UNITED STATES
DEPARTMENT OF AGRICULTURE

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

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Thursday,
November 4, 1999

Jefferson Room
Quality Hotel
1202 North Courthouse Road
Arlington, Virginia

The hearing in the above-entitled matter was convened, pursuant to notice, at 8:51 a.m.

APPEARANCES:

THOMAS J. BILLY, CHAIR
DON ANDERSON
CHERYL HALL
DONNA RICHARDSON
MICHAEL MAMMINGO
CAROLINE SMITH DeWAAL
MAGDI ABADIR
TERRI BURKHARDT
JAMES DENTON
COLLETTE SCHULTZ KASTER
CAROL TUCKER FOREMAN
LEE C. JAN
ALICE JOHNSON
DALE MORSE
ROSEMARY MUCKLOW
PAT STOPLER
DANIEL LaFONTAINE
NANCY DONLEY
KATHLEEN HONIGAN
GARY WEBER
KAREN HULEBAK
CAROL GREEN

APPEARANCES (CONTINUED):

MICHAEL MICCHELLI
CATHERINE WOTEKI
MARGARET O'K. GLAVIN
CAREN WILCOX
JOHN SURINA
CHRIS CHURCH
MICHAEL GRASSO
JANE ROTH
CHARLES EDWARDS
DAN ENGLEJOHN
PATRICIA STOLFA
JUDITH RIGGINS
ROBERT POST
NEAL YOUNG
JEANNIE SOMMERAUER
JILL HOLLINGSWORTH
KIM RICE
DENNIS SEXAS
KENNETH RERALSON
FELICIA NESTER
MARK MINA
JOHN McCUTCHEON
PHIL DERFLER
RON HICKS
MARLIN WALLER
JOHN ENGLEJOHN
DEL HENSEL
MARTY HOLMES

P R O C E E D I N G S

(8:51 a.m.)

CHAIRMAN BILLY: The opportunity for these companies to sell their products where they are now. So they are saying have this approach, address this possibility that you could be significantly restricting the opportunity of these folks to market. And I don't think it has anything to do with the -- maybe we could reverse the language and talk about specifically what the problem is that needs to be addressed.

MS. MUCKLOW: Might I suggest that you change the word, "marketability", to accessibility? I think the word, "marketability", may be the wrong choice or words there. And the other point that I would make is that this is a change in the law as has been mentioned several times.

Maybe this provision needs to be integrated with the other legislative initiative of the Secretary so that it can all be timed together. I have got some other comments, but that addresses that specific issue.

DR. WOTEKI: Dale?

MR. MORSE: I was just going to make some potential modifications of the wording to make it stronger on the safety/health aspects. For example, the first bullet could be something like, "We are in favor of mandatory inspection of exotic species which pose the same health

risks as currently inspected species."

The third bullet, perhaps that part of the argument could be moved down into the fourth bullet as another part of the cost benefit so that -- but I think we wanted to retain something about the safety in the third bullet, "Ensure the safety of the product in interstate and international commerce", because there was also a concern about products coming in from other countries that might not meet the same criteria.

So we wanted that to be retained someplace and then move this current, I guess, marketability -- or change to "acceptability to product" down into the fourth bullet as part of the increased detail that is going to be needed to get this through the cost benefit and the other issues, change the focus a little bit.

MS. DONLEY: Can I ask a question for clarification here? It is my understanding that the industries themselves want to be inspected. They want mandatory inspection on this. But the way that I am reading this -- and if I am reading it wrong, jump in and tell me -- but the way I am reading this is that they are saying, "We want mandatory inspection."

But they are asking -- it is asking for an immediate exception to current laws that apply that right now there is proposed legislation to move for the state-

inspected meat to go into interstate commerce. But they are asking for this immediately at the same time. So it's not asking -- it's asking for a special program, if you will, attached to this one document.

MR. MAMMINGO: That is incorrect. They have interstate commerce right now for state inspected exotics. They have international commerce if they can meet whatever criteria that another country might impose. They already have this.

What this is say, Nancy, is that if we bring down mandatory inspection upon these exotics, make them amenable to the federal statutes, then they fear that state-inspected buffalo would not longer have access to interstate commerce as it has now or state-inspected ratites could not go in interstate commerce.

So they are asking for mandatory inspection and leave the rest of the rules the same.

MS. DONLEY: But wouldn't that open up a huge Pandora's box by saying, okay, the rest of the amenable species industry is saying, "Wait a minute, if they can do it, why can't I?"

MR. MAMMINGO: Well, and then you can go to the cattle and pork industry and say, "Why can't I under state inspection?" This Pandora's box is always capable of being opened as long as there are restrictions over one part of

the team's efforts in interstate commerce which legislation has been proposed and agreed upon by this committee to address. If that comes to pass, it will be a moot question.

MS. DONLEY: Right.

MR. MAMMINGO: It is not that, but that is no guarantee that that will come to pass.

MS. DONLEY: And I guess I am suggesting that we take it in steps that -- in two steps, is take it to an amenable species and then once it is there is when the interstate legislation is passed which I think we are all reasonable sure that it will be. Then it moves right along at the same time at the same pace.

MR. MAMMINGO: I have no problem with that you have to say as long as you understand that they are saying we already have interstate commerce now.

MS. DONLEY: Right, I understand that.

MR. MAMMINGO: And this legislation could take that away for no other reason than buffalo are now an amenable species under the federal statutes and regulations. You know, they are just saying, "Okay, we will submit ourselves to mandatory inspection. Don't take anything else with it." I mean, you know, you can argue and take a stand on that issue. But the fact is that they have it now. They have interstate commerce now.

DR. WOTEKI: Caroline?

MS. SMITH DeWAAL: I would like to agree with what Dale suggested in terms of bringing the issue of food safety into the document more than it is right now. I think part of the objection about marketability is we really haven't seen much discussion in this document yet about the real principle here is a food safety principle.

So I would like to support what Dale suggested in terms of bringing food safety into the document more explicitly and moving the marketability down into the fourth bullet.

CHAIRMAN BILLY: And that would be done by in the first bullet adding language. Dale had some, but I wrote down, "Due to the public health risks", and then I put in parentheses, "(they pose the same health risks as other similar species)", or something like that. That is what you are talking about, some language like that.

MS. SMITH DeWAAL: Right. In the first bullet, and then didn't you have something in the third bullet?

MR. MORSE: Yes. I was just modifying the third bullet to, again, back the safety issue and sort of the safety of, I don't know, product in interstate and international commerce because there are concerns about the potential for international product I guess potentially entering the country if it doesn't have the same safeguards, and then move the marketability or accessibility into the

fourth bullet.

In the fourth bullet, I would also add in addition to the public health data, maybe to be more specific that public health and microbiological data. So we feel that it probably already exists in terms of culture data that documents the pathogens in these species, that that would make -- help make the public health issue because there may not be as many outbreaks associated with these species which are still small in frequency. But you certainly could document the risks through pathogens that are present.

MS. HONIGAN: I guess my thought on this, you know, when we were doing this that when we met again in six months, that Dr. Post was going to be back with our group. And really, on bullet points 1 and 2, you know, we are pretty solid on those.

But everything else, he was going to come back to the table with an update. In a year, he would have the completed paper. We would be better informed because hopefully we would have the paper ahead of the meeting and we could read it all through. And we would better understand.

So, I mean, I am not opposed to changing the language in these bullet points. Please understand that. But we are also looking for a significant update from him at the next meeting.

MS. SMITH DeWAAL: And one my concerns though is that I think it is important for us not to think about FSIS as a marketing program. I mean -- and that's -- when I see marketability in the third bullet, it -- and I think that is part of what Nancy has been reacting to.

It is like this isn't a marketing program. They may see opportunities once they have inspection to better market their products. But that is not what this is. It is a food safety program.

MS. HONIGAN: And that was never the intent of the subcommittee last night. I mean, we clearly thought that mandatory inspection should be there because of food safety reasons. Collette?

CHAIRMAN BILLY: So we were going to change "marketability" to "accessibility." I think that might be a better word. It is about access.

MS. SMITH DeWAAL: But it's access for who, Tom? I'm confused.

CHAIRMAN BILLY: For the industry. In other words, the industry, it's just what Mike just described. They currently have access to interstate commerce and foreign commerce. And the idea is that as you modify the law and develop this system, they end up with that same access. That's the issue.

In other words, it would all be under inspection

and whatever the criteria are. But they are just concerned. As business people, I can see where they are coming from. They currently have built a business that may have some of their product flowing to other countries, some of it flowing to various places in the United States.

And they are supporting -- we have heard from them, they are supporting coming under mandatory inspection. But in the process of doing that, if you shut off their markets, they may lose their business. And what have you -- you see, so it's like find an approach that among these other things also maintains their access to their current markets.

That's what they are saying. They are not about promoting the marketability or that kind of stuff. It is about dealing with the reality of their current businesses. And I think that's appropriate. I think Nancy raises an important point regarding how these things will happen.

And my sense is you are familiar with the concept paper that we have developed for interstate commerce and the process that we followed. It engaged not only this committee, but the public, you know, process where we arrived at an approach that seemed to develop a consensus. And -- but there are other parts to that process.

There is interaction between the Agency and the Secretary's Office, interaction with the Office of

Management and Budget. There is a whole process that has to occur. And so when we were talking about the process, it's that kind of process over the next, you know, six to 12 months, whatever it takes to do that.

So I think actually, Nancy, it probably will play out the way you suggested because if the bill for interstate shipment is on the Hill now, we are still working on the concept paper and have quite a lengthy process to get through to arrive at consensus. So it will probably, in fact, play out the way you suggested. I can't see this happening before the other. But whether it can catch up or not, I don't know.

MS. DONLEY: I agree with you, Tom. I just don't think we should be setting a precedent here by starting out with something and making a giant step instead of taking it in an orderly process.

MS. HONIGAN: Okay. So what if we strike bullet point 3? Is anybody in the full committee opposed to striking it completely and let it play out as Tom suggests? Bullet point 3 is the marketability of the product. Is it -- Lee?

MR. JAN: Well, I think we can't just -- I think it needs to stay there. We need to recognize that that is important. And that may not be perceived as a food safety issue or a public safety issue.

But on the other hand -- and you said don't make that precedent. We have already made that precedent when we said state-inspected product can't go into interstate commerce and that's a public safety issue. That is not a public safety issue.

So we have already set the precedent. I don't think we need to take that out and have these industries at risk of losing their ability to continue their business in the event that this interstate shipment doesn't happen. If the interstate shipment bill does not pass, that should not be a reason to not go forward with this bill. And if the interstate shipment bill doesn't make it, then I think we will have a reversal over that is supported because they can't afford to lose their business.

CHAIRMAN BILLY: And then we will not achieve our public health objective. You see, there are trade-offs here. And we may not.

MS. SMITH DeWAAL: Could I just make one further suggestion? Why -- if we know that Dr. Post is going to be coming back, why don't we just move that issue into bullet point 4 so that he is going to amend his document with more detail on the marketability -- maybe assuring the marketability of product in interstate and international commerce or something where it is -- where it makes clear that it is an issue that we want further information on as a

committee.

MS. HONIGAN: That would be fine.

MS. SMITH DeWAAL: Would that be all right?

MS. HONIGAN: Objections?

CHAIRMAN BILLY: And it would read --

MR. LaFONTAINE: I have a comment when you're -- I have another small editorial that I think we need to change. In the very first bullet, it says, "exotic species." And quoting from Dr. Post's paper in 9 CFR 352.1 -- I didn't know that off the top of my head by the way -- but exotic animals have a very definitive -- is very definitive, reindeer, elk, deer, antelope, water buffalo and bison.

My suggestion is we change that term from "exotic" to "non-amenable." That way it covers everything across the board and isn't misunderstood in the future.

MS. MUCKLOW: Thank you, Mr. Billy. I would remind you all that there is this bill that apparently Mr. Contour is going to introduce which amends the Poultry Products Inspection Act. And one of his constituents is that large producer in squab in California.

That might just be interesting to look at that and say case activity that may help people to understand the legal problems that we are struggling with because this provision and this recommendation by this committee is merely support for the Secretary to go expand the amenable

species for the Federal Meat Inspection Act and/or the Poultry Products Inspection Act.

We cannot allow -- I mean, the authority is not to us or even to the Agency or the Department under the present law to expand that which is voluntary into mandatory. I told you yesterday I was a political scientist. I also did some legal classes as part of the -- so you can call me a political legalistic scientist.

CHAIRMAN BILLY: We just need you take a HACCP course. That's what I --

MS. MUCKLOW: You're right. I've got to get that one, too, Tom. You are absolutely right. In the case of this particular company, it is quite interesting and it may help everybody to understand what we have all been talking about this morning because there are some people who are probably confused at this point.

California does not have a state inspection system like my friend to the right or Lee Jan or others. This company currently applies -- the one that got Mr. Contour to write this bill -- they currently apply and receive voluntary inspection from the USDA under the additional regulations that are available under the Federal Meat Inspection Act/Poultry Products Inspection Act.

They get a federal mark on their product to ship into state. If a state has an equal-to program that is

already inspecting the reindeer or the bison or whatever it may be and -- and you may have to help me on this one -- and there is no change -- and this change would be made in the law, that product could move or could not move interstate if it were -- couldn't' move interstate without the other piece of legislative authority.

So there is a concern that by moving the non-amenable species piece, those people would be denied access to interstate commerce which is why I suggest that the term, "marketability", which is probably stated in very good faith but isn't quite the right word, it is the access to interstate commerce. So that is the concern.

The other piece that I would like to speak to is the issue of nitrates. And, again, Robert Post may be able to tie me up in knots on this. But let me tell you my memories of the last 30 years on this subject because there is a lot of confusion as to why they can't use nitrates and what the three percent is and so on.

Currently, under the Delaney amendment to the Federal Food, Drug and Cosmetic Act, the use of nitrate which was debated very, very hotly in the 1970s in a report by a man called Dr. Newburn -- and he had a lot of rats that he fed stuff to. It was determined that there was a problem with nitrate. However, because it was in use widely in the curing of meat products prior to the Delaney amendment which

was '58 or '59, it had prior sanction for use in meat products.

Then came the turkey and the chicken hot dog. And they had to overcome the same threshold to show that, indeed, poultry products were cured with nitrites prior to the writing of the Delaney amendment. And somehow or other, they did that. And I don't -- was not intimately involved in that.

They were able to demonstrate a prior approval -- prior use before the Delaney amendment. Under the Meat Inspection Act, if a product that we want to make with using nitrates has three percent meat, it is -- or maybe it is two percent. I don't remember, Bob.

It is considered amenable to the Act. And, therefore, if you use that two or three percent, whichever it is, then you get to use nitrites with that product. If you make a pure jerky product from deer, you may not use nitrite because it doesn't have a history of prior approval pre-dating the prior amendment.

So the addition of the three percent meat makes it amenable to the Federal Meat Inspection Act and, therefore, allows -- or to the Poultry Products Inspection Act, therefore, allows you to use nitrite. I don't know if I have now confused everybody. That is my understanding.

CHAIRMAN BILLY: Let me say something more about

nitrites. I think that you are correct in the sense that the use --

MS. MUCKLOW: Say that again. I like when you say that, Mr. Billy.

CHAIRMAN BILLY: But I only think that.

UNIDENTIFIED VOICE: You only get one time.

MS. MUCKLOW: I want him to say it again.

CHAIRMAN BILLY: Another way of saying it is the meat and poultry products were grandfathered in terms of the use of nitrates. But I think --

MS. MUCKLOW: You say it more succinctly than I do.

CHAIRMAN BILLY: But I think what the larger issue though was one of the reasons there is concern about nitrites is because of the possibility, as an example, of the formation of nitrosamines which are cancer-causing. And there has been a lot of work -- a lot of studies and work to look at whether, in fact, in the various uses these types of compounds or other compounds may be forming.

There has also been a fair amount of recent work and what I understand are some pretty good studies that have been done regarding nitrites specifically and the risks associated with them. It would seem to me that this isn't just simply a matter of whether they are or they aren't grandfathered.

But I think given the public health concerns that exist, we ought to look at available science and information and take that into account in developing what is the strategy to deal with this. I mean, there are legitimate hazards that the nitrites are used for to address those hazards in the process of smoking the product or the other types of processes.

So I think we ought to do a thorough examination of this and look at the whole picture in terms of coming up with whatever the appropriate strategy is for the use of nitrites or any other similar kinds of compounds.

MS. MUCKLOW: A very creative man in the meat industry, his name is Ray McFarland. And he owns a mechanical de-boning business up in Utah, or did. He developed some years ago, quite a few years ago now, a slurry of celery and other vegetables which in his creativity, he was able to introduce into the making of bison jerky.

And that slurry of green vegetables was very high in natural nitrates which convert to nitrites. And he was able to cure product using that which was a very interesting activity. And if anybody wants to find Ray McFarland and figure out how to do that, they can.

There are other ways of getting a cured appearance and effect. And I will be glad to tell anybody about that.

You don't all want a lesson in my political sciences. But, Bob, is it two percent or three percent for amenability?

MR. POST: It is two percent or three percent or more raw.

MS. MUCKLOW: Okay. Thank you. I was right on both. I have been right twice today. Thank you.

CHAIRMAN BILLY: Yes, Rosemary -- or Lee and then Carol.

MR. JAN: I just wanted to make sure that this nitrite and amenability issue and it does -- is this point here, but that FDA is involved in the -- or you find out where FDA stands. We heard yesterday that if we make amenable -- Dr. Post told us that if we make it amenable, that that nitrite issue will go away.

But if we make it amenable now by adding three percent meat, beef or port. FDA in my understanding is not allowing -- is still not allowing the use of nitrites in non-amenables. They are now saying this is a pork sausage or this is a beef sausage or a beef or pork product with added ingredients, one of them being the non-amenable species.

So they are allowing the use of nitrites in that pork sausage or that pork product containing -- that is not amenable. So I want to be sure that that is clear with FDA.

And then on the other side of that, if these

studies that you are talking about and the new information demonstrates that nitrites are a health risk and a food safety concern, a significant one, not just that, you know, feeding tons of it to rats makes them sick, but if it makes humans sick, then we should probably move to not allow that in any product.

Otherwise, 20 years down the road, we are going to be in the same fix that the tobacco companies are. And everybody is going to be suing for their health effect. And that may not be a public health issue, again, financially, but it does relate to public health.

CHAIRMAN BILLY: Yes. Carol?

MS. TUCKER FOREMAN: I think that we are following in absolute order here because I am just going to connect to what you just said, Lee.

Just to set the historical record straight, when it appeared that Dr. Newburn had found that nitrites were in and of themselves carcinogens apart from the issue of nitrosamines, the Carter administration announced that if on review the Newburn study held up, that the administration would submit legislation to Congress asking that nitrites be prohibited from use in food products, eliminating the grandfather clause because there was no justification for continuing its use if, in fact, it was demonstrated that this was a health risk. That turned out not to be necessary

at that time.

MS. HONIGAN: My only comment was I think Dr. Post was aware last night that that would be part of your update to us at the next meeting, the nitrite issue.

MR. POST: If I could also clarify a point. Although the use of nitrite and nitrates all spoke for our prior sanction, in the FDA regulations for the use in meat, we have understood the position to be that FDA doesn't permit the use of nitrites or nitrites in the type of meat not referenced in the Federal Meat Inspection Act.

And that is where we get into the issue of if, in fact, these are amenable species, they are, in fact, in the FMIA in the future. Then will, therefore, FDA recognize them as part of the FMIA and carry that prior sanction over? And that's what we can certainly deal with over the next six months.

CHAIRMAN BILLY: Dan?

MR. LaFONTAINE: On the public health issue, as I was working this issue with your predecessor, Lauren Lang, he provided -- he had a literature research done in the National Agriculture Library. And it came out -- you know, I don't know how comprehensive it was. But it came out with two or three pages of various references of pathogens in these various species.

So I would suggest you dust that off and as a part

of your next go around, provide that to the full committee so it can show, you know, some of the papers in various scientific journals or articles that show, you know, the presence of some of these pathogens such as Salmonella and various species, and maybe even -- rather than just dust it off, go back and dig as deep as you can through whatever sources you have.

CHAIRMAN BILLY: Collette?

MS. SCHULTZ KASTER: Unlike Rosemary, I am not a political scientist. I am just a regular scientist. So maybe this is a naive question. But Dr. Post has reported that the paper would take a year to complete. And then assuming that this would go through a cumbersome legislative process and then assuming that we are doing this because there is a food safety risk associated with this topic, is there anyway to expedite the process? That is one question.

And then the second point that I have is this afternoon, we are going to discuss an inspector shortage. And that is a very real issue right now. As we think about adding additional areas that will need inspection, we will need to address that issue prior to adding the need for more inspectors.

CHAIRMAN BILLY: I think to be clear, the estimate of a year is to arrive at broad consensus on a concept paper like we did with the interstate shipment paper. So it's not

that it will just take that long to complete the paper. It is to complete the paper and share it with policy-makers at various levels in addition to the work that this committee will be doing.

So it is a process -- completing the process might be a better word where you would arrive at consensus on a paper. There are different views about the -- adding the non-amenable species. And I expect we will need a public process to sort out some of the issues that are associated with it.

I mean, it is fair enough for this committee to support -- take the position it has. But I can assure you it is not going to be a uniform agreement on that. And we need a public process to I think arrive at a consensus on a concept paper that forms the basis for legislation.

And if we are going to have a chance of achieving this, it is important that this process occurs. So it is really completing the process within that time period. If it can be sooner, fine. But I think that is a fairly realistic estimate given all that needs to be done.

MR. ABADIR: Would there be any effort to find out the number of species or non-amenable species that are not under voluntary or state programs at this time in your work with the -- ?

CHAIRMAN BILLY: In other words, like, for

example, do a survey or -- I don't know. Maybe Dan can comment on that because he was -- he has been thinking more about that area.

MR. LaFONTAINE: Let me make sure I understand the question. Was the question of how to find out what's not being inspected?

CHAIRMAN BILLY: Yes.

MR. LaFONTAINE: I don't have a good suggestion, you know. The folks that are not being inspected are not -- do not want to be public normally. And they are going to try to market their product in a somewhat clandestine way.

So I don't know of any straight-forward manner that you could do that or, you know, get that information. Just like many things, if it is out of sight, it is, in fact, out of sight and may want to stay out of sight.

MS. MUCKLOW: Could we say just quite manner and not clandestine?

MR. LaFONTAINE: Well, I don't know. Some of them are just that, at least to my --

MR. MAMMINGO: Sometimes it is easier to find out what's not being done by knowing what is being done. If it isn't being done by FSIS or the state programs or, for instance, in California that have kind of a unique thing, we can easily identify what we are doing under inspection.

So then we can say we are not doing armadillos and

giraffes and things. I mean, sometimes the process of elimination is better than doing what you are doing and say, "Well, we are not doing anything else. But we could."

CHAIRMAN BILLY: I mean, it's likely you could -- as an example, one source of information that the Food and Drug Administration uses is the business registration list that states have. But you will find often that some of these types of operations don't avail themselves to that registration process. So even the states are interested in finding them because they are avoiding other things, as well.

So it's -- we can -- maybe we can think about it and see if maybe you could sort of narrow it down and target just a limited geographic area or something and see what you might come up with. But it would be very difficult to do. And I don't know if it would be -- you know, there is a fair amount of cost that would be associated with investigating that. Any other comments or suggestions? Dan?

MR. LaFONTAINE: Can I ask that before we leave today, maybe we have an edited copy of this so we all go home with knowing what was asked based upon the discussions, whoever is going to do that?

MS. HONIGAN: Yes. I'm going to need to leave early. So, Terri, if you would make sure that you represent our subcommittee as far as getting the document changed for

us, please.

MR. POST: Do you have the draft?

UNIDENTIFIED VOICE: Excuse me?

MR. POST: Do you have the draft and the notes made?

UNIDENTIFIED VOICE: Yes.

MR. POST: Okay.

MS. SMITH DeWAAL: So I am sorry I was late. But we asked Tom Billy to write a letter to the NACMCF asking for this particular question to be put into it? Is that --

MS. HONIGAN: Yes, we went through those recommendations first.

MS. SMITH DeWAAL: Okay.

MS. HONIGAN: And in the December meeting -- well, I am assuming that Maggie was going to relay this information through Karen, that bullet point 2 is basically what we are asking for. And that Campylobacter would then be official put on this committee's next agenda.

MS. SMITH DeWAAL: All right. So the transmittal will go through Maggie and Karen, not through a letter. Is that correct or how -- I am just curious whether we responded to his --

CHAIRMAN BILLY: No, I think -- we would normally write a letter. So we would do that.

MS. SMITH DeWAAL: Okay.

CHAIRMAN BILLY: Make it formal. Okay?

MS. MUCKLOW: I move we adopted the amended recommendations of the subcommittee.

CHAIRMAN BILLY: Okay. I have a sense that there is a consensus. I see a lot of heads shaking. So I think we are there. Are there any other comments about this or --

MS. DONLEY: Can we -- a question. Can't we see what the amended thing is first? I am not comfortable agreeing to something I haven't seen.

CHAIRMAN BILLY: Okay.

MS. HONIGAN: Well, what I have reported, as Dan requested, you would see it before the end of the day. But what I have recorded, we are going to change bullet point 1, if I understand it correctly, to say, "Due to public health risk, we are in favor of mandatory inspection of non-amenable species." I think that brought in Caroline's point and Dan's, as well.

Number 2 bullet point was going to stay as shown on the paper. The third bullet point was going to be incorporated into the fourth bullet point. But where it does say, "Ensured continued marketability", we are going to take out that word and put in "accessibility." But that whole bullet point is being incorporated into number 4.

Number 4, I don't have it all written out here, but it was, "Have Dr. Post amend his document with more

detail." We had public health data. At Dale's request, we added, "and microbiological testing." Budgetary concerns, we have to incorporate these accessibility of product in interstate and international markets, etcetera.

So we are going to expand that and that is all information that Dr. Post is going to bring back to us at our next meeting. I did not think bullet points -- the remaining bullet points changed at all, that they would stay as written.

CHAIRMAN BILLY: And I think one other change was Caroline suggested using the word, "assuring", rather than "ensure."

MS. MUCKLOW: Okay.

CHAIRMAN BILLY: "Assuring", "assuring the accessibility." Okay. And one other -- Dale also mentioned in bullet 4 where it said, "interstate commerce", I think that the language he suggested was something like, "The health risks regarding" -- or, "associated with interstate and international commerce." So if we could just do something like, "Assuring accessibility and safety of product to interstate and" -- okay -- "international commerce." Okay. We are now --

MS. DONLEY: Excuse me, Tom. Tom? Sorry, this will be my last comment on this. I promise. You mentioned the word, "consensus", before. I just want to go on record

stating that I am in full support of having non-amenable species with mandatory inspection. I object to anything though that carries assurances of -- with trade issues, any attachment of marketability and trade issues involved with inspection.

CHAIRMAN BILLY: Okay. All right. We are now scheduled for a break. We will resume again at 10:00.

(Whereupon, a brief recess was taken.)

CHAIRMAN BILLY: Okay. I think we will get started again. Well, some of the folks are checking out. So I am going to provide them -- maybe we will wait two or three more minutes. Okay. I think we'll get started.

The next report is from resource allocation standing subcommittee and Lee Jan. The floor is yours.

MR. JAN: Okay. Thank you, Mr. Billy. Thank you for the opportunity for us to be able to work at night. I think we all enjoyed that. The HACCP system's in-depth review verification -- or in-depth verification review, that's what we talked about. And the subcommittee members did not receive the documents or the charge to the committee until the afternoon of the subcommittee meeting.

Therefore, we were unable to make an assessment of the appropriateness of the checklist, although at first look they do appear to be on target. We believe this type of tool is good and necessary. And as an example, it will help

in determining whether a plant's hazard analysis is a good, accurate and complete analysis.

The charge to the committee was to identify additional sources of technical information. The committee had not specific recommendations, but does recommend that interactive Agency industry HACCP group and neutral HACCP experts such as the International HACCP Alliance, certified HACCP trainers and other recognized HACCP experts.

The committee recommends the Agency considers further work on this document be scheduled, specifically obtaining input and critique from neutral HACCP experts in conjunction with the technical meetings scheduled for later this winter.

The committee is particularly interested in knowing that the questions asked in these checklists are appropriate questions. We want this to be the best possible tool for evaluating the effectiveness of HACCP plans and their implementation in the plants.

The committee did note that this present tool does not indicate whether a category is or is not acceptable. There is no space or area to indicate the acceptability of each question, area or checklist. We recommended that be included, giving more feedback to the plant.

The committee suggests that this tool be a living document in that continuous revisions are made as necessary

to improve the effectiveness of the tool, but that each provision be a final document before its use is implemented. Each revision should be made through the use of the tool in input from the reviewers, as well as results of using the tool.

Each revision should be done with the input of HACCP experts, including those outside the Agency, to ensure that the tool and, therefore, the review is fair and evaluation is valid. We want to keep in mind that the reviews are conducted to evaluate the HACCP system. The goal should be to ensure that the HACCP plans are effective and, if not, provide input to make them effective rather than a process to find fault with the plants.

However, if the plant determines -- or the review determines that there is failure of the HACCP system, immediate and appropriate regulatory action should be taken by FSIS to prevent distribution of unsafe products. The committee believes that the process of in-depth review should be an effort of cooperation, timing and coordination between the review team and plant management to reduce the time of the review, therefore making the process as efficient as possible.

We recommend that the Agency look at models from other regulatory agencies such as HCFA, the Health Care Financing Agency. They have a process that we thought might

make a model.

Before implementing the in-depth reviews, we believe it is essential that the reviewer be provided with formal training and education regarding this process. The training should include not only technique, but also a study of the supporting documents such as the '97 National Committee on Microbiological Criteria for Foods document to ensure a consistent interpretation of the meaning of the document.

The committee proposed a process for HACCP systems in that verification review as follows: First, the Agency provide the plant to be reviewed a notice and a date of the proposed review in advance. Second, the plant collects the documents required for a review and has them ready for the reviewers.

On the date of the review, the reviewers review the documents without requiring the presence of plant management. Plant management will provide working space in the plant or permit reviewers to remove the documents to an appropriate area to conduct the document review.

After the document review, the reviewer -- the reviewers interview the plant officials to discuss and ask questions regarding the findings of the document review. After that part, the reviewers will then conduct the system review portion in the plant.

An exit conference will be held with plant officials and after completion of the review and in that conference provide a preliminary report. If there are HACCP failures, immediate and appropriate regulatory action according to Sections 416 and 416 will be taken.

The Agency provides a formal written report to the plant within two weeks. The plant is given 30 days to respond formally in writing to the findings including corrective actions taken. The record -- the report then does not become available under the Freedom of Information Act until after this 30-day period has expired and the plant responsibly becomes a part of the record if the plant chooses to respond.

District managers are responsible to ensure that the plant takes appropriate correct steps to correct efficiencies identified and report to the review team or appropriate headquarter office that the deficiencies have or have not been corrected within an appropriate time frame.

And then the deficiencies are identified or determined at an appropriate time for correction and the Agency regulatory action. But it is imperative that the Agency action is consistent. That sums up what we discussed and our recommendations. So now we will open it up.

CHAIRMAN BILLY: Okay. Gary?

MR. WEBER: Gary Weber with the National

Cattlemen's Beef Association. Lee did a tremendous job in the group of pulling that information together and thinking about the dialogue we had yesterday where Mike Grasso was covering training and the HACCP models project.

What seemed to me to be something of a recommendation that you might want to consider is so often these programs are delineated and designed to find out what's wrong. And yet with HACCP and the way we are going and putting responsibility on the processors and the packers, there seems to be a unique opportunity here to identify the things that are going right and move that into the training program, move that into new HACCP model projects.

And in that context, perhaps as you look at allocating resources, those obviously where you have problems are where you need to focus on that first, but to coordinate some of these in-depth reviews with systems that you know are working well and have a focus of that, you know, why are they working well; and then as you learn that, integrate that into training and helping other people down the road.

And I think that would be an effective use of resources and not carry what could appear to be just a singular, sort of the dread of having this audit type approach, but could have the positive connotations that I am

sure, for example, evidence that things are going well. And that should be documented through this process, as well.

CHAIRMAN BILLY: Okay. Other comments? Dan?

MR. LaFONTAINE: I have two comments. Dan LaFontaine, South Carolina. In the top of the second page where we talk about, "The reviewers be provided formal training and education regarding this process", I would suggest we add one word, "audit process", because that's really what we are talking about.

And that's the kind of training that they need. And I have picked that up from, you know, one of our public speakers yesterday. That succinctly states the kind of training that they need. So that is my first suggestion.

My second suggestion, first of all, I want to compliment Lee and the group. This is quite a lot of work and very well formatted in a short time. I have one suggestion though and that is that integrated in this somewhere, the Agency needs a standardization or correlation cell, probably at the Technical Service Center or -- well, that would be an ideal place -- that provides the standardization of the reviewers.

Any audit system falls apart in a hurry. You can have the initial training. But if you don't follow it up with continuous correlation or standardization, it becomes disjointed in a matter of months. And along that line, at

least initially when these newly trained auditors do their reviews, that the initial reviews actually be looked at by this standardization cell.

Now, long-term that may be too onerous to funnel everything through a central point. But somehow, there needs to be a built in mechanism for standardization.

CHAIRMAN BILLY: Can I ask you a question? From your state program perspective, the process that is laid out here, do you feel that is something that is workable in your state?

MR. LaFONTAINE: Absolutely.

CHAIRMAN BILLY: And really, that is a question to all of the state representatives.

MR. LaFONTAINE: Let me add one thing. Tying in with your question, we did this very thing with the SSOPs. We developed an audit checklist. We trained. And I am the standardization officer in this case. So the philosophy would fit HACCP, also. Thank you.

MR. BURKHARDT: This process that is identified is these -- you know, mirrors the process that FSIS uses to evaluate state programs. It is the exact same process with introductory meeting, follow-up, so forth. So it works real well.

MS. MUCKLOW: Tom, as a member of that working group, I certainly commend the fine work that Dr. Jan has

done in chairing the session and bringing this all to us today. I simply want to underscore one of the points of discussion that we had last night that is included in here. And that is that we never lose sight that FSIS is an agency with powerful authorities for enforcement.

And there was some discussion here at the table yesterday that the document for your reviewers needs to be very fluid. We don't want to take away anything from the fluidity and the opportunity to change as they find new circumstances. That has to be done in a formal manner because the consequences of action that the Agency may take are very significant.

And, therefore, we would ask that the reviewers be using a final document. If you want to change it, you have a process to do that through your FSIS directive system. But they should not be walking around with a document marked draft. It needs to be a final document.

I think Dr. Jan will assure you that that was our collective wisdom. But being a representative of industry, I want to make sure that that point is abundantly clear.

DR. JAN: Yes, that's correct. We did talk about that. But I did want to say one other thing, too. That I did fail to put in the document that we talked about that I think is critical and we probably need to amend it.

We discussed that we felt that there was a need to

allow this training that we mentioned be available to industry and share the document with industry so that the industry is able to use this document to verify their processes and know themselves that their plan is an effective plan and they have done all the steps correctly, not in an effort to beat the system, but in an effort -- or at least what we believe this effort should be was to make sure that the HACCP plans are effective and they are working.

So we shouldn't wait until they get pulled up and it is their turn in the barrel before we find out whether or not their system is working. So we think the training should be available side-by-side for industry to learn how to do this audit process themselves. Not mandatory, but make it available.

CHAIRMAN BILLY: Nancy?

MS. DONLEY: I have a question, actually two questions, Lee, to the point that you just made about sharing with it. Is that something that is done by -- you mentioned the Health Care Financing Agency. Is that routinely how these verifications are done, that the member companies or industries are trained in what these audits do?

MR. JAN: Let me ask our person that is familiar, Donna Richardson. She is on our committee and she is the one that has had experience with those type of audits.

MS. RICHARDSON: Donna Richardson from Howard University Cancer Center. Since I am not -- since I am brand new and not familiar with the HACCP principles, I thought it was good to compare it to something that I was familiar with which was the Health Care Financing Administration's surveys when they come out to look at nursing homes and JCHO when it comes out to look at hospitals and NIH when it comes out to do research audits.

And in developing all of those materials, they work with the industry to look at what the evaluation process is going to be, how it is working. And then they also look at the systems that the particular facilities have to determine whether or not it meets the needs for the review process.

And so that's why I said, to perhaps look at areas where there are already these processes that have been proven and have gone through tremendous angst between the industry and the enforcing agencies to see what works and what doesn't work and how it can be improved upon. But in all of those, what it is supposed to be is a cooperative effort that is supposed to ensure public safety.

MS. DONLEY: Okay. And a second question I have is, is it by design or did discussion come up in the subcommittee at all -- I don't see anything in the document that was given from the Agency or in your write-up about

follow-up after these verifications. There is no -- nothing here about follow-up.

MR. JAN: We put that in number 9 --

MS. DONLEY: Oh.

MR. JAN: -- in number 9 of the process. The district managers are then responsible to assure the plant takes appropriate steps. So they would be doing the follow-up. We felt that it would be a better use of these valuable resources. They are proposing I think four or five review teams. And we've got in excess of 3,000 plants.

And rather than having those review teams coming back to do a follow-up, turn that over to the district managers who will probably be a part of the system, a part of the review anyway. They will know what the issues are. And they can then report back either to the review team or, if it is more appropriate, to whatever office in Washington to report that the recommendations or that the corrective action that the plant said they would take were, in fact, taken.

MS. DONLEY: I would suggest on that, on these checklists, that there be something on there that if corrective action should be done or follow-up action of any sort should be done, that there should be a spot for that to be indicated.

And also, and I guess one more question is on

these teams, is the plant inspector a part of that team, too, the IIC would be a part of that team?

MR. JAN: Yes.

MS. DONLEY: Okay.

CHAIRMAN BILLY: Dale?

MR. MORSE: Just a question about the audit document. As an epidemiologist, I would like to be able to analyze and evaluate information collected as part of a program review. And I assume that part of this is then computerized. But has consideration been given to having a computerized document up front?

It looks like a number of the questions have a yes/no answer so that you can sort of pull information from all these program reviews or there might be certain reviews where you have certain things you want to see whether they have done it specifically like beyond yes/no.

But if they had done this, this and that, that you would be able to get comparable data across different audit sections that then could be, you know, entered into the computer. That helps usually with standardization.

I mean, this is very user-friendly to sort of I guess the way a person would go through it. But I assume that some data from program reviews is collated. And you could make this into a combined computerized worksheet. And I guess you could even have a laptop or a computer that they

could enter it while they are there, as well.

And then you would have pooling of information that would help with training and standardization possibly. Maybe this is the wrong approach to apply that. But it seems like you would want to have information pooled on how the audits are going for the HACCP. And you could design the form.

You could also have the cover sheet go along with the steps that you have to take and make sure that there is a checklist on the front. I mean, there are things that could be done to make it computerized and standardized. But maybe this -- I don't know, some of the people that do the inspections might say that's not appropriate.

CHAIRMAN BILLY: No, that is, in fact, our intent. You know, I think the group -- the team made it clear yesterday, this is sort of hot off the press. And I think we need to take advantage of what you suggested and do that.

It is our intent to have it computerized. And our teams will have laptops available to enter the information, so -- and do some comparisons. So that is one of the things we intend to do. Rosemary?

MS. MUCKLOW: This is an audit team to make sure that the process is right. And while the team may enter in preliminary data, the great problem the government has with its great, big computer on the boat in the Potomac is that

preliminary data may be perceived to be final data. And, again, you are an enforcement agency.

And so as long as preliminary data is assembled and corrected and you only use it to guide you in the process as you are going through this, but the final stuff is for real. I have no problem with you using preliminary data to help, like the low voltage lights in my garden, you know. I mean, they are not really strong enough to read a book by. But they do help people from breaking their neck on moving rocks and so on.

As long as it is recognized that what you receive would be preliminary data subject to maybe reinterpretation or a different understanding -- because we are going to find out in the HACCP system is predicated on the fact that the HACCP program is the plant's program. And it isn't written to a standard predictable command and control system. And so there are going to be differences.

IBP's slaughter system is likely to be different from XL's. We just need to understand that there are going to be different and reasonable differences between different HACCP systems.

CHAIRMAN BILLY: You triggered another thought. One of the things we learned in our reviews of foreign country systems and one example that pops into my head is New Zealand. And there is a representative here I believe.

They have set up a very extensive audit program for their plants. And it is a centralized unit that carries out these audits. And they audit both the plants and in effect their own inspection processes.

And we avail ourselves of that information. And it really helps us in our review of a foreign country program because you have got access to all this audit data which you can analyze in various ways. And sometimes it will help steer you in certain directions in terms of managing your time while you are in the country to focus on the right areas.

So other countries are looking to us to similarly have audit information available as it relates to HACCP and so forth. So one of the purposes for this sort of down the road is to enable us to help foreign countries that are auditing our system have access to data and summaries and so forth that will be helpful, as well.

So it has multiple purposes. It is not just about the specifics of a given plant situation, but our whole system and how well it is working.

MS. MUCKLOW: Again, if I might just come back to speak to that issue and back in the first page in his report, Lee made reference to the fact that there are organizations. And, in fact, your Agency always has a representative attend the meetings of the International

HACCP Alliance.

And the Alliance is also in the process of developing audit processes because there are firms out there who don't want to wait for your auditors. They are pretty well right.

And so the coordination and correlation between the people who are the experts -- and I gave them free commercials yesterday. I don't want to go through them again today. But they are here in the audience again today. It is really important that we have that kind of discussion and work together because they need to be including what is important to you and you need to be hearing what is important to them as you develop the process.

CHAIRMAN BILLY: Yes. Caroline?

MS. SMITH DeWAAL: I think the Department needs to be cautious though in utilizing experts which have a particular industry bias. And we -- while we discussed the issue of experts last night, we would like the experts to be in the Agency and to provide the unbiased viewpoints as opposed to relying on experts who have a specific industry mandate.

CHAIRMAN BILLY: Okay. Any other thoughts on this? Yes, Mike?

MR. MAMMINGO: From the perspective of a small program, I can't say how essential it is that this auditing

process be developed and put in place and be validated as to being correct. Otherwise, as is a pitfall for those of us who are regulators, the process of the audit becomes the point of contention versus the results of the audit which is a benefit to the consumers and the industry and to us.

So I think this is really great, a great place to start. But for my purposes, let's make sure that this audit is proper and correct so that we don't have to fight a lot of battles over the process of the audit versus the findings of the audit.

CHAIRMAN BILLY: Okay. Anyone else? So what I heard in addition to what was on the paper is that it needs to be amended to add the points -- the following points: That the training should also be made available to the industry. That's one of the points.

Second is that we ought to find a way to identify what is going right in terms of the audits of plant systems and document them and incorporate it or integrate it into information that has been made available, as well as our training programs, to use the results of the audits, particularly those that are turning out well, and add that as examples under the training program.

And then another point that we needed to add was we ought to have or add a standardization unit that would establish and maintain correlation. And another one is that

changes to the documents should be done formally through the directives process or based on -- similar to -- to a process similar to the directives process.

And then finally, that the -- we need to ensure that the questionnaires and forms are in a format that lends themselves to entering the data into a computer to allow for both collation and analysis. I don't know if I've missed anything or not. I think I captured it all.

Oh, yes. And a one-word addition in the top of page two, the first paragraph there, "Training and education regarding the audit process." That's right. Lee, does that sound --

MR. JAN: I think those are the points that I picked up.

CHAIRMAN BILLY: Okay.

MR. JAN: And we will make those changes.

CHAIRMAN BILLY: So we will incorporate those changes as appropriate into the paper. And with that, I have a sense that there is support for these recommendations and moving forward? All the heads are nodding. Okay. Good. All right. Thank you very much.

Okay. The next and final committee report is from the Intergovernment Roles Standing Subcommittee. And Dan, you have the floor.

MR. LaFONTAINE: First of all, a special thanks to

some folks that helped us with this, Dr. Dan Englejohn and his colleagues from FSIS. And also I should note that Tom Schwartz from the FDA participated last evening. And that was extremely valuable for this topic.

The first topic that we discussed was reinforcing the food code by adopting key food safety provisions as federal performance standards. Before we started formulating our conclusions, we had to spend quite a bit of time sorting out what the idea or what the question was. And as we went through this, we came to the conclusion that what we were concentrating on was uniform federal performance standards for food safety. And so with that thought in mind, let me go through our comments and recommendations.

Our subcommittee supports the concept of developing federal performance standards for critical food safety factors as they relate to meat and poultry products. This will establish a national baseline -- national baselines that all federal, state and local regulatory agencies can adopt in a uniform manner.

The second point we wanted to make is these standards will provide a pathway for industry to develop validated alternate processing methods to meet the performance standards or, for regulators, to evaluate a variance to the standard which does occur periodically. So

you have a baseline that you can work from for an alternate procedure or to evaluate a variance.

The committee also felt very strong that it is important to retain, if they currently exist, or to develop some prescriptive procedures -- I call them safe harbors -- that small entities can follow if they do not have the technical expertise to develop their own procedures.

And I might embellish small entities being meat and poultry processors, but also looking at the entire chain. It could be the smaller restaurants or food service establishments or institutions that need a take-home menu, for the lack of a better word, of how to do that -- to cook that piece of meat for example.

And then we thought out of the box a little bit and thought about how can we make this visible to everybody and not bury it somewhere. And I don't know if it is possible, but we recommended one final -- one federal rule be developed for each performance standard that applies to both FSIS and FDA-regulated entities, the idea being if it can be done in the rule-making, it's here is where you go for the rule or how to cook roast beef or how to cook meat patties be it at a restaurant or large plant and not let it be hidden in some document that is not readily visible.

So that is a summary of our thoughts on this subject.

CHAIRMAN BILLY: Carol?

MS. TUCKER FOREMAN: Thank you. Carol Tucker Foreman with Consumer Federation. I would feel a lot more comfortable with this if we could convey somewhere in it that these are minimum performance standards. You could accomplish that by putting the word, "minimum", between "uniform" and "federal."

But because you have -- especially because you have in the second paragraph an ability for regulators to evaluate a variance and because the federal meat and poultry laws are preemptive, I wouldn't like to have any sort of communication or have this used in a way that prohibited states from going beyond the federal standard.

CHAIRMAN BILLY: Where did you suggest adding --

MS. TUCKER FOREMAN: Well, I thought in that very first line there, "Subcommittee supports the concept of developing minimum federal performance standards", or there was another place where it had -- yes, that would --

MS. DONLEY: Or should it be "federal minimum performance standards?" Yes.

MS. TUCKER FOREMAN: Thank you. That's fine. Thank you. That's more accurate. I just want it to be understood, this is a floor and not a ceiling.

MR. LaFONTAINE: That's certainly a good suggestion. And we -- performance standards implies

minimum. But it is certainly good to make that clear that that's what you are talking about.

CHAIRMAN BILLY: Okay. Caroline?

MS. SMITH DeWAAL: Does the committee -- or does the subcommittee see these performance standards as an alternative to the adoption of the food code?

MR. LaFONTAINE: No. Well, yes and no. What -- that was -- the first part of the discussion was, you know, the whole business of the food code and making it as a federal regulation. And if we walk through that, what we have to divide is standards versus enforcement.

And what we concentrated on was uniform national standards for critical food safety items. That's what this paper is about. And we decided that right or wrong, that the whole business of what the regulators -- what the regulators use or not use the food code, the whole enforcement issue was not the question being asked at this particular subcommittee.

So we set it aside and dealt with the issue facing us. That does not mean that that is not an important issue. But it was not the one that we tackled.

MS. SMITH DeWAAL: My other question -- and then I think I want to go back to that for a minute. But my other question is what do we mean by "key food safety provisions" and "critical food safety factors?" What are we talking

about? I mean --

MR. LaFONTAINE: Okay.

MS. SMITH DeWAAL: -- are we talking about cooking? Are we talking about refrigeration? What are we talking about?

MR. LaFONTAINE: We are talking about cooking. We are talking about cooling. We are talking about maintaining proper temperatures. I use the word, "critical", on purpose, tying it somewhat to critical control points, although I didn't say that when I wrote this.

It is those things that if they are reasonably likely to occur could cause a food safety hazard. So cooking, cooling, temperature control, concentrate on those as performance standards.

MS. SMITH DeWAAL: And I am all for that.

MR. LaFONTAINE: Okay.

MS. SMITH DeWAAL: My -- but I guess what I am wondering is -- and having been in a lot of discussions of layering, are we reinventing the wheel here? Are we -- aren't there already cooking and cooling standards that apply to most entities?

Are we putting in an alternate vehicle for states to adopt rather than adopting the food code because then we will have some states with the food code and some states with these federal performance standards which means there

will be less uniformity? I'm just wondering what we are doing and why we -- why do we need this.

MR. LaFONTAINE: Let's go back to the basis of why it was presented by Dr. Englejohn and others. What we have now is a fair amount of -- or some inconsistencies between the regulatory agencies as far as some of these critical hazards and critical food safety factors.

And this is a -- as I understand it, a strategy on the part of FSIS and I assume FDA to have some uniform federal standards that everybody can hang their hat on from the federal, state and local level.

Back to your question of additions. This will not be an addition. If there is an existing FSIS or federal standard that applies to a certain type of process, these new final rules would replace those. It would not be any layering that I see.

MS. SMITH DeWAAL: I am concerned that -- I like, by the way, number 4 which is the single rule. But the reality is that we have two different food safety agencies. And they do at times develop slightly different standards. Usually the standards are directed towards different entities.

So a cooked roast beef company will have a different -- a performance standard or a five log reduction whereas a restaurant may be specifically instructed with

time-temperature parameters. But I -- I mean, I am concerned -- these are FSIS regulations. And you are attempting to impact FDA regulations.

And what I have seen is that where there are differences, the agencies have actually gone to the National Advisory Committee on Micro Criteria for Foods. And they've fought it out there. And the Micro Committee comes back and says, "Well, this is what we recommend." And the agencies do whatever they want anyway.

So the -- I am just concerned that I am not sure this adds anything. It just puts another set of standards in place where we should already have some standards anyway that are just going to further confuse an area which is already really messy.

MR. LaFONTAINE: I disagree with you.

MS. SMITH DeWAAL: Okay.

MR. LaFONTAINE: I think this does exactly what you are suggesting; that it takes the separate rule-making and the separate past regardless of what the National Micro Committee says, and says, "We are going down the same path with a final rule that will be the national standard on critical items."

It sets the template or the baseline that everybody can use and everybody can look to and says if we follow this, whether it be a producer or a food service

entity, we have something that is solid scientifically. We can hang our hat on it. And everybody is performing it in the same way. That's what this says.

MS. SMITH DeWAAL: Is there any evidence that the standards which -- well, I will withdraw that question. How does the subcommittee anticipate them doing this joint rule? I mean, how do we really know how the agencies operate? I mean, are we anticipating rule-making here? What are we really -- maybe we should clarify that.

MR. LaFONTAINE: That's what I anticipate. But I should defer to the Agency to answer the question how you would orchestrate this.

CHAIRMAN BILLY: Well, we could -- they could be joint or separate rules that would apply the same standard to all the different entities that are regulated. So it could be a jointly signed rule or they could be separate rules published on the same day, setting the same standard across the board.

I would like to come back to your question to satisfy you and think about that while I make some comments. I mean, I think we ought to talk a little bit about what the realities are right now in terms of the food code. And I have to say right off the bat, I'm not up to date.

So I don't know if Tom Schwartz is here or anyone, but my understanding is that with the creation of the first

food code I think it was back in '93, there was -- an effort was then made to get the states to adopt it. And it's now been about six years later.

So we are on the order of about ten states that have adopted it. We have another 20 states or so that are working to adopt some version of the code. Some are still working on the '93 version and haven't completed the process and are missing out on significant changes that were made from the '93 to the '95 version. Some states are working -- of those 20 or so are working to adopt the '95 version. There is a '97 version and now a '99 version that was just published.

Summing all that up, there are quite a number of states that haven't adopted any version of the food code. The risks, as we talked about earlier, whether you are roasting beef or cooking chicken in a big plant somewhere under FSIS inspection or doing it in a store or doing it in a nursing home, the risks are the same.

And it seems to me that given the factual situation, it does make some sense to pull from the food code the key food safety standards that FSIS and FDA and others have worked hard to incorporate into various parts of the food code, to take those standards and establish them as national standards, uniform standards as suggested here.

My view is that I don't think it is going to have

any impact at all on the rate of adoption of the food code or whether states adopt the food code or not. The food code is a very comprehensive document. And I know there are those that have suggested that the food code in its entirety be adopted as a federal regulation.

I would like to see that happen given the rules we now operate under. There are hundreds of pages of prescriptive regulations, none of which have an economic justification established. You would -- if you started now, you might in 20 or 30 years achieve an objective like that. I think it's a little naive to presume that you could do that.

But what you can do for public health is pull the key food safety provisions and adopt them separately as federal standards so that whether a state adopts the code or not or they are adopting the '93 code and it is 1999, the federal standards would preempt and establish the minimum that has to be met regardless of the type of operation that it is.

So I think that's sort of what is intended here, is to move -- advance the food safety provisions and make them uniform and consistent across the board to address the food safety problems.

MS. SMITH DeWAAL: That's very helpful to see kind of what your vision is. My question still is though that --

I mean, do you anticipate these standards would then preempt and be enforceable in every restaurant around the country or -- I mean, the problem with the food code in part is it is the states, the local governments and the county governments that actually enforce the food code. So it's got to be adopted on multiple levels on the state level.

Do you anticipate that then -- you know, this might be a very exciting approach, to have an alternative where they could just adopt by reference a set of rules that provide cooking, cooling, refrigeration, hot holding standards. But I'm just --

CHAIRMAN BILLY: Let me --

MS. SMITH DeWAAL: -- I mean, do you see this as enforceable or is it just another document that we are going to fight to get the states to adopt?

CHAIRMAN BILLY: Many state and local entities -- I don't know of a percentage; someone might know -- have a regulation or a law in the books that automatically accepts and applies federal regulations once they are in place.

MS. SMITH DeWAAL: Okay.

CHAIRMAN BILLY: And so for many states and local entities, it would become an automatic process. So it wouldn't even -- they wouldn't even have to do anything other than the next time they publish their rules, they would cite the new citation for the new federal standard in

what we are talking about.

Others have to do -- take specific action. And in some states, it is the legislature that actually does it. So there is all variations on a theme. But nonetheless, whether they adopt it or not, it's the applicable standard that has to be met.

And I think through the efforts of state and federal agencies and others to provide training -- we have got a joint training activity for local regulatory officials in this area we are talking about. And it would afford us an opportunity to emphasize what the federal standards are as part of that training. And others could do that, as well.

So I think it would just advance this whole process. And at least as it relates to food safety, you would have these standards as reference documents, adopted or being worked on by the states. And the rest of the food code, some of it is advisory. Some of it is just reference information.

I think it is good to encourage states to continue to work to adopt the code in its entirety. But that rarely happens. And in the case of the food safety standards, there wouldn't be an option. They do preempt and they are the standards that have to be met.

MS. SMITH DeWAAL: And you would do this in one

rule or one point.

CHAIRMAN BILLY: Yes.

MS. SMITH DeWAAL: It wouldn't be mixed all over in the Federal Register or in the Meat Act or whatever. It would be a package of performance standards.

CHAIRMAN BILLY: That's what we've talked about. But, you know, that still has to be designed. I don't know exactly how we would do that. There has been some discussion with FDA about that.

MS. SMITH DeWAAL: Okay. I think it is important -- and then I will stop -- that -- first of all, with this explanation, I support what the subcommittee has done here because I have a much better understanding of it now.

I would recommend that it be in one -- that the regulations, including the performance standards and safe harbors, be accessible at one point in the Federal -- in the CFR or at two points if it is being done where FDA and USDA are both adopting them.

I also really strongly like the concept of one federal rule, as I also support the concept of one federal food safety agency because it gets -- I mean, this is just an example of the quagmire that we have when we are trying to regulate the same hazard in food all the way down the chain from the federal government to the restaurant we are going to eat in at lunchtime. So thank you for giving me

the time.

CHAIRMAN BILLY: Cathy would like to add a point, then Mike.

DR. WOTEKI: Yes. I thought I understood the concept until Caroline's clarifications. Let me ask a question both of Caroline and of Tom.

I had understood from the paper and from the discussion so far and from the subcommittee's report, my inference from all of this was that the food code did provide the safe harbor because of the greater specificity that is in the food code than what would be in the performance standards of what would be published.

And Caroline's qualification leads to a different conclusion that there would yet need to be a third set of regulations providing those safe harbors for the small entities. Is that correct?

MR. LaFONTAINE: Let me answer that question and then we will go on. What we are saying is there will need to be minimum performance standards that are uniform across that everyone can use. And that may be you must prove that you can do a five log reduction of X organism for X item. Having said that, in that same rule, we need -- if there exists or does not exist, provide a safe harbor.

For those folks who do not have the expertise in their type of business to provide those kind of validations

so that there is -- the committee felt very strong that, hey, we have got to put something there also that says, "This is a procedure you can use to maintain or create safe meat or poultry."

So we are looking at a package deal where you can accommodate -- or have a performance standard that can be used by those who have the expertise, but also a home remedy, for the lack of a better word, that everyone can look to that says, "This is also a national standard that if I do this, I am maintaining food safety."

CHAIRMAN BILLY: Let me add to that. Currently, and in the recent past in fact, FSIS has not been successful in an approach that would both establish a performance standard and include in the same rule a safe harbor-type prescriptive example or way of doing it. OMD has not accepted that kind of approach.

So the alternative that we have chosen is to issue Agency guidance that normally takes the existing prescriptive formula out of the regulations that we are changing and puts it into the guidance document, and then making a commitment that we will maintain that guidance document and in some instances add other options, as well.

It would be an alternative to use the food code as what would be the prescriptive examples. In many instances, that is what is in the food code now. In some instances

though, the standard that we would establish might require us to circle back and go through the food code process to get the food code changed to make it consistent with the performance standards because there is room for further improvement of the food code.

So there are some options there. But I think while it may be the interest of Dan and perhaps the committee to have them both in the federal regulation, I am forewarning that the likelihood of that happening that way is not very great.

MS. SMITH DeWAAL: Can I just add though that there has been one change since perhaps you had that experience. And that is with the juice HACCP regulation where they put a really nifty performance standard in, but most of the cider manufacturers really don't know what it means.

When we are dealing with small businesses, it is real nice to say get a five log reduction. But the reality is for when we are dealing with small entities, it is helpful to them to say, "Hey, dummy, pasteurize." You know, "Achieve a five log reduction" is really nice language, but it's just simply not very meaningful. And I think OMD perhaps needs to be educated on that. So I like Dan's approach.

CHAIRMAN BILLY: Yes. Mike?

MR. MAMMINGO: I just think that we don't want to have any false expectations here of what we were asked to do or what this product is.

We were asked -- FSIS would like to go to the model food code -- it is not a regulation now, it is a model -- to extract from that food safety -- critical food safety information regarding meat and poultry to make it a part of a federal performance standard in FSIS which will be under Title 9.

Part 303 in Title 9 exempts the restaurants, the grocery stores from everything except adulteration, misbranding and for time control. It doesn't exempt them from that.

CHAIRMAN BILLY: And these standards.

MR. MAMMINGO: Okay. Say that again.

CHAIRMAN BILLY: There is a provision in both the laws that allows us to establish national standards for -- as they would apply to meat and poultry products across the board.

MR. MAMMINGO: Understood.

CHAIRMAN BILLY: The exemption applies to whether we can enforce or not. So when we're not --

MR. MAMMINGO: That was my next thing. And you said it before me. The expectation -- and I have no such expectation.

I think it is a grand idea because no matter what has happened anywhere else in government, in the relationship between FSIS and FDA, this is at least an extension of the hand from FSIS to FDA in saying let's take these things and make it a part of our FSIS performance standard under the meat and poultry regulations because it is good and it provides guidance for people at any level. From the small restaurant to the giant packer, it provides guidance.

But if there is an expectation here that suddenly enforcement is going to change at the restaurant and the grocery store, then you better put that out of your mind because that is not going to happen as a result of this. Isn't that correct? From any practical standpoint --

CHAIRMAN BILLY: Not from FSIS.

MR. MAMMINGO: Unless you get a mandate from Congress and a few zillion dollars, they are not going to rush out to all of these places. And that is the only thing that I want everybody to understand, was we have and expressed and discussed many concerns about do grocery stores and do restaurants know how to cook hamburgers or not. This is not going to fix that. And it is not going to codify FDA and FSIS requirements.

What we are doing -- and it seems fairly simple. You are going to another agency that has responsibilities in

food including meat and poultry, taking some critical elements of their model, and incorporating it into federal performance standards.

And while you always have the authority under the federal statutes to reach out to meat and poultry at the retail store and in commerce, this is not an enforcement vehicle to suddenly change what you are doing. Is that correct?

CHAIRMAN BILLY: Yes.

MR. MAMMINGO: Okay. In that respect, it's kind of hard to argue about this.

MS. DONLEY: If I can jump in, I was on this particular subcommittee. And I want to thank everyone in that subcommittee for being exceedingly patient with me because I needed a tremendous education in this subject. And I was the one who was really thinking this could be the greatest thing since sliced bread because now we will be having things cooked safe, prepared safely and correctly all the way down through the line.

I was brought back to reality and told that we can't get to that point from here. We just -- it just can't be done. But our hope was and the intention is that it will be something maybe that the states can wrap their arms around a little bit easier than a whole food code, that we can make some differences somewhere on a limited basis, that

peer pressure among states might further bring others along into it.

And I still have a problem in my head of why can't we just -- why can't government just say, "Hey, listen, this is the way it has got to be done and the only way that it should be done because it is the safe way to be done." And I just, again, want to thank the subcommittee for being very patient. And I started out by just saying we should just adopt the whole doggone thing. And I guess this is the best way that we are going to be able to do it.

CHAIRMAN BILLY: Yes. Rosemary?

MS. MUCKLOW: I come from an industry that can't understand why restaurants don't have to cook their hamburgers. I do remember when we were at the Hyatt a couple of several meetings ago, I suggested Dr. Woteki go to the kitchen and talk to the chef there because he wasn't cooking the hamburgers right.

We have all become extraordinarily frustrated at the obfuscation that this issue has had in the handling of the food code. And you make it more clear today that they are even more obfuscated than I even thought they were in that some of them were discussing one version of the code and there are four versions since 1993. And we've still got restaurants out there that don't understand the importance and value of cooking hamburger properly.

This I think gives us a benchmark. And it is something we can do rather as -- rather than just sit around and be continually frustrated about what we can't do. We can set a standard, a performance standard. It is a beacon in an otherwise murky future. I think it is the right thing to do and I commend the work of the subcommittee in addressing this issue.

Obviously, the cooking of hamburger is one of the major ones. The cooking of roast beef is also very, very important. We had illnesses associated with that 20 years ago. I just think it is absolutely the right way to go. And I commend Dr. LaFontaine for guiding the process to bring this document back.

CHAIRMAN BILLY: Dan?

MR. LaFONTAINE: I need to go back to the safe harbors issue one more time. First of all, I recognize that I don't know -- I know very little about federal rule-making. And I acknowledge that to get a prescriptive requirement in may be close to impossible.

My point is this, and I am going to play a little mind game. On January 6th of this year, FSIS published a final rule that regulates the cooking, the heat lethality, and the cooling of roast beef, corn beef, certain poultry products, etcetera. That is in the rule and it is clear.

They also kept safe harbors and they put those in

a separate document. I would guess there is very few people in this room that can tell you where to find those safe harbors. I happen to know because I have a reason to dig real deep.

My point is, and it goes back to what Caroline said, they get lost in the quagmire. And if there is any way you can figure out to put the safe harbors with the same visibility as the final rule, do it. Otherwise, you are just kidding yourself if you say you are going to put it somewhere else and everybody can find it. That is my only point.

I realize the difficulty you have. But it has to have uniform visibility or broad visibility for lack of a better word. Thanks for listening to me.

CHAIRMAN BILLY: Yes. To be clear, I am not encouraging or recommending that the committee change their recommendation in that regard. I am just sharing with you what our recent experiences have been. The fact that we have such a recommendation from the committee will enable us to perhaps try once again. Yes, Magdi?

MR. ABADIR: I have a question on point. In the first line when you talk about critical food safety factors, this is a very open definition of that. Can we specify, are we talking about cooking and cooling or are we talking about critical areas that can be controlled? Because this is too

wide to leave like that.

MR. LaFONTAINE: I will repeat what I said earlier. We are talking about those things that are critical -- those things that are very important to maintaining -- creating or maintaining a safe food: heating or a lethality step, cooling to prevent the growth of pathogens subsequent to cooking, and the maintenance of temperature whether it be a raw or a fully cooked item.

That is the kind of items, the same type of things that would have a reasonable likelihood of being identified as critical control points. That's where we should concentrate first. And that's why I used the word, "critical", kind of tying it into potential critical control points.

CHAIRMAN BILLY: Would -- if we substituted for "factors" the words, "process control measures", that would read then, "Critical food safety process control measures." Does that make it clearer?

MR. LaFONTAINE: Are you suggesting critical food --

CHAIRMAN BILLY: Food safety process control measures. Those are all parts of the process as you describe them.

MR. LaFONTAINE: Yes, and to go a step further, Nancy just handed me, "Such as including cooking, cooling,

temperature maintenance", give some examples if that's okay with everyone. I will make those editorials and get those to Mike. And we can print this out again this afternoon.

CHAIRMAN BILLY: Good.

DR. WOTEKI: Can I --

CHAIRMAN BILLY: Sure.

DR. WOTEKI: -- I would like to ask a question again to the subcommittee and I guess also to the full committee. As this is drafted, this report, it has a title. And the title is actually I think the purpose for the report. Would it be possible to amend this to actually have that as a statement of purpose as opposed to a title? Because I think it really then -- the rest of it flows.

And it begins to address the question that I wanted clarified earlier, as well. Because as I understand it, the intent is to not set up a competing process for the food code, rather to reinforce the food code and provide some additional incentives to states to adopt the most recent, up-to-date versions of the food code.

MR. LaFONTAINE: I certainly agree with what you are saying. I will have to listen again what you are actually suggesting.

DR. WOTEKI: Well, I -- my suggestion for discussion is that the title of this paper, "Reinforcing the Food Code by Adopting Key Food Safety Provisions as Federal

Performance Standards" --

MR. LaFONTAINE: That should be the entry sentence basically?

DR. WOTEKI: Yes, it be stated as, "The purpose for the following recommendations is to reinforce the food code."

MR. LaFONTAINE: Yes. I certainly agree with that if everyone else does.

CHAIRMAN BILLY: Caroline?

MS. SMITH DeWAAL: We also should note for the record, but also it might be appropriate to add something to this. That it's very important if you do this that you update them as science becomes available showing they are out of date because it is always great to have a new set of performance standards. But five years down the line, they may be out of sink with what the science is.

And so the commitment here has got to be to not only develop them, but to update them as appropriate to meet the best scientific knowledge.

CHAIRMAN BILLY: Rosemary?

MS. MUCKLOW: Again, I feel sometimes that I am a historian.

CHAIRMAN BILLY: You are.

MS. MUCKLOW: But when Carol Foreman was Assistant Secretary of Agriculture and there were illnesses from roast

beef, under her administration, an emergency regulation was published. It is one of the rare occasions when this Agency published an emergency regulation for the cooking of roast beef to assure the safety of product.

This Agency has the authority as new science becomes available even to take instant action which it does very rarely. Carol was absolutely right to require that. And it then forced a revisiting. And then a more formal process and a better regulation was ultimately adopted for the cooking of roast beef. But there was an emergency need at that time.

So those vehicles do exist in the regulatory process to make those kind of changes as science becomes available.

MS. SMITH DeWAAL: So could we add just a clause to it to make sure that updating it is part of our recommendation?

MS. MUCKLOW: I don't think that's necessary. I think it happens anyway.

MS. TUCKER FOREMAN: I am not sure it could happen today with the regulatory burdens, the burdens that are placed on the Agency with regard to risk assessment, development and cost benefit analysis. I don't think you can do anything quickly anymore, although I am going to urge you to on Listeria.

CHAIRMAN BILLY: I think it is an important point about that to work in here somewhere that the performance standards be updated consistent with new science or some language like that. I think that's a good idea.

MR. LaFONTAINE: Give me one second here. Let me read back to the committee what I have captured. And then we will move on to the next subject if that's okay. Following -- or using Dr. Woteki's suggestion, I have written a new introductory sentence. And it says, "The subcommittee endorses a concept of reinforcing the food code by adopting key food safety provisions as federal performance standards." Is that what you had in mind?

Okay. And then we go on with the rest of this, "The subcommittee supports the concept of developing minimum performance standards for critical food safety process control measures such as cooking, cooling and temperature control as they relate to meat and poultry products."

And then there is one additional one which I haven't put in yet, would be your suggestion about that the standards be updated as new science evolves. So I need to integrate that. I will put this together with Mike and we can re-do it and hand it out this afternoon if that's okay. Any other comments? Mr. Chairman, are you read to move on?

CHAIRMAN BILLY: Yes, sir.

MR. LaFONTAINE: All right. We had double-duty

last night. We had two topics. So we worked well into the night. Not really, but it did take a while to air the subjects.

The second subject we were given was the topic of regulatory reform. And once again, the FSIS folks were quite helpful in explaining this topic, Ms. Tucker, Mr. Englejohn and others. Once again, kind of as an introductory comment, we had to talk in general quite a bit to make sure we knew what was being talked about and what FSIS was asking us to do. Even though we had the questions in front of us, we needed further explanation.

After that preliminary discussion, what we came up with is the following statement on regulatory reform: "Using transparent and methodical rule-making with opportunities for interested parties to work cooperatively towards the objective, particularly on those that are identified as new regulatory agencies, for example, transportation" -- so in essence, we are saying be as transparent, as open and as methodical as you can to get all parties concerned to the table, just what you have been doing on many of these rules.

And we used transportation as an example because that is going to be a tremendous challenge to pull that off. Another one that we didn't mention here would be the cooling requirements for meat and poultry which are

nonexistent on meat and hidden so to speak on poultry. So we are saying be prepared for a very transparent and methodical path.

Number 2: "Incorporate scientific data and cite sources to support the rules as they are proposed." In other words, when you come out with a proposed rule, put up front all of the scientific data and references that you can. So when people start coming to the table, they have got something that they have had a chance to dig into.

Three, and it somewhat repeats the first one, but, "Make the process very public and make available in advance information on the subject to facilitate discussions in public meetings." We keep harping on this, but it is -- it just doesn't work when you come to this committee or to a hearing and you've got a handout that's five pages or ten pages. You are really lost in trying to make constructive comments.

Four: "Regulations should strive to improve food safety. Standards for one species should not be decreased in the interest of making them the same for the other species." I guess another way to say that, yes, there needs to be a level playing field. But don't compromise food safety on one species just in the interest of making them equal. I think you know what we are talking about on that.

And finally, "Gather as much economic data on the

benefits to support the cost of the regulations." We realize that's something you have to do as a part of your process. But Dr. Englejohn explained that is the probably the most difficult part of his rule-making process, is getting useful -- getting information, especially useful information, on the economic cost benefit analysis.

So that's a summary of our five recommendations on how you handle this regulatory reform issue.

CHAIRMAN BILLY: One suggestion that I would make is -- picks up on the suggestion that Cathy made earlier regarding the previous recommendations. Maybe we could take the title and turn it into a --

MR. LaFONTAINE: Sure.

CHAIRMAN BILLY: -- a sentence and join it with number 1, which would be something like, and I don't want to put words in the committee's mouth. So we would have to sort this out. But, "The committee supports continuing regulatory reform," and then add that to the first item or something like that. That might -- something like --

MR. LaFONTAINE: I can do that if there is no objection from anyone else or from the committee.

CHAIRMAN BILLY: And then these are sort of other qualifications as I understand it. Yes, Caroline?

MS. SMITH DeWAAL: I didn't sit in this part of the subcommittee meeting last night. But, I mean, we are

having a real problem with the Agency's willingness to move forward on needed, urgently needed public health regulations because they claim they don't have the risk assessment.

And I notice that in number 5, you say, "Gather the economic data on benefits." But is there some statement the committee could support on urging the Agency to move forward on regulations -- or not to wait on urgent public health issues for -- to complete lengthy risk assessments, but to move forward with available public health data? Because we frequently feel they have the data. We know the impact of some of these.

But they are waiting for these very lengthy joint risk assessments with -- you know, that multiple agencies and numerous committees are involved with instead of moving forward. So I want to get a sense of the committee because that is something that could I think strengthen significantly this recommendation.

MR. LaFONTAINE: I'll speak for myself personally, and this is not speaking for the subcommittee. The scientific way to evaluate the risk is -- to evaluate the food safety impact is a risk assessment. And I personally don't feel comfortable backing away from that.

MS. SMITH DeWAAL: Well, and we don't -- we support risk assessment. The issue is it shouldn't stand in the way of protecting public health. And, in fact, it

appears to be doing that today.

MR. LaFONTAINE: But you can't have it both ways. You can't support risk assessment and say, by the way, forget about risk assessment when I have -- make an empirical judgement that this is a food safety hazard and we can't wait. So either you buy into it or you don't.

MS. SMITH DeWAAL: They can target risk assessments to -- for example, I mean, they are not doing a risk assessment on Listeria in ready-to-eat meat products. They are doing a risk -- a very broad risk assessment dealing with all types of food products including frozen ice cream.

And that risk assessment, while it may be valuable, is not -- we don't need the answers to all those questions to get the information they need to fulfill their risk assessment requirements for rule-making on ready-to-eat meat products. So what I would like to do is to add language that says that risk assessments should be -- that risk assessment should be targeted to address -- should be targeted so that they don't delay urgently -- or rule-making on public health matters.

MR. LaFONTAINE: I had the privilege to sit in on a briefing in San Diego, the U.S. Animal Health Association meeting on the current on Listeria. The status of the current Listeria risk assessment by a gentleman from FDA,

they are doing it right. They have USDA, FDA, all parties concerned, they are doing a comprehensive review because just as important as maybe the ready-to-eat products is the soft cheeses on the FDA side.

And we criticize frequently that we've got one agency going off in one direction and another one in another. They are looking at it in a comprehensive way, very rapidly set aside some of the low risk item such, as you mentioned, frozen deserts, and finding out for the high risk products what is the risk and how do we -- you know, what risk do we assign to them.

So you've got to let the process do it properly and not jump in and tackle one entity and leave the rest behind. So I will just shut up. I think they're doing it right and they are working vigorously at it and making some good progress.

MS. DONLEY: Earlier this week, a plane went down. And hundreds of people were killed. And you better believe the FAA is moving as we speak on reevaluating and looking at putting in additional regulations or they are examining everything.

We shouldn't have to wait for planes to go down and we shouldn't have to wait for people to be getting sick and die from eating foods. We recognize a problem. And we shouldn't have to let the bodies pile up while we are

scrambling to accumulate data to support what is obviously -- regulations that are obviously needed.

So maybe for the purposes of this, could we put into some sort of language the need for, well, emergency -- an emergency response of some -- and I hate to do that. I hate the thought that we have to have the disaster first and then respond. But in this particular case, while we are waiting for this very comprehensive risk assessment to be completed, we've got a very identified segment that needs to be addressed immediately.

So I am just thinking out loud here. Is there something we can put together that says in a crisis situation, that we need to move forward immediately with regulations and get something moving while risk assessments are being -- while it is in process, while the risk assessment is in process? Is that kind of, Caroline, where you are coming from, the rest of the committee, Mike?

CHAIRMAN BILLY: Okay. Well, let's start here and work our way around. Collette?

MS. SCHULTZ KASTER: One of the benefits of risk assessment is that in the process you try to identify interventions and you weigh out the risk of something occurring against your ability to control that. And just the same as the airplane example, we have no idea why that plane crashed. There is a million reasons.

There is a million things that could go wrong with an airplane, just as in a biological system whether it is the bacteria or the meat supply or the dairy supply. There is a million things that can go wrong.

Science cannot just go out and blindly start to try to identify all of the things that can go wrong with the system. Therefore, we need to look at things that have taken place, identify what broke down in the system, use risk assessment, and then come up with interventions and regulations in that order.

And I support doing it in that order, even though unfortunately it takes longer than any of us want to -- nobody is comfortable with the situation, whether it is regulatory, consumers or industry. I mean, if this was the Nancy Donley Meat Plant, you would feel in a panic even though you had a vested interest in continuing your business. So nobody is comfortable with the time frame, but it is a good scientific process. And we need to support that.

CHAIRMAN BILLY: Jim?

MR. DENTON: I totally agree with what Dan and Collette are saying. One of the issues that we face, despite the fact that we think that what we are dealing with here in this particular committee with meat and poultry products are the most important things in the world, when we

look at a properly conducted risk assessment, we have to look at the entire food supply.

As Dan very eloquently stated earlier, we are trying to go about this in the most appropriate manner to identify those very critical issues in all foods to make sure that when we take the approach of trying to implement regulations, that they are being done in the most prioritized manner that we can possibly do that.

I think that if we divert or diverge from the systematic process, it leads us to make very poor decisions in many cases. I share the same concerns that both Caroline and Nancy share. I just happen to believe that there is a very systematic methodology that we have to use in order to arrive at valid conclusions.

CHAIRMAN BILLY: Okay. Caroline?

MS. SMITH DeWAAL: I think Mike was first and then I am.

CHAIRMAN BILLY: Okay. Mike?

MR. MAMMINGO: Move it on.

CHAIRMAN BILLY: Who wants the last words?

MS. SMITH DeWAAL: Anytime.

CHAIRMAN BILLY: Oh, no.

MS. SMITH DeWAAL: These aren't speculative risks. This isn't something that is going to happen in the future. We had an outbreak a year ago, almost a -- it was happening

actually a year ago right now that documented a significant gap in the system.

This isn't potential hazards. This isn't anticipating a plane going down in the future. It is reacting to the plane having already gone down.

What we learned yesterday during this session is that after a rule clears the Agency, there is still at least a five-month time period for it to clear the rest of government, for it to clear the USDA and then OMD. So whatever day they start, you have to -- and whatever comment period, whatever process they go through, we are talking about a multi-year process.

My concern here is that a year after this outbreak, we have no evidence from the Agency that they are moving forward with rule-making. And their rationale is, "We can't" -- "We don't have a risk assessment."

We know what the risks are. CDC just last month published another report documenting what the risks are. Listeria is responsible for about a quarter of the deaths from known causes in the food supply from foodborne illnesses. It's about a quarter of the deaths. And this is a very significant hazard.

We know there are gaps. We know how to fill those gaps. I mean, companies are already testing. We heard that yesterday. I know NFPA recommends testing. I know the

government recommends testing. But nobody is requiring it. And, in fact, the food lawyers for ten years have been telling companies not to test.

And we need to fix this problem. We can't wait for them to analyze every possible food source for Listeria and put them on some kind of list. We already know what the food is that's at the top of the list. And we would like to figure out how to get FSIS to understand the urgency.

The language I am proposing simply says, "Risk assessments should be targeted so as to not delay rule-making on public health matters", so that we -- the Agency understands that they shouldn't wait. They should move forward. If this risk assessment the FDA is in charge of isn't moving forward in a way that is going to facilitate their rule-making, then they should do a more targeted rule-making to facilitate it.

So I would like the committee's opinion on whether we could add language that simply says, "Risk assessments should be targeted so as to not delay rule-making on public health matters", so that we're not in this situation where we are sitting around waiting for a risk assessment that really isn't going to answer the questions that they need answered to proceed with their rule.

CHAIRMAN BILLY: Carol?

MS. TUCKER FOREMAN: Yes. I'm sorry. Mike, you

go right ahead.

CHAIRMAN BILLY: Oh, I'm sorry, Mike.

MR. MAMMINGO: That's all right.

CHAIRMAN BILLY: I thought you wanted the last word. No, go ahead, Mike.

MR. MAMMINGO: Oh, I just would like to reiterate what I said yesterday. Our friends, the scientists, you cannot take them away from their discipline of risk assessment. You can't change that. You can't abbreviate it. And what we are talking about here is really two things.

You are talking about a methodical, disciplined approach to risk assessment and what my friends at the table are concerned about has to do with the legal and political and policy issues of doing something because you think it needs to be done.

I think Carol did that with her roast beef thing. I was out there in the sticks when that came to pass. She decided she was going to do something. And she was willing to stand up in front of God and everybody and fight it out with them even if it went to court.

And those of us that have been in court a time or two know that the courts are sympathetic to protecting the public health. And even if you don't have a chapter and verse rule but you can show you have taken an action to

protect the public health from a real hazard, the courts have been sympathetic with that.

Now, that's -- and then fortunately -- or fortunately, the fact of life is in your position and in mine and those of the rest of us that are regulators, we are confronted with situations that we have to make decisions on. Are we going to take the scientific, methodical, disciplined approach to address a problem over time or are we going to take action right now, this minute because we think we are compelled to by our conscience and by what we know to be a fact?

And then, are we willing to stand up in front of God and everybody and take the heat for it? In that respect -- we kind of beat that term, "risk assessment", up an awful lot because as, you know, there are risk assessments about playing golf when it is lightning, and then there are risk assessments that we need to do to determine what the effect or what the possibilities of a hazard are over time and what's appropriate to do scientifically to address that.

I have no problem with being on the hot seat. And you certainly don't either. We can't escape it. But I think we have two different issues here involving this fine phrase of "risk assessment." What you are asking for is what, for example, Carol did. That is aside from this process called risk assessment.

And I don't have any advice for you, sir. That's just the straw you've drawn in this business, to listen to your constituents and determine when you are willing to go out on a limb whether you have a specific rule behind you or not to demand something. And I guess that's about all I have to say about that.

CHAIRMAN BILLY: Carol?

MS. TUCKER FOREMAN: Well, you said it so well that I really hesitate to say anything more. I just think, you know, balance, balance, balance. You have to balance the industry and the scientist's need to have as close to the final answer, the best possible data against our need.

We are going to eat three times a day, please. We've got to do it every day. We've got to have the best protection that we can have based on the best information that we have at a point where you need to take action. And it is never the final answer in science.

And part of this is you've got to be prepared to say, "Geez, you know, we were wrong about that one and we are going to fix it now." Caroline I think is asking for a balanced amendment to this recommendation. She is not asking you to throw out risk assessment, but to target it so that you move this process as quickly as possible.

My last comment on everything that we get into on this discussion is that meat and poultry products are

different from all the other food out there. They come to the public with an imprimatur of safety placed there by the United States Government. I think it is an additional responsibility on the government to act expeditiously to do everything possible to make sure that they are, in fact, safe.

You know what, sometimes that is going to place an unnecessary burden on the industry. And it is the trade-off for having your "Inspected and Approved" U.S. Department of Agriculture sign on there.

CHAIRMAN BILLY: Okay. I have some suggested wording for number 5 that I thought maybe I would put out and maybe you can think about it while we get some additional comments. I will read it twice so you can get -- sort of capture it.

And it would be, "The Agency is encouraged to anticipate the need for risk assessments and cost benefit analyses and gather scientific and economic data to support the timely development of regulations." I will read it once again. "The Agency is encouraged to anticipate the need for risk assessments and cost benefit analyses and gather scientific and economic data to support the timely development of regulations."

MS. TUCKER FOREMAN: Tom?

CHAIRMAN BILLY: Yes.

MS. TUCKER FOREMAN: I don't think that quite does it because I don't think you could have anticipated the problem with Listeria monocytogenes. There are a lot of ones that we could have anticipated, but I am not sure this is one of them.

And I don't disagree with it, but I don't think it is enough in this instance becomes sometimes -- you know, I think Caroline's suggestion goes more to the point of target the risk analysis to get the fastest possible action that is reasonable.

CHAIRMAN BILLY: Dale?

MR. MORSE: I guess I think there has to be a mechanism for some kind of emergency rule-making. I just think in terms of our state basis, if we didn't have that availability, just the two outbreaks this fall with the E. coli, over 1,000 cases and linked to an unchlorinated water supply and then finding out there were six other county fairs that have the same systems with some of them having events the next couple of weeks.

If we didn't have the mechanism for emergency -- if we had to go through a risk assessment to see what those water supplies, were they potentially safe or with the West Nile, if we had to go through the risk assessment to evaluate the spring and for mosquitoes, then no action would have been taken.

So at certainly the state level, I can't imagine an agency without the ability to take some emergency responses, even though they may not be perfect. And then we modify it since I think the Agency needs to have the availability of some kind of emergency response basis, an interim -- even though then you can modify it through the risk assessment, I don't see them as mutually exclusive. I think you have to have both capabilities.

So I think there are times you have to go ahead and act quite dramatically on the science available at that time. And then you improve it with the risk assessment later on.

MS. TUCKER FOREMAN: The Administrative Procedures Act has provisions for emergency action. Have you ever considered invoking the emergency provisions with regard to Listeria?

CHAIRMAN BILLY: I don't believe we have had a specific review of that done by general counsel. There has been some limited discussion in the Agency about that possibility, not just with regard to Listeria, but to deal with some other problems, as well.

A compounding factor is the change -- the USDA Reorganization Act which requires cost benefit analysis for -- including risk assessment for rules. And so the question is there is sort of a legal issue there that would have to

get sorted out in terms of whether that overrides or affects the provisions in the Act you mentioned.

MS. TUCKER FOREMAN: I would be really surprised. And I think that is worth finding out just for information. There is no emergency provision in the USDA Reorganization Act?

CHAIRMAN BILLY: I'm pretty sure there is no.

DR. WOTEKI: I would like to ask a question for clarification. We started out this discussion about the regulatory reforms that the Agency has underway. And this set of recommendations addresses those regulatory requirements.

We have spent quite a bit of time talking about Listeria and the adequacy or the inadequacy of the Agency's response to the outbreak a year ago. In the materials that were provided to the committee and that we did discuss yesterday there are descriptions of the actions that the Agency undertook. I would refer the committee back to those.

And at least during the part of the time that I was here and in the morning, I heard a recommendation or thought it was -- would be framed as a recommendation that the Agency should consider -- should undertake labeling of specific products. That was what I think you brought up, Carol, yesterday morning.

Caroline, your comments today have gone to the risk assessment for Listeria and your concerns about the risk assessment that is now being undertaken, that it does not address immediately the specific -- it's not specifically addressed to L.m. in ready-to-eat meat and poultry products.

And you see this as a serious deficiency. And you would like to see -- you would like to see that risk assessment speeded up so that rule-making for environmental testing could proceed that would be based on that risk assessment.

MS. TUCKER FOREMAN: And product testing.

DR. WOTEKI: Okay, and end-product testing. I view these things that relate to these elements as really being separate issues from this question of regulatory reform as it was broadly put to the committee for review and recommendations.

And I guess I am posing this as a question to the committee: Do you see these as being two separate issues which albeit are related because they certainly have resource implications for the Agency, or do you see them as being one? And if you do see them as being one, could you explain to me why -- what that relationship is because I don't see it.

MS. SMITH DeWAAL: Regulatory reform brings us for

those of us who were working in Washington at the time that the Republicans took over Congress all of the issues of risk assessment and cost benefit analysis. And those are contained in the materials that we talked about yesterday on this issue. It is also contained in number 5 of these recommendations.

A problem that we are having with regulatory issues with this Department is that we can't -- when we approach the administrator and say, "Why are you not doing more? Why have you not done this?", he says, "We do not have a risk assessment. We do not have a cost benefit analysis."

What we are hearing is that the Agency -- there are tremendous hurdles in front of this Agency right now to address acute public health problems. And so I think this fits very well within the context of recommendations from the committee to the Agency on how to improve their rule-making.

And the language that I have talked about would be added just to number 5. That does talk about -- I'm not -- and I do want to clarify something that you said. I am not criticizing the risk assessment that is being done. What I am saying is it is not the right risk assessment to support the rule-making that we believe FSIS should be oriented towards.

And so if that is what they are waiting for, if that is what they are holding out and saying, "We don't have a risk assessment; we have to wait", then what I think the committee could do is to encourage them to make -- that risk assessments should be targeted so as to not delay rule-making on public health matters because that is exactly what we are hearing: "We can't do it. We've got to wait. We've got to delay."

And from a public standpoint, this is a huge problem because if the Agency hasn't started the risk assessment, if the Agency hasn't started the preliminary steps to getting a proposed rule out, we are literally five years away from having a regulation.

So we need to light a fire here and to get you guys moving. And I think this language from the committee would communicate this urgency. And I do think that it fits in well with this whole topic.

CHAIRMAN BILLY: Yes, Jim?

MR. DENTON: I think I'm going to have to disagree with Caroline on this one because as I understood the issue of regulatory reform as it is outlined in the program and with regard to the documents that this subcommittee was given to work with, I think we are looking at developing a system that is a lot more responsive.

As we look at the recommendations that the

subcommittee had, one of these is to incorporate scientific data and cite the sources to support the rules as they are proposed. It's part of that systematic orderly process.

I see the L.m. issue as a separate issue that is what I would term -- and this may not be an appropriate term -- but it's a rapid response to an emerging problem. Now, that may or may not be able to be addressed in regulatory reform. It's going to be hard enough to get regulatory reform accomplished with regard to getting all of the inputs into that -- in the appropriate time frame and in the appropriate process.

I think that it still has to be systematic, has to be orderly. We have to look at all the scientific parameters with regard to the public health risks. That starts at the very top of the list every time we are dealing with one of these issues.

Now, what we are contending with is that right now, we are trying to come to terms with Listeria monocytogenes in a well documented outbreak. That is an outcome. That's not a risk. I mean, that is a given outcome that that situation occurred.

But what do we do if next month we have something else that pops up as an emerging issue with regard to a foodborne illness outbreak that is not L.m., but it's something else? We have to have some orderly process, well

defined, in how we approach this.

I think that dealing with L.m., dealing with Campylobacter, dealing with E. coli 0157:H7, all these because they have been demonstrated to be the root cause of some foodborne illness outbreaks, we would never be able to prioritize which one of these that we were going to address first if we didn't have that orderly process.

So I see the regulatory reform issue as one by which we document everything that we are trying to do from the standpoint of good, sound science and with regard to the cost of getting it done. There may be a parallel system, going back to what Mike said, about how we address these emerging issues that come up that catch us by surprise because they do catch us by surprise.

CHAIRMAN BILLY: Yes, Carol?

MS. TUCKER FOREMAN: Jim, let me disagree. I am not addressing this in terms of Listeria monocytogenes or E. coli 0157:H7. I have spent most of my life dealing with the regulatory process. The regulatory process should not unnecessarily get in the way of public -- of action to protect public health.

The argument we are making is that the USDA Reform Act of 1994 has been cited on several occasions as making it difficult for the Agency to respond in a timely fashion. What we are asking for -- and I might suggest changing

Caroline's language to say that, "The risk assessment should be targeted so as to encourage the most rapid response appropriate."

What we are asking for here is that you not use regulatory reform to slow action, but to use regulatory reform to get us all deliberate speed. And the requirements imposed on the Agency from outside have tended to slow that action. We are not asking that you not do risk assessment. We are just asking that you target risk assessment so the Agency can act as quickly as possible.

CHAIRMAN BILLY: It sounds like my knowledge. Nancy?

MS. DONLEY: I've been flipping through a couple of these pages here. And something just kind of came to light. And I think, Dr. Woteki, it kind of comes with your point here.

Those of us that were back when the whole regulatory reform issue came up, that it sets off certain, you know, buzzers in our heads and all. I think here the Agency is referring to regulatory reform -- correct me if I am wrong -- as reforming currently regulations.

MR. LaFONTAINE: That's correct.

MS. DONLEY: Not the regulatory process. So we've got kind of two -- we do have two separate things here. But it doesn't at all change or minimize this other conversation

that we are having.

But it is -- and what it kind of jumps out at me as saying is why are we working on reforming the current regulations. We are arranging the duck chairs while the ship is going down because we are removing these particular regulations and not moving forward on things that need immediate attention like the Listeria problem.

So it is -- we may have a little bit of problem with semantics here. But I think the conversation has been very, very useful as far as the regulatory process that the Agency uses needs to be reformed.

CHAIRMAN BILLY: Yes, Rosemary?

MS. MUCKLOW: The very large outbreak of Listeria monocytogenes, whether one likes it or not, was a pretty unique situation to a specific firm for very specific conditions that are highly unlikely to be repeated in any other particular location.

The knowledge of what occurred in that particular facility is well known and heeded by the industry across the board. It doesn't -- and the industry has learned about those circumstances and they are very unlikely to occur again on a matching process.

Listeria monocytogenes is a serious problem. Meat, poultry, lots of other food products. And having an organized risk assessment and evaluating it and looking at

it across the board -- now, maybe in wisdom, in hindsight, it should have been done in the late 1980s following the huge outbreak in Los Angeles with the soft Mexican cheese. We are doing it in the late '90s instead of in the late '80s.

It is being done using the best resources that the greatest nation in the world has available to bring to bear on that subject. And that process needs to be completed. I would suggest that Food Safety Inspection Service is not like Nero watching Rome burn, that the Agency has done quite a few things, that the industry has done quite a few things to try to correct the concerns that are out there.

Our own organization, I think I mentioned this yesterday, with others that are in attendance here today developed guidance materials for the industry. You have helped us to disseminate them. Maybe they can even be better helped through better distribution.

I was talking to somebody today telling them one of the state friends -- I think it was Terri, wasn't it? -- and telling him where to go look on our website because he needs to get them out to the small plants in his state.

Maybe we need to renew our efforts to disseminate the helpful information to see what we can all do cooperatively to reduce it because it is people and the companies that employ those people that are going to help to

make sure that we minimize and make food safer.

Regulations of and on themselves don't make the food any safer. And we have already been through that this morning when we talked about taking our performance standards and making them readily available. It is when people read that, when the small and large companies read that, when we give them helpful information to help make food safer for people that the food thus becomes safer.

The Agency is correct to wait for its risk assessment before it moves forward in a process. If, indeed -- and I am not an expert in the emergency regulations -- if, indeed, this is truly of an emergency nature that you feel that you have to act, you will take the same kind of authority and the same kind of heat that Carol Foreman took in the late 1980s when she saw that we needed to change a regulation on roast beef.

Now, we may all fight and kick and scream. But as Mike Mammingo has made it very clear today, when you go before a judge and you tell him that this is the body of scientific opinion that had you take this course of action, we all know as an industry that you are likely to prevail unless you have been highly capricious and we can undermine that argument. You will most likely prevail.

I think, therefore, that your position is correct. I will go away from this meeting, as I am sure people in

the audience will, and renew our efforts, not that we haven't put them out there earlier this year, but renew our efforts to get firms and people in this industry and beyond this industry to understand that this pathogen is a serious problem.

We are already at a zero tolerance for it on product. It is a pathogen of foodborne significance that is not permitted on a cooked, ready-to-eat product.

There are enormous efforts out there to make sure that the food we are putting out is safe because the companies that I come to this table to represent are in the business of selling food every day, every week and every year. And if they don't make it safe, they won't be in business tomorrow.

CHAIRMAN BILLY: Okay. Gary?

MR. WEBER: Rosemary, just before you made that statement, I was going to say I know that there is an enormous amount of effort going on out there. And no one would want to wait for a regulation to be promulgated when there are some very fundamental principles that can be applied today.

But I have seen -- and I have worked for USDA for over ten years -- and I have seen that routinely, that when there are problems emerging, why, I don't know, people don't take the initiative and get out and talk and raise the

awareness of it is beyond me because you can see it coming.

And -- but companies -- a company went out of business over this essentially. Change is occurring. And one thing the Agency could certainly do, and it sounds like, Rosemary, you've already initiated, is get the word out to people. And the principles are there. If that's not being done, Caroline, then that is where there is a huge problem because every QA person out there should know what needs to be done. And I would argue they are going to do it.

We have had huge success in anti-battic residue prevention and elimination not because of regulations, but because of commitment of the industry and veterinarians and animal scientists and education of every single sector.

But in this arena, what is going out to extension both at the end of the processing side and to the consumer's side on this? I don't know who is initiating that. That should be something that you should be supporting and pushing hard as a priority.

I am reminded many years ago -- and the reason I support the risk assessment is a family member was the second in command of a large dairy operation, processing operation here in Maryland -- or in Maryland.

And he came to our house one evening and he said, "Don't buy any of our milk." And I said, "Why?" And he said, "We have a huge Listeria problem. We don't know why.

But it's a big problem." And I knew where their milk went. And it just so happened it was a place I usually bought my milk. And I didn't.

But here the QA people were trying to solve it. But in the absence of having a structured risk analysis, risk assessment where these people were aware -- and they solved it themselves. But what worries me I think, Caroline, we have to have stuff on every one of these fronts.

We've got to have -- know where this thing is coming from or in five years, we will have another food source cause the problem. And we better know that or we're not being responsible.

We have tons of education material that can get out there today. And I am not averse to pushing that side of the regulations. But I think if you don't hit every one of these simultaneously and in a multi-faceted approach, we are not doing our job.

MS. TUCKER FOREMAN: How about putting a label on all the packages that say, "Cooked, ready-to-eat; good if used by -- USDA Inspected?" How about doing that. Would you support that, Gary?

MR. WEBER: I think people need to do what -- consumer education is critical.

MS. TUCKER FOREMAN: No. Would you support having

USDA require as a label until we get the risk assessment finished as an interim step?

MR. WEBER: I think that makes a lot of sense. I don't know whether consumers would adhere to that. I would like to, you know, review that and see if that's effective --

MS. TUCKER FOREMAN: Well, at least it's a step.

MR. WEBER: But it's a step.

MS. TUCKER FOREMAN: It's a step.

MS. SMITH DeWAAL: Can I just --

MS. TUCKER FOREMAN: But, you know, we are off the risk assessment.

CHAIRMAN BILLY: I want to get you back on it. We are running out of time. I understand. Caroline --

MS. SMITH DeWAAL: Thank you.

CHAIRMAN BILLY: -- for a final word on this. Then we are going to break for lunch.

MS. SMITH DeWAAL: Okay. Thank you. I just want to note that what the subcommittee put together clearly anticipates future regulations. "Incorporate scientific data and cite supports to support rules as they are proposed." Regulation should strive to improve food safety, gather economic data on benefits to support cost of regulations.

We are talking generally about regulatory issues

here. I believe that without a mention of the problem that we are seeing with risk assessment, this set of recommendations is incomplete.

I think Gary's point and Rosemary's point is excellent. And, gosh, get out there and let's solve this problem. I don't want to wait for a reg. either. But we -- it takes one company not doing the voluntary program. It takes one milk company that has people out there warning people not to buy their products because they are still selling them even though they know there is a problem.

We need a level playing field. We need everyone in the industry to know what is expected of them. And that is why we need regulations. I think this document is incomplete. I do agree with Carol that the language should be, "Risk assessments should be targeted so as to encourage the most rapid response to public health matters." And that's my last word.

CHAIRMAN BILLY: We are going to break for lunch. But just before we do, my suggestion is that, Dan, you try to capture this language and then have some discussions. And then we have our remaining issues discussion at 4:00, we will come back and look at what you've come up. And if there is acceptance, that's great. And we can bring it to closure. Rosemary?

MS. MUCKLOW: Before you break for lunch, you have

Phil Derfler coming over. Is he going to talk about the action plan or inspection shortage? I guess the action plan.

Could he also tell us your current situation as far as the retail exemption is concerned? You know, there was the Honey-baked Ham decision and so on. It is a matter of interest to me and to quite a few people in the audience here. I'm sure if he could give us a short update on that, we would like to know.

CHAIRMAN BILLY: Yes, we will ask him. Yes.

MS. MUCKLOW: Thank you.

CHAIRMAN BILLY: Okay. So we will break and be back at 1:15.

(Whereupon, at 12:16 p.m., the meeting was recessed to reconvene at 1:15 p.m., this same day.)

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

(1:18 p.m.)

CHAIRMAN BILLY: My intent is to initially kick off the discussion this afternoon in terms of the Agency briefings with the subject of NRs which we talked about yesterday and were provided some data from Carol Foreman, and thought that what we would do is share with the committee some basic information about NRs and then respond to the data that has been made available and make some suggestions about where do we go from here.

So I have asked Dr. Mark Mina to lead this discussion. And he is prepared to do that at this time. So Mark?

DR. MINA: Okay. Good afternoon. It is a pleasure to be here this afternoon. As Tom indicated, I gave you an overview on NRs and also particularly I want to talk a little bit about how they are used in the plant setting and what are the plant responsibilities versus the inspector responsibility, and how we use that data in taking regulatory actions at future steps in the process.

This is the new NR -- it's kind of trick to use the microphone and --

CHAIRMAN BILLY: Why don't you take it out of the stand.

DR. MINA: I will take it out. This is the new NR

that we are using in HACCP plants. And I just want to point -- talk about significant blocks on the form. I am not going to go through the whole form in great detail. But I want you to pay particular attention to these two boxes here, "Food Safety" and "Other Consumer Protection."

So if a violation is found or identified, the inspector is required to classify it is as either food safety or other consumer protection. Block 9 is also is of a particular interest to us because we need to classify the deficiency in several categories and use that as an indicator for HACCP effectiveness in that plant.

So if we go through that block 9, it is broken down into two major categories. One is "SSOP", and that is in Section B, and "HACCP." So the deficiency is either SSOP or HACCP. And if you break it down further, it is either monitoring, corrective action, record-keeping or implementation. And the other difference on HACCP is plant verification versus implementation.

And then we also check the product or facility or E. coli, E. coli testing. And we also break the product whether it is economic, misbranding or protocol. And, obviously, on facilities as you see on the form, "Lightning structure outside premises" and "Produce base."

Let me explain that product base is probably a misnomer. But the product base indicates that we have a

deficiency that is not on direct product contact surface. It could be on a table leg or on the wall. But it is not on the product contact surface.

We have asked our inspectors and instructed them to fill in block number 10 which is a description of a noncompliance. We want it to be very explicit on what they found.

CHAIRMAN BILLY: Mark?

DR. MINA: Yes? Okay, thank you. So we want the inspector to be very explicit on the description of the noncompliance. And also they will sign it. I want to go back up here that we notify plant management and we put the name of the person that we notified.

Plant management response, there are two boxes. One is "Immediate Action", what they are going to do right now to correct this deficiency. And particularly, if there is product contamination, that is dealt with immediately. That doesn't happen an hour later or two hours later. We take immediate control of that product. And they need to correct that problem and either make that product wholesome or dispose of it otherwise.

On some other deficiencies -- and that doesn't show very clearly on this form unfortunately. It is kind of hard to fit it in the frame. But "Further Plant Actions",

long-term actions, what they are going to do to fix this problem permanently. So it is not just correcting the problem, what you are going to do to prevent it. That is the whole basis for HACCP, is the prevention system.

See, we are moving from a system where the inspector has identified deficiencies and the plant reacted to those deficiencies. We are moving to a system that the inspector responsibility is to evaluate the effectiveness of HACCP implementation in that plant; how effective are management controls.

And it's not to be pointing deficiencies for. We will make the determination whether the HACCP system is effective or inadequate based on some of those trend indicators. And I am going to explain that a little bit later.

So we make an overview. We evaluate the whole system, not on a deficiency-by-deficiency. Any questions on the form?

MS. TUCKER FOREMAN: Would you -- could we get a Xerox copy of it?

DR. MINA: Sure, sure.

MS. SMITH DeWAAL: For the E. coli section, that's just the E. coli sampling?

DR. MINA: Yes.

MS. SMITH DeWAAL: And just have "Other." So all

the descriptives there would be in box 10 as to why that was the --

DR. MINA: Right. Well, there are two parts to the E. coli box. One is if they have a program; and if they do have a program, are they following their program. So obviously, if they don't have program to test, we suspended the operation in those plants. And so if we have implementation problems, that's what goes in here. And the description tells us exactly what the problem is and what we need to correct it. Okay?

MS. DONLEY: Excuse me. Can I ask one question? Is a separate report filled out for each individual problem that is found or is it something that goes through the day and can multiple violations, if you will, be on one report?

DR. MINA: On the schedule -- every inspector gets a schedule. And that directs them on which activities they need to conduct. On that schedule, they mark whether that activity was acceptable or unacceptable. And they use the trend indicator so we know what are the areas that they are talking about. The full description of the deficiency stays on the NR.

CHAIRMAN BILLY: But I think the question, Mark, is if you are doing that and you perform one task and you find a deficiency, you fill out a form.

DR. MINA: That's correct.

CHAIRMAN BILLY: You find another deficiency on another task, do you fill out another form?

DR. MINA: That's correct.

CHAIRMAN BILLY: So each and every deficiency you might find --

DR. MINA: Right.

CHAIRMAN BILLY: -- in a plant is tied to a form.

MS. DONLEY: It's a separate form.

DR. MINA: That's right.

CHAIRMAN BILLY: It requires reaction from the plant, is that correct?

DR. MINA: That's correct.

MS. SCHULTZ KASTER: Yes, but I thought that as we started, that inspectors, for example, after pre-op were consolidating their observations. So one inspector might find a deficiency. Another inspector, although it is the same activity across the inspectors, then there would be different sets of observations on the same NR.

DR. MINA: That happens with SSOPs. And we take the most critical ones.

MS. SCHULTZ KASTER: So they could list all of them --

DR. MINA: Yes.

MS. SCHULTZ KASTER: -- to communicate them to the plant and then use the trend indicator for the --

DR. MINA: Right. I will show you the trend analysis in a minute so you can see where those fit.

CHAIRMAN BILLY: But there still would be individual identification of each --

DR. MINA: Yes, of the --

CHAIRMAN BILLY: -- non-conformance as they are observed. And then they would be consolidated if they apply to sanitation, is what I am hearing, in terms of informing the plant.

DR. MINA: The individual record is maintained. It is not thrown away or destroyed. The individual record is just compiling the data so we won't have a whole lot of paper to deal with. Okay.

Let me move a little bit into the trend analysis. Just before we go into trend analysis, I think it is important to kind of at least understand this chart here. And as we talked on the NRs, you recall that we had an SSOP section. And that is broken down into monitor and productive action record-keeping and implementation.

And there is a letter attached to that. The same with HACCP, economics, E. coli and other inspection requirements. I will keep that close by so we can refer to those letters. I don't know if you can see that.

CHAIRMAN BILLY: Can you slide it up a little bit, Mark, so it is up on the -- yes, up further, even further,

further up. Oh, that's it. That's better.

DR. MINA: Okay. This is some of your plant HACCP trend indicator by activity codes. 01 is for SSOP and sanitation. And that is a produce shift. And we have 122 tasks scheduled and 22 unscheduled tasks. And the number of tasks not performed is 0.02 percent.

"No data" means that maybe the task was performed, but they didn't input that into the computer. So we didn't receive any feedback. So 38, we didn't get any feedback in the computer for summaries and performed 66 tasks and two non-performed, two total not performed. If you recall this chart, that's an important part I think that I want to emphasize.

Keep that in mind. I can put the two charts side-by-side. But you see a number under C for monitoring for SSOPs. So that means we found a discrepancy or a deficiency or a violation in monitoring out CCPs.

Okay. In this case, we found 37 of those meaning the plant either did not record their finding on their record or did not monitor it. And go on across for sanitation, you have to keep in mind these.

DR. WOTEKI: So SSOPs are C, D, E and F.

MS. ROTH: C, D, E and O.

DR. MINA: C, D, E and O, yes. They are not in alphabetical order. Okay, see, that's what is a little bit

confusing I think. They are not in alphabetical order.

CHAIRMAN BILLY: Now, Mark, these are summary data for beginning, it says, calendar year '98, first quarter and ending calendar year '99, third quarter. So this is one and three quarter years worth of data.

MS. ROTH: This is an actual plant.

DR. MINA: An actual plant, that is an actual plant. This is an actual plant. And also --

CHAIRMAN BILLY: So that's a year and three quarters worth of data.

DR. MINA: Yes.

CHAIRMAN BILLY: I just wanted to --

DR. MINA: Right.

CHAIRMAN BILLY: And what each line like the O-1, the first line there --

DR. MINA: That's an indication. That goes across.

CHAIRMAN BILLY: Okay.

DR. MINA: And that's for first shift and second shift. We are capturing also the second shift. That's for the whole plant on the SSOP.

CHAIRMAN BILLY: Okay. So that means -- let me make sure I am clear. So like the first line across, the O-1, Shift 1, and there was somebody scheduled and unscheduled. Unscheduled I assume means the inspector --

DR. MINA: Yes.

CHAIRMAN BILLY: -- happened to see something and has the freedom to check that out and add that to their work.

DR. MINA: Or even without seeing something, they decide to go to an area that was not schedule for a reason.

CHAIRMAN BILLY: Okay.

DR. MINA: And they have the freedom to do that.

CHAIRMAN BILLY: Okay. And then the first number there, the C, the 37, that means there was 37 instances in the year and three quarters where an NR was filled out for an observation that the inspector made. And that whole process occurred where the plant was notified, the action required, the plant responded immediately, and then also identified what corrective measures they would do for the longer haul. That's how this would work.

So 37 instances of that occurred in this year and three quarters for that plant for this particular item. Okay. I've got it.

DR. MINA: That's correct.

MS. MUCKLOW: That's 37 instances of noncomformance.

CHAIRMAN BILLY: Yes.

DR. MINA: That's correct.

MS. MUCKLOW: Okay. And how many were there, 140

or -- I can't see the number from here.

DR. MINA: Sixty-six were performed. We scheduled 122 and -- 122 were scheduled, 22 were unscheduled, and then 66 were performed.

MS. MUCKLOW: And 37 didn't make the grade.

DR. MINA: That's monitoring for SSOP, SSOP monitored. That's how you read that chart. Yes?

MS. DONLEY: Does -- excuse me, Mark. Does -- so out of -- roughly 50 percent of the scheduled inspection functions were performed?

DR. MINA: Yes.

MS. DONLEY: Only 50 percent?

DR. MINA: When they say, "Number not performed", we have the total not performed is two. That, obviously, does not add up. Those numbers are not adding up. That is why everybody is struggling with it.

MS. DONLEY: See, because I am seeing it is -- boy, do I need new glasses.

DR. MINA: Don't we all.

MS. MUCKLOW: He needs a new chart.

MS. DONLEY: Is that 66 performed out of 122 scheduled?

DR. MINA: That's correct.

MS. SMITH DeWAAL: And "No data" means you don't know whether it is performed or not?

DR. MINA: Yes. We didn't get feedback from the inspector or through the computer, the management assistant person. So I don't know why. And you see those not very frequently because the rest of the column you probably see a lot of zeros. So all the input then in the computer --

CHAIRMAN BILLY: So this would have --

DR. MINA: -- and as you know, we can have a computer glitch.

CHAIRMAN BILLY: So there are seven quarters here.

DR. MINA: Right.

CHAIRMAN BILLY: There are seven ones in a row. So there are seven quarters covered by this data. So I assume that's the first quarter of '98. Then the second quarter, third quarter and so forth --

DR. MINA: Right.

CHAIRMAN BILLY: -- for the first shift.

MS. DONLEY: And does that mean that of that 122 functions or whatever -- again, I'm sorry, I can't -- I am going to use round numbers -- 120, 60 were performed of the scheduled. So that is 50 percent of the scheduled inspection tasks were done and 50 percent that they performed, there were 37 or another roughly more than 50 percent NRs issued.

CHAIRMAN BILLY: So this would have been the period where the -- on January 26th of this first quarter

was when this plant implemented HACCP. So for 26 -- 25 days, it was under the old system. And then the rest of the quarter, it was under the new system. And it looks like there were adjustments in the process where the plant and/or the inspector were getting comfortable with the NRs, which were new, and carrying out the HACCP assignments.

So if you look then at the next quarter, you had 130 scheduled. You had 28 -- 95 were performed. Then the next quarter is 132, 111, then 94 and 89. So it looks to me like there were adjustments where the inspectors then were able to come close to carrying out the number of scheduled tasks, plus carrying out unscheduled, as well. So that's the trend. I assume that's probably what you were getting at --

DR. MINA: Right, that's the trend.

CHAIRMAN BILLY: -- in terms of -- yes?

MS. TUCKER FOREMAN: You know, this is not easy to understand. And it is impossible because I can't see it.

CHAIRMAN BILLY: Okay.

MS. TUCKER FOREMAN: And so just you have to understand that the explanation here is going to be insufficient because I don't have a piece of paper that let's me know what you are saying, Mark. And I can't read your slide.

DR. MINA: How we can help you, Carol -- I can

appreciate your concern.

MS. TUCKER FOREMAN: You can give us some copies of it. And maybe when I go home tonight, I will be able to figure it out.

DR. MINA: No problem. No problem.

MS. TUCKER FOREMAN: But we are going to suffer a lack of clarity through this meeting --

DR. MINA: Okay.

MS. TUCKER FOREMAN: -- because I can't read it.

DR. MINA: Okay. The purpose of our discussion here is to give you an overview of how the system works and what kind of data that we have available and how we use that data in making decisions at the in-plant level and also at headquarters. That's the purpose of the presentation. Yes?

MS. SCHULTZ KASTER: I think Carol's point a little bit is what this illustrates is we are discussing something that wasn't on the agenda like Katie talked about all morning. It is something that we don't have materials in-hand or nobody was prepared to discuss because it was a recent addition to the agenda.

I would kind of question whether or not we would want to hand out this specific sheet. I mean, is that what you are comfortable doing, handing out one plant's specific sheet to the group or would it be better to hand out an example with explanation --

DR. MINA: Well, there is no plant number on that sheet.

MS. SCHULTZ KASTER: I understand that. But it is still somebody's information. So I think it just speaks to maybe that if this is important, we put it on the agenda for a future topic. Everybody prepares in an appropriate fashion. And then we have a detailed discussion. Thank you.

CHAIRMAN BILLY: Well, one of the suggestions that the Agency was going to make and I can make it now in light of this discussion is that we have the Agency prepare a report for 1998 and pull the data together in a report form and summarize it and explain it and provide that to the committee in advance of the next meeting, and then have this item on the agenda with adequate time to make sure everyone understands it. And the committee can react to the data and information that is provided. So that's --

MS. TUCKER FOREMAN: That would be fine by me. I would like to ask a couple of questions based on the material that you passed out yesterday that is from the website. That -- on page 7 of that material, it -- first of all --

CHAIRMAN BILLY: That's the enforcement report, right?

MS. TUCKER FOREMAN: Yes, Peer Enforcement Report.

But starting on page 5, it describes NRs and appeals from them. And then on page 7, it says that the NRs issued April 1 to June 30th, 1999 -- that's one quarter -- were 29,354. So we might be looking at not very many up there. But for all the plants involved in HACCP in that quarter, there were 29,354 out of -- arising from 766,433 inspection tasks in HACCP plants.

The 1998 data for NRs, obviously, you would expect them to be higher in 1999 because all those new plants came on. But there were in the second quarter of 1998, 16,979 NRs; in the third quarter of '98, 18,745; in the fourth quarter, 18,944; the first quarter of '99, 28,995.

CHAIRMAN BILLY: What page are you on again?

MS. TUCKER FOREMAN: Well, that I am using from earlier enforcement reports.

CHAIRMAN BILLY: Oh, all right.

MS. TUCKER FOREMAN: The only data that are on page 7 are for the second quarter of 1999. I presume -- but I have a series of questions based on that. One is I presume that among all the plants involved in HACCP, the NRs are not evenly distributed.

DR. MINA: Yes, that's a correct assumption.

MS. TUCKER FOREMAN: There are some plants that rarely have NRs.

DR. MINA: That's correct.

MS. TUCKER FOREMAN: There are some plants that have lots of NRs.

DR. MINA: That's correct.

MS. TUCKER FOREMAN: Consistently. What action does the Department take to deal with those people who consistently have large numbers of NRs?

DR. MINA: If we go back to these classification categories, it depends on the seriousness of those NRs. And we have taken also our enforcement report which reflects strong enforcement action that we took in many, many plants because of the significance of our findings.

You can have a large number -- the number by itself does not indicate a problem per se. But it raises a flag. And we look into it very closely to make sure that these numbers are not in those categories that we are very concerned about. It's like HACCP implementation and product conditions. If the product is shipped outside the plant that is not wholesome and is not in an acceptable manner, that operation is suspended right then and there.

MS. TUCKER FOREMAN: Can you tell me how many times --

CHAIRMAN BILLY: Well, let me add to that a little bit. This is where, unfortunately, you can't see the chart -- but this is where this chart is informative, because part of what we do is follow the trend. So while we are aware

that in each instance when an NR is issued the plant is expected to respond to that -- if it's a product contamination, immediately; if it's not, then within a short time, and both correct the immediate situation and then make a change that prevents that from happening again.

So then we follow the trend. And it's not just in these general categories. We will look specifically within column C or D or O or whatever and say is there a pattern here where not withstanding the action that the plant has taken to deal with the immediate situation, their corrective action to prevent it in the future is there is a pattern of failure of that fixing the problem on a permanent basis.

Then that starts to -- that forms the basis for taking further action than what is immediately done in the plant. So it is a judgement that involves the inspector. If the inspector believes that there is a repetitive failure in a particular area of noncompliance, then the inspector notifies his or her supervisor. And then a compliance officer is brought in.

And then that forms the basis for regulatory action that could be withholding the marks, that kind of thing. So there is a whole process that is tied to the trends that are occurring in the specific areas within these columns in terms of what's going on.

So if there are failures but they are in different

areas, you know, and they only occur once in each of the different areas and then they are corrected, that is different than a repetitive failure in the same area and the plant is not, you know, preventing it from happening in the future. So there is -- that's how that works.

So it is tied to -- it is an attempt by the Agency to move from the old process of relying primarily on "just get the problem fixed right now and if it happens again, then get that problem fixed again and then again" to moving to the process that you are dealing with. And if there are repetitive failures, then taking more formal action against the plant with regard to sanitation or HACCP. And that's a basic -- that's basically how this works.

MS. TUCKER FOREMAN: I have two -- can I go on?

CHAIRMAN BILLY: Yes.

MS. TUCKER FOREMAN: The -- so a large number of NRs reported at one plant might be the same problem happening again and again and again. It might be a labeling failure that just happens every single day.

In the data that the government accountability project got under the Freedom of Information Act from the Department, it showed a number of plants with over 1,000 total NRs in a period of three quarters in 1998. In a number of cases, there is no report of any enforcement action being taken. Why would that be?

CHAIRMAN BILLY: Well, I don't -- there was action take on each NR.

MS. TUCKER FOREMAN: But, Tom, there were lots of plants that had one, two or three during three quarters of the year and there are lots of them -- there are a fair number that had 800, 900 and 1,000. But they don't show any enforcement action being taken against the plant. If you have the same error repeated day after day, why should Zacki have to compete with somebody who screws up every day if they do it right every day?

CHAIRMAN BILLY: Well, I think that's why you need a more detailed breakdown of these data to show whether, in fact, that is the case or not. And, you know, provide examples and an analysis that shows whether, in fact, even if there is a large number, are they repetitive in the same area; do they relate to food safety; and what was done about it.

Beyond the action that the inspector or team of inspectors at the plant take, then there is a weekly meeting where they talk to the plant manager about the overall situation. And then the circuit supervisor plays a role in terms of monitoring the trends, and the district manager. And there is a whole process there that is looking at the situation on that basis.

So it's -- while in some instances numbers are

important and should trigger action -- further action by the Agency, that turns on the specifics of what the NRs were issued for and, you know, what part of the plants and so forth.

In a great big plant with multiple shifts, you can have a lot of things happening. So you also arguably ought to look at the amount of product that is being produced and the complexity of the operation, as well. I think all those are factors that we take into account in terms of whether we should take further action. But I think we ought to address that thoroughly in the report.

MS. TUCKER FOREMAN: I guess I think that the term, "NR" -- I understand that this is just an attempt to make the PBRs change to deal with HACCP. You know, HACCP is sufficiently different that maybe we need to have something that is not where everything is just lumped under the term, "NR."

It says on page 6 of your document, "The problems reported on NRs and PBRs vary from minor labeling discrepancies to serious breakdowns in food safety controls." I think it misleads the public when you have something -- when you lump those two things and everything is called a violation, a noncompliance.

It also then says that when deficiencies occur repeatedly or when the plant fails to prevent adulterated

product from being shipped, FSIS takes action to control products and may take an action to withhold and suspend production. And later on, you tell me how many -- it reflects on about page 9 I think -- how many pounds were detained.

When you start putting this together, this detailed information for the committee, it would really help to know more than how much product was detained. What other actions are available in terms of enforcement beyond the inspector just saying, "You have to fix that before you go on?"

I think there needs to be some capacity to quantify actions that were taken in a more specific way. If it was a labeling problem, how many times did it occur before they said, "You can't use that label anymore. We are going to stop production until you get it fixed?" When it was a serious food safety error, then clearly we need to know what the inspectors did.

And it really is my view that those companies that either, because they are inept or because they are -- don't place a sufficient importance on complying with the law should not be allowed to compete unfairly with those companies who go out every day and try to do it right.

There should be some penalty associated with the fact that you just occupy an awful lot of the Agency and,

therefore, the taxpayers' time and energy and money. And I don't see anything in this system that makes a provision for that.

CHAIRMAN BILLY: Well, I might insert there that, you know, the Agency -- the Secretary has strongly supported getting the Agency civil penalties that we think that --

MS. TUCKER FOREMAN: We all agree.

CHAIRMAN BILLY: We think that --

UNIDENTIFIED VOICE: We don't all agree there.

MS. TUCKER FOREMAN: Okay.

CHAIRMAN BILLY: We think that could play a useful role in this very example in terms of that distinction between different kinds of plants where you've dealt with the product, but they are, in fact, occupying a lot of inspector time dealing with many NRs and following up on those NRs, as well as the rest of the system I described.

MS. TUCKER FOREMAN: And since it costs money for a plant to comply with the law, I am not sure, Rosemary, why anybody wants to defend plants that either are incapable of complying or refuse to comply on a day-in, day-out basis. Why should they be allowed to compete unfairly with those plants who take the effort and the time to do it the right way?

I guess that would at least for the time being until we get some more information take care of the

questions that I have. But as -- you know, there is nobody who is a stronger supporter of HACCP than I am. I think I understand that NRs may frequently reflect that a problem was detected and prevented from causing a human health threat.

But the data that I have from the Department don't show me that in a convincing form. And if we want to have public support for this, then I think we have to have a better reporting system and particularly with regard to actions taken.

One last comment, obviously, the plants are terribly unhappy with this because the number of appeals filed is fairly small. And the -- if you once again look at that page 7, and the number of won are even smaller. So that of all those 29,000 NRs issued, only 80 plants filed appeals and a total of 223 appeals were filed.

MS. HALL: With regard to the civil penalties for problems created by plants, you do have the option to withhold inspection. And in some cases, that would be more costly to the plant than a civil penalty that you might impose.

I guess from the industry standpoint, what we look for is that there would be even application of any type of penalty or any problem that you would create for the plant such as withholding inspection. But I look at the number of

NRs that some plants as compared to others. Even from the industry side, it raises big questions as to what is going on there.

And I don't see how that is being evenly applied. I don't see what -- you know, I don't see exactly what is going on with those NRs. So if we could have some explanation, it would really be helpful from the industry side, too.

CHAIRMAN BILLY: Okay. So we will do that. We will prepare --

MS. TUCKER FOREMAN: One last comment. It really -- because this information is out there, because we raised it in this meeting and the documents were copied and passed around, I think it is really important for the Department to get back to us as quickly as possible because, obviously, there is some public impact from that.

CHAIRMAN BILLY: I agree. Okay. Yes, Collette?

MS. SCHULTZ KASTER: I don't want to bring up a whole new can of worms, but I do want to clarify one thing that you said which is to make a judgement about numbers of appeals and a plant's feeling about an NR that it has received, that may not be the best measure to go to because

I think we all know that there are other reasons why or why not NRs would be appealed or why people might not appeal. So I would caution you to use that as a gage of

acceptability of the NRs and the numbers.

MS. TUCKER FOREMAN: I accept that.

CHAIRMAN BILLY: Okay. Rosemary?

MS. MUCKLOW: Thank you for bringing this. And I terribly relieved that I don't have to strain my eyes to read any more of Dr. Mina's chart. Like the first two, I will need new glasses from the Agency.

I think it would be very useful for us to have the kind of discussion that you have had in some public meetings at some time in the future with respect to a progress report. Clearly, this is one example where we would like to have the example ahead of time to study because you don't give us much of an evening either. You have kept us working in committees.

And I worked hard in committee last night. If I should have not attended my committee meeting so I could go study my papers for today, that was not clear to me then. So -- and I am not good about reading things when I need to be listening. And so it's certainly an item that needs to be looked at for the future. And you certainly have a lot of this information available.

The one thing I don't want to be doing at this advisory committee is getting into micro-managing how you run this system. That's your job, not our job as an advisory committee. And getting into grungy details of

exactly what this number in this column means and so on, your people need to come and explain to us the overall trends of what they are finding.

And I hate to be here and I will not be here to micro-manage the Agency. If I don't like what you are doing, I know what I have to do and it's not in this room. And I would hope that you would bring us maybe at the next meeting an overview of what you are finding. The number game is a very difficult one. And anybody can play with the statistics and prove anything they want with it.

CHAIRMAN BILLY: Okay. Well, I think we have gotten good guidance. So we will prepare a report and get it out as quickly as we can and then include this on the -- with adequate time on the agenda for the next meeting. And I would like to thank Mark for pulling stuff together pretty quickly.

DR. MINA: Well, that's -- I need to just make one point, is that we try to be very responsive to the committee concerns. And we did a lot of scrambling between yesterday and today to get some data together. And it doesn't project the best way we want it to project. But I think we need to regroup and come up with all the information that you requested.

MS. MUCKLOW: Thank you, Mark. And, you know, I'm not demeaning in any way the work that you and your guys did

to come here to tell us this today. That was very kind of you and we all have a little bit better knowledge of it as a result. But I don't want any more of those charts up there. Like Carol, my eyes don't take it.

CHAIRMAN BILLY: All right. We are going to move on. The next item is the evaluation of the pathogen reduction final rule. And Jane Roth and Don Anderson will lead that discussion.

MS. ROTH: Thank you. If we turn to Tab --

CHAIRMAN BILLY: Move the mike close so that people can hear you.

MS. ROTH: If you turn to Tab 10, there is a one-page description of what -- can you hear? Okay. Tab 10 of your loose leaf has a one-pager that provides a quick overview of the evaluation of the pathogen reduction HACCP final rule.

This evaluation is being undertaken by Research Triangle Institute. It is a multi-year contract. And Don Anderson on my right is going to give you an overview of the studies that are being undertaken as part of this evaluation.

MR. ANDERSON: Thank you very much. I know that we are a little behind schedule this afternoon. And there is a lot of business, probably more pressing business perhaps than this to get through. So I will try to keep it

short.

I will talk about who we are and what we are doing and some of the kinds of things that we are looking at. But I won't go into any detail on methodologies. But me and a couple of my co-workers that I will introduce will be here this afternoon if you would like to try to catch us in what little free time you do have.

My name is Don Anderson. I am from Research Triangle Institute. RTI is in the Research Triangle Park, Raleigh, Durham/Chapel Hill area of North Carolina. We are an independent, not-for-profit, university-affiliated organization. We are actually I guess legally owned by the three universities down there, Duke, UNC and North Carolina State University. And we frequently collaborate with faculty from those.

And we are very pleased to have been selected I guess almost a year ago, maybe nine months ago, to help the Agency with its several year, I guess it's a four-year evaluation of the various types of effects of the pathogen reduction HACCP rule.

I would like to introduce a couple of people that are here with me today and maybe they could each stand: Sherry Kates from Research Triangle Institute is sitting back here. She is going to be leading the consumer studies and the animal production studies that I am about to

discuss. And Dr. Morales, also from RTI, is here. And she is going to be leading the foodborne illness and hazard reduction studies and helping me with several of the other studies, as well.

There is actually a larger team than RTI alone. We are also working with several researchers closely from Texas A&M University, most notably Dr. Zelsa Morano and Gary Acuff at Texas A&M are helping with -- helping us with several of these activities.

We are also working with a food safety economist, Dr. Neil Hooker, who was recently -- or has just completed a post-doctoral fellowship at Texas A&M. And is now almost literally en route to Colorado State University where he has accepted a position there on the faculty. And he is helping us with some of the international trade impact studies.

And it would be difficult to acknowledge the assistance so far of all the people here in the Agency. Many people in this room we've met with many times on our -- and in some cases, on multiple occasions. But I would like to in particular acknowledge all the help from one of Jane's staff, Cynthia Willem.

Cynthia, could you stand for those people who might not know you? She has worked tirelessly to help us formulate the evaluation questions that we are going to be looking at and to basically facilitate our discussions with

people inside and outside the agencies that we need and will continue to need to work with for the next few years.

I am not going to go over each of these topics right on this slide, but rather I have got one slide for each topic. So you can see what we are going to be addressing.

Let me say while I am here though that these evaluation questions or the studies we are going to be conducting essentially arise from one of three main things. The FSIS five-year strategic plan lays out a number of goals and objectives that we are going to be looking at. The PR HACCP final rule itself, of course, has goals and objectives in it that we are going to be evaluating. And some of these are actually more as a response to the Government Performance and Results Act than they are to either of the others.

First and foremost, when the pathogen reduction and HACCP rule was promulgated, the intent was, of course, to reduce the incidence and severity of foodborne illness and to reduce hazard levels of various types in meat and poultry products.

The five-year strategic plan that I referred to sets a goal of a 25 percent reduction in foodborne illnesses attributable to meat and poultry products over a five-year period which is basically '97 which you can think of as pre-

HACCP to 2000 which, of course, is the year when HACCP is supposed to be fully implemented through the industry, and also clearly states that we are looking for reductions in hazard levels in meat and poultry products and particularly pathogen hazard levels in raw carcass meat.

So these two objectives are, of course, one of the key things that we are going to be evaluating in the study. We want to see whether or not these stated objectives or these goals are being met or to what extent they are being met. And to the extent that we can, how are these goals being met; what are the key initiatives in the Agency that are leading to those accomplishments; and to the extent that some of the goals are not being met as fully as you would like, what are some of the impediments to that.

On the foodborne illness question, we are going to be working closely -- and Dr. Morales is going to particularly be working closely with members of the Foodnet team at CDC. We have met with them in person one time and had numerous discussions with them. They, of course, are independent from the Agency. And it is their business to track foodborne illnesses attributable to all sources, but including meat and poultry.

And they will be using the best, most timely data they can from Foodnet, PulseNet and other sources to track the change in incidence of foodborne illness over time.

And, in fact, they have already started to do that.

You know, there was a recent report, I guess it was in March, in MMWR. And they are already starting to report some gains in the fight against foodborne illness. And they will be continuing those activities. And we will be working with them as best we can to provide assistance to make sure they can do the best job possible with that.

On the hazard side per se, we don't want to just track illnesses by themselves because illness reduction and hazard reduction won't necessarily correlate perfectly. So we also want to track hazards separately. The Office of Public Health and Science here in the Agency, of course, has been collecting pre-HACCP and continues to collect, if you will, post-HACCP data on hazard levels, chemical, physical and primarily I guess biological and pathogen levels.

And we will be working with OPHS to make sure that we can bring the best data that we have and that we can get from other sources to determine whether hazard levels of being diminished at the rate that we would like to see.

At the same time, we are looking at, if you will, the intended effects of HACCP. We will also be looking at the mostly economic implications or repercussions of HACCP in the meat and poultry industry. We are interested in seeing basically whether HACCP and other farm-to-table initiatives are affecting the performance and the structure

of the meat and poultry sector, but also the animal production sector.

We will, for example, be looking at whether or not the compliance with HACCP and PR is causing an increased exit rate from the meat and poultry industry. That has been a number of concerns, stated concerns that the -- that compliance with the rules may cause exit from the industry to increase. And that is one of the things that we want to evaluate over time.

We will also be looking at changes that -- or changes that might occur in the industry that wouldn't necessarily manifest themselves in exit. There may be productivity changes in the industry. Those productivity changes actually could be positive or negative. And we will conduct that analysis by basically doing interviews with industry and other individuals to see how productivity is changing.

Also, the Economics Research Service, of course another part of USDA, is preparing -- at this time is preparing an information collection request for OMD approval to do a survey of firms in the meat and poultry industry to ask questions about the impact of HACCP and pathogen reduction on them.

We spent some hours very recently reviewing and commenting on the ERS survey instrument and will continue to

work with them to make as sure as we can that the answers that we would like to see answered -- or the questions we would like to see answered will have data collected in the survey when they field it next year.

We will also be looking at international impacts. I won't go into details here, but we will be looking at whether or not the final rule and compliance with it are affecting the ability of companies in this country to export meat and poultry to other countries and whether it is affecting the ability of companies here to import meat and poultry products into this nation.

I think also, very importantly, we are going to look at whether or not the HACCP and pathogen reduction rule in this country is kind of by an osmosis or other sort of effect, maybe having positive impacts on global food safety, maybe through more global adoption of PR HACCP or HACCP-type standards. We will be doing that by talking to Codex officials, officials with the Foreign Ag. Service, and maybe using some other methodologies to do that.

We will also be very interested in seeing whether or not the pathogen reduction HACCP rule itself or other farm-to-table initiatives are changing consumer knowledge, awareness and behavior of food handling practices and the like. There -- again, there are a number of ongoing surveys that track the use and knowledge about safe handling

practices and about consumer confidence in the food supply.

There is an ongoing FDA/FSIS food safety survey that was conducted in '93, '98 and then is scheduled to be conducted again in 2000. And we will be using that data to analyze trends in consumer knowledge, behavior and confidence.

We will also be conducting some special studies to basically examined whether or not selected consumer initiatives are reaching the intended targets. We may, for example, conduct an analysis using focus groups or other data collection methods to see whether or not the "Fight Bac" campaign is effective or whether the thermometer-use campaign is effective.

Again, these are all studies that are intended to see whether the more in-distribution and consumer-oriented initiatives are having the intended positive effects that the Agency hopes they would.

So continuing in the farm-to-table continuum, we've talked about some of the analyses that we will be looking at towards the consumer. We will also be looking at some of the impacts looking back towards the farm.

Specifically, I mean primarily what we want to see is whether or not coincident or because of farm-to-table or rather pathogen reduction HACCP and other farm-to-table initiatives, we want to see whether or not farm level animal

production practices really are improving, whether they are changing for the better.

Again, we will probably have to do some primary data collection to do this, some interviews and small-scale surveys and activities such as that. And particularly, we are interested in seeing whether the Animal Production Food Safety Program's state partnerships are having positive impacts on animal production food safety.

So we may, for example, do some case studies, interviews and case studies in states with and without state partnership programs to see whether those state partnership programs are having a positive impact and where they are having a positive impact, try to feed that information back to the Animal Production Food Safety Program here in the Agency so they can double their efforts in those kinds of activities that are working and maybe change the kinds of activities that there might not be as much evidence that they are working.

There was a lot of talk this morning about the adoption of the FDA food code and why it is and isn't being adopted in various areas. One of the things that we do want to look at in our study is whether or not those businesses that transport, distribute and retail meat and poultry products are adopting either voluntarily or because of state requirements or local requirements that are safer food

handling practices.

So, again, we've got a number of activities planned here. But one of the things that we think we probably need to do or intend to do is go into some of those states that have adopted the food code and find out why they did and what prompted them to do that, and also to see what kinds of activities or what initiatives here in the Agency were undertaken that prompted them to adopt those food codes.

So there is a lot of concern -- there was a lot of concern this morning about the number of states and localities that aren't adopting some of these practices. And hopefully, we can find out some of the reasons why those states that are reticent to do so maybe are and maybe look for some improvements in that area.

I save this for last, but in some ways it is one of the foremost things in my heart at least. I have come to think of this fairly recently as the Agency kind of -- the Agency's requiring industry to use HACCP. And the Agency now, I think, partly with our process here is starting to apply HACCP principles to its own operations.

Essentially, the Agency is trying to -- they have been trying for some time, and this is maybe another effort or a continuation of that effort, to assess where in the meat and poultry system from farm to table the most and the

greatest hazards like. I mean, where -- it is essentially conducting a hazard analysis of the entire farm-to-table system.

We are going to be over the next few years conducting a hazard analysis farm to table which essentially looks at all of the entities in the meat and poultry sector where meat and poultry products are handled. We will be looking at the types of products the different entities handle, the processes that they use to process the meat and poultry product, and the volumes of products that these various entities process.

This is essentially following a hazard assessment framework that was proposed a couple of years ago by Dr. Frank Bryan that essentially looks at product, process and volume as a hazard ranking system. And we are going to methodically go through all of the currently inspected state -- currently inspected meat and poultry establishments to look at product, process and volume, and assign hazard rankings to those different types of processes. Then we will go through a similar process within distribution facilities.

At the same time we are doing that, we will be looking at -- hopefully in a new way or maybe a more simplified way -- what are the regulatory resources or the Agency resources that you have to address these problems. I

mean, almost everything -- I sit back -- my tongue gets sore after two days because I bite it, you know, the whole time sitting back there in the audience.

I am an economist and I think about trade-offs. That's -- I think about cost benefit analysis. And one of the things I know is that on any given day, the man over in that chair has a given set of resources that he can work with. And he can't do everything for everybody all the time. So there are trade-offs that have to be made.

There are either explicit trade-offs or there are implicit trade-offs. And what we are going to try to do is give a tool to make more informed and more explicit trade-offs so that we see, given a pool of resources, given the hazards that we've got distributed through the farm-to-table system, where should I devote those resources of different types to do the best job I can today of addressing those hazards and trying to reduce foodborne illnesses.

One of the things that this process may reveal possibly is that we don't have enough resources to do everything that the public expects us to do or that Congress tells us we have to do. So we will go through the process of identifying the hazards farm to table, identifying the resources that we have to address those, and then -- and this is in many ways the hardest part; these two are relatively easy as complicated as they are -- is to then

develop some guidelines for intelligent resource deployment.

Given that we have a distribution of hazards throughout the farm-to-table sector and given that we have at least at any point in time a fixed set of resources, how can we more efficiently use those resources to visit establishments, to do compliance activities, to do sampling, to make decisions about should these products be exempted from inspection because of what type of meat they have or whether it was produced in a state-inspected plant or a federal plant, all of these kinds of exemption decisions that you have to grapple with.

Hopefully, we will be able to develop some guidelines using these resources and these hazard profiles that will at least give some first cut suggestions about how resources might be better allocated to address these risks.

Then to kind of finish that activity up, we will develop some indicators of success. That is, we will sort of evaluate ourselves and say, okay, we have suggested some guidelines. Now let's be bold. Let's try to implement some guidelines. Let's set up some kind of objective indicators of success; how would we know if we are doing a good job with our resources. Let's identify those indicators.

Let's conduct some field trials, some tests. And then let's go out and get feedback to see according to these indicators how good of a job are we doing. And then

finally, making that known or giving that information back to the decision-makers so that they can make adjustments in their resource deployment.

I know that this is -- in some ways, this is kind of vague. It is not highly specific. But it is a process that we are working towards. We've actually made I think very good progress on developing these hazard profiles. I would hope that six months from now, we will have all of the hazard profiling of the currently inspected establishments done and then a database and deliver it to USDA for use.

So this I think is an exciting part of the study because it is really looking at whether HACCP and pathogen reduction is allowing the Agency to do a better job of what it is doing in the same way that we are expecting industry to do the same. So I will stop there. And if anybody has any questions, I will let the Chair decide how long the discussion should go.

CHAIRMAN BILLY: Okay. Thank you very much.

MR. ANDERSON: Okay.

CHAIRMAN BILLY: Yes, Caroline?

MS. SMITH DeWAAL: Thank you. And I thought your presentation was very good. And I am excited to see the Agency doing this kind of evaluation. I do think that some of your questions are going to be tough to answer simply just in the HACCP pathogen reduction framework because

things like increased exit rate from the industry and consumer knowledge are so based on some of the increases in pathogen awareness.

And in the industry, with the exit issue, I mean, the need for new technologies in some instances is going to knock people out. So I just think the evaluation is excellent, but really you are looking at a somewhat broader question which is the awareness of pathogens in the food supply and then the need for industry, consumers and the government to respond to that. So it's almost -- it's great work. It's almost bigger than what you've laid out.

DR. ANDERSON: Okay.

CHAIRMAN BILLY: Other comments? No. Okay. Let me bring this to closure. Thank you very much, Don.

DR. ANDERSON: You're welcome.

CHAIRMAN BILLY: One other -- this is something -- this presentation and what we are doing is something I feel quite strongly about. It is important for regulators to evaluate themselves and the impact of what they are trying to do and to do that in a transparent way where everybody has access to and is aware of what's working, what isn't working, so while -- what may not be working at all.

And so over the next three or four years, as indicated, we will be sharing a lot of additional information and some new models and developing an ability to

really focus our resources where the greatest hazards are and do that in a justified kind of way.

Okay. The next item is the MOU with FDA on field communication. And that's going to be presented by John McCutcheon. So John.

MR. McCUTCHEON: Thank you. Good afternoon. This is a very short presentation. So if there is no objection, I could do it just from here. Can everybody hear me all right?

And MOU is a memorandum of understanding. It is a new tool for FSIS that was developed about a year ago. This is an agreement between the two agencies, the Food and Drug Administration and ourselves, that we share information and we work together and we communicate with each other on issues, regulatory issues of common interest.

We have, as you probably are aware, about 17 district offices. I say about because the last time you looked, you might have found that we have 18 district offices. We did consolidate the Boston office with our Albany office within this last year. So FSIS now has 17 district offices. FDA has 20 district offices throughout the United States.

We developed a wiring diagram so that we could figure out which FSIS office should talk with which FDA office, and then have had meetings between the agencies. We

have focused the attention here on our district managers and have required the district managers in FDA and FSIS to be the ones that are going to make this process work.

The intention here, and this is a new tool for us that, as I say, was developed about a year ago. Both agencies signed it. Then in March of last year -- well, no, March of this year rather, last spring, there was a training session that was held for the district managers and the staffs in the district offices to explain what the purpose of the MOU is and the mechanisms for making that work.

The intention here is that where there are joint regulatory actions that can be taken, that the two agencies work together. We do have examples of that. And what I have is a proposal for the committee, if they are agreeable to it. As I say, the process started with a training session last March. And we have agreed as part of the MOU that there will be an evaluation each year of how the process is being undertaken.

That process is going on right now. We decided to shorten the year a little bit for the first year. And we have the districts having joint meetings during the month of November, right now. Gary Pierce as my counterpart at FDA and I will participate in a sample of those evaluations. That's where one or the other agency will host the meeting in each of the district offices so that the staffs get

together and discuss the progress that has been made.

What I would like to propose to the committee is that when that process is completed, Gary Pierce's and my job will be to consolidate that into an overall report. And I will go over six or seven of the different types of issues that will be evaluated during that process. And then at your next meeting, then I would propose that we make a presentation along how that particular evaluation came out because we will have more specific information.

What we will be gathering during the month of November is the list of enforcement actions, the joint enforcement actions that have taken place. We do have a number of those that have already occurred where we have gone into a plant. And if we have some particular problems that we are observing and if the plant is also having some problems that could potentially affect FDA-type products, we communicate with each other about that.

And then we coordinate the type of action and share information and gather samples for each other. And we have had some experience in doing that and working the information together.

Along with our General Counsel's Office, of course, we have to be careful that we don't do work on somebody else's regulation or statutory authority. So we are quite cognizant of the responsibilities that we have

there when we work together.

We have developed with the two computer groups a joint list of plants that are under both areas of responsibility. And our computer staffs are maintaining that so that we have in the district offices a list so that we know which plants are involved here.

We will developing a list of the joint actions that have taken place. And from that, during the evaluation, we will be asking questions of how did it work; what problems did we have; what communications problems came up and how were they addressed. And then we also want to follow up with what changes have taken place in the district level contacts; how has that been working; and what changes might we need there.

We are also going to be concerned about what additional training might be necessary for each party to understand how this could work better. We also want to find out what we didn't include in the MOU in terms of activities that we might include such that from the experience we've gained, that we can then share that from one district to another, and then any obstacles that were encountered in implementing the MOU such as things that are in there that maybe should come out. These would be sins of omission and sins of commission, if you will, of how can we improve the process.

So very quickly, I wanted to give an overview and point out that such a document does exist. It has been used in a number of cases. We are doing an evaluation right now and that evaluation will be completed before the end of the calendar year. And then we would be available to give an overview and a more detailed perspective when that is completed. So if there are any questions, I would be glad to address those.

CHAIRMAN BILLY: John, how many plants -- I remember a number of about 800. Is that correct in terms of --

MR. McCUTCHEON: That's correct. That is the current number of plants that we have that are on the joint list.

CHAIRMAN BILLY: Okay. Lee?

DR. JAN: You said that you have to be careful that you don't try to use or implement somebody else's regulations or use other regulations. And I wonder why is that. And what I'm thinking about is particularly in some of these plants that have a meat processing area and maybe a non-meat processing, maybe making tamales on one side and tortillas on the other. In fact, we see quite a few of those.

Why couldn't that inspector that is there every day go ahead and do the FDA regulations, impose those or

carry out those regulations on the other side rather than just making sure that some of that -- those activities do not contaminate this side?

It seems to me that that would be a better utilization of the resources. And also, on that same line, where FSIS does not have the regulatory authority -- and a prime example would be temperature requirements on red meat, why could not that inspector reach over and use FDA regulations where there is a requirement that product be 40 -- perishable product be 40 -- right now I think 45, in the future it will be 41 or below before it shifts?

We are doing that in Texas. I don't know if that's legal or not, but cooperatively.

MR. McCUTCHEON: I'm not the lawyer that would probably give the best answer to that question. But we have statutory authority under our Meat and Poultry Inspection Acts including the Egg Products Act which define what we can do. And we get appropriated moneys, you know, to enforce that Act.

And if you sort of stray from those requirements, then people do get upset that you are spending money for other activities. I think the purpose of the MOU though is to minimize and -- or, if you will, the lost opportunities of where if we see something and a marginal cost or opportunity of seeing something can be passed along to FDA,

we do that.

And the purpose then of the MOU is to facilitate that process. So if we see something that it involves an FDA product that we think they would be interested in, then we have now a good mechanism to pass that long. FDA then engages itself in that and follows up with it. So that we do use your eyes and awareness to pass that information along. And that's permissible and that's what we are doing.

DR. JAN: Well, that -- I think that's a good first step, you know, make each other aware. I think that's excellent. But couldn't that MOU, maybe the next step cover some of these financial things and maybe do some trade-offs? I'm sure you can't transfer money across budgets. But maybe there is something in that MOU that then they could give in-like service back to FSIS.

MR. McCUTCHEON: Well, I think we should explore and push the envelope as far as and as hard as we can on that. I agree with that. There is also a training issue that they -- the FDA people don't necessarily know our Act and we don't necessarily know their Act and the ins and outs of what is needed there. So that you also get into the issue of knowing what authority the other party has and behaving appropriately.

CHAIRMAN BILLY: Cathy?

DR. WOTEKI: Yes. I might add to what John said.

Among the things that we are doing in the strategic planning activities of the President's Council is examining all the legal impediments to do exactly the kind of thing that you've suggested. I think you are absolutely right in characterizing this as a first step towards better utilization of resources. And we are using the strategic planning activity to examine barriers to improving that kind of cross-utilization.

CHAIRMAN BILLY: Caroline?

MS. SMITH DeWAAL: I might point out that Lee's very logical approach arises from the fact that they have only a single food safety agency down in Texas. So they can use their thermometers to inspect either side of the aisle in these plants. And perhaps in the considerations of the President's Food Safety Council, they might consider some of the leadership from the state of Texas in solving some of your own problems.

I do have a question for Mr. McCutcheon regarding I see this MOU as a one-way street where FDA is getting increased oversight of its products hopefully, if you guys happen to see something, without really increasing their inspector base.

Can you give me some -- I mean, how are these meetings going on the district level? How many inspectors do they actually have? How do you deal with the fact that

their inspectors may be dealing with a medical device plant one day, a drug plant another day, and a food plant the third day? So give me a sense of how this works in real life.

MR. McCUTCHEON: Tom was with FDA more recently than I was. But when I remember the FDA inspectors --

MS. SMITH DeWAAL: I remember that.

MR. McCUTCHEON: -- that they did get credentials in certain areas. And they don't generally go from a medical device to a food plant within the same week or day period. But they might have changed that.

But the meetings that we have are at the management level in the district offices. We don't have the inspectors there, so I can't give you a count of how many people they have behind the scenes that we don't see. I would say that with the evaluation that is going to go on, we will get some input on that.

The experience that we have had though with FDA has been that in the case of one of their products in particular, that it worked out very well that we were able to work cooperatively. And there are more instances, but that's what I am aware of right now. In terms of the sampling that was done, the resources that were available to get information on the FDA side and so forth, it was truly a joint and cooperative effort.

MS. SMITH DeWAAL: Are they giving you information about your products?

MR. McCUTCHEON: Yes. They are contacting us about issues. Although call the district office and let them know because they do go into plants also when they do have investigations. And I myself was on a place like Marriott for example, not to pick on anybody.

But obviously, they do meat and poultry items as well as non-meat and poultry items, and so plants of that type which comprised the list that Tom mentioned of about 800 plants. They do have an inspection capability that they also get information from various sources that target some of their investigations, too, that are followed up on.

MS. MUCKLOW: Tom, let me just ask John, will this memorandum, John, help to facilitate a closer working cooperation on the identification of livestock with animal residues? Will it reach into that area or is that just a whole different can of worms?

MR. McCUTCHEON: I guess I would have to agree with it is a whole different can of worms in that we really haven't explored that area. It may be something that will come out, but we just haven't had any cases of residues that we have tried to follow up with.

And also, we are primarily involving the food area, if you will, as opposed to the veterinary area more.

If you are thinking of the Center for Veterinary Medicine and that, we have other ways of cooperating with them that we have had for a number of years through the RIVA system and the way we have shared data there.

MS. MUCKLOW: Yes, I am thinking of that.

MR. McCUTCHEON: Yes. And that -- in fact, FDA's offices for a number of years have had terminals with -- the RIVA system is the residue violation system database that we have that we share information with. And that was going on for sometime before the MOU even started. So, and that does continue.

CHAIRMAN BILLY: All right. Thank you very much. We are scheduled for a break about 3:00. So I think what I would like to do is move forward and deal with the inspector shortage briefing. And if we run over a little bit, then I will shorten the break. So that may create an incentive. I'm not sure. This briefing will be led by Dr. Mark Mina. So Mark.

DR. MINA: Thank you, Tom. I don't know why I get all these choice assignments. FY '99 was a particularly difficult year in terms of our resources. Can everyone hear me or do I need to get up there? Okay.

MS. MUCKLOW: Don't go near that screen again, Mark.

DR. MINA: I won't. That's why I am staying here.

FY '99 was a particular difficult year in terms of our resources. As you all know, we have limited resources. And I perceive the comments that Don made about stretching these resources to cover a lot of things that we would expect it to cover and the public expects it to cover.

Two main factors contributed to maybe our shortage of resources in '99. One was the significant increase in plant productions. And that is in cattle and swine and particularly poultry that went beyond our expectations. And so that was one of the main factors that the result was maybe some of our shortages.

The other factor is the strong economic condition in the country. Our ability to recruit a large number of inspectors was really hampered because of the strong economy. And they can get maybe a better job, a higher paying job than working for FSIS. And so that makes it extremely difficult for us to recruit people.

And to give you an example of how that translated to our shortages, we used to get roughly 2,000 applicants on our national register. And last year, we were lucky if we got about 800 on the national register. And in certain parts of the country, we don't get any, none.

Having 800 names on the register, that does not normally translate to 800 inspectors. The declination rate was at least 50 percent, at least 50 percent. So that

number is reduced already to 400. And so those are the two main factors I think that contributed to our difficulty in '99.

We have recognized the problem early on and we have reallocated many of our resources. We took a lot of action to reduce our travel meaning headquarter travel, district travel, inspector travel, to come up with some additional resources that we can add to our existing resources to eliminate some of those shortages in the plants.

Starting this year and maybe starting -- maybe -- let me back up, two or three months ago, we embarked on a very aggressive recruitment program. We put a lot of things in place that we had not done in the past or we did not really need to do in the past.

But today, we live in a different environment. And as I indicated before, the economic conditions in the country is pressing us to do things that are different. And we need to do very creative in recruiting instructors. And I am glad that Mr. Ron Hicks and his staff are here. And I think they are probably better equipped than I am in telling you about our aggressive recruitment plan.

We have been working very, very closely with our personnel staff to make sure that we recruit enough inspectors for us to do the job that we are required to do

in FY 2000 considering, again, our limited resources in 2000. But we will do everything that we can to make sure that all the jobs are fully staffed and fully covered. With that, I will ask Ron Hicks to --

MR. HICKS: Okay. Good afternoon. I am Ron Hicks, Deputy Administrator for Management. With me is Marlin Waller who is my HR Director, Human Resource Director. Mark is right, we have had a very difficult year in terms of dealing with the ability to staff our food inspector ranks.

Trying to keep up with attrition has been most difficult. There was a time when it was fairly easy to go to a register, as Mark has indicated, and find the number of people that we needed to fill jobs. And now all of a sudden, we are finding out that we are not the only game in town. There are other games in town. And we have to be far more aggressive and created in trying to make sure that we recruit the caliber of people that we need and the numbers of people that we need.

So we've dealt with one of the issues that we had to deal with in terms of the necessary resources to do that. Now we have to put in place mechanisms to make sure that we can actively recruit and have on board the numbers of people that we actually need.

We have begun the process already. Marlin Waller

can tell you some of the things that we have done in order to try and keep up with attrition and recruit the numbers that we need. We need to do more. And our commitment to you here today is to tell you that whatever we need to do over the upcoming months in order to staff our ranks is what we will do.

So I would like for Marlin to talk to you about some of the things that we have done and some of the things that we will be doing. We will be meeting with Mr. Billy next week to provide him with a more detailed plan to what we had already thought was a fairly detailed plan for recruitment.

But as we are finding out right now, we need to keep up better than what we have kept up. So there is more information that will be forthcoming that will be developed to enhance what we already have put in place. But let me let Marlin Waller talk to you just briefly about things that we already have done and what we intend to do.

MR. WALLER: Thanks -- excuse me. Thanks, Ron. All right, thank you. Thanks, Ron, and I am happy to be here, as well. I will say within our division, within the Human Resource Division, we have been working very hard to identify food inspector candidates. As Mark and I think has Ron has indicated, it is probably as difficult or more difficult than it has ever been to do that. But we don't

think it is insurmountable.

So as Ron said, we are in the process of developing a very specific plan. Some of the things that we have already done is held a recruiter training session in which we trained recruiters in each of our district offices. That will be sort of an ancillary help to our Human Resource people and actually we will conduct outreach types of activities at conventions, at schools and other locations.

We have advertised quite a bit in the past and we are looking at more targeted advertising and just better ways to spend our advertising money and to maybe even be better to allocate a little more money to that. We have explored pay incentives.

We actually have some recruitment bonuses in place for veterinarians in certain parts of the country, so -- where it is particularly hard to recruit. And we are looking at locations for where it is very hard to recruit for food inspectors, as well, and hope to have something in place for them soon.

We are also looking at some possibilities of paying for moving expenses to the first duty location for food inspectors. We have commonly done that for veterinarians, but haven't done that for food inspectors in the past, and are now looking at that.

We are planning on making more and additional

visits to schools and conventions and other organizations where we would commonly be able to find food inspector-type candidates. As Mark has indicated, we have a register in which in order for candidates to actually be able to be on the register for us to hire them, they have to take a test which we hold at various locations around the country.

And we are looking at holding those tests in different locations, holding them more often, holding them in areas where we really have inspector shortages. So hopefully we can speed up that whole process and actually be closer to the places where we actually need the applicants.

We are looking at different kinds of hiring authorities, actually looking at ways to bring on people on a temporary basis while they have the -- and then have them go through the testing process so that we can get them on early on and then maybe -- and then, you know, have them go through the testing.

We are also within our office just trying to streamline the process. It does take some time in the system we have to actually get people through that system and to make sure we've followed all the applicable procedures. But we are looking to streamline that. And we are just looking to have a better outreach within our Agency.

And obviously, if anybody here has any ideas on

things that we could do, we would be more than welcome to -- more than welcome those. But we are just looking to also make sure that we use all of our people in our Agency to help us identify candidates.

So those are just a few of the things that we are intending to do and have already started doing. So hopefully we will be able to get the shortages reduced very quickly. Thank you.

DR. MINA: We are also particularly interested in hearing from the State Director that he may or may not be experiencing the same problem that we have and how we can help each other maybe dealing with some of those situations.

CHAIRMAN BILLY: Right. And in particular, if you would provide us a list of your state employees so we can write them letters. Dan?

MR. LaFONTAINE: It's interesting, that was a perfect lead-in to what I have to say. Something very unusual has happened in the last six months. And that is that I am getting calls from FSIS inspectors wanting to come to work for the state and take a pay cut.

And the reason is the tremendous concerns about job security and, "Oh, you are going to have a job, but you might have to move." And I am relating this back to the HACCP models project, you know, the change to consumer safety inspectors, consumer safety officers.

I know you are doing a lot of information through the Thursday report and every method you can to try to get the word out. But when you are on the chicken line or the turkey line and your plant is going to go be a model plant and they know that part of the objective is to reallocate some of your resources, you can talk until you are blue in the face. There is a lack of job security.

So bottom line is work harder -- that is a part of your problem. And they are telling their friends, "I don't think now is the time to come to the USDA because you may not have a job. You better try something else." I think -- I haven't heard that mentioned. And that's real out there.

When they call me and they want to take a $3,000.00 cut to do the same work because that's how much less we pay for the entry level, that speaks for itself. They want to stay where they are at, in their communities with job security. Family and job security first.

DR. MINA: Thanks.

CHAIRMAN BILLY: Lee?

DR. JAN: I heard -- actually, I heard I think two different areas of your problem. And maybe they are not. But at one point, you indicated you are not getting the candidates. And I think that was the biggest issue here. But you also said that you cut travel in the different -- in the central office or at headquarters and in the regions to

get more resources.

And so that would tell me that you also have a money problem, that you don't have the money to fund these positions that you can't get applicants for. Is that my understanding, that you have both problems or do you have the fund and just can't get the people?

DR. MINA: It's more complicated than that. It's very complicated, Lee. And I don't think a simple answer would do justice to that problem. It is a combination of all of the above.

DR. JAN: Okay. Well, let me tell you, you asked for suggestions and how could we maybe work together.

DR. MINA: Right.

DR. JAN: And I will tell you briefly what some of my problems are. I've got it fully staffed, 100 percent staffed. And that's not a problem. But we have a legislative mandate that caps at the FTEs and the dollars. So just looking in the future, if this bill comes to pass and we a seamless inspection system, and to help the Agency out I can recruit -- and I can get the people to do -- so I can take on more plants. But we might need to look at it.

But my problem that's going to limit me is an inability to get FTEs even if you come up with 60 percent or maybe if somebody would become wiser and say, "Maybe you ought to pay 75 percent", whatever. But the money -- if I

could get the money, I still won't get the FTEs.

But we might could take what's kind of in the picture already and maybe modify the cross-utilization where you fund these people and we recruit for them and we kind of have a cooperative situation that way. I don't have to come up with FTEs or dollars and you -- we will help you fill those positions. And we will take on more plants, you know, the smaller plants to our limitations. It might help out. That's it.

DR. MINA: If I heard you correctly, that's predicated on Congress passing the interstate shipment bill. And that bill is in Congress, as you know. And that decision is for Congress to make. And when they make that decision, we might want to consider this proposal. We are concerned about the immediate need today and how we alleviate some of this problem today through 2000.

MR. HICKS: Lee, when I look at that issue and what I've put my finger on it, I think that's the real crux of the problem, is dealing with an action that we will have in Minneapolis to fill a job and to go to the applicant pool to try and fill that job.

And there are very few people, if any, who have either applied for that job or which we wish to select. Then we have to go out and recruit again. And that happens over and over and over again.

That's what I see as really the major crux of the problem, is the tracking of people and then, too, holding onto folks that we want to hold onto, would like to hold onto, but have decided that because of the change that we're going through, the tremendous change that we're going through and the uncertainty that that generates, another option may be more appealing to them.

And we do have to do as good a job as we can do to put together information for folks to give them a clear picture as to where we are going, what we intend to do with them and for them, and are we best to create job security.

We have a group called Work Force of the Future, in other words, a group, a task force that is designed to just that, to make sure that all the pieces of where we are going and where we are headed make sense to each other but, more importantly, makes sense to our workforce so that they can understand clearly what is going to happen with them and where their job opportunities may be. So that's a very key piece that we have to make sure that we implement and make sure that it works.

CHAIRMAN BILLY: Collette?

MS. SCHULTZ KASTER: I could go on about this for a long time. I have a lot of notes that I have taken. So the first thing -- so I'll try not to do that. I will start by doing that.

But the first thing that I want to say is that I want you to understand how urgent the situation is because the feeling in the field is that you don't understand the urgency. It is an urgent matter to the industry. It is an urgent matter to consumers. And it is an urgent matter to your own employees. And there are costs to all three of those segments associated with this problem.

I am disappointed that -- in your response, that it's too complicated to say whether it is a matter of needing more bodies or needing more money because I think that we need to understand which one of those or what combination of those that it is. And so I hope that you will elaborate on that.

We are very empathetic because we are all, no matter whether it is the meat industry or restaurants, we all are facing this situation right now. But this is something that you need to take very seriously, that the people in the field need to see you taking hard action on -- because this is a big deal right now.

CHAIRMAN BILLY: Let me elaborate a little more on the money question. Last fiscal year, the budget allocation we received from Congress was one where we were provided not only some of the increases that we asked for, but also had some funds earmarked for certain areas of expenditure.

We weren't provided funds to cover all of our cost

increases. Certain ones, you know, in terms of the salary increases and other cost increases, for example, our share of the funds related to the states in the cooperative programs we have there.

So what we had to do last year was to severely restrict the expenditure of funds in areas other than what we call front line. Those are the inspectors, the first line supervisors, the compliance officers and the lab personnel that do the analyses. That's our front line. And those -- we did not limit those funds other than within the framework of the total amount of money that we were provided.

We put in place things like a one-for-three hiring freeze in the non-front line hiring areas. So in headquarters, in the district officers, managers were only allowed to replace one out of three people that departed. We limited travel. We limited training. In fact, we cut back severely on training, all of which was to not just maintain the workforce, but an attempt to increase the number of inspectors commensurate with the growth that was occurring in the industry.

One example is the growth that occurred in the poultry area, a six percent growth. That six percent growth represents in round numbers about 450 million birds in 1998 -- in 1999, excuse me. And each of those birds have to be

looked at individually. And so when you translate that into the number of inspectors, additional inspectors or capacity that you need, it is indicative of what we were wrestling with.

So there was an attempt to build our employee base. But, in fact, we struggled with it because of the reasons already mentioned. Now, for our new budget -- current budget this year which isn't quite settled because we've got this business going on about an across-the-board, just slightly less than one percent cut that the President has vetoed. And I can assure you that if that actually occurs, that kind of across-the-board cut, it will have a very direct impact on our ability to hire inspectors.

But Congress has indicated to us they want us to spend a certain minimum amount of money on inspection and provided the Agency, all toll, about four million dollars less than what the President asked for.

So we are now in the process of sorting out what it is we can do and what it is we can't do and cover what we anticipate will be a demand for an additional, beyond just maintaining our workforce that we have now, an additional 100 to 200 additional inspectors that will need to handle the further growth projections of the industry in this new fiscal year that just started October 1st.

So it's not just maintaining. There is growth in

the industry. And we have to provide -- cover that in order for the firms to operate and receive the mark of inspection. So it's -- in part, that's what Mark was getting at. It's not simple.

We've got funds to provide for some increase in the number of inspectors. We are not sure that is going to be enough to cover all of the growth and demand that we are going to have.

And if it isn't, then in an overall, finite pot of funds, then what are the things that we will have to stop or not do to handle what will become an inspector shortage or reoccur as a shortage if we are able to achieve what we are doing here in terms of hiring an additional number of inspectors in the next several months.

So it won't be a one-time fix. It will be a constant struggle I think over the next year and perhaps over the next several years if we've got the same kind of economic conditions in the country in terms of being able to hire entry-level people at about $10.00 an hour which I know we've had an example cited to us where there are school bus drivers, school bus driver jobs that pay more than $10.00 an hour or McDonald's in certain locations where they are having the same problem or -- and many other examples.

So it is difficult given the pay structure and what we are able -- so we are trying to come up with

incentives and other ideas that will facilitate this process and solve the problem.

It is not in our interest to have an inspector shortage. It just creates nightmares for us. So we are going to work really hard to do that. And we are going to mount some additional efforts to hopefully achieve elimination of the shortage. Ron?

MR. HICKS: I fully appreciate the sense of urgency that you are referring to in terms of what the folks in the field need to see. I wish there was an urgency meter that I could hold over my head so you could see exactly where it is pointed.

When I leave here, Marlin and I are going up to visit with two district managers as part of an overall union meeting and district meeting. And part of our jobs there are going to be to talk to the district managers about these very same issues.

I am headed out to Chicago week after next to talk to a district manager out there to wrestle with some of those issues. And I have a few upcoming meetings in December. And a large part of that is to talk to folks, with my people, to find out how we can start to tackle this issue in a very real way.

We can list 100 things that we are doing. And without something that says how urgent we feel about this,

there are just 100 things in a list on paper. But I can guarantee you that behind those things that Marlin has mentioned and others that have not been mentioned then is a commemorative resources that we have which says we have got to tackle this problem with field operations and get it done.

CHAIRMAN BILLY: Okay.

DR. MINA: I want to echo what Ron said about the sense of urgency. For me, that is my number one priority. And I think that was evident for the district managers. We had a district manager meeting last week. And that was the number one topic of discussion.

And Tom and Maggie attended the meeting. And we had a full discussion of the issues and what we need to do.

And so everyone is fully aware of it. And we are working very hard to resolve it.

CHAIRMAN BILLY: Donna?

MS. RICHARDSON: Thank you. Coming from a profession that goes through shortages every ten years where it is critical, I can understand the concerns. To make it more real to me, other than this sense of urgency -- and I understand you are talking about needing approximately 200 more inspectors in the future to deal with the demand -- is what are we talking about in real people now? What are the FTEs that you have allotted for inspectors? And then what

are your actual vacancies?

And I know having worked in the VA system that oftentimes the FTEs are reduced because you have less money for those FTEs. But what I thought I heard at the very beginning is that you do actually have an actual vacancy rate now.

MR. WALLER: Yes. We are right now -- in our in-plant staffing, we are right in the vicinity of 7,400, maybe a little over 7,400, 7,420, somewhere in that range. And we are shooting or targeting to get to near 7,600. But at the same time, we have a very high attrition which either ranges somewhere in the 20s, sometimes up to 30 or so per month. So, I mean, that sort of amplifies the situation and just indicates how many additional people we have to hire just to keep up with that attrition rate and to get to the targets that we are looking for.

CHAIRMAN BILLY: It is not an FTE problem. We have adequate FTE. It's just getting people.

MS. RICHARDSON: But you have actual vacancies.

CHAIRMAN BILLY: Yes.

MS. RICHARDSON: Now, your attrition rate that you have now is -- is that markedly different than you had five years ago?

MR. WALLER: It's a little higher. It has been a little higher over the past year, but not an extreme amount.

Within a couple per month maybe is the difference. So it's not a lot different.

MS. RICHARDSON: So what we are talking about is a chronic problem as opposed to something that just happened in the last four years of this really --

MR. WALLER: Yes, well, I think it does go in spurts. But I think as people have indicated here earlier, the difficulty is more just attracting candidates and applicants. I think in the past, for food inspector-type candidates, we really didn't have to do a lot of special recruitment efforts.

The number -- the people were available generally. And for many of the reasons that we have outlined here including how the economy is, it's just more difficult to find and attract candidates. So I would say that's maybe one -- the primary difference from the past. I mean, we have always had this attrition rate, but we have generally been able to keep up with it.

MR. HICKS: I think what we have here is a chronic problem that seems to be getting worse than what it has been in the past, that we've always experienced these highs and lows and a certain level of attrition. But a number of factors seem to be coming together now to make it a little bit worse than even what it has been in the past.

CHAIRMAN BILLY: Okay. Caroline?

MS. SMITH DeWAAL: What is the impact of the failure to get the consumer safety officers? Would that expand the population from which you could draw? Are there any -- or would it actually make the job more difficult because you are paying people more to do the job? What's the impact of that?

DR. MINA: We thought there is a good opportunity for us to maybe increase the pay at least to attract more people. And obviously, we're going to have higher qualification and have the scientific background. That is different than a GS-5 that we higher today. And so that -- we did not have that problem.

MS. SMITH DeWAAL: Is there any opportunity to get that added to the supplemental and perhaps the industry could help you get that particular provision passed?

CHAIRMAN BILLY: Well, we think that the addition to the mix of people we have, of people classified as consumer safety officers that are college graduates with a minimum of 30 hours in the relevant sciences is not only important in terms of dealing with this recruitment issue -- it will help there.

But it also is consistent with this transition that we have underway, the discussion that we had about doing the in-depth reviews is an example where placing consumer safety officers throughout the field, in district

offices, in supervisory positions and inspector positions can bring the capacity to do not just the inspection tasks, but the analysis and the monitoring the trends, the process audits, that kind of thing, and create a better capacity in the Agency to deal with those things that are part of our future.

It's sort of a two-fer. I think it will help us in both respects. I know the industry is pinned on us a lot for, you know, better training, upgrading the skills of our employees. And we think adding some number of consumer safety officers to the mix with what that means is part of the process that we need to follow through on.

We have an obligation to report to Congress I think it is by February 15th, this coming February 15th, a report that lays out in more detail to Congress our plans with regard to consumer safety officers and the role that we expect them to play.

And in particular what Congress has asked us to do is to do an analysis that shows them the least cost approach to adding consumer safety officers to our mix of employees or our workforce. And I think that is a reasonable question for Congress to ask is, you know, "We can see that this will have budget impact. We want to know" -- "see an analysis that shows us what the least cost approach is for achieving what you are after."

So we will be doing that report and then having discussions with Congress with the hope that we can move forward as planned to add some number of consumer safety officers. And we don't know the right number. It might be 1,000 or 2,000 out of a total of about 7,500, something on that order, perhaps a few more. Yes. Rosemary?

MS. MUCKLOW: When we became aware of this acute problem at the Agency several months ago, I think it was in discussion with Dr. Mina, we even as an organization and some other organizations have also now done this, put ads in our publications to try to get people to come work for you. We hope that that has been helpful. We don't have any feedback and we certainly don't get a commission for this activity.

The thing that I would be very interested in knowing is that I know that when you are hiring for slaughter plants, you hire at the GS-5 level I believe it is. And within a very specific time frame, those employees move to the GS-7 level. If you are putting people into processing operations, depending on the complexity, they are GS-8s or 9s. And I never remember what the veterinarian in a slaughter plant is. And you have several grades of veterinarians.

I think it would be informative if you could from time-to-time tell us what your vacancy rate for each of

those classifications is. I think if that were -- I don't think it is a big secret that you are looking for X number of people who are veterinarians, you are looking for X number of people who are line inspectors or processing inspectors. You may want to group them and not just list them as 5s, 6es, 7s, whatever it might be.

I have also been told in the discussions that I have had that in an agency as large as FSIS, with that size of workforce, you are always going to have vacancies. I mean, it is part of the game. And so having vacancies is nothing new. It is the size of the vacancy problem that you currently have that you are trying to resolve.

It is a serious situation. And I know by rumor only that, you know, there was some poor old supervisor. By the time he had filled in all the line spaces he had to and done the veterinarian's work and so on, finally he's not going to come to work himself. I mean, you can't work people at both ends of the clock and expect to have a workforce left.

We want as an industry to do whatever we can. And the constituency that we have may be one of your best constituencies for hiring. And so we will be happy if you want to send us ads. I have no problem putting them in our newsletter. I know there are people out here who have done likewise and probably feel the same as I do.

Let us hear from you. We can be a good resource for people. We are not wild about that revolving door. But it is important and I think we can probably be helpful. And I don't know, maybe Gary Weber can help. We've got some cowboys out there. They would probably rather put a gallon and a half on them. So, you know, try it.

CHAIRMAN BILLY: Thank you, Rosemary. In fact, you are going to get your wish because another report we are going to start issuing quarterly to Congress is a report on our vacancy situation.

MS. MUCKLOW: Good.

CHAIRMAN BILLY: So you will get a lot of details.

MS. RICHARDSON: When does that start?

CHAIRMAN BILLY: January. Yes, Donna? This will be the last one and then we are going to move on.

MS. RICHARDSON: That will be our first quarter.

CHAIRMAN BILLY: First quarter.

MS. RICHARDSON: To follow up on Rosemary's statement, having worked with Senator Shoemer on the issue of what the hospital industry can do about the nursing shortage, that if, indeed, this is an urgent issue, not just for the Agency and the industry and the consumers, of looking at a partnership very similar to one that was developed with the hospital industry when we had the nursing shortage.

And that was an upward mobility program where the hospitals encouraged and subsidized their employees, their lesser skilled employees, to go to nursing school. And that increased the numbers of nurses. Up until the last year, the nursing shortage had decreased.

And so I would encourage the industry to look at how it might offer subsidized tuition packages for their lesser skilled workers, encouraging them to go into these fields. And that way you get people who know the industry from the ground up. And you can assist with ensuring that you have the skilled people that you have been pressing the Agency about.

CHAIRMAN BILLY: Okay. Thank you very much. It is now almost 3:30. We have one more important topic. And so what I would like, with the indulgence of the committee, to ask you to do is I would like to take about a ten-minute break, so even faster than the earlier shorter break. And feel free to bring back your coffee or whatever and have it at the table. And then we will carry on. Thank you.

(Whereupon, a brief recess was taken.)

CHAIRMAN BILLY: The next item is an important area. It is sort of an alert or a heads-up that we want to provide to the committee and explain it. And for that purpose, we have produced a white paper. And here with us are Phil Derfler and Dan Englejohn to present the essence of

this paper and inform you about what we are concerned about and what our thinking is. So, Phil.

MR. DERFLER: Hello, and I'm happy to be here. Not really. But what I wanted to do was present a little bit of an introduction to the white paper that we have prepared. Even though we started -- we issued a policy on E. coli 0157 in January, in a lot of ways, this white paper marks the start of a process more than anything else.

The white paper, you were just handed it, it starts with a background discussion as to how we got to where we are now with respect to E. coli 0157. And it starts out by pointing to five factors that contributed significantly to our current thinking about this pathogen.

It points out first that because E. coli 0157 was an emerging pathogen in 1994 when it, you know, sort of burst on the scene and subsequently, we had only limited data available with which to work and to formulate our policy.

The second factor that was very significant was this pathogen proved very difficult to find. And the low rate that it was discovered raised the question as to whether this recovery rate was attributable to the fact that it was a rare pathogen or whether the methodology used to test for it was not sensitive enough to find the pathogen.

As a result of the fact that it was not found very

much, the Agency has never taken the position that E. coli 0157 was a hazard reasonably likely to occur in the ground beef or meat operation. The third factor that was significant was the fact that we couldn't find it meant that we could not repose a lot of confidence in a negative finding when we did testing.

And so, for example, when we looked for it and did find it, that that finding was more significant than it might otherwise be. So, for example, in the directive that we have which you received a copy of it now, once there is a positive finding, the Agency will then test for the pathogen in the plant for 15 consecutive days and will not continue this sort of daily testing until there are 15 consecutive negatives.

The second thing is our directive says that plants -- we will not take a sample of a plant does its own testing. However, once a positive is found, that is not the case for at least six months, until there is six months of again negatives.

Another factor that derives from this, the lack of confidence in the negative finding, is the fact that we started testing at retail locations. We wanted to make sure that we take every opportunity we could to try to find the pathogen. And testing as we got closer to the consumer provided some additional confidence although not as much as

we perhaps like.

The fourth factor is the fact that most of the outbreaks that occurred that were attributed -- you know, related to this pathogen were attributable to ground beef. A risk assessment was done. And they were very closely associated. The outbreaks were very closely associated with ground beef.

And what we found is Americans were not used to thoroughly cooking their ground beef patties. So that led to the Agency's policy of that if we found it in ground beef, if we found E. coli 0157 in ground beef, that product would deemed to be adulterated, the only pathogen that -- in raw product that we had made that -- taken that position.

And finally, the only methodology that we knew that was effective in getting rid of the pathogen was cooking. And so that was the centerpiece of the guidance that we gave and, for example, the guidance material that we published in January on how to deal with 0157.

But now we can see -- or it appears to us that there are several significant developments that are in the offing. And this has led us to focus on this matter and bring it to you today because it is likely as a result of these things that we can see coming together, it is likely that we will be back with you in the future about this matter as these developments unfold.

First of all, new information is emerging to suggest that E. coli 0157 is not as rare as it was once thought to be. In September of 1999, FSIS began using new methodology to test the samples of E. coli 0157 that we take. And as a result, we have gotten 21 positives over the last month or so. I mean, these are a little bit older data because I think we've actually gotten two or three more positives since we wrote this.

But the new -- the finding of the pathogen with the new methodology suggested to us that it may well not have been the rarity of the pathogen, but the sensitivity of the method that was the basis for the findings that we were making.

Further evidence that E. coli 0157 may occur more frequently is the recent foodborne illness data that was put out by CDC that was alluded to this afternoon. That showed that there were a lot more illnesses related to E. coli 0157. They were less severe than perhaps had previously been thought. But there were a lot more illnesses associated with this pathogen. While not all of them were attributable to beef, I mean, it does suggest that the pathogen occurs more frequently than we had thought.

In addition to these data, the American Meat Institute currently has a study ongoing at slaughter. There are 12 plants involved in which they are sampling carcasses

with the hide on, after hide pulling and then after interventions -- after their pathogen reduction interventions. We think that this study will provide us with significant new information about the rate of occurrence of this pathogen.

Finally, another factor that has led us to -- you know, provided evidence than was previously thought is some new research that was announced by ARS, work that was done at the Clay Center in Nebraska where they went out and looked at feed lots. And they found evidence that it was -- that the pathogen was present in most feed lots and may well be present in almost 50 percent of the animals that were presented for slaughter.

The second major development that we can foresee forthcoming is the completion of FSIS's risk assessment on E. coli 0157 on ground beef and on some trimmings. We hope that this study will help us to, you know, better -- make better decisions as we move forward and sort through our regulatory options.

We expect the study with all peer review and everything like that to be done in the spring of 2000, although next month it is our understanding that a presentation on the risk assessment will be presented at the National Advisory Committee on Microbiological Criteria in Foods, thank you. And so we look forward to hearing what is

presented then.

The third major factor -- or third new information that we have that is likely to have a significant effect on our policy is information that we have been presented on blade tenderized roast and steaks based on work that has been done at Kansas State University.

As you will recall, in January, we announced our policy that E. coli 0157 was an adulterant not only in ground beef, but in non-intact meat products. This new data was started I believe as a result of that policy. And now there is a whole lot more information that they have developed. And we need to evaluate that as part of our policy development process.

Fourth, we can now see that there may well be interventions other than cooking that will be available to deal with this problem. We have a rule to authorize the use of irradiation in meat products, as well as poultry products. And we are hopeful of getting that final rule through the process soon. It deals with questions about labeling, about the use of the process and its effect on E. coli 0157. So this is a hopeful development.

There are several other considerations that are also likely to come to bear. As more and more plants come on line with HACCP, the question becomes more and more significant given what appears may be the increased

prevalence of this -- not increased, but the fact that this is not a rare pathogen. It is squarely the question as to whether or not this pathogen is a hazard reasonably likely to occur in plants.

And the other area that we hope there will be develops is in the production level where research is being done and possible interventions on the farm to try and reduce the pathogen -- the occurrence of the pathogen.

Given these developments and the fact that we see ourselves launching a process, we have developed a set of questions and areas for consideration that we see ourselves looking at as we move forward. And Dr. Englejohn will briefly describe those.

DR. ENGLEJOHN: Thank you. In the paper, we've identified six different areas that we think are highly relevant as to the information that Phil just presented. The first is that if, in fact, we find E. coli 0157:H7 with some regularity on carcasses and the hides of those carcasses, a decision about when to determine it is reasonably likely to occur is one which we feel we need to grapple with.

The information that we have presented, although not final information -- it certainly is preliminary information about feed lot cattle. And so we focused the question on if there is a difference between feed lot cattle

and other cattle, does that change the decision-making tool. So that is the first area of consideration.

The second would be the Agency's testing program that we have in place. Most of you who participated in the public meetings and the process that we have had in place this past year related to E. coli 0157:H7 know that most of the concerns have related to the testing program that FSIS has in place.

We have raised some areas here that now we believe are open for consideration and certainly have identified them in order to elicit some questions in your minds and concerns that you may have. And those relate to the proportion of samples that we take in plants versus at retail.

The Agency has modified that over a period of time as to what proportion we do retail versus in-plant. But we also think that this is something that we need to consider more in a forum involving public input. The second would be the issue of 15 consecutive samples after a positive is found by FSIS.

This is an issue which the Agency initiated in the directive. It has been under question and we certainly would like to raise it now in the advent that we have 0157:H7 being addressed in a HACCP environment, as well as if interventions in place, what is the relevance of having

the consecutive sampling scheme as we have it.

Then thirdly would be if, in fact, we find a positive sample, we presently have a six-month trigger. And the issue becomes one of what is the relevance of that six-month trigger, should there be one, should it be a shorter period of time, should it be a longer period of time. And then that follows into exactly what is happening within the plants in terms of the programs that they have in place, as well.

We also have a targeted program of how we select plants. The issue is how we better define that particular targeting scheme. FSIS is also highly interested in the value of sampling carcasses as opposed to just ground beef at this time.

The third issue goes to the plant's generic E. coli and the Agency's Salmonella pathogen reduction results in that we have not factored them into the directive that we have for a sampling program, as well as all pathogens. We believe that there is some value in investigating and using that data as indicators. And so we are opening that up for consideration.

The fourth issue relates to what effect the plant's own testing or if it has a HACCP program, their verification program, as to whether or not targeted testing in those plants is of particular relevance.

The fifth issue relates to the non-intact product issue. The information provided by Kansas State researchers was a part of a thesis that was developed. It is available in the FSIS document room for your viewing.

But it deals with the issue of blade tenderized steaks, the level of contamination that is translocated from the surface into the interior, and then the cooking requirements that are necessary for making that product safe. That paper deals with more than just E. coli 0157. It deals with other pathogens including I believe Listeria and Salmonella.

We also have to deal with the issue of cross-contamination of product, non-intact product such as a roast that is blade tenderized and cross-contamination of other products within the facility or within a consumer's home, as well as temperature abuse of that product and the potential for grow-out or larger numbers of that organism being on that product than would be expected, and then handled appropriately by the cooking directions that may be contained on that product.

And then finally, the Agency is interested in the voluntary programs that establishments may have with regards to the producers of products that comes into their facilities, as well as other activities that plants may have in place to target in terms of a strategy for how they deal

with 0157:H7.

So we believe that these findings that Phil has presented as well as the considerations that we have identified as specific issues that we need to grapple with open up an area in which we certainly are seeking information from the committee as well as the public.

MR. DERFLER: I think we are looking forward to publishing a Federal Register notice in the next month or so that makes a lot of this information available to the public and then following that up with another public meeting either in the middle of January or early February. So that is where we stand right now.

CHAIRMAN BILLY: Okay. So this is, as we indicated, if you will, a heads-up alerting the committee. Obviously, if you have any thoughts now, they are welcome. But we are commencing with a public process that will enable us to make decisions about changes in our current policies and procedures as it relates to E. coli 0157:H7. Any questions or comments? Carol?

MS. TUCKER FOREMAN: Mine is really rather minor in the interest of history. E. coli 0157:H7 began emerging at least as early as 1986. And there were deaths from it in 1986 -- '82?

MS. SMITH DeWAAL: '82 was the first outbreak linked to a fast food chain.

MS. TUCKER FOREMAN: I think it would be useful to have the background reflect that because USDA did not recognize it at an earlier time. Because there was policy in effect at the Department that caused the Department to consciously ignore the emerging pathogen here. So I don't want history to be rewritten.

CHAIRMAN BILLY: Okay. Caroline? Collette?

MS. SCHULTZ KASTER: In your areas for consideration under point number 1 where you are talking about making a potential recommendation on feed lot cattle, whether or not the pathogen is more likely or reasonably likely to occur on that, I think I would encourage you -- maybe that is one approach.

But equally or more importantly, to try to identify why that might be occurring in those feed lot cattle, to encourage that from a research standpoint more so than just making a delineation of the population because we may not know -- again, there may be harborage in the non-feed lot cattle, as well. And we may be making distinctions that we don't want to make.

CHAIRMAN BILLY: Okay. Caroline?

MS. SMITH DeWAAL: Phil, when will the data from the AMI -- when and how will the data from the AMI study be transmitted to the Agency and how will that be made available to the public?

MR. DERFLER: It is our understanding that the work is complete and that they are looking at putting the data together now. It is our expectation that when they are done with that, they will provide the data to the Agency and we will make it publicly available.

MS. SMITH DeWAAL: Will that be available on your constituent alert, the availability of that study, or in some other way where you can --

MR. DERFLER: Yes, ma'am.

MS. SMITH DeWAAL: Okay.

MR. DERFLER: And when we get it, we will let you know.

MS. SMITH DeWAAL: I also am -- I am troubled with the issues of the non-intact products. They are -- I think the data that Kansas State brought into that meeting was the first time any of us were really aware that 0157:H7 could be transmitted to the interior of the meat products. And it has actually changed our advice to consumers with respect to those non-intact meat products.

Luckily, most of them are going -- well, from what I have been told by the industry is that most of those are going to restaurants and aren't -- they're not being -- this is tenderizing which might involve needles or other mechanical devices. And a lot of them are going to the big steak chains and the big restaurants.

I hope that is true in that the stuff that people are buying in local supermarkets is fully intact. But it would help us if we knew the Agency was double-checking that information. I mean, we need to get the best advice out to consumers. And if the advice needs to be that they need to change their cooking practices for roast or steaks, we need to know that as soon as possible.

UNIDENTIFIED VOICE: Nobody orders rare at Outback?

MS. SMITH DeWAAL: Well, they -- that's yes. That is a good -- that is a very good point. And it's -- and, you know, you are hoping that in the restaurant chains, they are using thermometers. But, no, it is a big problem and we've really got to figure out what the right advice to consumers is.

MR. DERFLER: But I think that it is important that we say that. I mean, they have been in subsequent to the public meeting with additional data. And they are suggesting that cooking temperatures than the 160 would be adequate to kill the pathogen. So, I mean, these are data that we are looking at and we are evaluating. But I don't -- you know, I think it is important that record be current.

MS. SMITH DeWAAL: They have been in to see me subsequent to that, as well, I think probably the same week they came to see you. So -- and their -- the Kansas State

reading of the data is very, you know, "This isn't a big concern. Even 140 would kill what's there." But, I mean, we are looking at something with a very low infectious dose.

We have had outbreaks linked to roast beef. I mean, our data set on outbreak shows at least one outbreak linked to roast beef in the early '90s. So, you know, and I am just concerned what I should be telling my concerns about how to cook these products. So as soon as the Agency knows based on that data, I hope you will inform us.

CHAIRMAN BILLY: Yes. Nancy?

MS. DONLEY: I've got several comments. Just in response to what Caroline said, we had over 300 people fall sick in Illinois this year, this summer from infected meat. And these were whole-cut meat, chunks of meat. And we had over 300 illnesses.

This was at a party that was held. It happened to be held in a cow pasteur. And they had large cuts of meat on spits that were roasted. The illnesses were definitely traced to the beef. That is something that needs to be considered in all of this.

I am going to come right out and say it. I am really disappointed with what I see here. I was really excited to see on the agenda that there was going to be an E. coli 0157 action plan.

And frankly, I thought this is great. We can

really go now full speed ahead and do something about this, that we are going to expand our focus on this issue. We are going to start going backwards and taking a look at it at the animal level or manure level, and that it was really going to be a take-action plan.

I think this is an inaction plan. The Agency had put out over this past year a new definition of the term, "adulterated", and they never did anything about it. Under pressure from industry, an industry coalition has conducted their own research which, I'm sorry, I think before anything can be drawn from that, it has to be peer-reviewed. The protocol has to be looked at.

And in the meantime, it has stalled what I think could have been very good consumer protections from going forward as far as the terms of adulteration. These areas for consideration are -- many of them are taking -- are saying, "Shall we un-do some of the things that we currently have going for us?"

I don't see anything that is saying, "Let's go the other direction instead, requiring plants" -- that it's now going to -- are we calling this a reasonably likely to occur hazard and should the Agency be looking -- are we going to start making it mandatory testing for beef-producing companies to be testing for 0157.

I don't see this as a plan. I see these as

questions being raised. And they are questions that I find very, very troubling and very concerning.

CHAIRMAN BILLY: Okay. Are there other comments or suggestions? Okay. To sum up then, again, this is a heads-up that the Agency is starting a new policy process that will re-examine its current policies on E. coli.

There is clearly new information to indicate that the organism is much more prevalent than our current policies were based on. And we will refine this draft paper.

We will be publishing it in the Federal Register in about a month or so and then following that with a public meeting as a step-wise process to arrive at a set of decisions regarding whether this is an organism reasonably likely to occur and the impact that has, other regulatory actions that we should consider.

And also, I think some of the other factors that have been raised regarding consumer information and efforts that should come forth in terms of the animal production end of this process, as well. So I would like to move -- okay, Jim, and then we will move on.

MR. DENTON: I have a quick question for you, Tom. The statement in here that new information is emerging that suggests that 0157 is not as rare as thought indicates that this new information comes from several sources. Do you

happen to have those references or --

CHAIRMAN BILLY: Yes.

MR. DENTON: -- citations that we can review?

CHAIRMAN BILLY: Yes.

MR. DENTON: Okay.

CHAIRMAN BILLY: Why don't you get with one of these folks when we are finished here and they will provide it. Okay. It's now a little after 4:00. And on the agenda from 4:00 to 4:30, we were scheduled to look at the remaining issues and the plans for the next meeting.

I thought of the products of the committees. We should look at in particular the regulatory reform revision. There is some modified language here. And we kind of left that item a little unfinished. I thought perhaps Dan could run through the changes that were made and then get a sense from the committee in terms of the acceptability of what's here. So Dan?

MR. LaFONTAINE: Yes. Let me kind of summarize since it has been a few hours since we talked about this. On the regulatory reform paper, two major changes. The lead-in -- a new lead-in sentence which says, you can read it, "The committee supports USDA/FSIS continuing the current effort of regulatory reform using the following approach." And then the A, B, C, D and E are the same as the previous paper.

And then the add-on as authored by Caroline with my help is, "F) Risks assessments should be targeted to encourage the most rapid response to public health matters." So that was the final add-on. Comments and questions from the remaining committee members? Do we have a quorum?

CHAIRMAN BILLY: Sure.

MR. LaFONTAINE: All right. Hearing no objection, so moved.

CHAIRMAN BILLY: I think this looks fine. Okay.

MR. LaFONTAINE: I don't intend to go through any of the other papers, although we have each received the modifications based on earlier discussions.

CHAIRMAN BILLY: All right.

MR. LaFONTAINE: Unless anyone feels a burning need to go back and look at one, I would rather move on. There were a couple of other questions that were raised while we have Phil and Dan here. One was -- and I guess Rosemary has left. So maybe what we ought to do is just call Rosemary unless there is a larger interest.

She wanted to know about the status of our work in the area of retail exemptions. So unless someone else on the committee wants to hear a brief response to that, we can just call Rosemary and let her know.

DR. JAN: I would like to hear a brief response.

CHAIRMAN BILLY: Would you? Okay.

MR. DERFLER: I mean, we recently published a notice in the Federal Register about our reaction to the HBH case.

DR. JAN: I can't hear you.

MR. DERFLER: I'm sorry. We recently published a notice in the Federal Register announcing the HBH case and how it will affect our policies. We are looking into developing a Federal Register proposal on -- what?

MR. MAMMINGO: The case?

MR. DERFLER: I'm sorry, the Honey-baked Ham case.

MR. MAMMINGO: Excuse me?

MR. DERFLER: The Honey-baked Ham. I'm sorry. You live here -- whatever. We are looking at the possibility of doing a handling regulation based on the Meat Inspection Act and the Poultry Inspection Act about how product is handled after it leaves the establishment along the lines of the paper on exemptions that was presented at the last Advisory Committee meeting, and then looking at the other issues related to exemptions, moving off of -- or growing out of the effect of that, that handling proposal.

CHAIRMAN BILLY: So we've issued a notice in the interim as a result of the court decision. In addition, we are looking at developing a new regulatory proposal along the lines that Phil indicated.

MR. LaFONTAINE: Let me --

CHAIRMAN BILLY: Okay, Dan?

MR. LaFONTAINE: -- ask one or just a quick follow-on question. Tell me again what your strategy is. You are going to do what next?

MR. DERFLER: Yes, develop a performance standard for the handling of product outside of the inspected establishment which we think would include transportation, distribution and retail. And then depending on how that -- you know, as we work through that, look at some of the other issues related to the retail exemption in particular. So that is the main focus of what we are working on.

MR. LaFONTAINE: I guess I will defer comment or judgement until I see what you put on the table. But I have to kind of pick up Rosemary's sword here and carry it for a moment. The whole retail exemption issue is a big quagmire as you know. And it needs, among many other things, some urgent attention. I will leave it at that.

MR. DERFLER: No, and this is one of the dockets that -- I mean, you heard before about the fact that as our resources are shipped and most of it ships out of my office. But we are doing the best we can.

CHAIRMAN BILLY: The other item, very briefly, is a request that we just provide an update on the pork sausage performance standards.

DR. ENGLEJOHN: This would be the Salmonella

performance standards? Is that the question?

MR. LaFONTAINE: Correct. Correct, I was the one that asked that.

DR. ENGLEJOHN: The bra sausage.

MR. LaFONTAINE: Bra sausage, correct.

DR. ENGLEJOHN: Correct. We have developed the rule and it is in the process -- it will be expected to be -- it's going to be undergoing our legal review within a matter of days. I think it is actually ready to go to our General Counsel for a briefing.

I will need to note that it was designated as a significant rule. And as I explained yesterday, that does have some ramifications for how it gets through the process.

MR. LaFONTAINE: Tell me a little more. I've been hearing it's in the mail, on the way for about two years. And I am not trying to be negative about this. Going under legal review, etcetera, what does that mean? When can we expect to see it, best case, worst case, come out of the shoe as a final rule?

CHAIRMAN BILLY: Even I'm interested in this answer.

MR. LaFONTAINE: I'm sorry? Say it again?

CHAIRMAN BILLY: I said even I am interested in this answer. You know, remember the Johnny Carson thing with the --

(Laughter.)

DR. ENGLEJOHN: I see it in six months, the proposal in six months. As a proposed rule. And then there will be a, what, 60-day comment period, an opportunity to review the comments. We will have to draft the final rule and then -- I mean, you know, depending on the level of comments and the amount of controversy that the proposal engenders, the better we do it the first time out, the quicker there will be a final ruling.

MR. LaFONTAINE: I'm going to calculate my six months.

CHAIRMAN BILLY: Okay. Caroline?

MS. SMITH DeWAAL: This is very frustrating. I am about to ask about where the performance standard is for whole turkeys. But if what I am hearing is that it is going to take, what, how many years did you say until we got a rule? Why aren't you doing -- why aren't you doing this all together? Do you have one for turkeys? Where is it?

DR. ENGLEJOHN: It is included in that document.

MS. SMITH DeWAAL: Okay. So you've got one document coming with all of the performance standards that we don't have in place right now.

DR. ENGLEJOHN: For Salmonella, yes.

MS. SMITH DeWAAL: For Salmonella.

DR. ENGLEJOHN: Yes.

MS. SMITH DeWAAL: Okay.

DR. ENGLEJOHN: You can expect a final rule on minor species soon, much sooner than that, much sooner than six months, which would deal with the generic E. coli.

MS. SMITH DeWAAL: So we will have E. coli performance standards and -- I'm not blowing your ear up, am I? Okay. We will have E. coli standards in place --

DR. ENGLEJOHN: For the minor species which --

MS. SMITH DeWAAL: Which includes turkeys?

DR. ENGLEJOHN: It includes geese, guineas, ducks, sheep -- I can't think what else.

UNIDENTIFIED VOICE: Goats.

DR. ENGLEJOHN: Goats.

MS. SMITH DeWAAL: Okay. And then the Salmonella standards will all be in place, a final rule, by when?

DR. ENGLEJOHN: Well, again, it's a proposal that you can expect in six months. And I would say another six months after that, you could expect a final, a year from now.

CHAIRMAN BILLY: I don't want to --

MS. SMITH DeWAAL: So by next Thanksgiving we might have a performance standard for turkeys?

CHAIRMAN BILLY: I think that's as reasonable a target as any. Keep in mind, what they said is the Agency has finished its work on the proposed rule. So now it

starts through the review process.

And at each stage, then there is an interaction that occurs. And it is open-ended. It's not like we set deadlines on the legal review, departmental policy reviews, the OMD review and so forth. So --

MS. SMITH DeWAAL: Perhaps you could give Dan and I a list of people to call weekly. Just an idea.

CHAIRMAN BILLY: All right. I am going to move on unless -- go ahead, Lee.

DR. JAN: Regarding the E. coli performance standards for minor species, is that going to be a specific big M and little m sponging or is that going to be an SPC process like we have in a major species?

DR. ENGLEJOHN: I'm sorry. I don't recall.

DR. JAN: But I can tell you, at least now, that the SPC in the major species does not give the plants nor the regulators any information that's useful. I want to know what to do if you exceed big M or little m. There is no big M, little m.

And the instruction we are getting from the tech. center now is that a plant cannot exceed if they don't have a -- have anything to exceed, they can just take their samples and they are done. And so we really need to have some kind of guidance. And we need a performance standard that we can use.

CHAIRMAN BILLY: Well, we can put a note together and get it out to all of you in terms of an answer to that question. Okay. All right. I'm going to move on to the plans for the next meeting.

As indicated here in the agenda, our current plan is to hold a meeting in April. I've got a list of five items that I believe are the ones that are an out-growth of our discussions the last two days. And I will run through those. And then we can get any further input from the committee.

First is the models project, continuing to provide the committee with an update on that. As we indicated, we will have a lot of additional information by that time. And I think it is important to continue to get input from this committee as we move forward with that project.

There also -- in the intervening time, there will be a public meeting, as well. So -- but I think it is important to get further input from the committee.

A second item is Campylobacter. And we have taken action to further communicate with the micro. committee. And they will be meeting and we will have their input. I think it's important. And given the timing of the ongoing baseline studies and so forth, I think we will have a lot of information to share with the committee and have a -- we could have a very meaningful discussion at that time on

that.

Another item is Listeria. As I said yesterday, it is the intention of the Agency to produce another white paper that will lay the ground work for a public process to re-examine the current course we are on in terms of our plan that we put out some months ago which included both short-term, intermediate-term and long-term actions that we plan to take.

And this white paper will take into account the new data and information and experiences we have had in the intervening time. And, again, our plan is to produce such a white paper and then to use that, publish that, and then schedule a public meeting for sometime probably shortly after the meeting we are going to have on E. coli.

The next item I have is the -- continuing to work on the non-amenable species. We talked that through. Dan and his team will be continuing to work in that area. We should have a refined paper at that time which we can provide you in advance and get further input, and then get -- also get input in terms of the additional actions that we should be taking to advance that effort.

And then the final item I have is in the area of NRs and related material. And there it is our intent to produce a detailed report with extensive discussion about a data set. I am thinking 1998, but we can decide what that

is.

But it will be a significant set of data. Break that down, do some analysis of what the numbers mean and provide as clear an understanding as we can for all of you in terms of those data and the significance related to enforcement actions, recalls, retained product and those kinds of things.

So those are the five items that I believe came out of the discussions we have had the last three days. But I would like to open it up for any other ideas you have had or anything I have missed. Dan?

MR. LaFONTAINE: On that last subject, the NRs which is a complex issue, what I think would be useful for all of us, myself included even though I am involved in that, is maybe go through a scenario of a plant with significant problems and how you methodically took regulatory action, leading up maybe to suspension and abeyance.

And then also take a second example where maybe the numbers are big, but it is not as significant as the first case, to show your decision-making process.

CHAIRMAN BILLY: That's a good idea.

MR. LaFONTAINE: Real -- with data that is, you know, not public who the plant is. It could even be a make-believe plant. But it will be better if it would be some

real scenarios.

CHAIRMAN BILLY: A real situation, yes.

MR. LaFONTAINE: I think that's really what everybody is looking is a gut check on how you are making your decisions and go from there.

CHAIRMAN BILLY: Okay. That's a great idea. Any other items? Yes, Collette?

MS. SCHULTZ KASTER: Can I just encourage that we look at the most current data possible or include that -- if '98 is important, then let's look at '99, too. But I feel kind of funny looking at a block of '98. I guess I don't understand why that is the magic time period.

CHAIRMAN BILLY: Well, you know, I understand and --

MS. SCHULTZ KASTER: But by the time we meet again, we should have a nice block from 1999 that can be added to it.

CHAIRMAN BILLY: That might be possible. And in fact, you know, it is a transition period. So even in '98, you've got the transition for the large plants; '99, the transition for the small plants. So you are going to get some aberration based on what the process is.

But if we explain that as part of the report and particularly in some of the trend data and can show overall trends and what the experience was with the small plants and

also maybe break it out for the large plants or something where they are well into this with the '99 data, maybe that makes more sense. So -- but we will look at that and try to make it as meaningful as possible.

MS. SCHULTZ KASTER: One other thing real quick.

CHAIRMAN BILLY: Sure.

MS. SCHULTZ KASTER: If you could also touch again on the inspector shortage and if you do have the vacancy report, if we could take a look at the vacancy report and get an update from that group on the success that you are having with the things that you are trying to do.

CHAIRMAN BILLY: Okay.

MS. SCHULTZ KASTER: Thanks.

CHAIRMAN BILLY: So let's add that item and we can provide the reports and then have appropriate discussion. Caroline?

MS. SMITH DeWAAL: In Nancy's absence, I guess I have to ask for the report on the E. coli action plan or inaction plan, depending on how you want to look at it. But can we get an update on what and where the Agency is going with that?

Because I think part of the frustration is that we went through a public meeting six months ago on this exact issue. And we are concerned about where -- why we haven't seen final directives out on E. coli in other than community

products and things like that. So if we could get another update on E. coli.

CHAIRMAN BILLY: Okay. Other -- yes?

MR. ABADIR: What about this presentation on this where the focus on the others?

CHAIRMAN BILLY: Okay. We can include that if you want. That's fine.

MR. LaFONTAINE: What was the topic?

CHAIRMAN BILLY: The in-depth audits. You know, the system that we are putting in place and the guidance. Maybe we can make a judgement about that because if -- you know, depending on where we are at, we could provide information for you in advance and then make a judgement about if we are at a stage where further discussion at the meeting is appropriate or not. We are open to it. So, yes, okay. Anyone else? Okay.

All right. We have four people that have asked for opportunity to provide comment from the public. The first is Del Hensel. Del, if you would come forward and -- yes, please.

(Away from microphone.)

MR. HENSEL: Yes, I am Del Hensel from Denver. I am the President of the National Bison Association. That's a group of 2,400 producers. Most of our producers are small farmers trying to make a living on a farm.

My prior time I was here, I spoke to the issues. So I won't repeat what we said. I do this on my own voluntary time. And I don't have a lot of money. So I come here on a voluntary basis because we are so set on giving our product out and not having a problem with what we've produced.

I would just like to clarify a couple of questions that were brought up today. One was that in regard to how much product would there be on the market that is not being inspected. And that would vary from area to area. I come from Colorado. In Colorado, you can eat unamenable species. You can kill them.

And I know of occasions that there are several restaurants that buy meat that comes from that food source such as that. Other states allow that, also, and some don't. So it varies.

I would guess that probably less than five percent of the product is not inspected. And inspection is directly attributable to the cost. And in some cases, a plant would -- because -- I know we have rules in the USDA that probably shouldn't be done.

But in some plants, an animal could cost $100.00 and that's just for one animal to be inspected because of the fees. And that's an hourly fee and it depends on how much the inspector decides to charge against that animal.

So that discourages inspection because that runs up the cost that people don't want to pay if they don't have to. And if they can just follow it into someplace and sell it, then that's easier to do.

Another question that Nancy brought up, I wish she was here right now to hear the answer to this. But she was concerned about the fact that the marketability of the product. I want to bring an example of how this works.

For example, South Dakota. In South Dakota, a lot of bison is produced. If you look on your chart there for states, they are one of the top states in production. But they are one of the lowest states in consumption.

So there are a lot of small operators, not only farmers, with small processing plants that depend on the bison industry to inspect the product, the state to inspect the product and send the product to either the east coast or the west coast.

So let's say we went with the mandatory inspection, we have all these people that now are abiding by the rules and doing state inspection which they feel is adequate, which it probably is. But the minute you put the mandatory federal inspection, they can no longer ship that product to the east coast or the west coast.

So not only are you putting the bison producer out of business, you are putting a lot of small plants out of

business that depend on that and the economies in small cities.

Now, if that were to happen, if we were going to try to get legislation which just has to go through the Senate bill, the minute we try to get this done, we would have half of our membership up in arms and saying, "We are going to fight this to the hilt", and then the legislation would not go through. So we would be defeating the purpose here.

So the economics and the safety go together no matter how you look at it. They work together. You can't have one without the other because I -- we could not come up here and push for this inspection if I knew that I was putting my neighbor out of business. So that is the two things I wanted to bring up. So are there any questions I can answer?

CHAIRMAN BILLY: There's one. Lee?

DR. JAN: Thank you. Let me just make a comment. I would just urge you and your association to work with FDA or at least to get their input on the nitrite issue. I know that is an issue that comes a lot of the time. I saw that in your letter, that you talked about the nitrite issue. And I think you need to be clear, have a clear understanding that it is the FDA issue on the nitrites.

And I am just concerned that the industry may be

under the assumption that by going to mandatory inspection under USDA, that nitrite issue is going to go away. I am one that don't believe it will. I hope it does, but I don't believe it will.

And I just urge you before you put all your money and all your effort behind this that you know clearly what that issue may do to the industry. And that is just a word of caution.

MR. HENSEL: Yes, sir. And I understand that issue very well. And I have heard opinions both ways that, yes, it will go and other ones that it won't. There is a very important study that should have been completed that FDA has sponsored on nitrites.

And you know the drafts that generally regard it as safe. And this may be passed on to other -- if this study comes out that -- it's a very important study. Is anybody here familiar with that study that was just to be completed this summer?

CHAIRMAN BILLY: I've read a summary of it, yes.

MR. HENSEL: And did it come out -- and you maybe know how it came out.

CHAIRMAN BILLY: Well, it implied -- the results imply that nitrite itself may be less harmful to people than what some had originally thought. I guess that is a brief summary of it.

MR. HENSEL: That's kind of what I understood. And I thought if that was the case, then perhaps we could get the -- because it -- it's absolutely more dangerous to have meat untreated.

A good friend of mine almost died from buffalo jerky that was untreated in South Dakota. And by the time they got him to the hospital, they couldn't believe how sick and how painful this was. But it is so important to get nitrites in pure muscle jerky. And so is there anything else that --

CHAIRMAN BILLY: Caroline?

MS. SMITH DeWAAL: I just -- the effort to get the interstate shipment bill through Congress would be greatly benefitted by the bison industry and the emu people and the pigeon people. So all the effort -- I appreciate all the effort you guys are making to come here and talk to us. But we are going -- once that bill gets introduced, that would help solve part of this problem.

And once that bill gets introduced, I hope you will make the same effort to come to Washington and go to the Hill and tell them why we need that bill passed, as well.

MR. HENSEL: Yes, we plan to do that. Thank you.

MS. SMITH DeWAAL: Thank you.

CHAIRMAN BILLY: Thanks a lot. The next person is

Felicia Nester. Then we will move on. Bernie Shire.

(Audio missing due to technical malfunction.)

MR. SHIRE: I don't know what happened to these, but apparently they are still around. And at that time, the Agency used those studies to base a lot of what it was doing on inspection. We think that maybe either the studies need to be dug out or maybe the Agency needs to do another study to come up with this kind of information.

The problem today is with the changing food distribution, with retail changing, with the processing changing. There are a lot of people that want to get out of inspection. And we don't support that.

We think and most of our members think that people should be under inspection. And maybe this is something that the Agency can look at doing to refine their efforts in inspection and to bring that together so they will have a more -- a uniform approach in what they do.

CHAIRMAN BILLY: Thank you. Any questions or comments?

MS. SMITH DeWAAL: Bernie, are you supporting the effort to get a single food safety agency and a risk-based inspection system?

MR. SHIRE: And a what?

MS. SMITH DeWAAL: A risk-based inspection system so there is a level playing field for all products with the

same risks.

MR. SHIRE: Well, we haven't decided about the Agency. But we do support it.

CHAIRMAN BILLY: The final request is Marty Holmes.

MR. HOLMES: I am Marty Holmes, North American Meat Processors. And I have got just a few quick things. One is just -- and to clarify a few things on the Kansas State study that was referred to earlier by Dr. Englejohn. And it was kind of discussed a little bit.

What that data showed was that even cooked at rare temperatures of 130 degrees and putting in a sterile ice water bath, that there was no difference between the risk associated with intact and non-intact steaks. So just -- and that was inoculated to five logs on the surface. It was actually mechanically generated.

In answer to Nancy and Caroline, they both brought up two situations of outbreaks with intact -- non-intact product. They were outbreaks that occurred on 0157:H7. At least my understanding, Nancy, on the cow pasteur, the meat that was consumed in that cow pasteur, that was not inspected meat. That was actually custom killed on the farm. So I think that is something worth considering at least.

And then, Caroline, my understanding on the cooked

roast beef standard, that the only report that the CDC has in their data is that that was actually a cross-contamination issue, not because it was mechanically tenderized or injected in any way. So you may want to check that out. That's just my understanding on both those situations.

The last thing I want to bring up is something that Dr. Jan -- or Lee Jan brought up that Mark Mina earlier had talked about, having any problem with the state trying to find more inspectors for the federal government. That's find. If you want to spend your commissions, that's fine.

My concern is that if the state -- if a state was encouraged to take over more federal plants, then they basically are forced into a TA situation without their consideration. You know, I know that that was kind of said in jest and tongue-in-cheek.

But at the same time, it would be a serious matter if a federal plant all of a sudden because of an inspector shortage on a federal level was basically turned into a TA plant overnight without any of their considerations brought to the forefront. Thank you.

CHAIRMAN BILLY: Thanks. Any questions or comments? Anyone? No? I see that Felicia has just returned. So, Felicia, you have the floor.

MS. NESTER: That was a place-holder. And believe

it or not, I've got nothing to say.

CHAIRMAN BILLY: Okay. Thank you. All right. I would like to thank the committee for your fine work and your diligence and really hard work including last night, and thank the public as well for your participation in this important meeting. Thank you all very much. Have a safe trip home.

(Whereupon, at 4:43 p.m., the hearing in the above-entitled matter was adjourned.)

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

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Docket No.

Arlington, Virginia
Place of Hearing

November 4, 1999
Date of Hearing

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