we would be concerned about that source being used for all of the days in grinding, et cetera. Obviously a little bit different with ready-to-eat, because that's where your process is much more significant.

So as we learn more about organisms, we're having to look at things a little bit differently, so I know that does factor in a little bit. So I don't disagree with what you're saying either, Mark, it's certainly relevant for us to be able to say. The important thing is, we want to be able to get representative samples, because we are looking at your process, but with E. coli O157, we can't mitigate the fact that we are looking at source material.

Thank goodness as an Agency, as an industry, things are driving back at slaughter, which is decreasing the amount of O157:H7 moving through a process, which is where the impact can happen, but having said that, once it's in a group of product, we've got to deal with that group of product.

DR. JOHNSON: Okay, how about wording to address this to say "FSIS should notify plant and retailers in a timely manner to allow these companies to hold product without disruption to business"?

MR. TYNAN: Dr. Johnson, that's under Question Number 2?

DR. JOHNSON: It's Number -- Jill says it's number -- yeah, it's Number 2. Then the next comment would be: "FSIS should be trained and expected to express the importance of holding product when notifying plant management." How about that?

DR. JAN: One thing, Alice. Lee Jan. I think I'd maybe modify those words, "without disruption to business" but maybe "in a timely manner to allow businesses to make a reasonable business decision regarding the product," because --

DR. JOHNSON: "Should notify" --

DR. JAN: Because, you know, we can't be -- I mean, we need to be reasonable, but we can't let business dictate over public health.

UNIDENTIFIED FEMALE: What's the wording in the E. coli directive?

DR. JAN: "E. coli"'s one of the words.

(Laughter.)

DR. HOLLINGSWORTH: No, they're -- in the Q & As, there's a specific statement in the Q & As about why pre-notification is important.

DR. DENTON: So the company can still fill its orders, or FSIS is not supposed to disrupt the company from filling orders?

DR. HOLLINGSWORTH: Yeah, there's wording in there --

DR. DENTON: It's something to that effect, I thought.

DR. JOHNSON: Dr. Jan, your wording was "timely manner to allow plants and retailers to make appropriate business decisions as to holding product"?

DR. JAN: Yeah, or "related to the product" or something like that.

DR. JOHNSON: Okay.

DR. JAN: It gives them an opportunity but doesn't say that we're not going to disrupt business. Sometimes it's unavoidable.

MS. ESKIN: Yeah, if they say "come back next month."

DR. JAN: Yeah, right.

(Laughter.)

DR. JOHNSON: Business decisions on holding product. Okay, so the statement now reads, under Question 2: "FSIS should notify plant and retail establishments in a timely manner to allow the establishments to hold product" -- "to allow the establishments to make appropriate business decisions on holding product." Comments?

UNIDENTIFIED FEMALE: Can you read it again.

DR. JOHNSON: "FSIS should notify plant and retail establishments in a timely manner to allow these

establishments to make appropriate business decisions on holding product." And that would allow for switching suppliers, cleanups, whatever's needed to be done. Everybody agree with that?

(No response.)

DR. JOHNSON: Okay. And to Mark's point on education and training, "The Agency encourages the education of small and very small plants. Plan, hold, and/or encourage information meetings, such as Saturday seminars. This information sharing can be from universities, trade association, et cetera." How's that?

(No response.)

DR. JOHNSON: Any other comments?

DR. MASTERS: We do have some answers.

DR. JOHNSON: Okay, good.

MR. WILLIAMS: Charles Williams, OPPDE, FSIS. The retail exemption (inaudible), retail stores are stores that -- whose sales are at least 75 percent to household consumers, they may sell a maximum dollar amount to hotels, restaurants, and institutions on a calendar year basis, currently the exemption limits are $53,600 for sales of meat food products and 43,600 for sales of poultry products.

DR. JOHNSON: Thank you. But we have changed that bullet to read: "Level of assurances on process control may be altered if plants elect to no longer be under inspection as provided by meat and poultry statutes."

MR. TYNAN: Dr. Hollingsworth, you had another question or a comment?

DR. HOLLINGSWORTH: Different one.

MR. TYNAN: Just one.

DR. HOLLINGSWORTH: (Chuckles.) Jill Hollingsworth, FMI. I'm wondering whether or not the group talked any about the idea of looking at test-and-hold specifically on a pathogen commodity basis, and I guess what I'm thinking there is like, for example, the fact that the Agency decided that BSE of a carcass would require mandatory test-and-hold, might there be specific situations where a pathogen or a product might lend itself to a situation where test-and-hold is appropriate, versus other products where it may not be necessary to mandate it, and I guess there I'm trying to think of -- based on this, does this in fact also apply to the idea of BSE in carcasses.

DR. JOHNSON: We did have this discussion, and I think we talked about it and related it a lot to the residue policy that's currently in place. If there's a lesion, if there's a suspect, and that's what we understand the majority of the BSE testing is, being done based on suspect, then there's the hold component to that. If it's verification, more of a surveillance, then we think the policy that we've discussed here -- that was I think in the sub-committee -- please chime in, but that was basically the discussion on the BSE and the residue, because currently we do hold carcasses

with suspect residue.

DR. JAN: I might add that on BSE, those aren't suspect, those are just high-risk.

DR. JOHNSON: High-risk, okay.

DR. JAN: They're not suspect BSE.

DR. JOHNSON: Thank you.

DR. MASTERS: Barb Masters, FSIS. I would add further that these 20,000 healthy animals are not necessarily even high-risk, they're only animals in a surveillance program because they are in fact animals that were born prior to the feed ban, so they are just a category of animals for which we have interest, so in reality the animals that likely will have passed inspection are not even the high-risk animals, but for those animals for which we and the Department have an interest in having information as to what's going on in the population of animals, the high-risk animals would be those animals' central nervous system symptoms, dead animals from the farm, et cetera, and those animals will not make it into the food supply, they will be condemned on antemortem, so --

DR. HOLLINGSWORTH: Will the 20,000 be held?

DR. MASTERS: The 20,000 animals will be held.

DR. JOHNSON: But there is an interest, there's a reason --

DR. MASTERS: There's an interest in those animals, yes.

DR. JOHNSON: There's a reason those animals are considered to be --

DR. JAN: Based on emotion more than science. (Laughter.)

DR. JOHNSON: All right. Anything else?

MR. TYNAN: Mr. Detwiler, you had a comment?

MR. DETWILER: Darin Detwiler, educator. Should you go ahead and define the small and very small plant and the exemption information we just got possibly in this documentation, to prevent further confusion?

DR. JOHNSON: Okay, so we should put a little asterisk down and put our retail exemption --

DR. MASTERS: And you can add that was based on the April 30th, 2004, Federal Register, so that's the current -- so it matches the date.

DR. JOHNSON: April 30th, 2004?

DR. MASTERS: Correct.

DR. JOHNSON: All right. And we defined -- in our group we actually talked about what's small and what's very small and we defined it based on the pathogen-reduction HACCP rule.

MR. DETWILER: Either list it or make the reference back to where to find that definition.

DR. JOHNSON: Okay. Anything else?

MR. TYNAN: We have general agreement, then, from the group with the way the report has been modified?

(No response.)

MR. TYNAN: I see no opposing viewpoints, so we're going to accept Sub-Committee 2. Okay, I give you a choice, we have choices in life: would you like to take a quick break or go immediately to food security?

UNIDENTIFIED MALE: (Inaudible.)

MR. TYNAN: Five-minute break, let's take five. It's now -- by my watch, it's about 10:37, so if we could come back here about 10:45, please.

(Off the record at 10:37 a.m. and reconvened at 10:50 a.m.)

MR. TYNAN: All right. Finally, but certainly not least, the sub-committee report related to food security. I think Mr. Govro was the sub-committee chairperson, so I'm going to turn it over to him to talk about the report.

MR. GOVRO: Thank you. Mike Govro, Oregon Department of Agriculture. I'd like to start off by thanking the members of the sub-committee. We had Dr. Bayse, Dr. Hollingsworth, Michael Kowalcyk, and Mark Schad, as well as a number of USDA FSIS representatives, Karen Stuck, Dr. Maczka, Dr. Santiago, Ron Hicks, Mary Ann Albertson, Linda Russell, and, on occasion, Dr. Masters.

I think we had a good representation of viewpoints and we ended up with sort of a brainstorming session that I thought was kind of fun, a lot of ideas going back and forth and a lot of synergy there, and hopefully we came up with something useful.

This question was asked of a sub-committee at the June 2003 National Advisory Committee meeting, and it was actually exactly the same question, but it was framed under the broader category of increasing industry awareness for food security, and four questions were asked at that time, including the question: Should FSIS mandate that plants have food-security plans.

At that time the answer from the committee was: No, the Agency should not, and the answer remains no, for a number of the same reasons.

A couple other concerns that were brought up -- it was felt at that time and in this meeting that a cooperative, collaborative approach between industry and FSIS would best achieve a higher level of food security. There are definitely some problems associated with mandating rules.

One that was brought up is that once you establish a rule, for many plants it becomes an exercise in paperwork and just simply doing whatever is necessary to make the inspector happy, and we didn't think that that would be productive.

Also, as we thought through how rules could be implemented and where that would lead, it seemed that it would be an expensive, drawn-out, and contentious process for both the industry and the Agency.

During the last meeting a number of collaborative approaches were suggested to the Agency, and rather than just

repeat those, we came up with a bit more and suggested a food-security partnership between FSIS and industry. The participation by industry in this program would be voluntary. This strategy is to provide incentives for industry to participate and achieve a target level of food security.

Partnership would provide recognition for achieving a target level of food security in a plant. We even named this partnership, we called it the Partnership for Food Security, and thought that it could be modeled after the Partnership for Food Safety Education, which came up with the "Fight Back" campaign. The partnership would establish goals and objectives, along with an awareness campaign.

I may ask Dr. Hollingsworth to expand a little bit on the Partnership for Food Safety Education, I think she's probably most familiar with that, but one of the aspects that I thought could be incorporated in this was the recognition program and the voluntary aspect of it, which, in other areas of the food industry, has been a useful tool.

For instance, USDA has a program of certifying Good Agricultural Practices on the farm, which at this time is a voluntary program, but many farm companies are participating, and they're doing that largely because the people that they sell the product to are requiring it of them, and we're seeing programs similar to USDA's certification program pop up both in state agencies and in private certifying companies. We think that this would provide an incentive to

the industry to participate in a voluntary program and expect some of the same market pressures would come to exist almost immediately. In fact, I think probably some of those pressures are already there through private certifiers, and I think having a USDA FSIS stamp of approval by participating in this partnership would be of a high level of interest to the industry.

In a collaborative effort, we thought that both parties in the partnership would need to bring certain things to the table, and we wrote down a few of those, and by all means don't think that this necessarily is a complete list, but among those we wrote down that there would be joint training on conducting self-assessments, we thought self-assessments were important, and certainly, as we discussed this, no one wanted to be the one to say, "Well, food security is not an important issue for industry or the Agency to address," and at the very least it would be valuable for every company to do a self-assessment of their level of food security.

The plant assessments would be done with industry conducting the assessment and FSIS providing vulnerability assessment information. Development of the self-assessment guidelines, that probably should be the second bullet point, actually, after the joint training on conducting self-assessments, or perhaps even the first bullet point.

There would need to be something to ensure that

mitigation strategies are taken, as appropriate, as found to be appropriate by the self-assessments. There should be information sharing, data sharing, an outreach component, and each partner would need to commit to providing the resources to carry out the goals of the partnership.

The Sub-Committee recommends that FSIS give appropriate consideration for the security of proprietary information resulting from the self-assessments. We talked a little bit about making information protected where it's necessary but not so protected that the people who need it cannot get it, and I understand that's been a problem. On the flip side, we don't want to make information available to people who might use it for bad purposes.

FSIS should consult with the parties involved in creating the Partnership for Food Safety Education to learn how to develop this partnership, and if the resources are available, go ahead and proceed with that.

And then we also recommended that FSIS provide a report at the next meeting on the progress on this subject. And I just might ask Jill to expound a little bit, if you would, about the Partnership for Food Safety Education and how that's worked and what kind of success it's been.

DR. HOLLINGSWORTH: Jill Hollingsworth, FMI. I think probably many people, certainly the FSIS people, have a pretty good understanding of the partnership, but what happened in our discussion, I think, that we started talking

about: can a true partnership be developed with the government and the industry, and we were using the word that industry and government need to collaborate, and we felt that was just such an overused term that we needed to put a stronger structure in place, and that's when the idea about the Food Safety Education Partnership came up, where there are actually representatives designated within the government who represent their position on food safety education, there are industry representatives, there's actually a means and a mechanism for generating revenue to keep that program going, to advertise it.

They meet on a regular basis to define: what are the issues, how do they want to get out to the public. In this case it would be, really, more: reaching out to the industry, but the whole idea that the industry and the government can work together on a mutually agreed-upon set of goals, objectives, and with an understanding that food security will benefit not just the industry but the whole country and that it needs to have that kind of incentive and that push behind it.

So it was: using many of the techniques that have worked for the Partnership for Food Safety Education. In some ways it's a little bit different, because, for example, within the Food Safety Education Partnership, the goal was to, really, educate the consumer; in this case it was: to work with the industry to be sure, particularly for the small

and very small plants, that they understand that there are probably things that they could do better to enhance their security but that they're not going to be told how to do it, they're going to get assistance in looking at: what is my facility, what is my product, how can I do what I do better and more securely? So that was the idea.

We're really throwing you a seed here to plant and grow. We did have some discussions about who would participate in the program and who would not and what do you do with those who choose not to participate, and personally I feel that if this program were put in place and allowed to grow, at some point you'd need to evaluate it, determine what level of participation you had, how effective it was, and what to do about those who chose not to participate and where you still recognized that there were deficiencies that needed to be addressed, we thought that this would be a good first step in trying to do something in the form of a partnership, and obviously down the road you may have to consider, you know, what to do about those that don't participate.

DR. MASTERS: Barb Masters, FSIS. It's evident you had some dialogue on the sharing of information, since you indicated you understood we had some concern with that. You had asked yesterday what information we had, and the reason the answer was "We don't have it" is at the time of Liberty Shield, when we had our folks going out to look at voluntary compliance, we had to move quickly because of Liberty Shield,

and the question was "What do we do and is this information FOIAble and how do we keep it out of the wrong hands," so the safer answer was, "Don't keep it," because of practicality of Liberty Shield happening so quickly.

Did you guys talk at any length at all of how you do that? I certainly would welcome any thoughts you have on that, because it's clearly an area of concern, that you need that information in the right hands and need to keep it out of the wrong hands, and I don't know how much detail of discussion you had there. And it's better to do that when you're not under the auspice of "Liberty Shield happened today" and make something happen today.

DR. HOLLINGSWORTH: I think that that was part of the reason why we felt like if it was done as a partnership, then the plants basically own their own security plans, the government does not have them, the government does not have a document or any information that would be FOIAble other than guidance documents --

DR. MASTERS: Right, which we want everyone to have.

DR. HOLLINGSWORTH: Right. On the self-assessment side, the idea was that the government can help the industry understand how to do a self-assessment, what kinds of things to be looking for, what kinds of mitigation strategies to put in place, but that the information on what the plant has, as far as their security plan, would not belong to the

government, and the government's role would be: identifying those plants that can say, you know, we've gone to the training or we've done an assessment, and so there would not be, I guess, the burden on the government of having possession of things that could be released.

We also even talked about: in some of these sessions, the trade associations might be a good venue for working with their own industries on those things where we don't want it to get out, and so if the government was not present, then they wouldn't be under any obligation to release information, and so we talked about ways of keeping the information within the industry but sort of having the government as our partner, as the umbrella partner, to make sure everyone's looking at their own situation.

So I don't know if that addresses your question, but --

DR. MASTERS: It helps with the understanding that the information itself would be owned by the plant and the government would have the -- almost a backbone, the structure of "Here's how to do the assessment," that sort of thing. That does help. Thank you.

MR. GOVRO: That's our report. Any comments from the sub-committee before we open this up to discussion?

(No response.)

MR. GOVRO: Well, I don't see any, so let's go ahead and open it up to the full committee.

MR. DETWILER: Darin Detwiler, educator. Would this partnership for food security then be extended beyond the borders? For instance, would there be companies in Canada or other countries that would then be part of this partnership because they are importing across our borders?

MR. GOVRO: Mike Govro. That's a good question. We didn't discuss that, and I'm guessing that -- and maybe the FSIS can comment, that it would probably depend on resources available.

DR. MASTERS: Barb Masters, FSIS, and I can say that, again, it's a good comment and I can at least indicate from a North American perspective that North America is going everything possible to harmonize Canada, Mexico, United States. Beyond that, I think the resources would come into play, but it's certainly an excellent point. David.

DR. CARPENTER: I'd like a clarification of government agency semantics. Some of my colleagues at CDC have referred to this activity as food protection instead of food security. I mean, are we all going to embrace common terminology?

DR. MASTERS: Barb Masters, FSIS. I can tell you that from FSIS' perspective, we went with, as you know, Dr. Maczka, we were looking at food security, it's clearly one for which there's a lot of questions. I can tell you that I met with the folks down at CDC myself, I can't keep up with my own calendar, it's been a couple of weeks now.

I know that with your new -- I can't keep up with the name of your reorganization, or restructuring --

DR. CARPENTER: (Inaudible.)

DR. MASTERS: Whatever you're calling your restructuring down at CDC. You have a new person in charge of your food security, or your area of security. And Dr. Maczka is going to be meeting with those folks to see if we can start some collaboration with your folks down at CDC, so hopefully we can get some more harmonization.

DR. MACZKA: We work very closely with FDA, we work very closely with EPA, we're working closely with customs, so there is a lot of collaboration, and we're hoping to increase our collaboration over (inaudible) term, but I'm not sure we're at the point of partnership yet with some of the other sister agencies because of the differences in our regulatory authority, but we're trying to increase that work that we're doing with CDC, but at this point we are looking at -- food security, I can tell you it's a word we grapple with greatly, you know, bio-security, I mean, it just -- the things you conjure up with these terms, we are looking at providing food security.

MR. TYNAN: Other comments from the Committee, questions, issues about the partnership?

(No response.)

MR. TYNAN: Perfecto, Mary Ann, did you have any questions regarding --

DR. SANTIAGO: Maybe a short comment. This is Perfecto, with the Office of Food Security. This is my first time I participated in the individual deliberations of the Committee, and one thing that became very clear right away was: there was a joint commitment to food security right at the beginning. I must commend Mike for leading the group. For a while there were a lot of statements of commitments, but when the word "collaboration" came out, then the juices started flowing on all the different ways of partnering came.

So I think this is really where we can make the most impact on food safety, rather than requiring the comply model, anyway. So with the permission of the senior management, we will proceed with developing implementation strategies for this and report at the next meeting.

MR. TYNAN: We already have an agenda item for the next meeting, great.

(Laughter.)

DR. MASTERS: Barb Masters, FSIS, and I can say that in what Dr. Santiago was saying, Dr. Maczka had already asked -- had already sent me an e-mail last night to get it on my calendar, so obviously she was impressed with the work of the Committee, as was Dr. Santiago.

MR. TYNAN: Other comments, thoughts, or questions?

(No response.)

MR. TYNAN: Are we in agreement with the Sub-Committee? Yes, Dr. Jan.

DR. JAN: I just want to make a comment. I think that's good work and makes a lot of sense, and the guidance and all those things, self-assessments, is right on target, but I wonder if maybe the Office of Food Security or Homeland Security, FSIS, would also consider developing a vulnerability assessment team that could be available to industry upon request, to have another set of eyes, from experts, because sometimes you've got all good intentions but it is kind of nice to have somebody come in and look at it, from the outside, and these folks going to be thinking as a bad guy, because it's a whole lot better to come in with the bad-guy frame of mind, because you can see things on how you can penetrate and cause some problems, and I just -- you know, just for consideration.

DR. MASTERS: We can take that comment back. Thank you.

DR. HOLLINGSWORTH: If I can respond to that, Jill Hollingsworth, FMI. Dr. Jan, I think it's an excellent idea, and actually, in our discussions, I do believe we talked about: as a partnership, that would be the kinds of things that we would look at, where industry could go to the government for assistance without the fear or the concerns about: they're going to come in and regulate something or they're going to cite me for something I haven't done, that it would truly be the -- and that was where we talked about the collaboration, that the industry could go to the

government for assistance, likewise the government could ask the industry for input on: what are you doing? what's working? what's not working?

So the idea was in fact to have that kind of thing, and I think specifically talking about a team or some way the industry could seek out help is an excellent one.

MR. TYNAN: Dr. Johnson.

DR. JOHNSON: I like the idea of a team that's specially trained. I think we need to be careful in using like some of our inspectors and our front-line supervisors, that are already there, because it's -- like the rest of us, we see it all the time and sometimes we can't identify,

So I think a team with some special training, and it, you know, might be useful if they get some exposure in different areas, as opposed to letting it be someone in-plant or in that district, that is very comfortable with the facility, I think we might lose out a little bit on that.

MR. TYNAN: Are there some changes, then, that the Committee wants to make with the report, to incorporate some of those ideas?

MR. GOVRO: This is Mike Govro. Should -- Lee, can you restate your suggestion so we could add it as a bullet point or as a paragraph.

DR. JAN: Well, I think probably a bullet would be adequate, but my point is that the Office of Food Security, I guess -- is Homeland Security gone or --

DR. MASTERS: Food security, yes.

DR. JAN: So now we've got the Office of Food Security. Someone that's outside of inspection create the team, a specialized team, to be available to industry on a request basis, not come in as a strike team or anything, come in as a request for --

DR. MASTERS: You took all the fun out of it for Dr. Santiago.

(Laughter.)

DR. JAN: But like they mentioned, so there's not a concern about any repercussions or negative findings or that would lead to an inspection issue or NR or anything, just strictly as another set of eyes, specialized folks, that know terrorism techniques or think terrorism, think bad stuff, and they could come in with those eyes and look. So I think just a bullet that Food Security consider developing a vulnerability-assessment team to help industry upon industry request, something of that nature, and it might add that any documents produced by that team would belong to that establishment, wouldn't become public record, any recommendations or any of those kinds of things, it'd strictly belong to that -- it wouldn't go to anybody else, it would go to the plant.

MR. GOVRO: Well, the bullets we have under the point of "Both partners would commit the following," I think maybe we should just include this as a separate paragraph

below, and I'm writing that sentence right now, that "The Committee recommendations that the Office of Food Security" --

UNIDENTIFIED FEMALE: "-- and Emergency Preparedness."

MR. GOVRO: -- "and Emergency Preparedness provide" --

DR. JAN: Or "establish a vulnerability-assessment team." And that could even be contracted out, there are some ARAs, one company, that does vulnerability assessments, and they -- you know, it wouldn't necessarily have to be FSIS employees, it could be contracted, or parts of it contracted, with all that FSIS money.

(Laughter.)

MR. GOVRO: "The Committee recommends that the Office of Food Security and Emergency Preparedness establish a vulnerability-assessment team to assist plants in conducting" --

DR. JAN: -- "vulnerability assessments."

MR. GOVRO: Okay.

DR. HOLLINGSWORTH: And Mike, I had put in there "upon request," so that the industry would request the assistance if they needed it.

MR. GOVRO: Okay.

DR. MASTERS: This is Barb Masters. The only question I would have, for clarification, Dr. Jan, is: are

you talking vulnerability assessment or are we really talking self-assessment here? We're not talking the --

DR. HOLLINGSWORTH: Yeah, make it "self-assessments."

DR. MASTERS: Just for clarification.

DR. JAN: What I was thinking was team -- the plant does self-assessment, but they may invite --

DR. MASTERS: I'm just being sensitive of the word "vulnerability assessment" when the term "vulnerability assessment" from an Agency's perspective is a (inaudible) big-level, behind-closed-doors, secret-level clearance, so I'm just looking for a word other than -- you're talking a plant-level vulnerability assessment.

DR. JAN: Plant-level vulnerability assessment, right.

DR. MASTERS: So the plant assessment.

DR. JAN: So we could call it a plant assessment.

DR. MASTERS: I just want to make sure I understand what you're suggesting.

DR. JAN: That's fine.

DR. MASTERS: Okay.

MR. GOVRO: I think that's the term we've been using, is "self-assessment," the plant evaluation (inaudible).

DR. HOLLINGSWORTH: And maybe instead of establishing a vulnerability-assessment team, do we want to

say "establishing a team of food-security specialists"?

MR. GOVRO: Okay.

DR. JAN: Food-security specialist, right. That way we'll stay away from "vulnerability."

(Pause.)

MR. GOVRO: Okay, so the sentence as I have it now is: "The Committee recommendations that the Office of Food Security and Emergency Preparedness establish a team of food-security specialists to assist plants in conducting self-assessments upon request."

MR. TYNAN: Other thoughts and comments?

(No response.)

MR. TYNAN: If there's no other controversy about the report, I guess it's acceptable to everyone. I think we're pretty well done, I think we have next on the agenda a period for some public comment. If there is anyone in the audience that has some comments or concerns they want to make at this point regarding the report, please do so now.

(No response.)

MR. TYNAN: Everybody's ready to go home.

(Laughter.)

MR. TYNAN: Okay. Well, I have just a couple logistical things, and then I'll leave it to Dr. Masters maybe to close the meeting for us.

I wanted to mention to you that on November 16th and 17th is our tentative dates for our fall meeting. That's

November 16th and 17th. I think we had originally planned a date earlier in the month for some reason the government wants to have an election --

(Laughter.)

MR. TYNAN: -- so we pushed it back a little as opposed to push it forward, we thought that would give us a little bit more time. That does cause some practical problems for some of you in terms of your business arrangements and so on, I realize that Thanksgiving does tend to be a big period, probably, for the industry. I apologize. I don't think there's another way we can do it. If that date does not work for you, we will do our best to find some other date that's a little bit more acceptable for the Committee as a whole.

I also wanted to mention, on a different note, that the November meeting will be the last meeting for this cycle of the Committee, so the two-year period will be up and it will be necessary, then, to recharter the group for the June 2005 meeting.

I just wanted to mention to you that probably in early September we'll be putting out a Federal Register notice to solicit applications for the Committee. You have an opportunity to actually do three, I was under the impression it was two, it is actually three terms. If you're finishing a third term, then you would be prohibited from applying again. But everyone on the current Committee would

have to reapply for the next term.

So, as I say, that will come out in September, hopefully we'll have selections done by early in 2005, be able to get it to the Department and get a new committee chartered in and established for June 2005.

So those are the two things that I wanted to mention, and from my personal standpoint, I also want to mention I appreciate all the efforts that you all put into helping us with the meeting, I think this was an improved process, a better format, from my perspective, and if there are other suggestions and thoughts that you have at any time, please feel free to ship them along and we will do our best to build them into the process. So hopefully this meeting went a little bit better than the last meeting --

(Laughter.)

MR. TYNAN: -- (inaudible). So thanks again for all your help and your support, and I will turn it over to Dr. Masters for the final note.

DR. MASTERS: Thank you, Robert, and I think a lot of kudos goes to Robert, he went to a lot of efforts to make some changes to the format based on the feedback and comments we received from this committee, and I think we owe him a round of thanks.

(Applause.)

DR. MASTERS: Not yet perfect, always room for improvement, but I think we made considerable improvements

from where we were, and we're committed to continue to make those improvements, and he's now met the standard of getting the documents out early and I don't think we'll let him go back. Right, crew?

(Applause.)

DR. MASTERS: So many thanks to him. I think you did a great job getting this set up and I think it went very well, and I think that's reflective in the output we got from you all. I think when you're -- I think you've demonstrated that even when you weren't given the material ahead, you were willing to work even through the night to get us good feedback, but it's very evident when you're given the material ahead you took the time to read it, to give us very thoughtful comments, and I think the process worked very well.

Again, I recognize you're not here under anybody's volition but your own, and it serves us all well when you're here, wanting to give us good feedback, and I think we got a lot of good feedback this time, and again, I've already gotten some meetings set up based on some -- hearing some things at the sub-committees, which is exciting to me, that people are hearing things that they like hearing, that they want to do, that's what this process is about, is hearing recommendations from the outside so that we're getting input, so that we can not rely on ourselves but get recommendations from our stakeholders so that we can move forward with good

ideas and make improvements as an agency.

I'm here as an acting administrator, trying to do my best to keep the ship afloat, but, having said that, I'm a person that doesn't like to sit still long and I like to do things for a reason, I like to do things for a positive reason, and so I like hearing good ideas and I like moving with good ideas.

So I've gotten a lot of good suggestions, and so we will be able to hopefully report on some of those and hopefully be able to go back -- I heard one of the suggestions was to go back a few of the meetings and at least let you know where we've gone with some of the suggestions, so we'll try to do that I November.

So, again, thank you very much for spending a couple days with us here in D.C., those of you that came in from out of town, those of you that took time from your office schedules to be with us here in Arlington, we appreciate that as well, and those of you that came in from -- the audience, we appreciate your attendance as well, we know that you gave up some time to be here to listen to what we had to say, and we appreciate that.

So thanks to all of you for being here, and we'll look forward to taking this and digging through it and following up on it, and we'll get those reports back out to you, with the technology as it was, and we'll move from there.

So, again, thank you for a job well done, we appreciate it.

(Applause.)

(Whereupon, at 2:15 p.m., the meeting was adjourned.)

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CERTIFICATE

In Re: NATIONAL ADVISORY COMMITTEE
ON MEAT AND POULTRY INSPECTION MEETING
Place: ALEXANDRIA, VIRGINIA
Date Held: JUNE 3, 2004
Time Held: 8:30 A.M.

We, the undersigneds, do hereby certify that the foregoing pages, number 470 through 568, inclusive, is the true, accurate and complete transcript prepared from the reporting by BOB ADDINGTON in attendance at the above-identified hearings, in accordance with applicable provisions of the current USDA contract, and the below-signed persons have verified the accuracy of the transcript by (1) comparing the typewritten transcript against the reporting or recording accomplished at the hearings and (2) comparing the final proofed typewritten transcript against the reporting or

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