UNITED STATES
DEPARTMENT OF AGRICULTURE

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

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Loews L'Enfant Plaza Hotel
480 L'Enfant Plaza, S.W.
Washington, D.C. 20024

Wednesday,
November 1, 2000

The hearing in the above-entitled matter was convened, pursuant to notice, at 8:40 a.m.

APPEARANCES:

On Behalf of the USDA:

THOMAS J. BILLY
CAREN WILCOX
RONALD HICKS
CATHERINE WOTEKI
CHERYL GREEN
YOLANDA LOCUS
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On Behalf of National Advisory Committee on Meat and Poultry Inspection:

MAGDI ABADIR
TERRY BURKHARDT
JAMES DENTON

CAROLINE SMITH DeWAAL
NANCY DONLEY
CAROL TUCKER FOREMAN
CHERYL HALL
KATHLEEN HANIGAN
ALICE JOHNSON
LEE C. JAN

APPEARANCES (CONTINUED):

On Behalf of National Advisory Committee
on Meat and Poultry Inspection (Continued):

COLLETTE SCHULTZ KASTER
DANIEL LaFONTAINE
MICHAEL MAMMINGA
DALE MORSE
ROSEMARY MUCKLOW
DONNA RICHARDSON
GARY WEBER

P R O C E E D I N G S

(8:40 a.m.)

MR. BILLY: Thank you very much and good morning, everyone. Rosemary, I thought I would give you an accounting. We had 96 children that came to the house last night for trick or treating. And I told each one of them that this was on behalf of me and Rosemary Mucklow.

MS. MUCKLOW: Did you dress up as Scrooge?

MR. BILLY: I don't need to. I know that the subcommittees met last night. And this morning, we were going to spend talking about the discussions and the results of your discussions, ideas that you have come up with, share those with the whole committee and hopefully out of that process will come forward some recommendations for consideration by the Secretary.

Then this afternoon after lunch, we are going to have a couple more briefings, one on the issue of nonamenable and exotic species, an area that this committee has been working on for a while. And then finally, a discussion about an approach that we are considering for how we carry out our responsibilities for non-food safety

consumer protection areas that are part of our responsibility under the Acts.

Let me see if there are any initial concerns or points that any of the committee members would like to make? Anyone? Okay. Well, the first subcommittee is the one chaired by Katy. And they focused on HACCP Phase II. So at this time, it is my pleasure to turn the meeting over to Katy to explain to us what they did and what the results are. And then we can have a full dialogue on that product. Katy?

MS. HANIGAN: Thank you. Mr. Billy, we had two questions that we were to answer. I guess I will look to you as far as do you want us to discuss question 1 in its entirety and then do question 2 or do you want us to present our findings, et cetera, on both questions and then open it? How would you like us to do this?

MR. BILLY: I really kind of look to the committee. My view is that they are pretty interrelated. So it might be useful to go through all of it and then we can circle back and deal with each of the areas. So --

MS. HANIGAN: Okay. Then last night, we did meet.

And two of our colleagues are going to present our recommendations. But the first question we talked about was what can industry do to improve the quality and the effectiveness of their HACCP programs. We were trying to come up with bullet points of recommendations and suggestions.

And the second question was what can FSIS and the states do to improve the effectiveness of their role under HACCP. And some of the guidelines that we worked under was we were not going to reinvent HACCP last night. And we were not looking for any fundamental changes. And we decided that we would provide bullet points back to the full committee to convey our message.

And we did have a full two-hour run at this last night and found out that many of the things that applied to question 1 also applied to question 2. So with that, I am going to turn it over to Alice Johnson. And she will present our recommendations on question 1.

MS. JOHNSON: Alice Johnson, National Turkey Federation. We had a real good discussion last night. It was real fun. Our first question was what can industry do

to improve the quality and effectiveness of their HACCP plans. And the bullet points that you have on your paper, if I remember right, gang, we didn't prioritize these. We just bullet pointed them. So don't think that there is any special order or any significance to the order.

One of the first things that we talked about when we talked about quality and effectiveness of the HACCP plan is the accountability. And I think Dr. Denton will talk about that under the agency role, as well. We talked about scientific accountability for what you have in your plan. And you can see further down, we talked about the scientific underpinnings.

We also talked about accountability from the professional standpoint in the way we interact within our own companies, as well with industry agency personnel. And then we talked about intra-company. Communication is an issue I think on both sides of the fence whereas, you know, management needs to be fully supportive. Everybody needs to be aware of what is going on. So we thought that would be a real plus.

The next bullet, "Stop fighting HACCP, common

understanding", I really don't like the word, "fighting", but that is what we decided to use. And we talked about resolving the philosophical differences. In all of the discussions that we had, be it industry or the agency role, we talked about the need for common understanding, looking at the role of prerequisite programs, where they play in HACCP plans and clarifying the definition of a hazard. And that -- we got into a lot of detail on those that I think we will probably talk about after we go over the bullet points.

But the group thought that in order for industry to have what is a quality and improve the quality and effectiveness of their HACCP plans, that there needed to be this understanding because right now, we are still kind of at a loss for what does quality plan mean. It means something different to industry than it does to the agency. Before we move too far along in the HACCP, the next steps, we need to resolve some of these differences in the way we are viewing HACCP.

We've talked a little bit about scientific underpinning and a thorough reassessment. I think that you will find some really good HACCP plans out there in the

industry and then you will find some that have just come off of a generic model. It is the company's responsibility to be sure that they have the scientific justification for why they made their decisions.

As far as the quality and effectiveness of a program, the documentation needs to support what they are talking about, be it their critical limit or why they determined this hazard was not reasonably likely to occur. And we also talked the thorough reassessment.

And this was not just a paperwork exercise, that the companies need to take this seriously. Currently, FSIS requires that it be done once a year. And there needs to be a thorough thought process with this. And we encouraged reassessment periodically through the year as needed.

And then we talked about education, training and communication one more time which is common between I think what Dr. Denton will tell you on the agency, Part II. I feel like it is very important for people dealing with HACCP to be, as the agency talked yesterday, not only trained, but educated on the principles and the science behind it. So I will turn it back to Madam Chairperson.

MS. HANIGAN: Go ahead, Dr. Denton.

DR. DENTON: Thank you, Katy. The second question that our subcommittee dealt with yesterday evening was what can FSIS and the states do to improve the effectiveness of their role under HACCP. And I have to state with a statement of agreement with what Tom just said, that these two questions are very interrelated.

The first bullet point that we see here is that we are seeking to achieve a common understanding of the hazards associated with each process and each species. Underneath that, we dealt with two issues. One is a clarification of the definition of a hazard. And there in parentheses you will note that there was not a complete subcommittee consensus with regard to that. There was a great deal of discussion about the definition of a hazard potential versus a significant hazard and whether or not this was a way to get out of defining things as a hazard.

We do not see it that way. We think that there needs to be a very clear distinction on what constitutes a potential hazard and what constitutes a very significant hazard.

The second part of that is the role of the prerequisite programs. And here we are thinking in terms of the sanitation SOPs, SOPs and GMPs that are the cornerstones for any food safety assurance program that exists in any food plant. We believe that there needs to be a very clear understanding of what constitutes the roles of each of those prerequisite programs from the standpoint of what makes them distinct from the HACCP plan, yet a foundation for the HACCP plan.

Pardon me. I am having a little trouble this morning with my voice. It seems to be getting worse every day. The second bullet point is to identify what is acceptable for scientific validity in a HACCP plan. And here we included the concept of a nationwide basis. We think there is a distinct need for more uniformity of the application of the HACCP system across the agency, recognizing that there are some very distinct differences in how that is viewed within certain regions of the country.

The third point is one in which the point was made with regard to very small processors not having resources to develop and defend many of their scientific positions with

regard to HACCP plans, that there probably needs to be some existence of the safe harbor to accommodate these types of operations.

And then, of course, we get back down to this accountability issue, much like what Alice discussed in question 1. We believe that there is a need for improvement in accountability, both on the scientific basis by which we approach HACCP decision-making, the professional basis on how these decisions are carried out in the field and intra-agency accountability.

That is somewhat linked to what we see here in number 5. We believe that there is a very strong need for improved communication and congruency amongst the headquarters staff, the field staff and the technical center in Omaha so that everyone is working off of the same set of parameters with regard to HACCP.

We also believe that there is a strong need for joint education and training for all FSIS employees. And by joint, we mean that FSIS employees and industry be trained simultaneously so that everyone, everyone knows the fundamental underpinnings of the scientific portion of

HACCP, recognizing that there are very distinct differences on what the expectations are for the companies and what the expectations are for the agency. Yet the science is the same in the two systems.

And the last thing that we felt like was needed to really improve this is objective and measurable evaluation tools with regard to how the agency conducts HACCP within the framework of what their responsibility is, perhaps even including performance standards with regard to how that is done. Thank you.

MR. BILLY: Thank you.

MS. HANIGAN: I would like to open the comments, if you will, to those committee members seated at the table. You are welcome to comment, question. And I assume, Mr. Billy, that you will recognize them from this point? Thank you.

UNIDENTIFIED VOICE: Full committee or subcommittee?

MS. HANIGAN: No, full committee.

MR. BILLY: Okay. Nancy?

MS. DONLEY: Nancy Donley from STOP. I appreciate

the comment that, was it Kate of Alice, maybe you made that -- it was Alice -- that industry is responsible, has to be responsible for the effectiveness of their HACCP plans and the need to reassess and their plans periodically.

There is still -- and I don't see how -- there is nothing that was specific that was mentioned on what can be done about plants that just frankly don't have adequate HACCP plans. And by that I mean that for lack of knowledge, for lack of interest, there can be various reasons why these plans are not effective, they are not valid.

And how can we, as we move into HACCP II, correct those plants that have ineffective HACCP plans because the public is only protected as far as how well those plans are designed in preventing food safety problems? And I don't have any reassurance that the plants get out of this by just saying, hey, yes, we have to reassess it. I don't come away with any reassurance that anything meaningful is going to get done unless we lay out some specifics of what should be done.

MR. BILLY: Katy.

MS. HANIGAN: As a response, Nancy, I don't think

our committee addressed that last night. And the way I looked at this -- and my committee members and subcommittee members I am sure will speak up -- my feeling was we have been under HACCP whether you -- regardless of the size of your plant now, either three, two or one year.

So there is FSIS staff out there in the field now. My basic assumption was if we still had HACCP programs out there that did not meet the seven principles and all that -- those different parameters, that those companies, those plants would have been identified already by FSIS staff. So we didn't -- we did not address that at all last night. I mean, we looked more into everybody has got HACCP in. Perhaps we plateau'ed off. Where do we go from here?

So maybe Mr. Billy can answer your question. But we didn't even address that last night.

MR. BILLY: I do think that a lot of our focus as we have implemented HACCP has been on ensuring that there are plans for each of the product categories where they are needed and that those plans have the basic elements covered and that the plant is following that plan in the sense of monitoring the critical control points and making the

records that are necessary associated with the regulation.

And so it is -- I think there is a difference between sort of having enough there to meet what one could describe as the basic requirements versus the quality and effectiveness of those plans which is what we have tried to focus on in terms of the industry and what the question was about. So I do believe it is the agency's responsibility to make sure that if a plant doesn't have a HACCP plan with all its components, then we should have by now reacted to that and dealt with it.

There are some ongoing situations in the very small plants where that remains a problem. But it is being addressed. The plants are taking the steps to correct the situation. So -- but I think it is a good point in the sense that -- and let me relate it to one of the other issues that are here that really was brought up under question 2 regarding the -- what FSIS and the states can do.

The vast majority of the plants, that is, the 6,000 under federal inspection and the 2,500 under state inspection do not have prerequisite programs other than what is mandated which is the SSOPs. So there is a petition that

has been submitted by a number of industry groups to try to address this whole issue of what are prerequisite programs.

But one would argue then that if, in fact, we and the agency and/or the industry should pursue some sort of a strategy that would come to a common understanding about prerequisite programs, then there is an awful lot of work that needs to be done with an awful lot of companies. And I mean in the thousands that would have to then establish something that doesn't currently exist.

Now, I know a lot of the large plants have them. But they are the small minority in compared to that total of 8,500. So if, in fact, there is an interest on the part of industry as an example to have established and recognized some sort of prerequisite programs, then there is an awful lot of work to be done. And then I guess a question back to the subcommittee and to the full committee is who is going to do that? Where is the leadership going to come from to explain and convince to thousands of very small plants that they need something more in terms of prerequisite programs?

I have -- you can answer that now or ponder it and come back to it later. It doesn't matter. Yes, Lee? And

then Terry.

DR. JAN: I didn't have anything.

MR. BILLY: Okay. Terry.

MR. BURKHARDT: Terry Burkhardt. I don't think, Tom, that was the thought of the subcommittee as far as mandating prerequisite programs was that it would be more of an allowance of prerequisite programs to be used in conjunction with HACCP plans. And our thought was that anything that is put in place to reduce the risk, you know, is acceptable and we should encourage it.

The question was whether it would be a CCP as opposed to a GMP. And that was the issue, not that we would mandate prerequisite programs.

MR. BILLY: Caroline?

MS. SMITH DeWAAL: Thank you. Caroline Smith DeWaal. One of the things -- and I want to follow up a little bit on what Nancy was saying. I think one of the disappointments of the first round of implementation was the Sara Lee outbreak. And the fact that it came to light after that, that a lot of the companies that prepared ready-to-eat products didn't -- or at least some amount of them didn't

include Listeria as a hazard reasonably likely to occur which is unbelievable to me. But that is my understanding.

And then the agency's response was to order a reassessment. I think it pointed to the fact that we need a common understanding of the hazards that are likely to be linked to different regulatory products. And I don't need to remind you, Tom, of the issues around seafood HACCP and the fact that we were there dealing with 300 different species. We were dealing with a wide variety of health hazards, some of them microbial, but also natural toxins, chemical contaminants that are not -- that don't occur at the same frequency in these products.

By comparison, meat and poultry products are -- have I think a less challenging range of hazards. They certainly have serious hazards. But FDA under your leadership put together the hazards and controls guide to help guide that industry in developing their HACCP plans.

There was a mixed understanding I think in the subcommittee last night. There may be a hazards and controls guide that is circulating. Nobody is sure it is being used. They think it came out either for the second

year of implementation or the third. It may have just come out for the very small plants. But nobody is teaching to it. Nobody is using it. And it is not clear that it is being enforced by -- from -- by the inspectors.

One of the things that I wanted to throw out was the concept of regulatory touch points, where -- I mean, what you guys are concerned about is where are you going to regulate. And the industry is concerned about that, too. And one way -- you can either regulate by going in and saying here are the critical control points you should have and you should -- you know, your critical control point for this hazard needs to be here or not there.

You can regulate at that level. Or you can regulate by saying here are the hazards you need to control and we are going to check you at the end of the line to see whether, in fact, you are controlling those hazards using measurable objective standards like performance standards.

And in terms of HACCP Phase II, maybe some of the struggles should be over identifying a common set of hazards by species and by process and then measuring at the end of the line whether those are, in fact, controlled using

performance standards rather than trying to dictate to the industry where their critical control points should be because I think a lot of the complaints we were hearing from the industry last night was about, you know, well, they are telling us we need to, you know, put our critical control point over here and not over there and I think they are wrong and I am going to -- you know, but I have to have the real one and then I have to have the fake one. You know, I have to have the one that FSIS is requiring us to have.

So I am just wondering from a regulatory standpoint, perhaps the touch point should be at the beginning and at the end and not necessarily at the middle. You know, that is just an idea and it is one that we wanted to put before you with some of these ideas. Thank you.

MR. BILLY: That speaks a little bit to defining the safe harbors which could be done in such a guide. The difficulty though in -- Caroline, in what you have said is I think that the balance that needs to be struck between maintaining the flexibility in industry to decide how they are going to manage the food safety hazards and, on the other hand, having the agency spelling out, even in a set of

guidelines, here is what ought to be done with regard to hazards and various products and controls to deal with them. So --

MS. SMITH DeWAAL: Can I --

MR. BILLY: -- I don't know if the subcommittee discussed that or not. I think that is an important area that perhaps we could have a little discussion on now.

MS. SMITH DeWAAL: Can I just follow up on that? There was a lot of discussion about the agency not -- and Alice and I actually went back and forth quite a bit -- about there should be the expertise and the knowledge within the industry to define their own hazards. But the hazards -- and I think it has got to be accepted understanding that HACCP was not and does not addressing emerging hazards.

Emerging hazards are going to happen and will then be added to the list of hazard. But we know what the hazards are around most meat and poultry products. This isn't rocket science. This is meat science. And it is not -- I mean, we can -- you can name a product and develop a hazard list fairly easily, even for non-scientists.

And I think that, you know, if you -- but if you

are enforcing one set of hazards over in one district and another set of hazards in another district, it is going to make for a very non-uniform application of HACCP. And so we are trying to figure out ways that the agency could be more uniform. And then again, in the hazards and controls guide, you set out for the seafood industry what the controls were for histamine, what the controls were for micro contamination.

And I didn't always agree with them. But you put on paper for the industry where those safe harbors were. Again, you know, there may be a hazard linked to, say, residues in a particular product. But if someone -- if a company says, well, we only purchase from producers who do not use this drug and, therefore, that is not in our hazard because we have controlled it in the incoming product, I mean, I guess that would itself be a type of control.

But those -- there -- they should be able to opt out of hazards depending on their own business plans and strategies. But to have a common set of hazards I think would be helpful in regulating -- in creating more uniform HACCP plans nationally. And -- okay.

MR. BILLY: Thank you. I have Alice and Nancy. And I would be interested in hearing from other members of the committee about this idea, some sort of hazards and controls guide. Alice?

MS. JOHNSON: Carol and I had a good time talking about this last night. And I want to address two things. First of all, Terry's remarks about the prerequisite programs I think were very good. It all goes to the flexibility of HACCP. If you have these in place and the agency and the industry can come to some common understanding on how they are to be used, then they are appropriate for use. If you don't have them in place, then it is -- your hazard analysis reflects different critical control points.

So I don't think anybody is pushing mandatory prerequisite programs, but just the flexibility to be able to use those programs if you have them in place and some sort of industry recognition that they are valid in supporting justification for hazard analysis.

Now, let's talk about the fun things. The mandating of hazards, when we first started talking about it

last night, you know, it does sound like it would make life a lot easier. However, it just totally blows apart the whole HACCP concept in my opinion. The flexibility to work for your hazard analysis and I think everybody in here can say that it is just such an eye-opening process when you work through a hazard analysis.

I have a real fear if you mandate hazards, we are going to have little cookie-cutter programs that aren't going to mean anything. And there will be no further work done. I think it will stop some of the innovations that a lot of companies are going through because here are your hazards and here is what you have to do them.

And I also think that it will stifle any type of meaningful reassessment. And you probably won't get the reaction to emerging pathogens, new hazards that need to be viewed because we are in this little box. And you know how hard it is. I like my little box. It is hard to get out of it. So I think it will really stifle any type of innovation in the industry.

I pulled off on the website this morning -- and the FSIS website is great. It sure beats digging through

files -- the hazard guide that was put out with the very small. And I think there have bene -- there was also one that was put out when the rule first came out that was very thick and very detailed. Whereas I think this is a good start and I threw it to Terry real quick and am running to sit down. So I would be interested in seeing what he has to say.

I think it is a good document. It is a good start. But maybe we need to work on refining that and making it more like the seafood document and offering that up as, you know, things to consider. But instead of just a list of mandated hazards, you've got the whole process and be sure that it is understood that it is a guideline and not regulated. Thank you.

MR. BILLY: Okay. Nancy?

MS. DONLEY: I said, and I will reiterate what I said yesterday, that I really appreciate that the agency once again is moving on and talking about HACCP Phase II. And as again, I hope there is HACCP Phase infinitum.

However, let's make it meaningful. And by that is if HACCP was the answer to food borne illness problems in

meat and poultry, we would not see a tapering off of numbers. We would have seen a sharp decline and that HACCP is the answer.

It is not the answer. If it was, we would be seeing very definite public health ramifications on it. With that said, I think right now, we have an opportunity to recognize the weaknesses that HACCP has. There are some weaknesses and we have a chance here to fix them. And that to make this dialogue meaningful, let's recognize where some of these problems are.

Some of the problems are that some companies and plants can do it better than others. And that doesn't reassure the public who is getting it from a plant that is not as good as doing it as those who are. One of the things that STOP had advocated from the get-go was that there be FSIS validation of HACCP plans. And we still believe that that is what should be happening.

We want -- the industry should be developing the plans. But we rely on our government to make sure that those plans are meaningful and that they are -- and that then, that the government is regulating a plan that they

believe in and that they can get behind and sink their teeth into and that it is really protecting the public's health.

We don't want government regulating ineffective HACCP plans. The public's health and safety stands to lose by it. So I really think that we really need to with this -- again, back to that point of thorough reassessments, my question I wrote here is by whom. And I would like to suggest that these plans be reassessed by FSIS.

MR. BILLY: Okay. Terry, then Jim, and then Katy.

MR. BURKHARDT: In our discussion last night, one thing we talked a lot about was the one size fits all and the difference that we have in the very small plants. You know, regarding Alice's comments, you know, for a large industry that have their own scientific staff and so forth, I think, you know, the flexibility there is wide open.

In the smaller plants though that don't have the scientific wherewithal to put the plan together, more of -- you know, at least we took more of a directing approach as to what the hazards were and what -- where CCPs were likely to be. And for the small plants, it seemed that they needed that help in conjunction with the university in providing,

you know, the training and so forth as to why those were important.

But the idea of one size fits all, it is going to apply to ever plant. There is a lot of difference between what goes on in a very small plant and a large plant. And I think HACCP principles apply to food production in a small plant has a lot of applicability. Let's monitor the whole food production process with HACCP principles.

But in the way it is regulated, you know, it is based on individual process. And what happens in the small plants is you probably have six plans when in a large plant that makes one product, you have one plan. And so administering it in a very small plant in many times is more difficult than in a large plant. The complexity is a concern. But we have worked our way through that. But in hindsight, if we would have identified what is to be expected ahead of time, it may have been easier for us.

MR. BILLY: Just a question on that, if we did that now, would that be helpful in the context of what you are experiencing?

MR. BURKHARDT: If we provided a little bit more

guidance on what are you considering as scientific validity and what are your expectations, I think it would be helpful to bring all the plans to a common base. And we have -- you know, we have a lot of very small plants that do an excellent job and are really on top of things from a food safety standpoint, but others that can bring their plan up to speed.

But that doesn't -- you know, in reference to Nancy's comments, the bottom line of the HACCP plans are what is the result of the product, what are the lab samples showing. The plan might not look so good on paper. But we have negative Salmonella reports, we have negative L.m. reports. From a food safety standpoint, it appears that the food production practices are working. And that should be the basis for evaluation of the HACCP plans bottom line. They are producing safe products. Whether they have scientific validity in their plan, they are producing safe food.

MR. BILLY: Okay. Jim?

DR. DENTON: I have to make a comment with regard to the comments that Nancy made here just a little bit. I

think that all of us recognize that HACCP is a system by which we improve the safety assurance program in meat and poultry processing that has been applied across public industries in advance of our involvement in meat and poultry.

For meat and poultry, this required a serious redirection of focus on the part of the companies and on the part of the regulatory agency. I don't believe any of us in the scientific community, the regulatory community and the industry expected an instantaneous response to implementing HACCP. If that is the case, then I am afraid that we have over-promised on what HACCP is capable of delivery which may have set some unrealistic expectations with that.

The reality is that HACCP is a system that results in improvement over a period of time that will be gradual, but it will be continuous improvement. And I think that that is probably the message that we need to take away from what we have accomplished to this point. But now is not the time to abandon this and give up on HACCP as a system because it is working.

MR. BILLY: Okay. Thanks. Katy?

MS. HANIGAN: Just a little bit more on this thorough reassessment. We had a very, very healthy discussion last night. And regarding thorough reassessment, I think that some plants like you said, Nancy, in your words could do that very well because they understand what is scientifically valid and what is not. And I also as Chair last night recognized quite a few people that were sitting in our audience in that room. And we definitely had an attendee last night tell us that there are small plants that they don't know what is scientifically valid and they don't know how to go about it. They just know that they are producing safe food.

So I think when we talk about who is doing the reassessment and how thorough it is, I think whether you are looking at industry or agency, it gets back to this whole thing of training, common understanding of, you know, what the hazards are, what are the scientific underpinnings, what are the safe harbors, are there any more because we have been subject to a number of regulations, directives, et cetera, being removed and being told that they are no longer a safe harbor, et cetera, et cetera.

It is not as easy to me -- for me it is not easy to say FSIS is going to do your reassessment because they don't know how to do it either. The plant inspectors are not educated. They may be trained. But they are not educated to the point where they could reassess one of my HACCP models.

And so I just want -- I mean, I just wanted to throw that out. I mean, I'm not disagreeing with your point on that. But it's just there is a huge gap between training and education on this whole thing on scientific validity. And the other point I wanted to bring up which, Caroline, you surprised me that you didn't bring it up this morning and I will probably -- my other subcommittee members probably just shake their head, yes.

I thought you had a very valid point last night when you talked about in my words the CCP of the month or the hazard of the month. That we need to be careful that if we do get out there and we put out something that is seen as more than a hazard guide, that people aren't just focusing on the hazard of the month or the hazard of the quarter and letting everything else go because then we are going to end

up with these cookie-cutter programs that Alice is talking about and we've lost the whole thing all together.

And you surprised me that you didn't bring that concern up. I thought it was very valid. And you articulated it much better last night than I just did.

MR. BILLY: Rosemary.

MS. MUCKLOW: I was otherwise on my broomstick last night. So I didn't get to listen into any of that discussion since I was in another meeting. But there were several things as I listened to the discussion this morning. First of all, various organizations came together with great seriousness and submitted to you a petition for consideration.

I'm not sure that that has bene distributed to this committee. It might be a good idea to distribute it because before we can go too far down the road of HACCP II, we really need to make sure that if there are things that need cleaning up from basic HACCP, that we address those.

So I would strongly encourage you to share that with this committee. This is an ongoing dialogue for change. And that might be useful. And I'm sure this

committee and whatever, what is the new word, redesignated form or something, resignated form, that is the new buzzword out, that it will be able to speak to maybe the petition and maybe that could be circulated.

The second point I wanted to make is that as Dr. Denton exquisitely stated and I can't be nearly as exquisite with the words as he is, but there is a philosophical change occurring and a re-balancing, if you will, a government's role and the industry's role in how we move forward to make -- to identify those hazards, eliminate them or reduce them to a reasonable level and make the food as safe as we possibly can.

One of the entities that has been fairly significant in working with the industry and working with all interested parties is the International HACCP Alliance. I think it might be very appropriate, again, as we evaluate where we are going with HACCP II to try to engage the professional people with the Alliance. And I am, you know, very pleased that the agency has utilized this as a major resource over the last several years.

Maybe we could invite Dr. Harris, who is a very

fine, distinguished and probably no -- she has forgotten -- my mother used to say this -- she has forgotten more about HACCP than I will probably ever know. She really does have tremendous capabilities and both from a practical and from the philosophical point of view. And that might be very helpful as we go forward here to work on HACCP II.

So that -- those roles need to somehow be better balanced than maybe we've got them as we sit around this table. Many of us are organizational members of the HACCP Alliance. It will be having a board meeting in the very near future. And I am sure you will have one of your senior staff attend as you always do. And we appreciate that because it does -- it is where industry and the agency with a lot of other people can come together.

I would tell everybody here that these are open meetings. Anybody in this room is welcome and invited to attend. They are not closed meetings. And that has been the policy of the HACCP Alliance since it was involved and since it was initiated six years ago.

One of the other things that has long concerned me is whether HACCP has indeed over-promised. And there has

been a little discussion here this morning to that issue. And somebody the other day got me to go look at the word, "safe", in the dictionary. It is an interesting definition. It is -- safe means without risk or without injury.

And we all use that word, "safe", with great abandon. You know, it pops up in almost every sentence. And when you are dealing with a raw agricultural product and many of the end products that come out of inspected establishments are not the piece that you finally put in your mouth, we are dealing with intermediate products.

And somehow or other, we have never quite come to closure to explain that you can't necessarily assure that there is no hazard in that end product that needs further preparation before it is going to be consumed. And looking at the word, "safe", and how important it is to all of us, I think we might want to revisit how we use that word in relationship to the products of our industry. We make them as safe as possible.

But we cannot make them absolutely without some risk unless hopefully we cook them and we have them so that they are as ready to put in your mouth. And even then,

there have been some problems like Listeria and the problem that it brings us. So I would suggest we may want to revisit and rethink a little bit about the word, "safe." I am always mindful for the smaller plants.

I think it is quite remarkable how well they have come along because they have had a very complex problem to deal with. Very large plants, as we have heard today, often have just one HACCP plan because they make one product. Many of those very small plants with very few employees have very complex operations.

And I think it is a credit to the organizations, to the agency, to the HACCP Alliance that they have performed and come to speed as well as they can. There has been some discussion here this morning about the prerequisite programs and how they should be recognized. I would suggest that for many years, the agency approved PQC programs. The prerequisite programs have some similarity to the role of the QC programs, the PQC programs.

There is some significant differences, too. But those PQC programs were a very useful way for smaller organizations to figure out how to meet the

responsibilities. Some of the tragic events in my neighborhood this last summer that were so terrible came about because a young man reached the end of his rope wrongly because he didn't understand how to deal with some of these very complex problems.

And so if we learn a lesson from that tragedy, it is that we need to figure out how those small firms have to deal with very complex problems. And we can't give them the blueprint. We can't just give them something that you fill in the boxes on because that is not the concept of HACCP. But at least we can give them some guidance.

And, again, maybe through the interactivity with the HACCP Alliance, this is one of the ways in which you can work to develop some of the supportive materials that can be very useful in this process. Thank you.

MR. BILLY: Cathy has a question.

DR. WOTEKI: Yes, thank you, Tom. Cathy Woteki. I would like to, first of all, commend the subcommittee for the discussion paper that you have put together and that we have been talking about so far this morning. As I listen though to the presentation, particularly both that Alice did

and Jim did, where you talked more specifically about the discussions that you had last night on each of these two questions.

I was struck by the fact that essentially that what you have elucidated right here are a set of principles. And as Jim talked and as Alice talked, you made those more specific than the way that they are described here. And one question then to this committee is are you going to go back and redraft this and bring in some of that additional specificity that was talked about? Because as it is currently drafted, it leaves very much open ended and unanswered a lot of questions.

And a case in point is the one under what FSIS could do, for example, under joint education and training. I don't think that you mean joint education and training with the industry across everything. As Jim talked about it, it was only with respect to the scientific aspects of HACCP.

And under it is a bullet that says, "All FSIS employees." Does the committee want all FSIS employees trained on the scientific aspects of HACCP including those

who do programming for us, those who are our contracts and procurement specialists, those how are the personnel specialists, or do you mean those who are actually in decision-making capacities with respect to the field force and the headquarters and the various centers around the country?

So my question to the committee with that as an example is do you want to provide some additional specificity on these issues? I think it would be very helpful on some of these. And that one is a case in point to do so.

MS. HANIGAN: I have a question for you.

MR. BILLY: Okay. Katy?

MS. HANIGAN: As the Chair of that committee, I think we do need to go back and be more specific. But my question to you is would that document be due back by close of business today?

DR. WOTEKI: It would be.

MS. HANIGAN: So then our subcommittee would need -- I'm sorry?

MR. BILLY: Yes. I think that is what we would

prefer if we can do that.

MS. HANIGAN: Then our subcommittee will need to meet at lunchtime. So why don't we plan on doing that because I agree with you. Yet it is almost too bad that we can't have a total -- and we did have excellent FSIS staff there last night -- I was going to say a total recording of all conversations last night because to go through all those conversations and then try to put it down in bullet points, it becomes extremely, extremely difficult. But then our committee will meet at lunch today.

MR. BILLY: Okay. That's good. Caroline?

MS. SMITH DeWAAL: Thank you. And I'm not -- we are going to meet at lunch today to respond to you, Dr. Woteki. I just wanted to make a couple of further comments, both based on Rosemary and based on Kathleen Hanigan's comments.

First of all, the one area where there wasn't a consensus is on the issue of whether we need to clarify the definition of a hazard which is what the industry is petitioned on. The example that was used for why we need to do that is because, you know, there can be abuses of the

"reasonably likely to occur" standard.

Those abuses shouldn't happen. The inspectors should be well enough trained that wet paint that happens one day in front of a poultry shop shouldn't become a hazard reasonably likely to occur in the HACCP plan. That is just ridiculous.

And the thing that -- the way I think to get out of that dilemma, so instead of losing up the standard to address what are essentially abuses of the standard, I think we need to get back to the concept of uniformity, how to give -- and I am interested this morning, most of the discussions has been this morning on what the industry can be doing, thorough reassessments and stuff like that to improve their plans and whether the industry or the agency.

But most of our discussion last night was about what the agency could do. And the complaints seemed to be about the lack of uniformity in the actual application of the regulation. And so I want to get back to the issue of hazards and defining common hazards and having those hazards agreed to and understood both by industry and the agency.

And we are leaving that -- we are leaving that -- you know, the regulation is written in such a way that it is just, it is open. You know, you could define any hazard linked to your product or miss any hazards. And it is not clear that the inspectors are well enough trained that they are going to come in and catch things like, you know, the -- you know, missing Listeria in the plant.

And so I am trying to -- we talked a lot last night about defining the hazards, but also not creating cookie-cutters plans. That is not the goal. The goal is to get away from the agency saying you have to define your plans this way. We need to know the hazards are addressed and we need to know that there are measurable objective performance standards at the end of the line that the industry needs to meet.

We talk about teaching to the test. The problem -- one of the problem with the current framework is that we have one performance standard for Salmonella. And that is a regulatory touch point and it is a very important one. The reason all the debate over critical control points is because that is how you regulate. That is your regulatory

touch point. And so I am trying to figure out how to get better consumer assurance at the same time by giving you guys appropriate regulatory touch points.

The focus on Salmonella has shown us that if you focus on Salmonella, you can reduce Salmonella. But it doesn't reduce Listeria. It doesn't necessarily reduce Campylobacter. So now we need to take what we have learned from Salmonella and expand it using performance standards based on pathogens and good indicators.

We need more performance standards. Those will provide a measurable objective of tools to evaluate each and every individual plant. We also need this common understanding of the hazards. And the hazards need to be tied to these performance standards for each species and each product.

I just -- I am going to finish with the issue of fighting HACCP. We have seen in the last year a variety of attempts to stop the performance standards. We have seen it in the courts. We have seen it on the floor of the Senate. We have seen people who claim and trade associations who claim to support modernizing this system, trying to send the

Salmonella performance standard back to the drawing board.

And I am outraged when I have to spend my days fighting with the industry on something we agreed to. We sat in a room and we agreed that we needed measurable objective standards. And they are going back on their promises to us. And if it is one company who brings one lawsuit who puts the regulation at risk, then you can forgive that effort. You can say that is one misguided individual. When the major trade associations representing industry join in, that is outrageous.

And I hope the trade associations take leadership and don't bring their industries back to the dark ages because then we will support carcass-by-carcass inspection by government inspectors and mandatory testing of every carcass. We will fight hard to get -- if -- HACCP is not meaningful without these things. And if we do away with those elements of control and measurable objective standards, then HACCP is meaningless to us. Thank you.

MR. BILLY: Rosemary, then we will have a break.

MS. MUCKLOW: A break sounds like a good idea. I am regretful that there is such a serious misunderstanding

of the Salmonella litigation and the recent legislative interaction. Way back early this year, I tried to meet with the lady who just preceded me. And she refused to have such a meeting. There needs to be dialogue. There needs to be communication. There needs to be better understanding.

This is not the time to argue either the discussions that have occurred in court, nor probably those that have occurred on Capitol Hill. I, again -- we would welcome sitting down and trying to better understand these issues and to communicate and to see if there is some common ground. I regret deeply that they would become a football in this committee.

MR. BILLY: Let's -- Katy, I think you are pretty well set now in terms of the dialogue and so forth. Okay.

MS. HANIGAN: Yes, very clear.

MR. BILLY: Okay. All right. Let's take a break now for about 20 minutes. We will be back at 10:00.

(Whereupon, a brief recess was taken.)

MR. BILLY: I think we will get started again. Okay. The next item on the agenda is the issue of sharing recall information with state and other Federal Government

agencies. And Mike Mamminga is the Chair of that subcommittee. So it is my pleasure now to turn the meeting over to Mike to share with us what they discussed and then open it up to the full committee for further discussion. Mike?

MR. MAMMINGA: Thank you, Tom. I would refer you all again to Tab Number 8 in your binder which contains the issue paper on current FSIS thinking about this proposed rule. And this also contains the four questions that our subcommittee was charged with discussing and answering. Up front, I will thank the subcommittee members and Mr. Jolio for being in attendance and helping us in our consideration.

The rule in the Federal Register is also attached. And we did compare that with the issue paper. And I believe that the issue paper follows the rule quite closely. It has to do with the administrator of FSIS may authorize the disclosure of confidential commercial information submitted to FSIS as part of a recall of meat or poultry products, and then has provisos to provide to that.

The state agency provides written information about their authority to protect confidential information

and a written commitment not to disclose this. It also has provisos that the Federal Government would -- these agencies would also provide a written commitment to keep this information confidential. And, of course, all of this information that might be disclosed is only done so after the administrator or their designee indicates that it is necessary in the interest of the public health.

It contains provisos that does not make -- or trade secrets are not a part of this disclosure and that this information disclosed to the cooperating state agencies or federal agencies is not a part of public information. In other words, it again specifically states that. Going back then to the questions that appear on page 2 of the issue paper, our committee was asked to consider whether or not this proposed rule had merit.

Quite briefly in considering the public health implications of knowing where products went and what the quantity, certain it would -- it has merit. And we answered that, yes, there is merit to the proposed rule.

The second question was how best would this regulatory change be implemented in cooperation with state

agencies and other Federal Government agencies. And we talked that over quite a bit. Some of us were familiar with the cooperative agreements. Others, with memorandums of understanding.

And yet we also realized that there might be other appropriate documents without trying to name them. So we answered that question 2 with the subcommittee recommends that FSIS enter into cooperative agreements, MOUs or other appropriate documents with state agencies or other federal agencies. FSIS will provide notice of adequate penalties for improper disclosure of proprietary information within the MOU or appropriate document.

We discussed this quite a lot because industry, obviously, has concerns about proprietary information that may come into the hands if someone decides FSIS in a state agency or another federal agency and that they -- when they enter into an agreement and provide these written assurances, that they also be forewarned that there are penalties for disclosing them. And I think that would be an appropriate part in any such document that you would want to enter into. But we discussed that a lot because there are

concerns there.

Question number 3, can committee members identify specific factors that would a) facilitate or b) impede implementation of such provision? For example, are committee members aware of any problems that have arisen under a similar rule adopted by the Food and Drug Administration?

And in our discussions, those of us who were there, we could not identify a specific problem or problems. Now, maybe they are out there and other committee members can share with us. But we did not know of any.

Going on, the question says, if so, do committee members have any ideas about how these problems can be avoided. Here, our answer to question number 3, we have said FSIS should limit MOUs or other agreements to state agencies that will assist in recall verification activities. There was a feeling, why would some agencies unrelated to food or food safety or have any interest in going out and helping verify that recalls were being effectively carried out, why should this information, why should it, why would it?

So we decided -- and maybe my fellow committee members can embellish these thoughts. But we just indicated that these MOUs or other agreements to state agencies, maybe that could be wordsmithed a little bit, why include any designated industry? Why not just say agencies that will assist in recall verification activities?

The fourth question to us was FSIS expects that state and federal agencies would use the proprietary data, the example given, the distribution data, in their own activities such as conducting recall effective checks or audits. What mechanisms should be developed to ensure that additional data gathered by state and Federal Government agencies as a consequence are shared with FSIS?

Well, we discussed that quite a bit because a cooperative agreement or a memorandum of understanding usually flows both ways. Obviously, you don't want it going just one direction. So a provision that we suggested in our answer to that question was MOU or other documents shall include provisions that state agencies share information with FSIS about recall efforts.

Those are our answers now. The folks that served

on this subcommittee, if you have other additional comments certainly, here is your time to make them.

MR. BILLY: Okay. Anyone from the subcommittee? Okay. Let's open it up then to the full committee. Alice?

MS. JOHNSON: Mike, in the committee discussions about the MOU or cooperative agreements, was there a discussion whether this should be like a blanket MOU to cover any time a state or FSIS feels that they need to distribute this, is this agreement an "each incident" type of deal? How did you envision that or was there any discussion?

MR. MAMMINGA: Alice, that is a very good question and we did discuss that because in our discussions, one of our committee members thought that maybe that should be the case. It should be a blanket thing where the administrator just sends this information out every time there is a public health interest in providing it.

On the other hand, and you correct me if I am wrong now, committee members, but we discussed -- it is kind of hard to dictate to the agency the specifics of that sort of thing when the administrator or their designee is the one

that ultimately is going to decide if the information is available at all.

So I guess -- this is me speaking now personally -- if I entered into a cooperative agreement with FSIS for this sort of information and in the regulation itself it says that the administrator or their designee would determine that, I guess I would leave it to that judgement to tell me when they thought I needed to know.

The information has to come from there. I can't generate it on my own. So I guess I -- in my opinion, I thought maybe it was a little too fine of a point. But I can see your concern. And I would be glad to hear if you think this can be improved.

MR. BILLY: Okay. Nancy, and then Collette.

MS. DONLEY: Yes, some of the discussion that had come up last night, frankly, I had put out on the floor a suggestion that all states regardless of -- that there be an MOU. But that all states participate in it and that the information automatically get sent to the correct state agencies.

But it is -- if I am understanding your question

correctly, Alice, it would not be on a recall-by-recall basis. That right now, as Mike was explaining, that his state participates, has an MOU and that there is 25 other states -- there is a total of 26 states that currently receive this information.

It has been going on for 30 years. It has been a very -- in his case, it has been -- we discussed at length the confidentiality concerns and that to his knowledge that among these 25 or 26 states, there has not been a problem of the "confidential information." And by that, it could be pricing and various things that has leaked out to the wrong parties.

So this would not be -- it would be totally unmanageable to do it on a recall-by-recall basis asking for each time for there to be a separate MOU being signed. So it would be something that states would just elect to participate in.

MR. BILLY: Collette?

MS. KESTER: My recollection of our discussion was that at the same time, the agency would filter that to the appropriate states, that it wouldn't just go out to some

blanket announcement, that it would occur as it has been occurring where if something is going on in Mike's state that he needs to know about as is happening currently with him today, he gets that information from the agency and it just wouldn't go out as a blanket to all the states or any possible agency within those other states.

MR. BILLY: Dale?

DR. MORSE: From a State Health Department perspective, we would consider this very positive and it should be blanket. I think it helps create a seamless system, maximizes the effectiveness and the number of people that can follow up on recalls, for example, health departments through their health department or -- agriculture market-type units have cadres of staff out in the field and when they do get enough information on recalls almost always find product still out on the pipeline that would still have been sold if it weren't for these notifications.

We have had instances such as with Sara Lee, an incident with recall ten days to two weeks afterward when product had been served to Meals on Wheels' high risk

patients that we feel could have been prevented if there had been this type of notification. So in our state, we currently -- there has been at least improvement notification recalls I guess.

We do get e-mails on a regular -- of a product being recalled, a lot number, but only that it has been -- some products sent to New York are not. And this leads massive confusion, especially if that product has been associated with an outbreak.

We get calls throughout the state, local health units wondering whether the product is there. We cannot give them that information. It becomes a particular concern if they actually have human cases which at that point may not know whether they are linked to the product or not. They don't even know whether the product is in their neighborhood. So they are quite angry that we can't provide the information.

So anything to improve this. It has been effective with some of the FDA product recalls, at least in terms of timeliness, in terms of us being able to assist in terms of taking action. Timeliness is still an issue. And

I guess -- so this is one stop. But there is one step in the process. But timeliness will still be an issue in terms of how quickly that information is put together.

And I guess we are not going there today, but it raises the question of the mandatory -- the need for mandatory recalls or in the absence of that, steps to improve the timeliness anyway, to try to speed up the speed at which we find out about the products to be able to assist with this.

MR. BILLY: Okay. I have Lee and Phil Derfler and Mike if it on this point.

MR. MAMMINGA: My point is just to, again -- I remember one thing, that there is a lot of recall information out there today. We get it from FDA and FSIS. And as -- this will improve upon that by being specific to certain recalls. We have to -- the rule requires the agency, especially if it is state agency, it requires them to provide both written statement establishing their authority and written intentions of keeping this confidential.

You may have some agencies that would apply, that

would have difficulty doing one or the other of those. So that kind of gets a blanket, a blanket to all states and all agencies. It kind of puts a little bit of limit on that as it should. But certainly for Dale and myself, many, many others, this would be a wonderful tool to specifically work at the -- protecting the public health with this additional information. That's all.

MR. BILLY: Yes, thanks. Lee?

DR. JAN: Yes. I would kind of like to echo some of the things that Dale said. But from a health department standpoint and a state position, the people of the state expect protection from health hazards from their public health department.

And if the public health department doesn't even know how much product is in the state, we know that there is some in the state, but how much, those are questions that are asked and particularly me wants to know how much product is in a state, how much is recalled. And if we don't have that information, we can't give the information to provide comfort or assurance that everything has been done.

And I think that the MOU or agreement,

arrangement, certainly there needs to be some parameters or guidelines. And maybe that would be renewed annually to make sure that the right agency is being contacted. But once a recall is announced or necessary for a public health hazard, that should -- the state should at least have the opportunity to be the lead and take -- instead of effectiveness checks being done by the USDA, effectiveness checks would be done by the state.

And then the state, if they in the pre-arrangements say we don't have the resources and all; we want FSIS's or USDA's help, we will ask for it, but have the state be the lead so that they can gather the data. And to the level that their people expect protection, they will get it instead of relying on the Federal Government. There is too much Federal Government involvement in their lives anyway.

So we can bring it back down to where it needs to be in the states with the states having the ability to go to Big Brother and say I need help. Otherwise, leave it at the state level.

MR. BILLY: Okay. Thanks. Yes. Phil Derfler,

and then Terry.

MR. DERFLER: I just wanted to follow up with a question to Dr. Morse. We obviously tracked the FDA rule very closely in drafting our proposal. And in conversations that I had with people from AFTO, when I said that that is how we are going to approach it and when they actually saw the rule that we published, they suggested that there were problems with FDA's rule which is sort of the basis of the question here.

So I just wondered if you in New York or in Texas who weren't on the committee whether you were aware of problems that your state was having under the FDA regs. that we need to be aware of as we develop it.

DR. MORSE: Did they give you specific examples?

MR. DERFLER: No. I mean, just, well, you will be hearing from us. But I just wondered if you or Terry or anybody was aware of the specifics.

DR. MORSE: I'm not aware of specific problems. Timeliness, again, is what I brought up when I talked to the program. They said there is still the timeliness issue which there will still be delays in finding this information

out. And sometimes the announcement of the recall will occur before you get the other details.

So you -- there still might be delays. And so you are left with the recall almost the same. You know, it is in your state; I don't have that information. So that was mentioned, the only issue that I heard. I would be curious.

MR. BILLY: Terry?

MR. BURKHARDT: I had a question, Tom -- Terry Burkhardt -- on this. I will give you a scenario. Let's say there was a national recall. The state was provided with the information. And the state reported, let's say, to the press that they detained X number of products at various locations. Would that violate the confidentiality of the agreement, if the state reported where they found the product?

MR. BILLY: Phil?

MR. DERFLER: Well, the answer is I don't know. I mean, probably there would be ramifications from it. I think if you factually said where you detained the product and in the process of doing that did not disclose the entire customer list, I think we would have an argument that all

you are doing is doing that.

I mean, if it winds up in doing that you are disclosing the entire customer list, I think -- I mean, the problem with that is that we are likely to get a lot less cooperation from industry. It makes it less likely that we are going to be able to have the information available to share with you. And so that would be a problem.

MR. BURKHARDT: But generally when that happens, when you have an outbreak, there are demands by the press as to where is the product, has it been contained. That -- you know, those are the questions that have to be answered. And we have tended to answer it by state and by the -- answering the question as to whether or not we think we have got pretty good control on it.

MR. BILLY: Okay. Mike, and then Nancy.

MR. MAMMINGA: I'm sorry. When you go so far as to detain product in commerce under your compliance program, you at that point open the case that is under investigation. You don't have to disclose anything about that until you are prepared to do that with advice of counsel. And at that point, you can again revisit the issue of proprietary

information and address any Freedom of Information Act questions you get according to advice of counsel. So that doesn't seem like a big deal to me.

MR. BILLY: Okay. Nancy?

MS. DONLEY: I think -- Nancy Donley. I think this proposed rule I think is very, very positive as a first step. I don't think it get goes far enough and that in that it does not identify to the public at large where recalled product has been distributed, where they, the public, may have purchased it and brought it home and/or consumed it.

So I think this is a good first step. I would like to -- we would like to see it go even further where consumers can -- because consumers many times make -- would not be able to -- I would be very hard pressed if someone said to you what brand of potatoes do you buy; we have recalled potatoes of X brand or I'll buy my potatoes based on brand and based on price.

Consumers will not understand that, okay, this particular meat or poultry product is being recalled. What will trigger in them that, oh, I better go check my refrigerator, is if they know that it has been distributed

to Jewell and Dominick stores in the Illinois area. And that is what going to make them open up their refrigerator and take a look.

So I applaud the agency for taking this step forward. I think it is going to be very helpful from a public health standpoint. We just encourage it to go one step further.

MR. BILLY: Okay. Rosemary?

MS. MUCKLOW: I remember some discussions we have had. And I believe that the emergency program has implemented the policy allowing the affected company to review specifically the information about the recalled product because one of my greatest concerns is that we impugn the integrity of innocent product and don't get the right product identified.

And I appreciate that the agency has worked with the industry cooperatively to make sure that we get our hands around the right kind of product. Potatoes are a different game plan from meat. Every package of meat that goes through the retail business has some kind of mark of inspection on it and is very traceable through a mark of

inspection.

And the emergency program staff, when they issue a recall notice, I have noticed as I see them as they come across my desk at a frequency that I don't like that they are very clear in terms of giving consumers specific markings that they need to look for. And I commend the agency for its clear specificity. I think Charlie and his people are doing a good job in that regard. And I haven't always said that.

Recalls are best when they are cooperative. And the concept of having a state agency assist in that recall effort is absolutely appropriate. Again, it is going to be important that they are out looking for the right product which hopefully we have got that taken care of and that they do it under an arrangement which protects proprietary confidential information particularly of smaller firms. And I feel fairly strongly about that.

As with all such documents, the devil is always in the details. And it is not the responsibility of this committee to design the specificity of that memorandum agreement. You are going to have your policy people, your

lawyers and everybody else looking at it. And hopefully, you will share it with others to make sure that you have covered those bases. And we would look forward to seeing that.

We will be helpful and supportive as an industry because if there is product that people should not eat, then we want to be cooperatively helpful in getting that product back. And that is what cooperative recalls are all about.

MR. BILLY: Okay. Mike, that sounds like there is a pretty broad consensus in terms of your responses to the questions. I don't know if there are any last-minute thoughts from anyone or, Charlie, do you have anything to add? Okay. Okay. I appreciate that very much. Good job. And I will remind everyone that the comment period is still open. Is that right, Phil?

MR. DERFLER: Yes. Until the 20th of November.

MR. BILLY: So if any of you or anyone in the audience, anyone has further thoughts, we encourage you to provide written comment in response to the proposed rule.

MS. MUCKLOW: Tom?

MR. BILLY: Yes?

MS. MUCKLOW: May I go back and make an additional comment about the subject that we were talking about earlier? Sharon Sacks has kindly pointed out to me that the petition was distributed at the July meeting.

MR. BILLY: Yes, it was distributed and discussed.

MS. MUCKLOW: And discussed. So short is my memory. If anybody wanted another copy if they can't find their copy, maybe your staff would be kind enough to provide it.

MR. BILLY: Okay.

MS. MUCKLOW: But people should have it if they got their book.

MR. BILLY: Okay. We will follow up on that. Okay. Anything -- all right. I think then we will move on. Unfortunately, Pat Stolfa hasn't arrived yet. But she is on her way. And Phil is here. So I think what I would like to do is press ahead and if possible complete this next discussion and maybe generate a little extra time during lunch for Katy's committee to follow up on the discussions of this morning.

So let's move on now to the next subcommittee

discussions which focused on residue control in a HACCP environment. I will remind everyone that this is covered under Tab 10 in the book. And now it is my pleasure to turn it over to Carol to lead the discussion.

MS. FOREMAN: Thank you. Let me begin with a couple of introductory remarks. First of all, this was kind of an unusual assignment in that there was no detailed paper for us and we have a public -- you have a public meeting scheduled on this subject on December the 11th. So rather than working from a current thinking paper as we frequently do, you left us kind of on our own. And so, of course --

MR. BILLY: A huge responsibility.

MS. FOREMAN: We -- yes, it is always a dangerous thing to do, too, because we may have gone far afield from where you intended. We are working -- we did have access to the 1985 NAS document that Pat said yesterday you would use as a base to work from since it recommended using HACCP to control residues. And when Pat made her presentation yesterday, I think she made it clear that the United States does not have an effective comprehensive risk-based program to control chemical residues in meat and poultry products.

The biggest problem appears to arise from illegal residues -- from illegal drug residues, levels -- illegal levels of animal drug residues, excuse me, especially sulfonimides and antibiotics in market animals and that the problem appears to concentrate on a few repeat offenders.

Having said that as background -- one other point on background. We didn't address each of the individual questions. But I think we covered them all. We think the big issue is -- for a HACCP approach is the fact that you have such a scattered authority in this area that it is very difficult to implement a logical, coherent program. Hi, Pat. Glad to see you.

So our very first suggestion that you go the President's Food Safety Council or perhaps to the National Academy of Sciences to address the need for a coherent organizational structure for the regulation of food, animal, drug and other chemical residues. This is a place where if you don't have a single food safety agency, at least you might take advantage of the Food Safety Council to try to get some coherence here.

That you establish a ranking system that is

logical and transparent for compound, surveyed each year and that residue control be based on a risk management system that concentrates on areas of high risk, especially small producers and previous violators.

And that is really -- I should point out that the small producer issue is one where there seems to be a high level of violations among some small producers. Develop better methods for testing live animals. Encourage a HACCP approach to the overall problem. I have a particular attachment to the next point, number 6, seek legal authority to establish a trace-back system for animals.

This is the twentieth anniversary this month of the Department of Agriculture sending a bill to Congress seeking authority to trace animals back to the producer. At one point, this administration sent that bill to the Congress. But the last couple of bills haven't included that authority. And it is one that I -- we have a large amount of agreement among those people on this subcommittee.

Explore with ARS additional research on new and better testing methods for residues, especially for those drugs that may be in use by some of our training partners

but aren't used in the U.S. And there was a very strong feeling about limiting severely or prohibiting entirely the availability of veterinary drugs to non-veterinarians. We had a long discussion primarily led by Lee on the difficulty that is created by those drugs being available willy-nilly.

International issues, Tom, we would like for you to give as a quick run-down on the Codex activities in this area. And why don't I stop right now and get you to do that.

MR. BILLY: Okay. This is a very important area to Codex and has been for some time. There are several committees in Codex that deal with this area. There is a Codex committee on residues of veterinary drugs in foods. There is a Codex committee that deals with contaminants and pesticides, so various types of contaminants including pesticides or other types of contaminants.

The way the Codex process works is that countries identify concern about a particular drug or residue, environmental contaminant or residue. And that concern is then captured in the plan of work in terms of developing internationally a -- what is called an MRL, a maximum

residue limit, for that particular chemical whatever it is, whether it is an animal drug or whatever.

The Codex committees, the ones I mentioned, should be thought of as playing the role of risk manager. And based on those committees identifying the questions that they want answered, the matter is then referred to one of a number of expert committees that WHO and FAO have established. And these experts committees should be thought of as the risk assessors. They are the people that gather the scientific data regarding exposure and all the other information that goes into developing and recommending a maximum residue limit.

It could range from the risk is so low that there is no need for setting such a limit to establishing a very specific limit for a particular contaminant or veterinary drug or whatever. Once the expert committee has developed its recommendation, that then goes back to the appropriate Codex committee. They consider it. Most often, they accept it. Sometimes they have questions and there will be a sort of a back and forth process to arrive at something the committee is comfortable with.

And at that point then, the committee will advance that MRL, that proposed MRL to countries for comment, consider all those comments and ultimately then recommend to the Commission which is all 165 countries, that the MRL be adopted and recommended for use by countries. That process takes some time. It takes most often several years.

And one of the areas that I am focusing on as the elected Chairman of Codex is to accelerate that process and to improve the science that is used to develop these kinds of recommendations. The countries -- once there is an MRL that is recommended, then it goes back to countries for their consideration.

A country can choose to accept the MRL. Alternatively, they can set a higher standard if that is what they believe is necessary or maintain a higher standard if they already have one. And that is provided for under the various trade agreements. So a way of thinking about Codex is that it is a mechanism for establishing an international norm where you may already have such norms established in a number of countries, particularly the more developed countries, but not internationally or worldwide.

I don't know if that is sufficient for you or not.

MS. FOREMAN: I'm sure you will get some questions.

MR. BILLY: Okay.

MS. FOREMAN: Quickly going on through -- thanks, Tom -- through the international issues, establish ways to address more effectively the problems caused by the use of drugs in other countries, drugs that are not approved for use in the U.S. and address problems with residues in domestic products that are scheduled for export. And then we have three or four words there that I just failed to delete at the end of that sentence.

Going now to address the public education and public meeting issues that were raised specifically in the questions, there is a very large public concern about chemical residues in drugs. It tends to be below the surface most of the time. But when something happens, people react with great concern because it is not something you can control in your own home. As was pointed out yesterday, you can cook it all day long and it is still there.

So we thought that it might be a good idea to try to hold some public meetings and conduct seminars to expand the knowledge base among some interested public groups, particularly public -- American Public Health Association, groups of nutritionists and others who deal with food on a continuing basis. And, obviously, we think that that needs to be done before there is a problem of notoriety.

On making the public meeting a success, solicit ideas for new approaches to sampling. Emphasize producer and packer responsibility, especially if the animal is given drugs. I think that should be fit that are used in human medicine or not fit for human consumption where there is no level of acceptability for human beings. Emphasize ways that HACCP offers opportunities for new approaches to control residues.

And going back, I think there is one point I should have emphasized earlier which is there are -- that obviously, HACCP includes the definition of hazard, any hazard, chemical or physical that -- or microbiological that is likely to occur. Companies that are buying their animals from repeat violators know they have a hazard and they need

a CCP to deal with it. But is the easy step in this. The others get a little harder.

Do any members of the committee want to add on?

MR. BILLY: Could I ask one question? Just I'm not clear on how to make the public meeting successful, the number 2. You commented about the wording and I wasn't clear.

MS. FOREMAN: It's only because toward the end of that, it is given drugs that are used in human medicine and, therefore, residues are a serious problem or drugs where there is no residue level that is fit for human consumption. Lee, do you want to talk a little bit about that?

MR. BILLY: Okay. Lee?

DR. JAN: Well, I'm not sure about that particular issue. There are some drugs that are -- you know, they are not approved for use in animals. That may not be a risk to humans. But that's -- so that's -- maybe that's not a food safety issue. But that still would be I think a concern because it is a residue that has not been established.

And maybe the reason it is not used in -- or approved for use in food animals is because the company that

produced that particular drug didn't find the economic benefit of going to the expense of demonstrating its safety. So, therefore, it is not approved for use.

But then there are the other issues which I think whether they are a residue or not, another issue that was related to use of drugs and that it comes up is about using drugs and some of those in particular taken off the poultry market because of concerns that those drugs may lead to resistance in organisms that can affect humans.

And that may be a knee-jerk reaction or maybe there was a lot of science. You know, I don't know about the data supporting that. But I think that the concern is that we don't want -- we want to do what we can to prevent the increase in numbers of resistent organisms. And then that means taking it away from use in food animals. And maybe that is the best way to go until we find definite links or why is that happening.

But specifically, I don't know why else we would talk about these residues or drugs that were being used. I might add, if I may at this point, that we did talk a good bit about the HACCP principles and that with the low level

of -- I mean, the low level of drug residues that are found to do -- to expect FSIS or to expect industry to do testing to identify with the confidence when you get real low -- the lower the incidence, the more tests you have to take before you find it. That becomes a problem.

So if we rely on HACCP to do what it is supposed to do, the packer includes that if he is -- like Carol mentioned, that if buying from a repeat violator or other risk categories, risk groups, risk -- because there are some risk groups, someone buying for a dealer, someone buying through an auction where there is not a lot of control. Those risks are going to be higher. And then that is where the HACCP plan should at least -- well, it should be addressed. I think that issue should be addressed in every place.

But in those that are having those high risks, they may have to implement or insert a critical control point at that point. And then -- but with the idea of limiting or directing the sampling efforts of FSIS for surveillance or for any other -- or if the industry wants to -- needs to do testing to HACCP. But for surveillance,

limit that then to the high risk.

And as long as the majority of the livestock coming from uniform units, say, feed lots -- they go through a feed lot where they have veterinary -- generally have veterinary oversight for medical issues, parlors for swine or chicken houses that we have uniform groups, then those are probably a lot less risk. And that is not the place to do sampling. Sampling efforts -- there is only so many dollars for sampling. So put it where the risk is more likely to be picked up.

MR. BILLY: Okay. Good. Katy?

MS. HANIGAN: I have two questions, one directed to Mr. Billy and then the other one back to the committee. My understanding of residues was that FSIS at the plant level had backed off, if you will, on some of the STOP and SOS testing that was going on because of lack of positive findings. And, you know, I am just wondering if that is a true statement.

And then the other question I wondered is if the committee addressed at all last night the limited laboratory methods that would be available to industry to validate,

verify whether or not you've got residues at the plant level. So those are the two questions I pose.

MS. FOREMAN: Let me answer the second one real quickly because I think we probably want more discussion on the first. Under number seven, we did have some discussion of it. And we talked about the need for research on better testing methods. And that is listed under number 70 -- or under number 7. We had quite a discussion about getting the ARS especially to get into the development of additional, simpler, more reliable tests.

MS. HANIGAN: So that the committee did recognize or the subcommittee did recognize last night that currently available to the industry, to the public is not the methodology that would allow for this testing on a daily basis.

MS. FOREMAN: I don't think we got into that detailed -- I mean, we did not discuss the lack of tests that make any sort of daily testing reasonable.

MS. HANIGAN: Okay. Because I will tell you we -- the company I work for, we have been doing extensive research as to what is available to us. And we are using

the most available methods. But they are just not very good and there -- I mean, there is a lot of area there that needs to be developed.

MR. BILLY: Okay. And with regard to the first -- on the same point?

MS. KESTER: Yes, to build on what Katy said. I mean, we have actually worked --

MR. BILLY: Collette.

MS. KESTER: -- with the pharmaceutical companies that produce these drugs. And they are unable to provide us with reliable tests for either daily monitoring or verification activities, nor are there commercial labs available. So I agree with Katy. I can't emphasize enough, I would love to be able to test, to validate what we are doing upstream. But it is just not there right there. And that is an important cornerstone of this whole discussion.

MS. FOREMAN: Well, I just simply don't think that it is reasonable that the drug companies are going to do that unless you say to the drug companies you can't sell these drugs until you have a rapid, reasonable test for presence of residues. And there are a lot of drugs already

out there that you would have to withdraw approval for.

We did emphasize the need for public resources going into this. And it seems to me that the only alternative to that is to say to the companies you can't sell them if there is no test for them.

MS. HANIGAN: Can I just respond to that, please? And I don't want to get bogged down in the lab methods because I did tell Ms. Stolfa that I would definitely come on December 11th. I just want to make sure everyone in the room understands, you know, if you are looking for a chemical contaminant -- and I will just use in a meat product since that is what we are talking about -- and you want to do a GC analysis on it, you can't just run your sample through a GC and say, equipment, tell me what chemical contaminants are here.

You have to have a set of standards and say look for this contaminant. So it is not where we can simply take the meat, test it for every, if you will, residue that is out there or every drug that is out there. You have to tell the equipment what you are looking for. So many of these tests are going to require very -- or many of these drugs,

residues, are going to require very specific tests be built for them.

I mean, it is not as simple as running the meat through a GC analysis and saying what is there. The equipment doesn't work that way. It is very specific testing for very specific drugs just as it is for microorganisms, specific testing for specific bacteria.

MR. BILLY: Gary?

DR. WEBER: This is Gary Weber with the National Cattlemen's Beef Association. Just a few broad comments on this area. And we have a significant interest in this and have invested a lot in preventing residues of chemicals as well as antimicrobial compounds. And so our commitment remains there. But I also have over the years spent a lot of time with FSIS when I worked for the Department and still spend a lot of time with them monitoring this issue. But just a few things that I wanted to just touch on.

Number one, the scientific basis. I think that government in general has been slipping in terms of the technological superiority. And this showed up in terms of our interactions with the European Union and a seemingly

difficult time in finding laboratories that could test for some of the compounds that they were interested in. I think we could argue whether those were irrelevant or not. But they were -- we found that that technological superiority was lacking.

Recently, the FDA held a series of conferences where they brought in some experts including Jack Henyon from Cornell University who was probably one of the leaders in developing gas chromatography equipment tied to mass spectrometry to really look at compounds at very low levels with a great degree of sensitivity and specificity. And so the FDA recognizes that there are some concerns there.

We need government though to maintain this kind of superiority. I think from the standpoint of what was discussed yesterday about morale, about being able to compete for these sorts of scientists and keep them involved with government is critical.

A real quick bit of an anecdote on this, many years ago through some routine testing at FSIS, they were detecting what appeared to be some kind of a hormone substance in beef. And they weren't sure what it was. They

had never seen it before. And working at that time with Steve Sunloff who is at University of Florida, another toxicologist, it turned up that it was showing up seasonally, but it was a byproduct of a mold in some peanut hay.

Now, it probably shouldn't be there. And so efforts were made on the part of universities and University of Georgia and Alabama in the southeast to educate producers that this kind of hay at least managed in this way could possibly present a risk. And I am sure nobody ever heard about this in the press. But the industry was concerned enough that we could do things to ameliorate that.

But it was because FSIS had that technological capability and people were looking for these things, that kind of gave us that front end. And that was excellent. We need to maintain that kind of leadership.

We need a consistent national policy. AMI has provided leadership to pulling a lot of us together to talk about this residue issue in call dairy cows. And we have made a lot of advancements in our thinking there and reached a lot of common ground and have submitted a request to the

Department to take action on that. That needs to continue and we need to make every effort to stop that from happening.

These consistent national policies though require that if a packer is put into a situation where there is, so to speak, a regulator on this, that these cattle or pigs or whatever it might be don't just shift around to someone else and have FSIS and others just chasing after the animals moving along the line.

This relates a little bit, too, to trace-back. There has been a lot of controversy whether we can trace animals or not. But the fact is we can. Recently, there was a gentleman prosecuted in the state of California. He not only marketed animals under fictitious names through fictitious places, but he was traced back and he was convicted.

I have talked to the packers about this and said you can't trace animals back; no, we can't trace them. I said, well, do you have checks that are laying around where you don't know who to pay for the animals you bought. No. Well, they can all be traced. It is just a matter of how

much work it is.

And the cases where people have been prosecuted prove that. We are all for trace-back, but we certainly want to make sure the system will work. So there are a lot of cases where that is functioning quite well and we support that. There needs to be linkages to the Veterinary Medical Association and to our beef quality assurance programs. And hopefully at the meeting that you are planning in December that these folks can be in attendance.

Relative to methodology, I think it would be great that the Animal Health Institute and pharmaceutical companies can be present. My understanding is that a lot of these tests have to be produced by the companies. There has to be an approved method for detection before FDA will approve them.

So -- now, whether or not they are convenient or can be used in a laboratory is another matter. But I believe that detection is a requirement of approval. So -- but, again, we need to have them present to talk about those things. But this is a very, very important area that we want to make sure that government maintains a strong

presence for many reasons. And we certainly support that continuing in some way and doing our part, as well.

MR. BILLY: Okay. Lee?

DR. JAN: Yes, this is Lee Jan. Just wanted to kind of touch on, you know, we recognize and we did talk about, as Carol mentioned, the need for new methodologies for testing. But that doesn't -- not having those would not be reason not to apply HACCP principles. There are other things.

Any drugs that are legally available to be used in food animals do have a withholding period if necessary. And that has been demonstrated through testing when it is appropriate, provided dosages are correct. So if a HACCP system -- and it really needs to be pushed back down or up to the farm or the producer whether that would be mandatory HACCP or the quality assurance programs that are currently -- many of the producers are operating under.

But if that becomes -- if the packers would start relying on -- this is a requirement for animals that is coming here that they produced under a quality assurance program and any medication was done under the direct

supervision of a veterinarian, pesticides were used in accordance with pesticide application laws or someone that is a licensed pesticide applicator, there may be additional costs to the producer.

But if the people or the experts or professionals in the use of these approved drugs are involved, they have a little more on line if they allow the abuse and result in residues. A veterinarian may lose his license. A pesticide applicator may lose his livelihood and not be able to apply pesticides and those kind of things.

So I think we can still apply the HACCP principles, not saying that we don't need these other methods of testing. And certainly as we get those, then we can test the effectiveness of some of those principles. So that is -- and limiting the use of veterinary treatments to licensed veterinarians would be important -- the philosophy now or the way they look at it now, if someone has their own animals, they say they can treat them.

They can make diagnoses or get the drugs in those that are treating their own animals. But I think food animals need to be looked at as not belonging to the

producer. They are just a temporary caretaker. And the food belongs to the consumer. So any treatment that is done on the farm should be done as if that was being done under the practice of veterinary medicine.

And I think that in that thinking -- and I think that FDA would have to be involved in changing that thought. But I think that would help minimize residues from illegal or inappropriate use of drugs. There are a lot of other residues, chemicals and like you mentioned, toxins after toxins or mold from peanut hay. All those things would need to be considered and what kind of feed sources. But at least that is a beginning.

MR. BILLY: Okay. Thanks. Rosemary and then Caroline.

MS. MUCKLOW: As Carol has -- this is Rosemary Mucklow. Has Carol has indicated to you, it was a lively discussion and you just are lucky that you got all these bullet points laid down. The -- one of the points raised here at the table this morning is the difficulty of testing for drugs, even some on the market today and certainly for those who we have not heard about yet.

And that goes back to the very first bullet point. We had a lot of talk about that last night. And the -- one of the biggest problems in handling this issue is the diverse authorities, not only at the Federal Government level, but at the state government levels, too.

And the efforts of professional people like veterinarians making sure that when they give a drug to an animal, that they prescribe it and admonish the person who is going to actually administer the drug to the animal, often the owner of the animal, to follow the regulations very specifically.

I am still trying to get an answer to a relatively simple question in this whole arena which is phenylbutazone that the agency is running some tests on right now that is not approved for use in bovine animals is turning up in bovine animals upon testing. And I have been told by one veterinarian who shall remain nameless that he is permitted to give phenylbutazone to an animal on an extra label basis.

If that is the case, my question becomes is that animal red tagged for the rest of its life? Is its milk allowed to go into the milk pool? Is its meat allowed to go

into meat? As I understand it, it is not an approved drug. And once used on a food-producing animal, I would think it renders that animal ineligible for either milk or meat for the rest of its life.

Maybe for breeding purposes, it is fine. But for milk or meat, it would be inappropriate. It is very hard to get these questions answered. And thus, you see that the very first bullet point under the first item was that this is an issue that really calls for some assistance from the leaders of the departments who work within the scope of the President's Food Safety Council.

I like the concept that somebody suggested that the packer almost becomes the regulator here. There are some packers that have chosen not to handle animals that come from repeat violators. Clearly, in their business, the hazard of an unlawful residue is going to be a lot less than those who will buy those animals at some risk. And, therefore, we are looking at two different kinds of HACCP approaches by those two different packers. And we have to recognize that within the system.

One of the issues that we didn't touch on last

night but that really reoccurs to me today and is always a major concern is if we don't provide a legitimate inspected location for those livestock to be evaluated to enter the meat system, they will enter it through the underground system.

And I don't want to encourage diversion of animals that may contain residues and that we really need to look at under inspection because we make the barriers so great that we send them to the underground system. And the enforcement and compliance authorities who are pretty thin on the ground anyway have to go out there hunting for shade trees or worse.

So whatever we do in this area we need to do with great care to make sure that we are providing the safest meat possible with respect to residues to consumers and that it all carries a mark of inspection, either federal or a state marking states that have that authority.

MR. BILLY: Thanks. Caroline?

MS. SMITH DeWAAL: Thanks, Tom. Caroline Smith DeWaal. I think the issue -- this raises an issue of one of the new frontiers of food safety. And that is the area of

on farm controls. This is a very important area. We put a huge amount of regulatory resources and attention at the processing and packing level. But we need much -- if we are going to see great advances in the future in food safety protections, it really is going to be as a result of improvements on the farm.

That said, this presents an opportunity, the whole issue of residue controls really presents an opportunity to introduce producers and farmers to the concepts of HACCP in an area where they understand that they have controls and that they have the risk.

I think that the document that the subcommittee came up with is quite excellent. And it really -- there is a lot in it that I think is just very, very good and provides good direction to the agency. I do think that one of the issues that we -- we haven't talked about a lot, but I will note that Lee Jan I think made some excellent points on that, is the whole issue of veterinary control and administration of the substances.

In the human arena, these drugs are administered by physicians. They are sold by licensed pharmacists. And

they are subject to pretty strict controls. And yet in the veterinary area, frequently you will find a lot of drugs sitting around and being administered by farmers without a lot of controls.

You can go into feed shops and buy big bags of this stuff to mix into animal feed. We have actually it at CSPI press conferences, big bags of animal drugs and feeds. And it is -- I mean, it is outrageous that they are being administered so liberally in this area. So I think that this is a good direction for the agency.

I also like the idea that the trace-back, the issue of having Congress actually endorse the concept of trace-back. This is an important area and I am glad to hear that the National Cattlemen's Beef Association supports the issue of trace-back. And perhaps we could get that going in the legislative arena because I think that would also provide great consumer protections. Thank you.

MR. BILLY: Okay.

MS. HANIGAN: My question needs to be answered.

MR. BILLY: Yes, yes. I haven't forgotten. Katy had a two-part question. And one part -- we jumped to the

second part of her question. But the first part was, as I recall, whether in fact it is true that the agency after a certain number of results backs off on particular types of residues.

Let me take a shot at that. And I want to ask Mark Mina to elaborate further. In terms of the design of our program, one of the -- one aspect of the program is that we work through a collaborative process with the other federal agencies involved to determine where we focus our attention in terms of the wide, wide variety of possible residues that could be associated with the animals that we regulate as they are slaughtered.

And each year, we try to establish or refocus our priorities based on information from the various agencies, our experience and our results. And it is, in fact, the case that if after some period of time -- and it can vary depending on the particular residue you are talking about -- that we have determined that not withstanding why we focused on that residue to begin with we've got a bunch of negative results, we are not finding anything in our sampling programs, then we will stop that focus or are focusing on

that particular residue and use our resources for another high priority area.

As someone said earlier, you never have enough resources in this area. So you need to set priorities. And we try to do that. That is not to say that we won't circle back and check again. And we do that. So -- but it is, in fact, the case that we do set priorities. We do it on an annual basis, often for a particular type of compound, we may check for several years. It takes that long to get adequate data to satisfy ourselves that, in fact, this is or isn't a problem area.

So I hope that is helpful in terms of our overall policy. Mark, I don't know if you want to add anything to this or not.

DR. MINA: Yes. I want to kind of briefly discuss more specifically the comment I think you made earlier, Katy, that you are under the impression that because we have low levels of positives, we are backing off testing. And we are not doing that. The contrary is true, particularly in call cow plants. We have sent -- and that is based on risk. This is obviously the category that is most likely to

contain particularly antibiotic and sulfur residues.

And so we have increased significantly the testing in those plants. We have sent out a notice about a year ago that identified to the inspectors in charge several post-mortem lesions and conditions that can trigger their attention in terms of testing for residues. And we have several correlation meetings in Omaha for those IICs that are assigned to those call cows to make sure that we uniformly implement that policy.

There is a lot of room for improvement. But what I am trying to tell you is we are increasing the testing for residue, particularly in those plants. And as Gary mentioned earlier, we have been working with industry for about a year or so. Not only us, FSIS, but also other agencies, FDA, Packers Stockyard and others, to try to get a handle on this issue of residue, particularly in call cows.

And so we are making some progress in this area. We are not there yet. But that is work in progress.

MR. HANIGAN: Can I just make one comment? We as a committee, we have talked this morning about hazards and the definition and sound, valid underpinnings, et cetera.

And I just feel like I need to point out when we worked at Farmland at our hazard analysis which one of the things we did address was residue in these live animals that we were purchasing, if you go to the FSIS website and pull up what I call the blue book that talks about the drug residues and the amount of testing that has been done, et cetera, it would clearly support not feeling like that is a hazard reasonably likely to occur.

And we have been talking about sound scientific documents and what does the industry use. I just want to point out that that is one of the many documents that we pulled off of your website. So that is why I questioned not the backing off of the testing, but there is literature published right on your website that would say it is not a hazard reasonably likely to occur.

MR. BILLY: One of the thoughts that occurs to me, just picking up on that point, is perhaps as part of the public meeting and the discussion there would be a way where the same scientists and experts that meet annually to talk about priorities and where for whatever reason, there is a particular concern, there is a new drug or there is a

potential use of some drug, that type of information could be made available to the industry in a way where they could then as they reassess their HACCP plans, they could consider whether given the type of operation they have, they ought to modify their HACCP plan and include it in some kind of screening test or other options they have available to satisfy themselves with regard to that.

So that there is a -- part of what we talked about earlier is improving communication. Maybe there is a way to share some of that information in some way that would be useful to the industry, both the slaughter plants and the producers, as well. Katy and then Carol.

MS. HANIGAN: Just as a further response or clarification, even though we did pull that document as a reference, you know, I do want to state that we are doing regular screening of hogs that are coming into Farmland for residues just to make sure that although their literature showed that it wasn't reasonably likely to occur, I want to make sure that it applied to the animals we are bringing in.

But the one thing I do want to state is that the testing is not cheap, not that that should come into play

here. but when we get talking about small, medium and large, I really don't know how many dollars these medium and small people have to say, okay, there is the scientific literature; does it apply to what I am bringing in here; now I've got to have the testing done.

So I am just throwing that out, you know, food for thought. We didn't just simply take your document and say that's it. We have been validating it. But I would be very concerned if I was a small plant.

MR. BILLY: Carol.

MS. FOREMAN: Go ahead.

MS. SMITH DeWAAL: Katy, can I just ask a question? It is Caroline Smith DeWaal. Could you instead of doing just the verification testing, do you also ask for records from the producers of their drug use? I mean, I'm just wondering in a HACCP concept out this might work from your standpoint.

MS. HANIGAN: We do and we have done a number of different things. We actually held producer meetings to address the subject. We have actually sent mailings to their home. We have a calendar that goes through different

CCPs, not that all address HACCP in our facilities.

But regarding the residue, we have a large sign posted where you deliver your hogs, notifying the -- or reminding the producers again that Farmland is randomly screening for drug residues just as a reminder so that when they are dropping off their hogs and we are checking into this, you know, if they are inclined maybe not to be totally honest, there is the sign posted there.

And they never know whose lot number or tattoo number is going to be pulled on which given day for the screening. But, I mean, although we are doing that, I don't know how a small plant would do that. I honestly don't.

MR. BILLY: Okay. Carol, you were --

MS. FOREMAN: I just wanted to go back because some points that have been made recently I think bring us back to some over-arching issues here. One is we are dealing with all residues here, not just animal drugs. Two -- and Rosemary, I appreciate your pointing it out.

The system or the organizational system, the structural system for trying to address this problem approaches chaos theory. It is the damnedest, dumbest thing

you've ever seen in the world. If you go draw a picture on the wall of how the United States Government tries to regulate the presence of chemical residues, it looks like a Ruth Goldberg contraption.

And in my view, a lot of the problems that come out of it are the result of that. USDA as we all know, FSIS cannot go back before the slaughterhouse door. These are problems that are -- arise before the slaughterhouse door. And if you want to try to control it on the farm, FDA has got to do that. Well, you tell me how many people FDA has got to send off to farms unless they think there is a gross violation of the law. It is not going to happen.

And 25 years of MOUs and interagency committees have got us exactly what I think MOUs and interagency committees usually get you. You do have to be able to control to the extent possible your supplier. I think the government ought to be able to go back to the supplier and give you some assistance there.

But it is true that in a HACCP system, one of the key elements of avoiding the hazard is the control of the supply. And you know that. With all due respect, I would

say that that applies to processors as well as to slaughterhouses. If you control your supply, going back to the discussion earlier today, you have less possibility of ending up with product in your grinder that is full of Salmonella.

MR. BILLY: Okay. Rosemary.

MS. MUCKLOW: One of the points -- I got so carried away earlier that I failed to make it. And as you know, Mr. Billy, a couple of us have some requests in to you for some review. And we are -- on how you take people off the violator list or put them on the violator list. And we are extremely hopeful that you are going to respond to us soon on that one. We thought it was pretty black and white. But we understand that bureaucratic wheels move a little more slowly than we would like. But we are looking forward to that answer.

The other piece of the puzzle that we are most anxious to bring to conclusion is the development of a transparent -- and it is a popular word these days -- the transparent list of repeat violators. These are people that are like the one that Dr. Weber described, people who have

been prosecuted and found guilty of selling an animal into the food supply that contained unlawful residues.

And it has been the best kept secret of the Federal Government for 20 years now. It is time that that list was made available so that those packers who choose to try to reduce the hazard by not buying from repeat violators may do so. They may make that choice. Repeat violators are in lots of different parts of the country. And it is unfathomable to me as to why it is such a secret.

MS. FOREMAN: Can we put that on the internet? Why can't you put that on your website?

MS. MUCKLOW: That is what we have asked, Carol, and they are still mulling it around. And again, it bridges agencies. Two agencies have to cooperate to get one list. And that is a tricky thing in this arena. We are very anxious to have that list. I have developed my own list based upon the certified letters.

MR. BILLY: Is that on the internet?

MS. MUCKLOW: It is not on the internet yet, but I have threatened to put it there. I would rather it be the government's list because you can produce a more accurate

list.

MR. BILLY: Well, you could give us a jump start.

MS. MUCKLOW: I have thought about it. Believe me, I have thought about it.

MR. BILLY: Okay. Mike.

MR. MAMMINGA: This has really been a good discussion. I bought from a regulator in a small venue if you will. The length and breadth of the chemical residue situation as we have heard this morning is long and broad and tall. And we are not going to fix everything here. But we might be able to do some things. And I am looking at things that I might be able to do. And I am talking for myself.

But there are three issues today that seem to me fairly burning. And one you just got done talking about. And that has to do with repeat violators. We have got to target those people. And we can do that. we have the resources to do that and to get the bad actors either publicly humiliated or off the street or censored in some appropriate government way.

The second thing is I think I need to work at and

maybe agency and all of us work at is getting some resources into the area of another very excellent thing someone brought up this morning. And that is better detection methods. I think we would all like that. And I don't think it is outside the realm of possibility.

Now, we are probably not going to get a silver bullet. We are not going to get that magic piece of paper to lay on something and tell us what there is and the quantity of it. But it would certainly be better if we had some more tools than we have today. And lastly, coming from both animal production and food safety, the issue of animal food drugs or animal drugs that can end up in foods, the day of the feed store and the refrigerator at home and that, it has got to be addressed. It just has to be.

And whether the drug companies and the feed stores and my friends that raise cattle and hogs and sheep and goats and poultry would like to admit it, it is going to have to be addressed. We certainly have enough problems with humans and drugs. But that doesn't mean that we shouldn't try to address it. And those three areas I would just offer as something that maybe we can move on a little

more quickly than trying to solve the entire situation all at once. Thank you.

MR. BILLY: I would like to add one point, just picking up on that last point you made. And I didn't mention it earlier. There is very strong international concern and interest in this area of the use of veterinary drugs in feeds and feeding and that whole area of activity. And so the Codex commission established what they called an ad hoc task force with a three-year assignment to come up with some new international guidelines that address these very areas that you have just talked about, Mike, including putting drugs in feed, how to control that, the role of the veterinarian and so forth.

So I just wanted to mention that so people are aware that it is not just an issue or a concern here. It is an international concern that Codex has just begun to address in the last year. Carol?

MS. FOREMAN: I was going to suggest that there seems to be a pretty substantial agreement around the table on the points that Mike just raised. With the public hearing coming on December the 11th, I wonder if the

committee would be prepared to have us make a formal recommendation including those three points to be included in the record of the public meeting.

MR. BILLY: Any --

MS. HANIGAN: I think that is a good idea.

MR. BILLY: I don't see any -- I see a lot of heads nodding. So it sounds like -- very good. Cheryl?

MS. HALL: Thank you. One thing on the international issues, it says drugs that are approved for use in other countries. We also I think intended pesticides or other chemicals --

MS. FOREMAN: Yes, thank you.

MS. HALL: -- that are approved for use in other countries that are not approved for use here. When we first started the meeting of the committee, we talked about the limited resources that were available for inspection. We talked about the fact that we wanted to go to HACCP because there were other issues that needed some attention such as transportation, et cetera.

From the veterinary side, I realized there were problems with residues in certain animal categories and in

certain and particular drug categories that need to be addressed. But to take these limited resources that we discussed earlier and apply those to going back to the farm level I think is inappropriate.

Some areas need to be targeted. Some authority needs to be taken by FDA which already has authority to go to these areas that exist at the present time. And I don't think that there needs to be more authority to go to the farm level in areas that are under control with regard to residues at this time. Of course, I am speaking from the poultry industry. But we do not think it would be appropriate for USDA to target or to concentrate on the farm level in our industry. We don't have violations. We control that. We test for that. I appreciate your looking at that.

MR. BILLY: Thank you. Collette?

MS. KESTER: A quick question under education for the subcommittee to clarify, please. Under number 2, it says, "Use", blah, blah, blah, "experts to expand public understanding." What would the -- what is the understanding that you are trying to describe there?

MS. FOREMAN: The public knowledge of chemical residues in animals. And, in fact, by and large under control, it is some key areas of concern. Every time the food marketing institute has done its supermarket shoppers survey for about 25 years now, it is very consistent across the board.

This -- residues of drugs and pesticides are of very great concern to the public. We don't have any panic underway right now about that. It is then a good time to begin the discussion of is there a problem; what is being done to address the problem and expand public knowledge of this issue.

So that the next time there is a problem that breaks out, there is a little bit higher level of understanding and people are a little less frightened. I think we recognized that there is a risk there. But we thought -- I think it is fair to say that we thought that the risk involved in starting such an education program is less than the risk of wholesale panic when you do begin to find residues. And we will have another -- this will happen again.

MR. BILLY: Okay. Rosemary?

MS. MUCKLOW: To increase confidence, not to frighten consumers so that when something like the European thing blankets us again, we can tell people with a lot of confidence that we do have good programs in this country to manage the concerns and this issue, again, to give confidence, not to frighten.

MR. BILLY: Okay. All right. I appreciate that. That was really a good product of your efforts and we very much appreciate it. It is about 11:40. And what I would like to do now is terminate the meeting until 1:00. So, Katy, you have about an hour and 20 minutes.

MS. HANIGAN: Okay.

MR. BILLY: It is up to you to organize how you want to do it. You -- obviously, people could bring stuff back to this room if that would help or however you wanted to do it.

MS. HANIGAN: Okay.

MR. BILLY: Okay. Any other last minute things? We will see you all at 1:00.

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

(1:07 p.m.)

MR. BILLY: I think we will get started. What we are going to do is talk to Katy. And she is still putting the finishing touches on the revised paper. And then she would like to circulate it to her subcommittee. So I am going to insert the follow-up discussion on that between the two briefing items that are on the agenda for this afternoon.

The first briefing item is focusing on a project that has been underway for some time. And we have had past discussions with the committee and gotten advice from the committee. And what we would like to do now is to bring you up to date. To do that, Dr. Robert Post from the agency is here, as well as Dr. Rudolph Harris from the Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Pre-market Approval. I got all of it out. That's pretty good.

And what they are going to do is explain I think a fairly thick package that has been made available here and also on the table on this subject area. So, again, this is

just a briefing item to bring you up to date. So Bob.

DR. POST: Thank you. Well, I am pleased to be here to brief you on the significant progress of this agency project. I should point out that the document related to this project has been stamped draft and I will explain that a little bit later. As you recall, this project was initiated in earnest in May of 1999 when the committee recommended that the agency consider adding to the list of species that under mandatory inspection.

The agency agreed that additional species such as ratites and squab and serbiday, quail and bison should be added to those currently under mandatory inspection in order to be consistent with the USDA vision of a public health, risk-based, seamless federal and state inspection system.

In November 1999, a discussion draft of a concept paper was presented to the committee. The paper represents the first step in the process necessary to move toward legislative and regulatory modifications to add to the list of species under inspection. The committee requested that the concept paper be expanded, particularly in the areas related to the public health basis for extending inspection

to nonamenable species and on the use of nitrates.

At the last meeting of the advisory committee, I presented an updated draft of the concept paper. And the committee recommended that the paper be revised to incorporate available production data, to include recommendations using the criteria in the concept paper regarding which species to add to the list under inspection, and to expand on the statutory and regulatory changes that would be necessary to add additional species.

In addition, the committee requested that we provide a status report on the use or the issue of using nitrate and nitrate in products of exotic and nonamenable species. If you recall, last May, I mentioned that a public meeting was going to be held by the Public Health Service, DHHS, in Research Triangle Park, North Carolina shortly after the last committee meeting on the preliminary results of a study on the safety of nitrates that was conducted over a ten-year period by the National Toxicology Program.

The concept paper contains an expanded, detailed section on the use of nitrates in nonamenable species. And at the conclusion of my update, Dr. Harris of FDA's Office

of Pre-market Approval will give you a brief report of the status of this issue.

In response to the recommendations of the committee at the last meeting, I can report that the production data that were necessary to complete the cost benefits analysis were incorporated into the paper to complete that section. At the last meeting, I mentioned that we had just completed a survey of a sampling of state programs that sought information about the numbers and kinds of nonamenable species inspected and the time it takes for inspection for each type of animal in order to develop the costs of inspection. And these data are presented in Tables 3 and 4 of the paper for years 1998 and 1999.

As you recall, we were in agreement at the last meeting that the public health and food safety data were sufficient to conclude that nonamenable and exotic species appear to present health risks similar to those associated with meat and poultry products subject to mandatory inspection. However, we were still able to expand and strengthen that section of the paper with additional data on ostrich and squab that we received from a couple of

universities and from a couple of trade associations since the last meeting.

As recommended by the committee, we applied the criteria in the decision-making framework that is outlined in the paper for determining a list of exotic and nonamenable species that should be under USDA jurisdiction and, therefore, under mandatory inspection.

These criteria are that the animal and its products are used as human food. There is known microbiological risk and scientific evidence linking the species to human illness. The products of the species constitute a sufficient portion of the animal products consumed by Americans. The animals are in locations compatible with FSIS inspection. And the costs and benefits justify adding the species to the list.

I should point out that the fourth criterion, that the animals are in locations that are compatible with access to FSIS inspection, has minimal importance because the compatibility with and access to federal inspection can be accommodated fairly easily. And members of my working group learned that point in a very informative and well organized

field visit to the Texas Hill Country near San Antonio in September.

Dr. Jan and his staff were wonderful hosts of a three-tour of site visits to ranches, mobile slaughter units and processing facilities that process and handle deer, elk and quail. And these site visits were certainly helpful in strengthening the concept paper. And we thank Dr. Jan for that opportunity.

Using the criteria for determining which species should be added to the list, the concept paper recommends adding ratites, rabbits, buffalo, bison, serbiday and exotic bird species including quail, squab, pigeon and pheasant. They satisfy the criteria outlined in the paper.

In terms of the costs, the concept paper estimates that the cost to extend mandatory inspection to these nonamenable species would be about seven million dollars for the first year which includes conducting baseline microbiological and chemical residue studies and testing and, without these first-time costs, about 5.7 million dollars for the following years, primarily for inspection and compliance activities.

As I mentioned, the committee requested that we expand the information in the paper on the legislative and regulatory amendments that are necessary to add these additional species to those that are required to be inspected. As the concept paper explains, the Federal Meat Inspection Act would need to be amended to accommodate the additional species.

However, the Poultry Products Inspection Act would not need to be amended because the language is sufficiently flexible to allow for additional species. The federal meat and poultry regulations, however, would both need amendments to modify the lists of specific species that are covered. We also noted that the Egg Products Inspection Act and its implementing regulations would need amendments if we were to consider including egg products of currently nonamenable birds.

As you probably already know, some of our workload on this effort has shifted because in the Appropriations Act for 2001, Congress included appropriations for the mandatory inspection of ratites and squab. The Appropriation Act says that effective 180 days after the date of the enactment of

the Act which will be April 26, 2001, and each subsequent fiscal year, establishments in the U.S. that slaughter or process ostriches, emus, brias and squab for distribution in commerce as human food shall be subject to the ante-mortem and post-mortem inspection, re-inspection and sanitary requirements of the EPIA.

A group in the agency is currently planning the regulatory and program changes that will be necessary to handle ratites and squab. And that means we will need to work on amendments in the federal poultry products inspection regulations over the months ahead.

I should note that because the appropriations for ratites and squab came so late in the game, we could not make corrections to the concept paper in time for this meeting. And it has been stamped draft pending the appropriate revisions. We will get copies of the final version to the committee members as soon as we make the editorial changes to reflect mandatory inspection for ratites and squab.

Of course, now that we have essentially completed the concept paper, we will focus our work on the regulatory

changes for ratites and squab and subsequently use that experience to deal with the other species that we recommended for inclusion in the list of species under mandatory inspection.

And with that, I will turn to Rudy Harris from FDA to cover the issue of the status of using nitrates and nonamenable and exotic species including the recent addition of ratites and squab to the list of mandatory -- of those under mandatory inspection.

DR. HARRIS: I am, as Bob just indicated, Rudolph Harris, a team leader with the Office of Pre-market Approval in the Center for Food Safety. I have been with the agency for more than 20 years, primarily as a regulatory scientist. And as you know, the agency is under the mandate of the Federal Food Drug and Cosmetic Act and several other public health laws in carrying out its mission to assure to the consumer that the food supply is safe and wholesome for human consumption.

In 1958, Congress passed the Food Additive Amendment to the FD&C Act that provided a definition for a food additive. Under Section 201(S) of the FD&C Act, a food

additive is defined as any substance the intended use of which result directly or indirectly in its becoming a component or otherwise affecting the characteristics of food.

Now, substance added to food must be 1) generally recognized as safe, prior sanctioned or approved by specific FDA regulations based upon scientific data. Under the laws in which FDA administered, the use of sodium and potassium nitrite and nitrate is sanctioned food ingredients in the production of cured red meat products and poultry product. They are also sanctioned for us as fixative and preservative agents in the curing of red meat and poultry products.

Congress established the petitioning process for pre-market approval of food additive with the passage of the 1958 amendments, in particular, Section 409. This section provides a process for the issuance of regulation prescribing safe conditions of use of a food additive. This section also amended the food adulteration provision of the Act to deem adulterated any food that is or contains an added -- any added food ingredient that is unsafe within the meaning of Section 409.

The requirement for a petition, as outlined in Title 21, CFR, gives the ways by which one can submit a petition to the agency. We also have a web page where one can get information in terms of guidance for a petition submission. Guidelines are used to determine the chemistry of the toxicology requirement, as well as to help us determine safety.

Animal studies, as you know, are often necessary to show that the additive will not cause harmful effect at the level of human consumption. Some studies may utilize human subjects. But this is not required by the FDA. Since absolute safety cannot be determined, the agency must determine if the food additive is safe under the condition of use based upon the best scientific information and knowledge that is available.

With regard to the use of nitrites and nitrates to cure products of nonamenable exotic species, we have no current food additive regulation except for home curing that includes exotic species. The type of information that is necessary to expand the intended use condition for these products would require amending the regulation and

describing safe conditions of use.

Part 172.21 CFR permits the use of sodium nitrate and sodium nitrate for the purpose of preserving and fixing color and smoke in cured stable fish, smoke-cured salmon, smoke and cured shad so that the level of nitrite does not exceed 200 parts per million. These sections allow for the use of nitrate and nitrate for meat cured in preparation for home curing, but they do not allow for use in curing of wild game and exotic meat and poultry that are commercially prepared.

It is my understanding that the October 1958 amendments of nitrate and nitrite in meat and poultry product did not include these provisions for exotic meat and poultry. Therefore, we conclude that the regulation would need to be amended to permit these uses. This has nothing to do with the condition of safe use.

The safety concern has been raised with regard to nitrite and nitrate. At one time, the FDA proposed to revoke all nonessential uses of nitrite and nitrate because of health concerns, concern because they induce cancer. In early animal feeding studies, there was a belief that the

reaction of the residual nitrite caused a production of nitrosamines, a cancer-inducing agent.

The government has now commissioned new studies under the National Toxicology Program and a draft report has been issued which indicates that under the condition of this two-year study, there was no evidence of carcinogenic activity in male and female rats. However, there was some equivocal evidence of carcinogenic activities in one female mice-based study. Also, there was increased incidence of some hyperplasia in the male and female rats.

FDA's position is that the current evidence is not sufficient to prove that nitrite provides any unreasonable risk for its use. But there are uncertainties which prevent the agency from reaching any affirmative finding of safety for any new approval. We believe that the National Toxicology Program final report will influence any option that the agency will make in the approval of any new uses of nitrate. Thank you.

MR. BILLY: All set? Okay. Thank you very much. I would like to open it up now for any comments or questions from the committee regarding the updated draft

report and also the presentation by Dr. Harris. Rosemary and then Terry.

MS. MUCKLOW: Dr. Harris, at my age, your memory doesn't always remember everything. And sometimes it is things last week. But this was something about twenty-odd years ago. But can you tell me, how did the poultry industry overcome the Delaney Amendment to include sodium nitrate and nitrite in cured poultry products? As I remember, it was a separate step for those products to be accepted by contrast with red meat products, beef and pork which clearly had come within the prior sanction provision.

Do you have any knowledge or memory of that?

MR. HARRIS: Not really. But let me make an attempt. Now, some of the earlier studies, they did show where nitrite actually induced cancer. Now, those studies actually were not very, very good to my understanding. So some of the later studies are much better.

But in terms of the approval process in 1958, there were a number of things, as you know, that came a part or was allowed to be used because of being prior sanctioned at that particular time. So that prior sanction allowed a

number of things to be used. And they are still used.

MS. MUCKLOW: That was the red meat. But poultry was a second step as I recall because poultry -- hot dogs were -- there was a question that they were not known in 1958. There was a second step for poultry. And I am wondering -- what I am looking at and wondering is if there is some way to piggy back the new amendable species into the same process the poultry came by. I haven't done my homework and I don't remember that well enough. Does Robert -- do you have any knowledge, Robert?

DR. POST: No, I'm not aware of the circumstances. No.

MS. MUCKLOW: Well, I guess I am going to have to go back to the tombs and have a look. I've still got the Nuburn studies. If anybody would like a copy of them, I can --

MR. BILLY: Other -- let's see, Terry and then Mike.

MR. BURKHARDT: Terry Burkhardt. Concern about the legislation that now will mandate ratites and quail under federal inspection or mandatory inspection. And if I

understand it correctly then, the same would apply to states. They would be under mandatory inspection in the respective states.

The issue though is, you know, right now in the United States -- and the question would be about whether they would be limited to in-state distribute because right now you have half of the ratites according to your data slaughtered under state inspection and all -- which is 46,000 birds. And also, over 15 million pheasants that are slaughtered under state inspection.

Most of those birds or all of them now have access to the interstate commerce. Putting them under mandatory inspection in a state, would that limit them to in-state only distribution?

DR. POST: We are talking squab here and only squab, right? Because that's --

MR. BURKHARDT: Squab and ratites.

DR. POST: Right. And -- but you mentioned pheasants and --

DR. BURKHARDT: Well, I'm -- well, actually, in your listing here, you've got squab, quail and pheasant

linked together. So maybe there is a difference. My point would be right now, those birds slaughtered under state inspection have access in well established markets. By putting them under mandatory inspection if we don't get this interstate shipment legislation changed, you have allowed them to -- or you have cut their market.

DR. POST: With regard to the nitrite issues specifically or --

DR. BURKHARDT: No.

MR. BILLY: Let me help.

DR. POST: With regard --

MR. BILLY: I will help. The legislation is very specific to the ratites and squab.

DR. POST: Okay.

MR. BILLY: And it would be my interpretation subject to general counsel that now that they are under mandatory inspection, that would impact their ability to be marketed intrastate if they are inspected by state programs. So your concern is legitimate. Yes. I think that -- yes. So, anyway, we will be looking at all of those issues. We have started already. And we will be sharing information

with the states and everyone else. So we appreciate your concern.

DR. POST: In --

DEPUTY UNDER SECRETARY WILCOX: Tom, I would like to be recognized.

MR. BILLY: Yes.

DEPUTY UNDER SECRETARY WILCOX: Caren Wilcox, Deputy Under Secretary. That amendment was not endorsed or sponsored by the administration for the record.

DR. POST: If I could just also add that in the economic section of the paper, we deal with the economics issue of this and the fall-out from what is under state. So in some way, it is dealt with at least in a small part. But we will have to continue to look at it in the total setting.

MR. BURKHARDT: But also -- I just might add, also is in the states that have state inspection programs, the reason that they are slaughtered under state inspection is because the federal plants do not want to or do not have the capacity to provide that service. So, you know, they might not be able to get a place to have their birds slaughtered.

MR. BILLY: Mike?

MR. MAMMINGA: I just -- you know, this Agriculture Appropriation Bill that you speak of, we have read about it but I haven't seen it. I assume I can find it when I get on home and get on the internet or whatever. But that did -- the President has signed that?

MR. BILLY: Yes.

MR. MAMMINGA: So that is a done deal?

MR. BILLY: Yes.

MR. MAMMINGA: So now we are considering issues, as Terry has, where you hope for something long enough, you don't always know what you are going to get. It is kind of like Ms. Gump's box of chocolates, right? Understood, thank you.

MR. BILLY: Lee?

DR. JAN: I had just a question. When you mentioned that Agricultural Appropriations Bill and the ante-mortem and post-mortem inspection, I wonder if the bill specified federal inspection or did it just say ante-mortem and post-mortem inspection. And if so, state programs do have recognized ante-mortem and post-mortem inspection.

DR. POST: According to the bill language I have,

it is ante-mortem and post-mortem.

DR. JAN: So it could possibly be looked at that state ante-mortem and post-mortem inspection would be acceptable.

MR. BURKHARDT: Think out of the box.

MR. DERFLER: Well, except it specifies subject to the Poultry Products Inspection Act and it gives the 21 USC 451 rather than the Agriculture and Marketing Act.

MR. BILLY: Okay. Yes, go ahead, Lee.

DR. JAN: I had asked Dr. Harris a little bit more about the nitrite issue. I think what I got from your presentation was that FDA has no intention of changing the regulation to include the use of nitrite in the nonamenable species based on -- even following this latest report that couldn't -- apparently couldn't show or at least showed that it wasn't really a risk but at the same time, couldn't show that it was really safe to use nitrites.

I just would like to know, is there anything planned for the near future to maybe try and get a better definition or to try to get -- you know, I just get concerned that nitrites cannot be used in a meat that is not

meat by law. I mean, but when we consume it, it is still meat or it is consumed as a meat item.

And that nitrite is safe even though it is prior sanctioned. Prior sanctioned doesn't get you -- keep you from getting cancer if it truly causes cancer. So, you know, if it is truly a risk and truly causes cancer, then why do you continue allowing it in other products? And if it truly does not cause cancer or cause any health problems, then why not allow it in other products?

And I don't think you will see an increase in consumption of nitrites if you put it in other species because people aren't going to necessarily eat more meat. They just have a different variety. And so they are going to still consume and intake the same amount.

So, you know, for the industry -- and I understand that the method that FSIS -- I mean that FDA has now is -- if an industry wants a new use for any substance that is not grass, they need to come to FDA with a petition supported with scientific evidence. And that is easy to say. And it may be do-able with big industries.

But these nonamenable species producers, you can

look at the numbers, is not a great big industry, although it is a viable industry. But it is made up of many small businesses that just do not have the wherewithal, the funds or anything else to get that study that you want. So couldn't they at least be allowed to petition without that study and then let the Federal Government use their funds to do that study?

DR. HARRIS: I think that you have made a very good point. And I would answer by saying that it would be very nice if water was never murky, meaning that there is a process by which we go about doing certain things. And it also requires, like you indicated, a certain kind of resources.

The report itself, although it didn't show anything, but it is still a draft. I think that it will have some impact upon the agency. But it is a matter of how the resources and the agency eventually will address this issue. I am not in a position to offer you any definitive statement except for the fact that it is still some concern. And we don't think that it is an unreasonable one with the current uses as they are in the marketplace.

But it also, as I indicated, is not sufficient at the present time for us in terms of to make some additional things based upon how the law -- we wanted it to be as transparent as it possibly can. But it just -- the -- under the current situation, I don't see any new use. But that is not to say that it will not occur in terms of people coming in and enough people begin to work on this particular problem within the agency. I just can't give you a definitive answer.

MR. DERFLER: If I could -- Phil Derfler -- for FDA to go either way, it has got a burden that it has got to meet, either to band the use of the substance -- it would have to meet a burden because there are people that are using it based on the prior sanction. Or to list it, it has a burden, too. Right now, it feels that it can't meet either burden. So the status quo remains the same.

DR. HARRIS: I might add -- I guess all of you know that Phil has been involved with the FDA and as a lawyer for a long time. I met Phil while I was new at the time while he was at FDA. I had to add that.

MR. BILLY: You don't hold that against him, do

you?

DR. HARRIS: No, I don't hold that against him.

MR. BILLY: Nancy?

MS. DONLEY: Thank you. Nancy Donley. We -- I was on the subcommittee that worked on this particular issue. And it has come up every step along the way and it has continued coming up again that we had members of industries come and say, hey, listen, we want to be part of mandatory inspection. And so we worked with that. And it was something where the situation kind of came to us, if you will, to discuss it and to look at it and best figure out how to deal with it.

But then on the flip side of it is it saying, well, if you do this, you are going to destroy our industry or cut it in half because you are going to narrow our markets because now we are not going to be able to ship interstate or now we are not going to be able to use nitrates in it. You just -- you can't have it both ways. You have to deal with things, deal with the reality with things today. If you can't use nitrates, then don't ask to be put under mandatory inspection.

MR. BILLY: Rosemary.

MS. MUCKLOW: In all fairness to the people who wanted this provision, they thought they were getting a two-fer and they only got a one-fer because the two-fer died because it got hung up with some other stuff. And the other leg of the tree was the interstate shipping legislation.

And I think this committee's recommendations were very clear. The attachment is there. The people who put that attachment on the bill, they didn't talk to me before they did or apparently most other people in this room. I suggest they go get another attachment to another bill made quickly that will clarify that they could go interstate with this product.

Now, the nitrite issue is a different one. And I think the question has to go back to how did poultry get qualified. And they need to ride the coattails of that. And unfortunately, it is a bureaucratic process. And I sympathize with them. I have run up against bureaucratic processes in my life. I am still working on the violator list. Phil wasn't here to hear my speeches about that this morning.

But those processes are very complicated and lengthy. But I would think that the interstate shipment piece of this could be rectified fairly easily. I think the nitrite issue is a little more complicated.

MR. BILLY: Okay. All right. Thank you very much. As indicated, it is our intent to update this draft and that we will then make it available to the committee. So you can expect to see it. Okay. I would like to move on. Thank you very much. Thank you, Dr. Harris.

DR. HARRIS: Thank you.

MR. BILLY: Thanks, Robert. Okay. Katy, are you ready now?

MS. HANIGAN: We are ready.

MR. BILLY: Okay. What we are going to do now is break a little from the agenda and circle back and look at an updated and expanded version of the document that the subcommittee produced on HACCP Phase II. I believe it has been circulated to folks and -- okay. Okay. And we are making more copies. They are making copies. So for anyone in the public, it will be out on the table here momentarily.

So, Katy, why don't you lead us through a

discussion on this. And we will get a general reaction from the committee.

MR. HANIGAN: I think we'll just use the same format as this morning. We will walk through question 1 with you. And, Dr. Denton, if you would do question 2. And what we tried to do is you probably need to have your old or the original one we did this morning. We tried to keep the numbering the same. So we stayed in the same format. We just fleshed out more of the bullet points. So with that, Alice, please --

MS. JOHNSON: The question number 1 was what can industry do to improve the quality and effectiveness of their HACCP plan. And this morning, we talked about accountability and we tried to develop some principles under accountability. The first bullet point under accountability this morning was scientific. And we worded that to say in order to improve the quality and effectiveness of their HACCP plans, industry must take responsibility for the development of a validated scientific HACCP plan.

We talked about professionalism under accountability this morning. And we reworded to say the

quality and effectiveness of HACCP plans require a professional manner in implementing the HACCP plan as well as in the interaction with agency representatives. We went on to say that industry personnel must be accountable for conducting business in a professional manner. And we took the inter-company one out and I think we put it under the communication.

Under number 2, we had a topic this morning about stop fighting HACCP, common understanding. And a bullet point under that was resolving philosophical differences. Industry should seek to resolve philosophical differences in scientific and consensus forums. Industry should reach a common understanding with FSIS of the components of a quality HACCP program.

Under number 3 this morning, we talked about appropriate scientific underpinnings and a thorough reassessment. And we put under that category reassessment cannot be a pencil-pushing activity. The industry must evaluate their data, review the appropriateness of their scientific underpinning and anticipate problems by reviewing current company and industry problems. Industry problems

include recall and outbreak investigations.

And we took out under -- this morning, we had education, training and communication. And I think we took that out to just say that what applies under the role of agency would also apply under the role of the industry.

MS. HANIGAN: Dr. Denton.

DR. DENTON: Okay. Thank you, Katy. The second question that this task force had to address was what can FSIS and the states do to improve the effectiveness of their role under HACCP. The first bullet point is the agency should strive to achieve a common understanding of hazards for each processed specie.

The expanded version of that is the agency should strive to achieve a common understanding of the hazards associated with each animal specie and process utilized in plants operating under HACCP. This includes the clarification of the definition of a hazard including the distinction between a potential hazard and a hazard reasonably likely to occur.

An integral component of this issue is the role of the prerequisite programs including, but not limited to

SSOPs, SOPs and GMPs. The second bullet point identifies what is acceptable for scientific validity in a HACCP plan on a nationwide basis.

We have expanded that to include the agency should identify for all levels responsible in the agency including headquarter staff, field staff and technical service center staff as to what is acceptable for scientific validity in a HACCP plan. The goal of this activity is to ensure that the interpretation and enforcement of the HACCP regulation is being accomplished in a uniform manner across all districts in the U.S.

The third point indicated defining safe harbors. FSIS has many talented scientists and highly educated people and staff. FSIS needs to provide in their hazard guide book scientifically valid safe harbors for those hazards deemed as significant health hazards and reasonably likely to occur. These safe harbors would be voluntary.

With regard to accountability, the agency must base their regulatory decisions on scientific findings. Inspectors should utilize Omaha Technical Center to ensure scientific decision-making. Agency personnel must be

accountable for conducting business in a professional manner.

And here is a place where we modified the original outline and moved the communication component which was in number 5 up to a bullet under number 4 because we feel like it ties this together. The agency needs to strive to improve communication and congruency among headquarter staff, field staff and technical service center staff. This should address the issue of maintaining relevance in addressing new and emerging information as well as addressing the accountability issue.

Number 6, joint education and training -- pardon me. The agency should strive to conduct joint education and training including industry where feasible for FSIS employees responsible for HACCP implementation with a focus on field staff. Inclusion of headquarters and Technical Service Center staff is highly desirable as a means of ensuring continuity and uniformity in this process.

And number 7, objective and measurable evaluation tools: The agency should develop objective and measurable evaluation tools for assuring the accountability and

uniformity of HACCP implementation including performance standards and tolerances. We hope that helps.

MR. BILLY: Okay. I would be interested in reactions from the committee. Comments? Yes, Rosemary?

MS. MUCKLOW: Tom, just a minor one. I had hoped that in the joint education training and activities, that we would have had a reference to the International HACCP Alliance. Do you think it would be appropriate since they are so very much engaged in the accredited training and supported by the industry and the agency?

MR. HANIGAN: I open that I guess to the subcommittee. I didn't know that we were going to endorse, if you will, any one group. I mean, then we get into -- and I don't want to get picking associations, et cetera. But I just wonder if we should be endorsing any one group here.

MS. MUCKLOW: I don't think it is an endorsement. But they are a very knowledgeable international source of assistance and guidance that is supported by a lot of other organizations.

MR. BILLY: Caroline?

MS. SMITH DeWAAL: Thank you. I agree with Katy

on this. I think -- well, Rosemary, your endorsement, I'm sure, carries a huge amount of weight. I certainly don't feel qualified to pick one particular HACCP training group over another. And, therefore, I don't think it is within the purview of this committee to make that kind of a judgement.

MR. BILLY: Okay. Nancy?

MS. DONLEY: On this same -- Nancy Donley. On this same point of joint education and training, I just want to go on record that I can't advocate this particular position. I do and can advocate that materials be jointly shared. But I do not think that it is necessary for both industry and the regulatory agency to be jointly trained.

MR. BILLY: Okay. Phil, do you want to --

MR. DERFLER: I have a concern about accountability, the first bullet. It says, "The agency must base regulatory decisions on scientific findings. Certainly, science plays an important role in things that we do. But, I mean, our inspectors are still involved in plants making decisions on their -- a range of evidence including organoleptic findings in which the Court has told

us we have to use in the AFG case and various other types of evidence. So I guess I have a concern that this is a little too limiting.

MS. HANIGAN: In response to that, I guess when we were given the questions by Mr. Billy and we were specifically talking about improvement under HACCP, the whole foundation of HACCP is science, is it not?

MR. DERFLER: Not as necessarily a regulatory program.

MS. HANIGAN: But I think what we were trying to address here was how FSIS could improve its role under HACCP was the question we were asked to answer, improve the effectiveness of their role.

MR. DERFLER: Effectiveness, maybe. But this is a pretty broad statement.

MS. SMITH DeWAAL: Could I suggest an amendment that might make it more acceptable which is just to the extent possible or to the maximum extent possible because then it would take into account what your legal limitations are to that? Phil, would that work for you?

MR. DERFLER: That would help certainly.

MS. JOHNSON: What is appropriate under the statutes?

MS. SMITH DeWAAL: Yes, to the extent allowed under law.

MS. JOHNSON: Okay.

MR. BILLY: Another way of doing that perhaps is to say the agency should consider scientific findings in its regulatory decisions.

MS. KESTER: That would be acceptable to me.

MR. BILLY: Does that work? Nancy?

MS. DONLEY: Nancy Donley. Under point 7, objective and measurable evaluation tools, it wasn't brought up today, but it was brought up by I believe it was Caroline on -- Caroline yesterday that perhaps it is time to re-evaluate performance standards. And I would like to see here perhaps in the final clause of this sentence saying including re-evaluation of performance standards and tolerance, perhaps re-evaluation and -- what's the word I'm searching for -- re-evaluation and change of performance standards, something along those lines.

MR. BILLY: Now, where are you again? I'm sorry.

MS. DONLEY: Point 7, objective and measurable evaluation tools.

MS. HANIGAN: I don't know if we want to limit that to re-evaluation because you could have new performance standards, as well, which would not be a revision of a current.

MS. DONLEY: Say that again.

MS. HANIGAN: I would not limit that to re-evaluation of performance standards because we could have new standards which would not be considered a revision.

MS. DONLEY: Oh, so maybe re-evaluation and development of new performance standards?

MS. HANIGAN: I think that's what you are driving for.

MS. DONLEY: Yes.

MR. BILLY: Caroline.

MS. SMITH DeWAAL: Thank you, Tom. I am just a little nervous, I mean, that, you know, re-evaluation of performance standards can be construed in lots of different ways. I mean, what the goal here is that they use these tools and here are some of the tools that they need to use.

And I agree, Nancy, that they need to update their performance standards to reflect current industry practices and tolerances.

But I think that the statement as it currently -- as it is currently written is one that I am certainly more comfortable with than leaving this re-evaluation thing out there, Nancy, that -- unless we can agree to put something in regarding public health. So a re-evaluation --

MS. DONLEY: I hear what you are saying. Yes, maybe re-evaluation isn't the right term.

MR. BILLY: Okay. Terry.

MR. BURKHARDT: I just would like to comment. I am a strong advocate for joint training. We do it in our state program all the time. And for a couple of reasons. I believe that there is a better understanding from both aspects, both the industry and the agency.

This is what, you know, let's say a third party conducting training, a university or some other educational body. You get a chance to talk about the expectations and be clear about what the rules are. Your chances for success in avoiding problems down the road are much better. It just

seems to work real well in our particular setting.

And it also improves the ability to communicate things because you will have those discussions in the plant. And you do that in the classroom. And so being able to communicate is also improved by having joint training. So I am strong advocate and it does work.

MR. BILLY: Okay. Katy?

MS. HANIGAN: If you don't mind, I just want to make sure that I have, if you will, the last word because the only revision -- and I'm afraid that's what we are going to do here -- the only revision I have made on the document so far was question 2, number 4, bullet point 1, if you will: The agency should consider scientific findings in its regulatory decisions.

I think we just agreed to that. But I did not change number 7. So before this thing closes, I just want to make sure that the committee understands that is the only revision I made. And that was -- I think that was the wording that you suggested. Okay.

MR. BILLY: Okay. All right. Thank you very much. I think -- I would like to actually congratulate all

three subcommittees and obviously the full committee. As you are all aware, we have worked hard to find a better format where the subcommittees have an opportunity to really get into an issue and have a good discussion and bring it back to the committee.

And I think we have now found an approach here that works pretty well. So we very much appreciate the work that you have done and what you have developed here which will be forwarded to the Secretary and, obviously, be used as guidance by the agency in terms of addressing these issues you have focused on. So thanks again.

MS. SMITH DeWAAL: Well, thanks for making us go back and spend our lunch hour on it because it is -- it was worth it I think.

MR. BILLY: Yes. Okay. What I would like to do now is move -- let's see. We've done that. Let's go ahead and do the next item which is the -- another briefing. It is a focus on the FSIS approach to other consumer protection. It is covered under Tab 7 I believe.

And in this case, you are going to have three people from the agency that will be speaking to various

aspects of this briefing. Lynn Dickey, Charles Edwards and Loren Lange. And so I would like to now -- I'm not sure which of you will start. Okay, Charles Edwards. So, Charles.

MR. EDWARDS: I am Charles Edwards. And with me, obviously, I have Lynn Dickey and Loren Lange who are actually going to provide a really substantive portion of this briefing. What I am going to attempt to do is to do a little bit of reminding of the environment in which we are doing this work under other consumer protection activities.

As we have said, this briefing is to update you on the status of our review of the agency's approach to consumer protection activities. And we are focusing primarily on processing environments and specifically activities other than those that focus directly or indirectly on food safety and public health.

The agency has consistently emphasized that under the Federal Meat and Poultry Inspection Acts that it has a responsible not only to ensure food safety, but that it has other responsibilities with respect to consumer protection such as ensuring that products are properly marked, labeled

and packaged; that they are not economically adulterated; and that they do not contain components which while they are not unsafe, they are undesirable.

And what the agency has done is to group these assurances under the heading of other consumer protections. Obviously, the purpose of these protections is to ensure that consumers are not misled about the products that they purchase and also to maintain the integrity of markets for wholesome and unadulterated products that are properly labeled and packaged.

So it is clear that although these are not directly related to food safety, these other consumer protection activities clearly are a priority for the agency. I want to make just a few points to, again, set the setting, if you will, that we are conducting these activities.

First of all, as you know, back in 1996, the agency published its final rule on packaging reduction in HACCP. And in that rule, it emphasized that the agency has a defined strategy and that it has objectives with respect to food safety. And it had a long-term agenda in this regard. And that agenda was addressed towards reducing food

borne illnesses.

While the pathogen HACCP regulation provides the basis for a long-term agenda with respect to the use of food borne illnesses, it had very little or gave very little attention to the other consumer protections that were not food safety-related or health-related directly.

The non-safety aspects of that regulation were primarily confined to the sanitation standard operating procedures requirement that addressed product contamination when that contamination was not necessarily of a food safety nature. And the regulations did not include any reference to economic adulteration or misbranding.

FSIS initially addressed the concept of other consumer protections in a June 1997 Federal Register document on HACCP meat and poultry inspection concepts. In that document, the agency discussed its traditional inspection system and began to identify some of the barriers to the effective implementation of the packaging reduction HACCP regulation.

Some of those barriers obviously included its inspection resources. Clearly, the agency needed to ensure

that it properly and appropriately allocated its resources given the changes in inspection that were brought about by HACCP. But FSIS stated that all aspects of its traditional inspection activities will be re-evaluated, reconsidered and, as appropriate, changed in order to fulfill its statutory responsibilities.

So although it was clear that the agency needed to redistribute its resources to focus on food safety verification under the HACCP packaging reduction regulations, the agency also emphasized its commitment to not diminish its food safety achievements, but also to ensure that other consumer protections remained intact.

And we are continuing to ensure that the agency meets its responsibility in this regard. But at the same time, the agency recognizes that a new approach for assuring protections that do not necessarily or primarily involve food safety is needed. And such changes need to be consistent with the applicable principles of HACCP such as the farm-to-table strategy, a preventive approach and with the agency regulatory reform agenda.

So what Loren and Lynn are going to do is to

inform the committee about some of the recent and significant activities in this way. First of all, earlier this year, as many of you know, the agency published an advance notice of proposed rule-making to begin the public process of revising its approach to other consumer protection. And Loren is going to cover that.

MR. LANGE: Okay. Good afternoon. As Charles said, in March, the ANPR was published. And at the same time, the ANPR referred to a technical paper that has been available on the FSIS website. And I understand that the committee has received both those as handouts.

I will mention two things about sort of the NPR. First, I think the NPR lays out three sort of distinct reasons why the agency believes that it must sort of change its approach to other consumer protection activities, the first being the need to sort of clarify roles and responsibilities for FSIS and the industry.

The second is we need to use our resources far more efficiently than we do today. And the third reason was that we believe FSIS should be more accountable to the public on how it allocates its resources in the OCP area.

And we should be more accountable about making results available to inform the public on what our findings are and what our use of resources do achieve.

The ANPR identifies sort of four sort of major areas of change that we envision in the future. And the first is there will have to be revisions to FSIS regulations and certainly our directives and guidance to our inspection personnel. There will be changes in our verification activities, changes in our enforcement approaches. And finally, there will be sort of changes in how we believe industry will have to assume more responsibility for conducting activities to assure that the products comply with all of the OCP requirements.

Now, I was just going to sort of talk a little bit about the technical paper and how I think the technical paper sort of expands on what we mean by changes in responsibility and changes in verification activities and changes in enforcement because I think it sort of gives some sort of good background information to make illustrated examples of what we mean by that.

The technical paper really is sort of a

description of past FSIS inspection activities. It talks about the things inspectors did in plants to ensure compliance with OCP requirements. And we are talking about accurate labeling. We are talking about the food standards that set limits for fat and protein and added water. We are talking about nutrition labeling.

The paper also covers the -- what we call the laboratory analysis, food chemistry analysis. That's for fat, added water, protein, sodium and other nutrient contents. And the paper talks a little bit about the activities that compliance officers have conducted in the past.

It -- I think if one just sort of steps back and says what does our activity mean then, it certainly has been resource intensive in the past and it certainly has been focused on detection. I guess the strategy is -- I think when I joined the agency 20 years ago it would be described as if we look at enough product, if we analyze enough samples, if we observe enough formulations, we will assure that everybody is in compliance.

And I sort of look back at what we were doing back

then to put some things in perspective. When I came to the agency, the manual said inspectors should probably take a cooked sausage sample on every 35,000 pounds, send it to the lab for fat analysis. Well, if we did that today, I would think we would be doing 60,000 to 70,000 fat samples on sausage every year.

We were doing 15 to 20 what we call boneless meat re-inspection tasks per week in a plant. And that is a fairly resource-intensive task where the inspector, you know, collected a product of boneless manufactured meat and really sorted through it looking for bone fragments, blood clots and stuff like this. And there were criteria in the manual for pass and fail.

Just to put like that 60,000 samples a little bit in perspective in today's environment, the agency right now is in the process of sort of consolidating our food chemistry analysis in our eastern lab. We figured it's better to have one group that has sufficient resources and capability rather than a little bit left in all three labs.

And we are looking -- without adding additional resources, we think we will be able to conduct approximately

8,000 food chemistry -- or analyze 8,000 per year. That may be multiple analysis. It may be a full nutritional analysis. It may be, you know, 20,000 or 25,000 analyses, but to handle about 8,000 samples.

It is sort of curious if at the same time we put out the NCR, we propose getting rid of our PFF monitoring. And that had grown to about 7,000 samples a year. So if we were still sort of conducting that PFF monitoring product the way it was laid out in the regs., you know, we would have been using our 8,000 food chemistry samples, you know, to do all half a day.

I mentioned PFF because PFF was sort of in my mind at least, it was a move forward in some ways away from the sort of just, you know, blanket monitoring of every product in every plant because it did sort of lay out a screen that you started with, you know, a periodic sample. You got certain results. You moved to daily sampling. And if the results were even, you know, sort of worse in terms of compliance, you went to what was called a test and hold.

PFF, it is protein, fat-free. It is food standards. It is sort of, you know, set limits on the

amount of meat protein that must be in basically like the ham products and the boneless ham and ham end-products, the whole category of ham products and stuff. But it did -- it was a move away from this sort of just treat everybody the same because it sort of targeted resources.

But I guess I would just sort of conclude as I look forward is, you know, we still basically have just changed the frequency of a lot of these tasks under HACCP. And we really do need to think about what it means to target these resources, what it means to use it and where we should be conducting our samples.

And one last little anecdote. Last week, I was looking at -- I was looking at some results on the samples we took last year. And there was a -- we under the what we call PBIS HACCP, the inspection scheduling system under HACCP now. The sort of schedule sample is about one a month to take an economic sample and send it to the lab.

And in this particular plant, it was a sow slaughter plant that was making fresh pork sausage which has a fat limit of 50 percent. There was -- we looked at the sort of results. And again, we had scheduled 12 samples

with the inspector sending in about 100, about two a week.

It relates to one comment that was in the ANPR and should we really -- you know, what priority should we have on a food standard that allows 50 percent? Are consumers really -- if they are already eating fresh pork sausage that has a fat limit of 50 percent, should we have as a concern whether that product is really 51 percent or 52 percent?

And sort of the other issue is -- I will raise in terms of enforcement is if that plant really does have a problem in complying with that food standard and we need to do something about it, is taking 100 samples, you know, the way to do something about it? I think not. So with that, I am going to turn it over to Lynn Dickey who is the person that is going to talk about the comments.

The comment period on that ANPR closed in August. And she will talk about sort of what we have found from the comments to date and talk about what some of our next steps are in the area of OCP.

MS. DICKEY: Good afternoon. I am pleased to be here. I will give you a summary of our initial review of the issues addressed in the comments of the OCPANPR. A

total of 485 comments were addressed to the OCPANRP docket. However, 448 of these comments were in reference to other consumer protection and slaughter environments. And, therefore, they will be addressed by someone else within the public dialogue on the agency's HACCP-based inspection models project.

We received 31 comments that did address OCP issues in processing environments which is the subject of our briefing today. Two-thirds of the 31 relevant comments came from trade associations and consultants. And the other third came from companies, consumers and another federal agency.

In general, the comments did not address or advocate any particular strategy to deal with other consumer protections in an integrated over-arching fashion, but instead tended to address more specific OCP issues related to the commenter's particular interest. This isn't particularly surprising.

However, almost all the commentators -- commenters supported focusing the majority of the agency's resources on issues of food safety and matters that have a direct impact

on public health. Some commenters suggested that FSIS should consult with the FDA when we can't steal the people and the states -- who sometimes we steal those people, too, I guess -- to develop a coordinated approach to the management of non-food safety issues.

Many commenters also stated their agreement with the agency's emphasis on industry assuming its responsibilities for meeting OCP regulatory requirements and with agency personnel verifying that these protections are being provided. Some comments stated that the issue of quality and price value relationships are best handled through the marketplace.

Many of the comments received supported the continuation of the prior label approval system, stating that it provides necessary guidance for small and medium-size companies, although one company suggested eliminating the prior label approval system, stating that the cost of the system outweighed the benefits to consumer protection. This commenter also stated that the standards and labeling policy books should be eliminated because the system is too informal and the standards prescribed in it should go

through the rule-making process.

However, most comments did support the continuation in some instances of the expansion of the standards in labeling policy book, stating that it is an important source of product standards and its elimination would cause undue and unnecessary hardship to small and medium-size companies.

As I believe is partially supported by the variety of issues addressed in the comments we received, the agency's reassessment of its OCP activities will need to review and consider a large variety of existing agency activities as Loren also referred to. And to some extent, this work has already begun.

I want to turn now to a brief discussion of some of the ancillary agency work that is relevant to other consumer protections. In planning the activities, the agency needs to consider the relationship of its other ongoing issues and initiatives. The first of these is regulatory reform.

In 1995, FSIS began conducting a comprehensive review of its regulations to reduce regulatory burdens. The

agency's regulatory reform agenda had initially appeared as an ANPR in the December 29th, '95 Federal Register. In this document, the agency set forth its major objectives in regulatory reform, combining the meat and poultry provisions into a single set of regulations wherever possible, expressing regulatory requirements in plain language and replacing prescriptive command and control requirements with performance standards that clearly define requirements, act as catalysts for innovation and provide for a measure of accountability for achieving other consumer protections.

Since that time, a significant number of regulatory reform actions have been taken by the agency. The current consideration of revisions to FSIS's approach to OCP regulatory requirements is consistent with this program of regulatory reform. Two specific regulatory reform initiatives that are related directly to the revised approach to OCP are changes to the label approval system and the review of food standards.

In December 1995, prior label approval system final rule amended the inspection regulations by expanding the types of labeling that could be generically approved and

announcing its intention to make further changes after completing the reassessment of the prior approval system. Any changes to the current system will need to clarify and reinforce industry's responsibilities and the agency's oversight and verification role in assuring that other protections are met.

An alternative option to prior label approvals, which was considered but neither rejected nor adopted in the final rule, was to establish a system whereby virtually all label would be generically approved. Under this type of system, establishments would be authorized to use labeling without any submission to FSIS provided that the labeling complied with the conditions for approval and that establishment maintained such records as are required under the labeling regulations.

Another regulatory reform initiative that is expected to have a significant impact on the agency's OCP revisions is the review of food standards. In 1996, the agency published an ANPR requesting comments on whether to modify or eliminate specific standards or to modify its overall regulatory approach to standardized meat and poultry

products.

In December 1995, the Food and Drug Administration had published an ANPR requesting comments on similar possible changes to FDA's food standards. FSIS and FDA are now preparing a joint proposal to amend the standards of identity and composition regulations. The aim is to simplify food standards by providing a general definition of a food to ensure that consumers get what they expect when they buy a particular product without inhibiting industry innovations or reducing the usefulness of food standards to commercial training.

The results of the review of food standards and any further changes to the label approval system will bear directly on several agency OCP activities and the ways and means by which FSIS verifies industry compliance with OCP regulations. The revision of the Performance-based Inspection System also has a bearing on the revision of other consumer protections. In conjunction with the HACCP implementation, the Performance-based Inspection System was revised.

The system was updated in the revision to reflect

needed changes for HACCP, notably to eliminate any inspection activities in processing environments that were not required by regulations and to more appropriately classify inspection activities. With changes to the other consumer protection activities, additional changes to the PBIS will also need to be made.

And finally, the information derived from the new inspection and regulations models can be expected to have an impact on the revisions to OCP activities. As part of its overall strategy to reconsider how its human resources are deployed nationwide, the Work Force of the Future Initiative, FSIS is conducting model projects. For example, FSIS has initiated a small in-distribution pilot test project that will, among other things, explore the feasibility of conducting some OCP verification activities outside the plant.

Finally, I want to share with you some issues that are under consideration by the agency related to OCP revision. The first is our initial review and removal of redundant, overly prescriptive or outdated OCP requirements.

The agency envisions that within the framework of

an integrated preventative OCP approach, its revisions for assuring compliance with OCP requirements and processing environments will probably occur in phases that address the following: the identification of conditions, product characteristics or defects that are OCP concerns as opposed to food safety concerns; the development of performance standards for the OCP concerns -- food safety concerns will be addressed in HACCP plans -- and the development of procedures to verify that inspected establishments are meeting these standards.

An activity that the agency might consider undertaking prior to initiating these phases is a thorough review of current processing environment OCP regulations with the intention of removing any redundant, overly prescriptive command and control or outdated regulations that pose unnecessary regulatory obstacles.

Such an activity would be within the agency's ongoing regulatory reform initiative and consistent with the food standards reform. If a significant number of regulations were found and removed, the later work involved in distinguishing OCP from food safety matters and

developing OCP performance standards and inspections procedures would be reduced. Without a pre-review of the current OCP regulations, the agency would need to incorporate such decisions into each of the developmental phases.

The second issue under consideration is the order of OCP revisions. Following the establishment of an integrated overall conceptual framework for the agency's OCP activities, the order of proceeding with revisions to particular OCP activities will need to be determined. And several factors will have to be considered and dealt with. These factors include limiting agency resources and the high resources demand for food safety issues, consumer expectations, industry capabilities, and the interrelations among current and imminent agency issues.

The limited resources and high resource demands for food safety issues, as has been stated her several times, requires that the agency use resources available for OCP in the most efficient manner possible. With the publication of the ANPR and the analysis of the comments, the agency has begun the process of soliciting information

about consumer expectations and industry's capabilities concerning the relative order in which these activities will be revised.

MR. BILLY: Okay. I think what you have heard is some description of a very important part of the role that the agency has played traditionally and will play in the future which is those areas of consumer protection outside of food safety, the public health concerns, the proper labeling and the proper -- you know, the label reflects what is in the package and all the other types of things that were mentioned to you.

This is a large complicated area. And we have tried to just give you a flavor of the dimensions of it. It deals with regulations that apply to standards and labeling and a lot of the other activities that we have traditionally carried out. I think what is important for this committee to take away is that with the publishing of the advanced notice of propose rule-making, we have started a process and moving down a road. And we would like this committee to come along for the ride, if you will, and help us in terms of giving advice and counsel on the various aspects of this.

And perhaps what might be most useful would be to target for the next meeting a more in-depth discussion about the conceptual framework for this whole area so that all of the committee members can get their arms around the whole of the area and the sense of what is included. And then we can divide it up in some manner that we will talk through that will be -- this committee will be able to have the time to consider and then make recommendations on, as well as recognizing that we are going to proceed -- you know, that all of this involves notice and comment, rule-making and other steps as we work through this.

So with that, I would like to open it up for any questions or comment that anyone has in terms of what we have shared with you today. Yes, Mike?

MR. MAMMINGA: This probably as much as anything we will discuss has tremendous ramifications for those of us in cooperative programs because we are the communicator of these changes to another industry that is represented at this table by the people. And I think it is great. But we talk transparent and methodical and making sure that your partners know the order of business and what is going to

happen. For me to survive, that will be essential.

MR. BILLY: We agree your survival is essential.

MR. MAMMINGA: Thank you.

MR. BILLY: Nancy?

MS. DONLEY: Thank you. Just a general comment about this. Whereas this is probably not -- where food safety is certainly I think considered to be the most important priority that we all in this room should have, these areas are still important to consumers.

And I just want to say that particularly when you are looking at processing and FSIS is not there on a, you know, 24-hour basis, so to speak, that it is going to become tremendously important that the enforcement activities be very strictly dealt with and that there has to be a real effort that if there are problems, that they be dealt with swiftly by the part of FSIS. So I think enforcement in this is going to be key.

MR. BILLY: Carol?

MS. FOREMAN: Thanks. I really want to follow exactly on Nancy's point. This is Carol Tucker Foreman. And I think it is important to state at this point, I work

for Consumer Federation of America. These things are very important to us. Obviously, my concern over the years has primarily been about food safety. I want to tell you that the organization I represent cares very strongly about these other consumer protections.

There are legal requirements on the Department that you cannot walk away with without changing -- from without changing the law. There are competitive issues here, as well. If you are not going to have -- if you are not going to look at these things, then clearly people will be inclined to add a little more water to that sausage than it is legal to add to it.

I am in favor of risk-based staffing. You know my concerns about the inadequacy of the number of people that you have assigned to processing inspection. I don't think there are enough to even cover the safety issues. I think the direction to go here does require in the end, and it might help to deal with it sooner rather than later, some changes in the law.

If you are going to really have an effective change in the way you address other consumer protections,

you have to have civil penalties. I just think -- I know that you have asked for them.

But I don't see how you can effectively -- and if you can tell me how you might do it without civil penalties -- I don't see how you can expect to effectively reduce inspection resources assigned to this if you don't have a reasonable way to penalize the people who cheat. And civil penalties for those people who are sloppy as opposed to those who might be subject to a criminal action would seem to me to be a very good way to approach the problem.

Am I -- is there something wrong with what I am saying here? Is that a reasonable --

MR. BILLY: Yes. Let me comment. It is a -- exactly why the administration has expressed interest in securing civil penalties. This is a perfect example, what you have just said, of how they could be used as part of the basis for ensuring compliance with the law and regulation. So it would be a very useful tool to have to deal with this particular area.

MS. FOREMAN: I just -- if I could just add on a little bit. There are 7,200 inspectors right now.

MR. BILLY: 7,643 --

MS. FOREMAN: Thank you.

MR. BILLY: -- and a half -- no.

MS. FOREMAN: And how many of those are assigned to slaughter activities.

MR. BILLY: I don't know if I know that. There is about 2,000 assigned to processing plants.

MS. FOREMAN: Okay. You skipped over my -- I was going to make you go through them. And how many processing plants are there?

MR. BILLY: Probably about -- just federal, about 4,000 -- 4,000 to 5,000. I don't know the exact number, 4,500 maybe.

MS. FOREMAN: Some of those plants, as everybody in this room knows, are visited on a patrol basis. And that patrol I think is not based on a risk assessment. And it -- you know, we are going to raise it every single time that there is a real problem when you do not have the ability to have continuous inspection in plants that are doing things like grinding hamburger.

Caroline would like to capture some of those

staffing hours to give to food safety over at functions at FDA, as well. All of us would benefit by finding a way to enforce these provisions in a way that is less intensive in terms of staffing hours from USDA. But you can't walk away from them. And you can't have enough resources to do safety inspections and do a good job here. And the other mechanisms for enforcement just seem to be an absolute requirement. Thanks.

MR. BILLY: Okay. I think we are starting to wear you down. All right. Thank you very much for the comments. I will later when we talk about future meetings reiterate this desire to add this item to the agenda and to involve this committee as we work through this over the next couple of years.

We are now scheduled for a break. Since I have cut all your other breaks short, let's be back at 3:00 p.m. promptly. One other reminder for the public. There will be an opportunity for public comment about 4:00 or so. So anyone from the public that is interested in providing comment, I request that you register with the desk outside the room. Thank you.

(Whereupon, a brief recess was taken.)

MR. BILLY: During the break, we provided everyone a copy of a news release that I now would like to invite Dr. Woteki to address and share some insight with you in terms of this news release and what it represents. So, Dr. Woteki?

DR. WOTEKI: Thank you very much, Tom. As Tom said, there is this news release that we put out on Friday. And for those of you who are here as observers to this meeting, there are copies of this available on the table directly outside this room.

The news release announces that the Milbank Memorial Fund, which is a foundation that focuses on issues of health and public policy, is going to be convening a dialogue to examine issues of conflict and violence in the food work place, particularly focussing on issues with respect to the Food Safety and Inspection Service, the industry in which our employees are working. And also the organizations that represent the interests of our employees are all going to be invited, along with other interested parties to participate in this dialogue.

Some of you also may be aware of the fact that there was a Food Chemical News article about this topic that ran last week. And it was a little bit off the mark on some issues of fact. So I thought it would be worthwhile for all of you here to get a copy of this press release.

The dialogue is being convened under the auspices of the foundation. So it provides a venue that is quite different from this one. This advisory committee is invaluable as I said in my opening comments to you yesterday. But it is convened under the auspices of the Secretary of Agriculture.

In this case, this dialogue convened under the auspices of a foundation whose interests are in promoting good health, everyone who will be invited to participate in the dialogue by the foundation will be there as participants.

And I think that provides quite a different atmosphere for the conducting of discussions about how we can improve the way that we all work together to try to reduce the amount of conflict that surrounds the food work place and hopefully come up with some agreements about some

ways that -- some -- that these different groups can work together to try to reduce conflict in the future.

So this is provided, you know, to you for your information and also to correct the information that was provided through the Food Chemical News last week. I would be happy to answer any questions you might have.

MR. BILLY: Questions? Yes, Donna?

MS. RICHARDSON: Thanks. It is not a question. It is a comment. You may want to also access the expertise of the American Nurses Association and the Association of Occupational Health Nurses, both of whom did ground-breaking work on violence in the work place and have been instrumental in pushing OSHA to address this as a major problem.

DR. WOTEKI: Good. Thank you, Donna.

MR. BILLY: Anyone else? Okay. All right. Thank you very much. Now I will draw your attention back to the agenda. The next item is remaining issues and plans for the next meeting. As you are aware, this committee expires in late March of 2001.

At this time, we don't have a specific target date

for the next meeting. So we will have to leave that open for right now. But we will let you know as soon as we get clarification both with regard to the rechartering, the appointment of new members and the timing of that and any other related issues that will affect the scheduling of the next meeting.

Now, I would like to draw on your involvement at -- not only at this meeting, but in the past to suggest three topic areas that basically fall out of the past work of the committee and the time you have spent here in the last day and a half or so to suggest three issue areas that we might at least at this stage focus on in terms of an agenda for the next meeting.

The first would be continuing the dialogue and the input from the committee on HACCP Phase II. This is, as we have talked about, an important guidance you have given us already, some of the principles and other thoughts. We will move that ball on down the field some. But it will remain a work in progress for some time. So I think it would be useful certainly to the Department and the agency to have continuing input on that area. So I would suggest that that

would be one of the topic areas.

The second relates to the nonamenable species and the circumstance we find ourselves in in terms of the report being finalized, the Appropriation Act directing us to provide mandatory inspection for some of those species and the process we are going to have to go through to do appropriate rule-making and the other steps that are involved in making that a reality.

Again, I think the timing would be good to interact with the committee in terms of the progress that is made and any issues that we bump into regarding moving -- continuing to move forward in that area. And then the third issue area is the last one we just talked about which is this area of other consumer protections.

As I suggested earlier and I will recommend again, I think what the agency can do is to now that we have sort of set the stage and given you a sense of what we are talking about and our interests in getting the comments from you, I think we could provide a paper that would perhaps establish a conceptual framework and capture the dimensions -- the full dimensions of this and work with the committee

on that and then look at and assume sort of a step-wise process dealing with this whole area in pieces that makes sense and probably would follow logically in some sequence from one to the other.

I think that would be of tremendous benefit to the agency to get ongoing counsel and recommendations from this committee as we move forward. So there are three suggestions. I would like to now open it up for any suggestions any of the committee members have or a reaction to what I have suggested. Yes, Dale?

DR. MORSE: Dale Morse, New York. In regard to the first topic on HACCP, I think it would be interesting is -- I think is going to be interesting, Food Net data in terms of national surveillance of disease, Salmonella and Campylobacter, to eventually have that presented along with an update on the data for testing for Salmonella and Campylobacter.

MR. BILLY: Yes, that could be very timely. That data will come out of Food Net I think sometime in the March time frame. So that -- we include that as part of those discussions. Terry?

MR. BURKHARDT: Terry Burkhardt. This may tie in. But I wanted to ask you, where is the release of the Listeria monocytogenes risk assessment? Wasn't that supposed to be released soon or -- where is it?

MR. BILLY: I am tempted to say it is in the mail, but -- the -- it was receiving starting in late August very intensive review. The models had been developed. They had been run. The -- it is really a risk comparison of 20 different food commodity areas. And each of those commodity areas or groups -- commodity groups has a model associated with it, data and so forth to be used in carrying out risk assessment. It takes as I understand it 30,000 iterations of these models to complete the analysis, the risk comparison.

During the review, some of our modelers identified some glitches in the design of the model. And our modelers worked with the FDA modelers. And they figured out how to deal with these glitches. And I think it affected eight of the food categories or food group categories. So they have now gone back and they are just finishing re-running the model -- the models so that we will have all of the data

based on corrected design in at least eight instances.

Along with the models and the data from the models, the risk assessment models, there is a report that totals about 450 pages that captures all the data, provides analysis and so forth. And we are embarking on updating that report based on the new output from the various models. This is my estimate. And I am an eternal optimist.

My expectation is that we will have that -- all that work I have just described complete around the end of November. So one could expect the -- all that to come out and be made public about that time. And then there will be an opportunity for public comment on the report and the models and all aspects of it.

In the meantime, as most of you are aware, we have prepared a proposed regulation related to Listeria. And we, in fact, have completed based on the revisions our runs using the model. And our people are now incorporating the risk assessment that relates -- or assessments that relate to our product categories into that proposed rule-making as we are required to do. And then that will have to be reviewed by the Department and the Office of Management and

Budget and then moved forward.

So all these things are tied together in that way. But we will be moving -- our intent is to be moving forward. It could well be timely to consider that subject area as a potential agenda item, as well. If nothing else, perhaps a briefing although -- and I only -- maybe we could -- some of you would like to react. I am impressed with limiting the number of issues to about three and giving the subcommittees time to really get into it and come up with the kind of recommendations and so forth that we receive. So I would like to continue managing it that way.

I would be interested in any other thoughts anyone might have. Terry -- or Lee I mean.

DR. JAN: Well, I am interested in limiting it to three, as well. But I would like to at least put it on the burner somewhere or get it close to the other, the issue. And I think we have had it on before and I don't know whether we resolved it, but that retail -- I mean exemptions -- and I am not talking about like being like nonamenable species, but like is it the exemption issue where somebody is making frankfurters, they have to do it under inspection.

But if they go one more step and put it in a bun, they don't -- they can sell it without inspection. And so -- as an example, you know.

I think we need to get a handle on that exemption issue and -- you know, because I would at least like to get it back close to the other one so it may get it to the back burner and then move it forward.

MR. BILLY: Okay. We can certainly -- we will put that on the potential list, as well. Caroline?

MS. SMITH DeWAAL: I think -- I agree with you, Tom, that the limiting at three does give the subcommittees more time to really get good work done. I do think a briefing for this committee though on a series of questions that the agency is -- has hopefully pretty advanced thinking on which would include the Listeria where you've got, you know -- the President has actually asked you to do a proposed rule.

But in addition to that, the E. coli 0157:87 on non-intact meat and Campylobacter standard for poultry. So I think that those three -- I think it would be beneficial to have a briefing on each of those issues, but really at

the same time so the members of this committee can see what the thinking is and how these performance standards may be developing for the future.

MR. BILLY: Kind of quiet down at that end of the table. Any thoughts?

MS. HANIGAN: Well, I have suggestions for when the new committee meets if I could give you those.

MR. BILLY: Sure.

MS. HANIGAN: Okay.

MR. BILLY: Absolutely.

MS. HANIGAN: First of all, I just want to state my disappointment in the fact that the micro committee has not met. And the reason I want to just, you know, clearly state that is our committee sent them an issue well over a year ago which was Campylobacter. And they got back to us. And we did not feel that they had answered the question that we had asked. And we sent it back to them. And it has been a year now. And I just am really disappointed that that committee has the ability not to meet.

And I understand that they didn't meet because the Listeria reassessment was not ready. But I find it

difficult to believe that they had no other agenda items that were deemed significant enough to bring that committee together.

And then regarding the new committee -- when this new committee is developed -- and I don't want to step on anybody's toes. But I think it is important that maybe you provide a few more guidelines. And one that I would like to just suggest is it really is important that all the committee members plan on staying for the full two days and participating at night.

And I don't want to step on anybody's toes. But we really need everybody's opinion. I mean, that is why we are appointed or we agreed to sit on the committee. And I think you just need to briefly go through that with them. And then the other thing is on the subcommittees, I have chaired the subcommittee each time.

And I have always been willing to take comments from the audience in the evening if I so wish. And last night I was questioned as to why I was doing that when other chair people had said they had not. So we are not permitting that.

So I guess if it has been inappropriate for me to have done that for the last two years, I think maybe we should have some guidelines that said, you know, please don't do that. And I am not looking for a comment from anybody on that tonight. I am just saying maybe before you start again, you should go through some of that stuff with them.

MS. FOREMAN: I would like to make one comment on that because when I have chaired the subcommittee, we have been willing and, in fact, welcomed some comments from people. We have not welcomed nonmembers of the Meat and Poultry Inspection Advisory Committee to sit at the table as members of the subcommittee, but to speak so that we could take advantage of expertise that might be in the room. So at least two of the committees -- subcommittees are following that.

MS. HANIGAN: Just suggestions.

MR. BILLY: Yes. And there was an item that was mentioned yesterday that fits into this operating principles areas, as well, and that is in terms of handouts and so forth and being clear about the use of materials. So we

will follow through on that. Any other thoughts, Terry?

MR. BURKHARDT: It was really good and I appreciate your attempts to get us some material out ahead of time this time. It was -- you know, we were able to look through it. It helped our discussions later on. So that was much appreciated.

MR. BILLY: Thanks. Nancy?

MS. DONLEY: Just a couple of items of unfinished business that I had a couple of requests yesterday and perhaps they just went unnoticed or forgotten. I asked about getting the -- this is with the HIMP discussion, to get the pork -- the hog models, the traditional -- that it would be very helpful with the traditional, the HIMP and then the revised HIMP as a basis of comparison because we did get that with poultry.

And I had also asked a question saying -- a question -- oh, I'll go on with my next one first -- what about the -- are there any Salmonella performance -- or any Salmonella testing going on right now in the northern district -- Northern Dallas District? I would be -- still am interested in knowing about if there are any plants there

in the testing regime.

And then thirdly, I am left a little unclear, and I am sorry I didn't ask this question yesterday, with the redesigned HIMP. Is -- has that been -- is that in effect now or is that just still under discussion, these redesigned pilots?

MR. BILLY: Okay. Let me comment on HIMP. We will follow up on your other items and provide information to the committee.

In terms of HIMP, the HIMP project, the models project, we have taken to heart the comments that were made about the charts and the difficulty in understanding them and the other comments that were made. So we've got a group that has already started working to make changes and makes sure that we are making the right comparisons and so forth and present the data in a different way that I think will be clear and easier to understand. So once we have completed that, we will make that available to the whole committee and obviously make it -- share it with the public, as well.

We are also -- there is a couple of handouts that are on the table and have been made available to the

committee. One is the -- it was mentioned at some point yesterday the side-by-side comparison between the old -- or traditional finished product standards requirements and the new performance standards requirements under that project. So that information is available.

And also, someone asked for the RTI data from poultry. And that has also been available. That was made available some time ago at a public meeting. But we have made copies. And that is available, as well. And what our intent is is to make that available to everyone on the committee and to the public all that I have just talked about including your request regarding the pork, the hog area. And so we will follow through on that.

MR. DERFLER: Can I just make a comment?

MR. BILLY: Sure.

MR. DERFLER: There is a number of plants in which the redesigned HIMP is in place. All of it -- it will be in place in all of the I think it is 15 plants that are involved right now by November 6th. So --

MS. JOHNSON: Phil, is that in pork and growers both?

MR. DERFLER: Yes, both.

MS. JOHNSON: So you are redefining the pork.

MR. DERFLER: I think it is 14 actually, 11 and three, but yes.

MS. JOHNSON: Thank you.

MR. BILLY: Yes. Lee?

DR. JAN: I would like to let Nancy know that in north Texas, the Texas-inspected plants, we are testing for Salmonella under the program.

MS. HANIGAN: Good.

MR. BILLY: Go ahead. Phil?

MR. DERFLER: I believe we continue to test, too. It is what we do about the test results where the Court has said something, not our ability to test.

MR. BILLY: Yes.

MS. DONLEY: Well, it is not the ability to test. I just -- I recognize that not all plants are currently, you know, undergoing Salmonella testing sets. So I am just curious and just want to know if it is indeed going on.

MR. DERFLER: Yes, we are doing -- we are not changing who we are testing. And there has been no reason

so far to consider how the next goes.

MR. BILLY: Caroline?

MS. SMITH DeWAAL: I was reminded the other day that three members of this subcommittee, Carol, Nancy and I, all the consumer members, had written to the Secretary of Agriculture following the initiation of the Supreme Beef case asking that the names of plants that had failed three tests be published.

Is there any movement on that proposal because I think -- I appreciated your comments yesterday, Tom, except for one word where you say you encourage the industry to be in compliance. And I don't know what that means. But I know that we need to know if plants are not in compliance regardless of whether you can enforce the rule in one area of the country or not.

MR. BILLY: I'm just not aware of any plants right now who would meet your definition of having flunked three sets.

MS. SMITH DeWAAL: Do you not -- you don't publish the names of --

MR. BILLY: We are not aware of any plants that

have failed -- more plants that have failed three sets.

MS. SMITH DeWAAL: Well, there was at least one plant I believe after Supreme Beef.

MR. BILLY: Yes, there have been three.

MS. SMITH DeWAAL: Are you publishing -- you said three plants have failed three sets. How do you alert the public to that?

MR. BILLY: Well, it triggers the regulatory response. And we capture that in our enforcement report. And that includes the name and location and the status.

MS. SMITH DeWAAL: Okay. Well, I think it would be helpful for the public if we also got the name of that plant -- those plants.

MR. BILLY: Okay. Any other comments? Okay. I understand that -- I'm going to move on now to the public comment and then wrap up and adjourn. And I am aware of one person that has requested to provide a comment. And that is Tony Corbo who is with Public Citizen. And his comment areas will relate to other consumer protections.

MR. CORBO: Thank you. What I would like to comment on is that I have gone through and read I would say

a couple hundred of the comments that came in as a result of the proposed rule. And what struck me is that a large number of them were handwritten letters. These were not form letters. These were not pre-printed post cards that somebody just slapped a signature on.

And having worked in a Congressional office, when you get large volumes of letters, whether they are on point or off point, it would send signals to us that there is a problem out there. So I hope that in the deliberations both on the proposed rule, but on the HACCP question dealing with the slaughtering model, that those comments are taken into account because these were just ordinary citizens who sat down and took the time to send these letters in. And that is my comment.

MR. BILLY: Okay. Now, thank you very much. And I can assure you that they are and will be taken into account. We value that process very much. Okay. We might be finishing early here. I'm not sure. I don't know if I feel comfortable with that or not. Let me -- yes, too bad Rosemary left early. I would have told her she could --

I wanted to mention one other area.

Unfortunately, there are some rumors going around that I have either resigned -- one set was I resigned yesterday. Well, that is apparently not the case -- or I am out to resign or that kind of thing. None of that is true. What I have said recently is that I expect by this time next year to have shifted to a different position within the Department of Agriculture that will allow me to spend more time in focusing on my responsibilities as Chairman of Codex.

I intend to run for re-election. That election will be around the first of July of next year. And I have put on the table in Codex a Chairman's Action Plan that probably won't be a surprise to a number of you that -- where I am attempting to sort of reinvent Codex and make it work better. And I think that is a very important area, not only in terms of U.S. interests, but the interest of all the 165 countries that are part of Codex.

I don't expect anything to happen before next summer at the earliest. So -- and I am not ruling out any possibility in terms of what that alternative job might be. But it -- hopefully, what it would do is give me more time

to focus on the Codex area. This doesn't have anything to do with the election. This is something that I am interested in doing.

About that time, I will have been administrator for five years. And I think that there are very able people that I work with in the agency that will carry on the important work that FSIS is all about. So if you hear rumors that I am about resign and all that, just tell people they don't know what they are talking about. It is not true. That's a long -- a year from now is a long time.

I would like to thank each and every committee member. I appreciate very much your hard work and your commitment. It is very evident in terms of the kind of discussions we have and the recommendations that you put forward. Ron sat in on one of the subcommittee meetings. And he couldn't -- he commented to me this morning, he said I couldn't believe how hard those people were working on Halloween night and how earnest their discussions were. I'm not sure which group he sat in on, but I've got a hunch I know.

Anyway, he -- I think that is a compliment to all

of you. We very much appreciate your time and your effort. This is a valuable part of the process and one that we will continue to focus a lot of energy on. Cathy, I don't know if you would like to add any other comments?

DR. WOTEKI: Well, I think in my opening comments to the committee said many of the same things that you have just said in closing. So thank you.

MR. BILLY: Okay. We are adjourned.

(Whereupon, at 3:35 p.m. on Wednesday, November 1, 2000, the hearing in the above-entitled matter was adjourned.)

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Washington, D.C.
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November 1, 2000
Date of Hearing

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