UNITED STATES
DEPARTMENT OF AGRICULTURE

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

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THE UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

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INSPECTION MEETING	)	
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Wednesday,
May 5, 1999
Quality Hotel & Suites
Courthouse Plaza
Jefferson Room
Arlington, Va

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

THE UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

CHAIR

Thomas Billy, Chairman

Committee Members

Terry Burkhardt
Caroline Smith-DeWaal
Nancy Donley
Daniel E. LaFontaine
Rosemary Mucklow
Dale Morse
Carol Tucker Foreman
Kathleen L. Hanigan
Collette Schultz Kaster
Gary Weber
Alice Hurlbert
Michael M. Mamminga
Lee C. Jan
James Denton

P R O C E E D I N G S

(8:40 a.m.)

MR. BILLY: Thank you very much. On behalf of the Department of Agriculture and the Food Safety and Inspection Service I'd like to welcome all of the members of the Advisory Committee. That includes both the returning members and the new members. We very much appreciate your willingness to participant in what is a very important process. That process is getting advice from representatives of a cross-section of the stakeholders in terms of meat and poultry safety and inspection.

In the process of reappointing the Committee and the new charter we worked hard to bring some continuity to this process in that regard. You will note that about a third of the members are new. So another way of saying that we've got some old hands now that know the process and can help the new members as we work through various issues and develop positions or recommendations.

I think also we've worked hard to create the right balance in terms of the Committee. By that I mean, as required by law, have solid representation from the states. This is a very important opportunity for the state interests and the federal interests to be addressed in this kind of a setting beyond the other opportunities or methods that we have, but also a representation from what is a very large

and dispersed industry, the different parts of industry, the different species, the different types of operations, and then the public and the consumer community and the different interests there, those consumer organizations with different areas of concern and important perspective that they bring to the Committee and the process as well.

This Committee, the last Committee made some very valuable contributions to the Department, and specifically they made 18 recommendations, what I would characterize as significant recommendations. And I'll just one as an example. There are many examples, but the one that popped into my head when I was thinking about this was the issue of interstate shipment of state-inspected product.

Over the course of several meetings this Committee worked with the Agency and the Department to develop a strategy or an approach around which we were able to develop a consensus of all of the different interests. And that has been the guidelines, if you will, that we have used now in the Department to develop a legislative proposal that we forwarded to the Office of Management and Budget for their approval and forwarding to Congress as proposed legislation.

So the specific work, the debate, the discussion, the finding of the common ground and interests, the process that occurred in this Committee led to a blueprint, if you will, for the administration's approach for dealing with

that issue, and there are other examples like that as well.

Now I think that one of the things that would be nice to do, just to get started, would be to have the Committee members introduce themselves and just say a little bit about yourself and your affiliation, your interests, anything that you think is pertinent.

It would be nice if it was 25 to 50 words, something like that, but feel free to say anything thank you the really pertinent to having the other people that you may not have met before to get to know you a little bit, and you will have more time to talk, obviously, as the meeting goes on. So I'll introduce you in a minute, Cathy. Mike?

MR. MAMMINGA: Well, I'm Mike Mamminga. I'm with the Iowa Department of Agriculture in Land Stewardship. I'm the chief of the meat and poultry inspection program. I've been with the Department since 1972. I'm about to enter my 28th year. The issues before this Committee are very important to us. Obviously, as cooperators and collaborators with USDA/FSIS through our cooperative agreements, and so we are looking forward to our participation in this meeting.

MR. BILLY: Jim, do you want to turn the microphone so --

DR. DENTON: I'm Jim Denton, head of the Department of Poultry Science and director for the Poultry

Center of Excellence accounted University of Arkansas since 1992. I also serve as the as the Arkansas representative on the Steering Committee for the Food Safety Consortium as well as on the board of directors for a newly formed partnership, the National Alliance for Food Safety. Prior to that, I spent 20 years at College Station at Texas A&M working in the area of food safety research and education.

MR. BILLY: Nancy?

MS. DONLEY: My name is Nancy Donley. I'm president of STOP Safe Tables Our Priority. STOP is a national, non-for-profit food-borne-illness victims associate organization. We have both victims who have survived and those who have died from pathogens in food. We advocate work on policy advocacy issues, public education, and victim support and assistance. My own son was an E.coli 0157 victim. He died at the age of six after eating contaminated hamburger.

MR. BILLY: Dan?

DR. LaFONTAINE: I'm Dan LaFontaine. I'm with the South Carolina Meat and Poultry Inspection Department. Prior to coming to South Carolina six years ago I had 26 years' active duty in the Army in the food-safety arena and also am currently president -- excuse me -- chairman of the American Veterinary Medical Association's Food Safety Committee.

MR. BILLY: Thanks. Katie?

MS. HANIGAN: I'm Katie Hanigan. I'm an 18-year employee with Farmland Foods, and I appreciate the opportunity to serve on this Committee. I think they have a very important function and some very key issues in front of them, and I look forward to assisting with my knowledge of the industry and how the plants operate. So thank you.

MR. BILLY: Lee?

DR. JAN: I'm Lee Jan. I work for Texas Department of Health, and I'm the director of Meat and Poultry Inspection Program. I'm also the current president and of the National Association of State Meat and Food Inspection Directors and the Association of the Directors of the Meat and Poultry Inspection Program of all the states. I've been with the Texas Department of Health since 1987.

Prior to that I was in private veterinary practice for nine years, which I think gives me a unique perspective, having owned a business and now trying to regulate a business, so I can kind of see it both ways. And I also have experience in military medicine and currently am active with those, so I will keep my fingers crossed their.

MR. BILLY: Rosemary?

MS. MUCKLOW: I'm Rosemary Mucklow for the National Meat Association. I've come to the table to speak as a representative of all of the trade associations in the

meat industry. I'm serving -- this is my second appointment under the present charter.

I'm not sure how many times I've served on this Committee before. I think it is an important function and gives us an opportunity, A to get to know all of the various parties of interest in meat and poultry inspection and better understand and comprehended the differing views that we have to try to resolve. Thank you.

MR. BILLY: Thanks. Terry?

MR. BURKHARDT: Good morning. I'm Terry Burkhardt with the Wisconsin Department of Agriculture. I'm the director of the state program there, and this is my second term also. It was very enjoyable and very beneficial to be a member. I bring the states' perspective. When we talk about a seamless inspection program, the states have a very active role, and I bring that perspective as well as the small-plant perspective, so my pleasure to be here.

MR. Billy: Thanks. Collette?

MS. SCHULTZ KASTER: My name is Collette Schultz Kaster. I'm director of food safety and technical services with Premium Standard Farms. Premium Standard Farms is a medium-sized operation, but the thing that makes us possibly unique and brings me a perspective to this Committee that's unique, as we're fully integrated, meaning we control production from the sows through feed mills through the

plant.

So we have a little different perspective on food safety because we tried to do some things up front with that. I really appreciate the opportunity to serve on the Committee, and this is my first appointment to the Committee.

MR. BILLY: Thanks. Caroline?

MS. DEWAAL: Good morning. I'm Caroline Smith DeWaal, director of food safety for the Center for science in the Public Interest. CSPI represents about a million consumers, both in the U.S. and Canada. Food safety is really the number one, year after year, the number one issue of concern for our members. I have spent probably the last nine years looking at the food-safety issues from a consumer perspective.

I first worked with Tom Billy when he was head of the Office of Seafood over at FDA and worked through the HACCP issues on the seafood regulation as well as worked very extensively on the HACCP issues around the meat and poultry regulatory program. This is my second term on this Committee. Thank you.

MR. BILLY: Thanks. Alice, do you want to introduce yourself and say a little bit about your affiliations and interests?

DR. HURLBERT: I'm Alice Hurlbert. I'm with the

National Turkey Foundation. Sorry for being late. I'm just not used to driving around here; I use Metro. I work for the Turkey Federation, and we represent about 90 percent of the turkey industry, which includes the wild production end as well as the processing facilities. This is my first appointment to the Committee, and I look forward to working with everyone.

MR. BILLY: Thanks a lot. Dale?

DR. MORSE: Thanks. Good morning. Dale Morris. I'm with the New York State Health Department. In that role I oversee the Division of Infectious Disease and am involved in a number of food-borne outbreaks and am also PI of the emerging infection program in New York State, where we look at Food Net and participate in surveillance for a number of food-borne diseases as well. I also have grants with NIH on emerging infections, so I'm involved in Eastern and Central Europe in surveillance of food-borne disease.

MR. BILLY: And Dale served previously on the Committee. Okay. Thank you very much. As additional members arrive we'll have them introduced as well.

At this point, it's my pleasure to introduce Dr. Cathy Woteki. Cathy is the undersecretary for food safety, and in that role as one of the undersecretaries in the Department of Agriculture, she is the highest-ranking food-safety official in the Federal Government. She has in

her portfolio not just oversight of the Food Safety and Inspection Service, but plays a very key leadership role in terms of the President's Food Safety Council and all of the food-safety issues that the Department of Agriculture is associated with, through our interest in production, in agriculture production, and the other roles that we play in the Food and Nutrition Service as another example.

So she brings a very wide perspective to her role as the undersecretary and has been very helpful and responsive to the Agency in terms of the tasks that we have set out to do to improve the safety of meat and poultry. So it's my pleasure to introduce Cathy.

DR. WOTEKI: Thank you. Thanks, Tom. And welcome to all of you. I am delighted that we are having the first meeting of this reconstituted Committee, and I'd like to welcome the returning members and also especially to welcome the new members. This is a very active Committee, one that has made a number of recommendations that have been very important to the agency as far as providing advice on direction that the Agency the contemplating taking.

And also it's very important to the secretary because this Committee is advisory to the secretary of agriculture, and your conclusion, your recommendations that you reach on each of the topics that are on your agenda, either ones that you select or ones that the Agency requests

that you review and comment on. Your recommendations are actually forwarded to the secretary and are very important both to him and to me as far as considering directions as well that the Agency is contemplating undertaking.

So it is a very important Committee. It has over the last couple of years of its life played an extremely important role within the Department, and it's also meeting again at a point in time that is a really exciting one with respect to the food safety.

Clearly, the HACCP implementation has been a major issue for the Food Safety and Inspection Service over the last couple of years, and the future directions to be taken under that approach, I think, are issues that are clearly going to be important ones that you will be with making representations about.

The second aspect that makes this a really exciting time is the improvement of the scientific base upon which regulatory policy is developed. We've seen over the last a couple of years the completion of the first quantitative risk assessment for a pathogen in a commodity, a farm-to-table risk assessment for salmonella and teritítus in eggs that really I have pointed to a number of times as being kind of the prototype for major regulatory policy reviews and direction setting.

So having completed that first quantitative

farm-to-table risk assessment and seeing now the way that it is influencing the regulatory considerations in the policy development, I think it also indicates that the science-based and the methodology that we have for moving to a more risk-based approach in policy setting is here, and it's really a pivotal time in its development.

Terry Burkhardt, when he introduced himself, talked about the seamless food safety system that's envisioned. This Committee has played an important role in helping to move forward that concept by considering and making recommendations about interstate shipment of state-inspected meat and poultry products. And I think that this terminology, seamless food-safety system, that's envisioned for closer working relationships and shared responsibilities among federal, state, and local agencies, is also an important area for future work for this committee.

And I think as part of that, though, an important role that this Committee can play is also emphasizing the front and foremost role that industry place in assuring safety of food products, and industry is part of that seamless food safety system.

Clearly, there continues to be an enormous amount of interest at the highest levels in government about food safety, so your recommendations certainly also influence

decisions that are made at a national basis.

I'd like to spend some time this morning talking with you about two areas of concern. One of them is not immediately on your agenda, but it's an issue that has come over the last a couple of weeks, and I simply wanted to use this time to make you aware of what the Agency the doing, what the Department is doing, and how we are approaching the questions that the European Union has asked about the safety of the use of hormones in beef production.

So this area is at this point not on your agenda, but it has come up over the last couple of weeks, and I thought it might be important to just give you an update on that.

The second area that I wanted to talk about is one that over the last couple of years I've also kept you apprised of, and that is the work that is being done under the President's Food Safety Initiative and is now actually part of the work of the President's Food Safety Council. So I would like to update you on where we stand on strategic planning and some of the budgeting activities under the Food Safety Initiative.

And giving that we're starting at the beginning of the agenda, I'm not going to be parsimonious about time, Tom, if that's okay. In the last three weeks the European Union has released three documents. About two and a half

weeks ago they received a summary of a report on the hormone-free cattle program, which is a relatively small program under which the United States ships beef to the EU that comes from farms and feed lots that have been approved by the EU as producing cattle that are essentially free of hormones that are used for growth promotant purposes.

As I said, they released a summary of a report, and the summary has some information on it. Certainly, since it's a summary, it's incomplete, but the summary purports that they have done analyses on over 200 samples of meat from this program, and that in about 12 percent of those samples they have found residues indicative of the use of these hormones.

Now, as a result of that they have sent this summary to Mr. Tom Billy, and we have requested that they provide the complete report. It's very difficult to undertake review and undertake actions that are based simply on a summary, and to date we have not yet received that full report. It does raise, though, some troubling questions about why there are the presence of these residues in meat that is supposedly raised without the use of them, either through implantation or, in the case of one, as a feed additive.

The second document was provided to the Agency over the weekend. Again, it is a summary; it's not a

complete report. And it's a summary of the safety of these six hormones, three of which are naturally occurring substances, three of which are synthetic substances. The report reaches the conclusion that there are safety concerns for humans ingesting meat that would be derived from animals treated with these hormones. Again, we have requested a copy of the full report. We have not yet received it.

So it's difficult, again, to do an overall assessment. It's difficult also to understand if there is any new information that has been reviewed.

I think it's important, though, for you to understand and also very important to point out that these hormones have been reviewed, the safety of these hormones has been reviewed by multiple national and international and international scientific groups, and most recently the WHO/FAO Joint Expert Committee on Food Additives reviewed the safety of the three natural hormones and concluded that their use as growth promotants in cattle did not pose any safety risk to consumers of those products.

In reading the summary that the EU has provided, they seem to be making their argument on the basis of one of these hormones, which is one of the naturally occurring hormones, which, again, has just been reviewed by JACFA and for this the conclusion was consumption of meat from animals treated with this hormone, 17 Beta estradiol, does not prose

a risk to consumers.

So, again, we're in a difficult position of having only a summary report at this point in time and not having a full report. The third document that was also made available just in the last few case is a full report on the misuses and abuses, or the potential for misuses and abuses, of these hormones in beef cattle, and it reviews the programs of both Canada and the United States.

I wanted to at least bring these three reports to your attention, two summaries and a report, and also to indicate to you that there are a number of steps that we have already undertaken. One is to request that we get copies of the full report so that they can be reviewed.

A second step that we have undertaken is to assemble a committee of health experts and experts in animal health and metabolism, who when we do get the full report on the safety of these hormones, will be prepared to review it and to determine if there is any new evidence there and whether the use of these hormones does pose any safety risks.

I think the key thing to keep in mind is that if there is new information, it really does need to get a serious review and that this expert committee is fully prepared to undertake that. But I also at this point in time, there is no evidence provided in the summary that

there is any new information, and since the substance have been reviewed many times and most recently just earlier this year by the JACFA it's difficult to understand how they could draw a conclusion that is so different from what the JACFA report is. That remains at this point a question, though, that until we get the full report, it really can't be evaluated.

And Mr. Tom Billy and Dr. Steve Sundloff, the head of the Center for Veterinarian Medicine at the Food and Drug Administration are at this point and time actively reviewing the report that has been provided on the potential for misuses of these hormones.

So this clearly is a situation that because of the timing of your meeting and because of the fact that many of you may be asked questions about this, I thought it might be worthwhile to at least give you an update on the fact that we have received some information but that there is clearly an enormous amount of further information that is needed, the reports themselves, in order to do any evaluation. Dan, you had raised your hand.

DR. LaFONTAINE: Yeah. On that third report, the one dealing with uses and alleged uses and abuses; what was that based on? Was that based on some of their visits to the U.S. with their reviewing or residue testing program? Is that what it was based on, or is there something else?

DR. WOTEKI: Well, it's based on three things. In '97 and '98 the EU had some has sent audit teams to the U.S. They have also in that period of time also visited Canada, so that's one piece of evidence that is reviewed. They do also look at the residue monitoring programs in both countries, and they also cite the report that they had issued, or at least the summary of the report, that they had issued just two weeks ago on the hormone-free cattle as food-source of information.

MR. BILLY: I'd like to add something. The summary that we've been provided makes points like, well, since currently we have not included these six hormones in our residue monitoring program, there is the chance that it's being misused. We have in the past, and since we make decisions about what to monitor based on risk, and these are approved safe substances, and we have over the years spent a lot of resources monitoring and got negative results, you know, a decision was made not to waste resources looking for this.

They are approved for use, and there is no evidence that they are being misused. One can choose to spin that around and say, well, there is no monitoring program for this. It's an example of how we need to better, if there is more meat in the full report, I'd be interested to see what it is. There's also some citations that refer

back to the early eighties, and a lot has happened since then.

So it just -- we need a lot more information to see the basis for expression of concern about the misuse of these compounds.

DR. WOTEKI: Katie?

MS. HANIGAN: A question for you. A little more clarification. The six hormones that we're talking about; at one time were they tested for out of the plant, using, like, the STOP methodology? And the other question I have is, one third report on potential abuses and misuses; have they concluded there are abuses going on, or are they just saying there are potentials for it?

MR. BILLY: It's a little hard to answer your last question, which I'll address first. You know, they use examples like I mentioned on the monitoring program or the possibility that you could apply one of these small capsules inappropriately, that that's possible, that there aren't government inspectors on every ranch or in every feed lot where these materials are used, so how do you know? It's the kind of analysis or approach that appears to have been used.

One of the points that folks from the Food and Drug Administration made is that these hormones have significant costs associated with them. When they are

approved through the FDA drug review and approval process the amount that's permitted to be used is designed to get the maximum benefit in terms of growth.

So it's done in a way where there is not any incentive to use more. Using more doesn't get you more growth, and it costs money, so just from a pure economic perspective there is not an incentive to do that kind of thing. And, you know, that doesn't appear anywhere in the analysis, the summary of the analysis that we've seen so far. I don't know, Cathy, if you're going to mention about the curious timing of all of this in terms of the other related matters, but I'll leave that to you.

DR. WOTEKI: Okay. Caroline, and then, I think Gary had a comment.

MS. HANIGAN: Could you answer my first question, though? Did we originally test for them using, like, at the plants using SOS/STOP? Were three hormones originally tested for, and then we backed off, if you will?

MR. BILLY: I think that there was early testing back in the early eighties.

MS. HANIGAN: For all six of them?

MR. BILLY: I'm not knowledgeable enough to know that. Maybe Dan does.

DR. LaFONTAINE: What Mr. Billy said is true. I was involved in this thing when the military, in '88 or '89

where they stopped it, so there was a lot of testing by the USDA at that point for those residue. But to answer your question, the STOP test is for antibiotics, and the SOS for sulfa. So they have nothing to do with this issue. They would not in any way detect or not detect the growth hormones. Completely different issues.

DR. WOTEKI: Okay. Caroline and then Gary.

MS. DEWAAL: I have two questions. One is did the EU cite at all our relatively new law on allowing the extra-label drug use where drugs which may be approved for one animal might be used in a different animal for which there is no withdrawal time. That's my first question.

MR. BILLY: I don't recall a specific reference to the law.

MS. DEWAAL: In the misuse or abuse. Okay. Secondly, --

DR. WOTEKI: But they do address off-label use as well.

MS. DEWAAL: As one of the abuses --

DR. WOTEKI: As one of their potential abuses.

MS. DEWAAL: Okay. Secondly, I know you don't have the full report on the QA program for beef that's being shipped to the EU, but how do they -- do we have tests that distinguish between the natural hormone residue that might be found in the meat versus an excess amount of hormone? I

guess to clarify, in this 12 percent are they talking about excess hormone residue above some tolerance?

DR. WOTEKI: As I remember the analysis that's presented, and, again, it's very sketchy, most of what they have focused on is the presence of some of the synthetic hormones. There is one, I think, one animal in which or one sample in which they detected a level a that was high of a natural hormone, but we would need to double-check that, because I'm just doing this from memory of having read that somewhere.

MR. BILLY: As I recall, and I don't remember the units for the method, but the limit of detection was point eight, and they found and they found 1.0. And the error within the methodology is such that that's within the range or error. And we don't know any specifics on the methodology where we can do an analysis, so that's an example where we need to be informed by much more information to put that in perspective what it even means, if it's real.

DR. WOTEKI: Yeah. Tom's point is also very appropriate, that as part of requesting the full report we've also asked for all of the protocols that were used, because to understand the report, you also have to understand the methodology that was used. Gary?

DR. WEBER: Yeah. Just a couple of comments on

this issue. And to your point, Caroline and Lee, what they picked up on in some of the samples, I think the highest they found of tribolon was three parts per billion. The USDA or FDA has no action level because the residue never get to paint where they felt there was any risk at all. JACFA set a level of two parts per billion for their analysis, which is very conservative.

So one sample was at three, which is probably a normal variation again a mean of the analytical methods and not far above the detection limits for that particular product, so very low, very small amounts of that were present. Relative to the use of these products, and the EU accusations that they could be misapplied.

They were actually looking at insertion into muscles, and if you do that with these hormones, the rate of dissipation of the hormone into the bloodstream is so rapid that you waste them; they are not used. They are not available. And in the animal's behave, it changes their behavior, much like an animal that might be anesterouse, in heat. And so it's a very serious thing if somebody were to do that. It has ramifications for animal gain and performance, and it's just not done.

They are implanted in the ear, and that material, that ear is not put in the human food supply at all, and that's where any potential residues might be, but again

that's not included in the food supply. So just a couple of points of clarification there.

DR. WOTEKI: Good. Rosemary and then Nancy.

MS. MUCKLOW: I've forgotten what my question was. Give me a moment.

DR. WOTEKI: Okay. Nancy?

MS. DONLEY: I would like to commend you for your comment, Catherine about the need to reevaluate and look at new data as it comes in and not just have a preconceived set of ideas that, listen, this is the way that it is, and we've already done this, been there, did you know this, and not keeping an open mind. And I would just like to say that I hope that this expert committee has a good balance to it, that it's a very balanced committee and that all preconceived notions are left at the door.

DR. WOTEKI: Rosemary?

MS. MUCKLOW: I remember what I was going to say. I think I heard you say that they had conducted analyses on the meat that they had received. I think I also heard you say that they have come and done some auditing in the United States.

I do know what happens when the EU inspectors come to the meat plants. And so I would be very interested if you would tell us how that has occurred. Where they appointed by our government officials? What was the process

of their audit, and which agency did that? Was it yours or agency who?

MR. BILLY: It's not clear to us what, if any, audit they have done in terms of food lots or the animal-production end. We need more information about that. They did in the last year audit our inspection program at slaughter and processing, and they also audited the lab component of the hormone-free program that has been in place for about 10 years.

Cathy mentioned something important in what she summarized, which was that the agreement requires that the feed lot inform the EU that they are interested in being a supplier. They fill out some sort of application. It's considered in Brussels, and then they are approved.

Our agency doesn't play a direct role in that process, nor do we audit it. There is no arrangement for us to monitor that. What we see is an affidavit at the slaughter plant when the animals arrive, and if the affidavit is there based on the approval process of the EU, then we accept that. The same in terms of the labs. We have not routinely audited the labs.

The arrangement was worked out between the industry and the EU, and there have been concerns raised about the lab procedures. For example, the residue methodology that was in routine use for the last 10 years in

these labs to show hormone-free; this is a significantly different methodology than what the EU used to test product over in Europe after it had arrived.

We were not informed that they wanted a different methodology used or what that methodology is. We're still waiting to get the specifics on that. So one could say in one sense the program was functioning based on an agreement reached between the EU and those that organized the hormone-free program. It's a little hypocritical to turn around and use a different methodology, one that appears to be perhaps ten to a hundredfold more sensitive than what the monitoring testing was based on and then report that you are finding something when the monitoring program was producing negative results.

So there is a lot more to get sorted out here in terms of getting all of the information and doing a proper analysis of it and then determining what ought to done. We're prepared to work with the U.S. industry to see changes in the hormone-free program once we understand what it is that's expected and on what basis that kind of thing. So there is more work to be done in that area.

MS. MUCKLOW: Just one clarification on the Lee land quote. Is AFIS involved in any way, or maybe, Gary, can you can answer that?

MR. BILLY: Not to our knowledge.

MS. MUCKLOW: So we have not had our government, per se, engaged in the process, outside of the process.

MR. BILLY: Yeah. The hormone-free program, it's been an arrangement, by and large, between the industry and the EU, and --

MS. MUCKLOW: The reason for that is that it was not a food-safety issue.

DR. WOTEKI: Correct.

MR. BILLY: Yes.

MS. MUCKLOW: This was meeting a specification for a very specific buyer, which is outside of your domain.

DR. WOTEKI: Correct. Let me bring a little closure, then, to this discussion. Tom had suggested that we talk about the overall context into which these three documents fit. You're all probably well aware that the WTO has made several decisions with respect to beef, and the EU had presented its arguments to the WTO to a dispute settlement panel beginning back in 1997.

The dispute settlement panel found in favor of the United States. The EU then appealed that decision to the WTO and lost again. As a result, the EU is facing a May 13th deadline for implementing the WTO ruling, essentially to open their markets to our exports, and they essentially have failed at each of their appeals to the WTO. So one way of looking at the current flurry of release of reports is

that it's a way to further delay their fulfillment of their obligations under the WTO, which is essentially a decision that their government had committed to resolve disputes through the WTO when we signed those agreements several years ago.

So I think there is a broader context into which to place the release of these reports and the timing of the release of these reports.

I'd like now to move on to talk about the other topic that I wanted to discuss with you this morning, and that's the activities that are underway under the President's Food Safety Initiative. At the last time that this Committee met, the National Academy of Sciences had just recently issued its report where it reviewed the adequacy of the national food safety system with respect to protecting the health of the public and had made -- the academy report had made several recommendations about directions that should be undertaken to further strengthen that food safety system.

I've provided kind of a briefing to you that ran down all of the major findings and recommendations, and at that point I had indicated to you that the president had issued an executive order establishing a Food Safety Council, and in the executive order he had appointed his science adviser, Dr. Neil Lane, along with Dr. Shalala and

Secretary Glickman, the secretaries of HHS and Agriculture as the co-chairs of that council.

In the executive order he charged the counsel with developing a long-rang plan for food safety and also for developing a coordinated approach towards the budgeting of the food safety agencies. And in a separate directive to the council he asked that they review the recommendations of the National Academy of Sciences, and to report back to him within 180 days on how the agencies and the council plan to act on those recommendations.

Well, let's see, we're in May now. In March we sent the report to the president. The council sent its report to the president on how it planned to act on the recommendations from the National Academy of Sciences, and essentially the report embraces the five recommendations that are in the Academy's report.

It agrees that we should base our food safety system on science, and it points out that there are a number of actions that have been recently undertaken that demonstrate that we are definitely moving in those directions. It points to HACCP implementation in meat, poultry, and seafood as one example.

It points to the implementation of the active disease surveillance system and the Pulse Net information system for improving the ability of state health departments

in the identification of cases of food-borne disease as two examples, two additional examples of how we are moving to improve the science base for food safety.

It also points out that the council had already underway a strategic planning initiative and that would be a major undertaking for the council this year. It also agrees that attention needs to be paid to the legal basis for the food safety activities of the Federal Government and incorporates that into the strategic planning activities. And it also agrees very much with the last recommendation, that the food safety system needs very much to recognize the very important role that states and local governments play.

So the council has now moved to establish two task forces, one of them that will continue the oversight on the strategic planning activity, and I am co-chairing that strategic planning task force, along with Dr. Jane Haney, the commissioner of the Food and Drug Administration.

The second task force is examining the budget of the food safety agencies, and it is being co-chaired by Caren Wilcox, who is deputy undersecretary for food safety and will be here this afternoon with you, as well as by Mr. Lester Cash, who is a budget officer in the Department of Health and Human Services in their departmental budget office.

The strategic planning task force held under the

council's auspices a series of meetings through the fall in which we asked for public comment on a vision statement for our strategic plan. We are now working on developing goals and objectives for the strategic plan, and in the next phase we will be working very closely with stakeholders in the further review in vetting and inclusion of those stakeholders in the development of the goals and objectives for the strategic plan.

The president and the counsel expect that the strategic plan will be completed in July of next year, July of 2000, and beginning in January the council has set a deadline for the strategic planning task force that we begin seeking public comment on that plan, beginning in January. So we've done some preliminary planning. We are now going to be moving into the phase of working very closely with stakeholders, and as part of that I would like this Advisory Committee to play an active role in the review and comment on all aspects of the strategic plan.

So as part of your next meeting and in the interim between them we will be providing you with more information about the strategic planning process and schedule some time on the agenda of the next meeting to really do a thorough discussion of that strategic planning process.

The budget committee or the budget task force has actually got two I was. One is the development of a Food

Safety Initiative for the FY 2001 budget, and the second task that they have is the development of the coordinated budget that will be based on the strategic plan for the FY 2002 budget.

So these two groups' work has to be closely coordinated, and it also emphasizes the need for the strategic plan to be in very good shape by January of next year, because that's when the budget development cycle begins for FY 2002. So those things are very closely linking together.

So those are really the two major activities that the council will be overseeing this year, and as I had indicated to you, I think that this Committee has an important role to play in that process, and I look forward to sharing information with you, and as I said, having a major time set aside in our meetings over this next year for you to comment on that.

I might also point out that as part of the agenda for this meeting you are going to be looking at a proposed strategic plan for the Food Safety and Inspection Service and that I view that discussion as playing an important role in framing FSIS's approach to this overall strategic planning process. So actually the agenda today begins your involvement in that strategic planning activity.

Again, welcome to all of you. I really am excited

about this Committee and the reappointments and the new appointments and the role that you play in the policy development with respect to food safety.

MR. BILLY: Questions? Caroline?

MS. DEWAAL: Madam Undersecretary, you said there were five conclusions of the Council on the NAS report, but I only counted four, and you seemed to have left out one I was very interested in.

DR. WOTEKI: Oh, the single food safety agency.

MS. DEWAAL: No. It's the single leader in charge of a coordinated budget.

DR. WOTEKI: Yes, yes. Well, clearly that's also something that -- in the report to the president the council indicates will be part of the strategic planning activities. I believe the way that the report is worded is it says we will examine different models for achieving that goal.

MS. DEWAAL: And in your two task forces I note you've got strategic planning and budget, but the budget -- you can't have a science-based, hazard-based system under the existing legal requirements for the two agencies. And I note, there is no task looking at the legal authorities for the agencies jointly. Where is that being handled?

DR. WOTEKI: Well, actually, Caroline, it's a really good question because among the things that we have been talking about within the strategic planning task force

is how actually to frame that. There are a variety of different approaches that have been proposed, and we're still at this point considering how to go about doing it. It does pose some interesting questions because in some ways there needs to be a phased discussion.

The strategic planning, with its broad directions, needs to be established, and then we need to look both at the organizational structure and the legislative authority questions as they are then informed by the overall goals and directions. So how you phase this, how you approach it, is one of the things that we're currently talking about.

MS. DEWAAL: Yeah. I would just note, it doesn't take a brain surgeon to stitch up a little cut, and we don't need -- there are obvious glaring deficiencies in this system. We don't necessarily need a huge number of new studies. We need some solutions and some progress. I mean, the warts on this system are very obvious to anyone who looks, and I just hope that the council doesn't envision a process which studies them to death and never really comes up with any solution.

DR. WOTEKI: Well, I think your comment is actually very well taken. There are actually two very different perspectives. One is that, yes, there are some glaring problems; they need to be fixed. And that could be done fairly straightforwardly. The Academy report, though,

tends, at least my reading of it, to recommend that there needs to be a complete overhaul of all of the food safety statutes.

So, between those two approaches there is quite a bit of difference in how you would implement it. So clearly it's an issue that we're still talking about. We haven't reached any decisions about how to approach it, and we need to move forward on the strategic planning because that will, I think, then help to inform how that approach is taken.

And actually the report to the president as well also points out that there have been some major overhauls on aspects of the food safety statutes. It points out FQPA is a case in point and says, well, there probably isn't the necessity for opening some of these statutes.

MS. DEWAAL: But from a consumer perspective, we're 14 years away from the first finding that SE had gotten inside shelled eggs, and we still have no comprehensive government response to that problem. Fourteen years is a long time to sit on a public health problem, and we may have a great new risk assessment that came out a year ago. We still don't have a solution.

DR. WOTEKI: Good point.

MR. BILLY: Any questions? Okay. Thank you very much. I'd like to call your attention now to the agenda and briefly review the agenda, highlight some aspects of it, and

see if you have any questions.

We're going to briefly, between now and 10, talk about the subcommittees, the makeup of the subcommittees and the process we want to use, as we did during the sorting out priority issues for this Committee to address previously. It's the same kind of process, and I'll lay that out for you in a few minutes.

We also then will get an update after the break on what's been going on with the National Micro Committee as we have in the past, issues that they are addressing, so you have a sense of that. We think that there is an important relationship between these two advisory committees, and by design, keep you informed of what they are working on because some of their work, then, lays the basis for policy consideration, and we think that's an important tie-in.

We also will provide some updates on some of the issues that the Committee has previously worked on, and there are people that will be presenting that and an opportunity to ask questions and so forth. After lunch, or just before lunch, then, we're going to get into the area of the strategic plan for the Food Safety and Inspection Service.

This is a draft that's been developed. We're now sharing this with outside parties to get input as part of the process of moving towards a new strategic plan that

would cover the period of 2000 to 2005. So you will get a sense of what it is. Again, it's just a draft, so there will be good opportunity for this Committee to provide us some valuable input.

Then we're looking at some of the other issues that were previously on the agenda and we'll be introducing some new topics as well. And as you can see here, we're just going to work through a series of presentations, opportunity for discussion, and the purpose of that is to set the stage, then, for a fuller discussion at the subcommittee level.

So it's sort of positioning the issue, helping you understand what it is, what some of the conversations are, and then fuller discussion by the subcommittee, and then the subcommittee bringing back representations or conclusions to the full Committee first, and then if there is consensus, forwarding those to the secretary of agriculture.

You will see that at the end of the day we have a period for public comment. We encourage public comments. You can see that there's quite a number of people here with us, and there is a process for them to sign up and provide comment or input to the Committee in terms of our work and issues that we are discussing.

We then, to take full advantage of your availability, have an evening session where we look forward

to the subcommittees getting organized and get started. And as you can see, they meet, all three subcommittees will be meeting separately this evening. This is an important point in the sense of it's hard to be in three places at once. So this is going to require you to make some decision about which subcommittee you want to participate in.

Now having said that, I repeat again, even though you may not be in the one subcommittee, what they talk about, what they produce comes back to the full committee, so you have an opportunity for input. So I think in that sense it can work well. In dividing up the group we get a greater production, I think, in terms of input from the Committee as a whole.

And then, looking at Thursday, again, we'll come back, look at some of the key issues in terms of what the results of the subcommittee efforts are. We'll also look at sort of setting an agenda for the next year or so. Our process that we're going to use will be setting some priorities. You will be setting those priorities in terms of the sequence in which we will look at issues and have them addressed by the subcommittees and again provide an opportunity for some public input.

So, with that, what I would like to do is move on to the subcommittee membership and issues, and I will have you turn to Tab 3 in your book, and you will first see that

we have suggested a chairperson and members for each of the three committees. Now, these are suggested, and what we have done is to, from our perspective, thinking about the different interests that are represented, the expertise that each of you bring to the process, we're tried to create a balanced approach in terms of these subcommittees and their areas of focus.

It is fair game, if you wish, and as you think about this, to suggest changing the subcommittees. What occurred over the last couple of years is we found that this set of subcommittees seemed to capture the issues that were being addressed pretty well, and it was an effective way to deal with the work. But it's quite possible that we couldn't reconsider, reduce it to two, add one, but we need also to be mindful of the finite a number of committee members that we have and how we would make that work effectively.

On the agenda you will see that this afternoon at four there is an opportunity to talk about the subcommittee membership, and what I would like to encourage is this. If any of you have a burning desire to change subcommittees, over the course of the day I would like you to negotiate with someone to switch.

And keeping in mind sort of the ground rules that we were following of keeping a reasonable balance in the

subcommittees and reasonable numbers of people to do the work. Are there any immediate actions? Again, we'll come back to it, but are there any questions about what I have said or any questions for understanding, particularly from the new members.

Okay. We'll flip over to the next page under Tab 3, you will see here a listing of both the remaining issues and the suggested issues that we have pulled together to this point in time. Now, the returning members will recall that we went through a process where we identified all of the issues that people could think of, and then we prioritized those by each us identifying our highest five priorities, and that sort of established the work pattern for the Committee. The remaining issues were issues that we didn't get finished or we didn't get to because they were not one of the highest priorities.

So you need to think about these remaining issues, and some of them will be discussed, to some degree, during this meeting in terms of maintaining them or including them on our new list.

We also asked each of you and people within the Agency for suggestions about knew issues, and you will see here we have included, first, suggested issues from the Agency. They are right under the list of remaining issues, the first one being record keeping and sanitation

requirements for related industries and exempt operations, and there is some explanation there. We can talk more about that later, if you want. The input to the FSIS budget is pretty obvious.

It also picks up on what Cathy was talking and the in terms of your involvement in the broader issue of a coordinated food safety budget, and we think that's an important area for the Committee to be involved in.

Another suggestion is operational response to food emergencies, and, again, one aspect of that is the role that industry can play. And then another very important topic to the Agency is this whole area of data and information and the flow of data and information. The competing interest was in the Agency, the flow of information between the Agency and the industry and then the public.

And we just think there is room there for your involvement in a very important topic and perhaps some good guidance in terms of from your perspective how we should think about this area. And it ties back as well to the budgeting process and some ideas we have about the needs of the Agency looking to Fiscal 2001 and beyond.

If you flip over to the next page, we did get some input from some of the members Katie Hanigan made some suggestions. I'm not sure what the first one is. It sounds sort of sinister: Field execution task force. But I'm sure

she is prepared to explain what that's about. HACCP audits conducted by the agency; I think that's a good, important area.

It gets in part into the issue of how the Agency, beyond a plant having the fundamental components of a HACCP plan, what role the agencies can and should play in terms of evaluating the quality of a HACCP program. And I think that's a very important area for discussion to get some guidance from you.

Communication is always important, and we welcome that kind of issue and discussion there. Dan also made a suggestion in terms of risk-based inspection and the relationship of that to current policy as well as legal requirements in terms of continuous inspection and that being interpreted as daily inspection and processing facilities as an example.

And then Cheryl Hall, who isn't able to make this meetings also provided a topic, and that is as spelled out here, the zero tolerance for ingesta with established testing and trying to look at this in terms of whether given the consideration of ingesta and the extent to which it represents actual risks in introducing or bringing chloroforms -- not chloroforms, but pathogens, to carcasses, how we should look at that from a policy perspective and deal with it in the context of a zero tolerance. This is an

important issue for the poultry industry, in particular, one that is being wrestled with right now.

Now, if you flip to the next page, then we'll have a break here shortly, you will see that we have laid out here the process where we are inviting you to identify any additional issues you would like to identify, and we lay out here how to do that and then ask you to provide these to the staff by 5 p.m. this afternoon.

If you flip just to the next page, you will see that we've listed all of those that I've just gone through and left room here with additional sheets so you can list the issue and whatever you want to write up about it so that we can, all of us, understand what you're focusing on. And we will then follow a process, and this will be done on Thursday -- is that right? -- where once we get the organized list with all of the issues.

Then if you flip another page, you will see a process we plan to use where we're going to ask you to rank -- identify your five highest priorities among all of the items on the list and then for those five priorities rank them from one to five.

We will compile all of that information and then feed that back to you term the collective evaluation of the priorities, and that will then set sort of a framework for which issues we focus on initially and subsequently in the

following meetings.

Are there any questions about this any of you have?

MS. MUCKLOW: I've got some general questions but not about this before you go.

MR. BILLY: Okay, okay. Anyone have any questions about this process? Okay. If you do, you can check with Mike or any of the other folks, and they can answer your questions and make sure that we follow through on this.

This is a very important initial step in our process now with the new committee to set some good priorities, and once we see what we get as a result, then we can look at that and think about it, and if there's any further thoughts, we can consider those as well.

Okay. Let's open it up for questions or issues. Rosemary?

MS. MUCKLOW: Just a couple of things. I'd like to, first of all, say thank you to Mike Micchelli because he really does get us organized very well, even down to giving me instructions on how to get here from the Metro station. It was most helpful, Mike. Thank you.

I realize that the appointments to this Committee are made at the discretion of the secretary. I am very disappointed that he did not renew the membership on this Committee of the one person who provided extraordinarily

valuable service during the last two years and who represented very small companies, Myron Stalford. I don't know the reason for that.

We don't have a replacement for Myron, and this is the biggest year for this Agency implementing HACCP in very small plants, and we're going to miss his voice around this table. And I really felt I need to register my disappointment that we don't have somebody from that segment of the industry because it is a huge challenge at the moment. And many of us, including -- is working very hard with your district administration and with your filed-appointed people, but we've lost a valuable input at this table for the small plants, very maul plants.

MR. BILLY: I appreciate that, Rosemary. It was our intent to reappoint Myron, but he declined, and he did it at a fairly late date. So we are aware of that concern, and we are looking at that in terms of what we should do to address that concern. We have received some letters as well in that regard, but it was our intent to reappoint him, and we were disappointed when he found he was unable to be on the Committee.

MS. MUCKLOW: Well, my fellow Committee members will remember last year we were having some lofty discussion, and Myron gets up, and he says, listen, he says, you can have all this kind of discussion in the world. When

my inspector says you don't do it, it's the law in my plant, and that's the way it is. And he brought us a very fundamental viewpoint of the way things happen down in a small plant, and we can sit here and talk about how things are to be.

That's how things are, and it was a very valuable input, and I won't ever forgot, and some people around here will remember that moment. He was sitting right there, and can see him yet. So I'm glad you are revisiting that.

DR. WOTEKI: I might also point out, though, that it's incumbent on all of the Committee members to represent a multiple range of interests. You do have some smaller companies as members of your association. The state representatives that are here also are inspecting in small plants. So each of us does bring a different perspective from the segment of industry that we are representing or the segment of government that we are representing.

MS. MUCKLOW: I understand that.

DR. WOTEKI: And I think it's also important, though, when there are specific issues for which we are we are aware that there are particular concerns among the small plants that we figure out ways to reach out to get those opinions forward front of the Committee.

MS. MUCKLOW: Well, I understand that, but nobody stands in the shoes that Myron stood in. The inspection

people -- none of the people around this table, and I'm glad that you are relooking at that, and I'm sorry that he declined to come back, because he had tremendously valuable input.

The second issue I wanted to mention is that I'm delighted to know that our work over the last two years yielded 18 recommendations. One of the things I asked for early in the last term of the Committee was that as we came to each meeting we be given an update on where all of our recommendations sat.

I'm fairly jaundiced, sitting 2,500 miles away from Washington, D.C., that there is a big sinkhole in the middle of the city where all of this stuff disappears, and it's very useful to know what it is that we've actually done. And with a new half of this Committee, I think it would be even more useful from them to know what we've actually recommended and to know what the status of those are.

Are they sitting at the secretary's discretion or authority, have they moved forward, or have they been abandoned because they weren't good ideas? I think it's extremely important that as we come to every Committee meeting we have a list of what we have done in a positive sense. And I think it's even more important that we have that now.

DR. WOTEKI: That's in your book.

MR. BILLY: Rosemary, if you will turn to Tab 4, it's not an inclusive list of all 18 because several have been addressed, and these are sort of the current or active ones, and you're encouraged to look at that. If you wish, we can provide the others as well, but they have all been followed through on.

MS. MUCKLOW: I think it would be useful because otherwise we may become repetitive.

MR. BILLY: That's fine.

MS. MUCKLOW: I'm sure you won't allow us to become repetitive, but I think it's, as we've had recommendations and as they move forward. I appreciate this page. I haven't gotten through every page, and I might have known you had the squirrel hiding in the book, at least half of the squirrel, but thank you very much.

MR. BILLY: You're welcome. It's an important point. I agree with your point.

MS. MUCKLOW: I'm sad that I'm not going to be able to stay overly long with you, and I'm going to miss the issue on exemptions, which is on my subcommittee or on the subcommittee on which I serve. I have no plans to change, but I won't be there for that meeting. I understand I may not have anybody actually sit in my place. May I have them participate in a subcommittee meeting and speak my peace?

MR. BILLY: Well, I think the committees are open to the public, and the subcommittee chairs can provide an opportunity for the public to provide input.

MS. MUCKLOW: Is my chair going to be at the subcommittee today? Is she coming?

MR. BILLY: As far as I know, she is.

MS. MUCKLOW: Good. Okay. It's an issue I'm very interested in.

MR. BILLY: Good. That's what we like to hear. Anything else, Rosemary? Anyone else? Okay. How long is our break? All right. We'll see you back at the table at about ten-thirty. Thank you.

(Whereupon, at 10:00 a.m., a brief recess was taken.)

MR. BILLY: We will get started again. The next item on the agenda is a short briefing with regard to the National Advisory Committee on Microbiological Criteria for Foods. Unfortunately, Dr. Karen Guloff, a recent addition to our staff, had to leave on a personal emergency a couple of days ago, so we're going to be a little more limited in terms of what we're actually going to be able to say about the Micro Committee. But Dr. Kaye Wachsmuth is here, and she is going to talk about Karen and her new role as well as some general items on the Micro Committee and answer any questions you might have. So it's my pleasure now to

introduce Dr. Kaye Wachsmuth.

DR. WACHSMUTH: Good morning. I guess the first thing I'd like to do is tell you how pleased we are to have Karen Hulebak. Karen joined our Office of Public Health and Science about a month ago now, I think, as the chief scientist. We may come up with another title, but for the moment that seems to fit the best.

Karen's background is in micro and a doctorate in toxicology, and then a lot of post-doctoral experience in risk assessment and risk sales. And I think she is going to be extremely helpful to us in a lot of ways within the Agency, but she also was probably the primary author of the first iteration of the President's Food Safety Initiative, which means she is very aware of all of the issues and some of the subtleties of some of those issues that will come before the Committee, and I think that's going to help us progress those things.

Karen will be the executive secretary for that committee on an interim basis, and some of you have in the past met or listened to Dick Ellis brief you, who was the executive secretary. Dick will be going to FAO in Rome to act as the -- I guess he will be the acting secretary for JECTRA. That's the food additive expert unit group for FAO and WHO.

He will be there from a year, so I think that's

good for Dick, and we'll try to shift things in the Committee so we can move ahead with that. We'll have several staff changes there, but most of those, I don't think any of you would be aware of, or hopefully you would never be aware of.

We are having the next meeting in May in Chicago at the Ambassador West Hotel. It will be Wednesday, May 26th, through Friday, the 28th. Wednesday and Thursday will be working group sessions. On Wednesday the Meat and Poultry subcommittee will discuss campylobacter. They will see the data and the information that you will see this afternoon, and some of the questions they will ask may depend on your discussions this afternoon they will be asked.

They will also try to finalizes guidelines. These will just be hazard identification for the small plants, not HACCP plans or anything more involved, just what are the basic hazards in some of the generic configurations for the different species slaughter and processing.

The Risk Assessment subcommittee will meet on Wednesday as well to talk about vibrioparehemaliticus. It's an FDA-led project for shellfish.

Thursday, again, two working groups. One will look at the qualification through verification. This is a produce, HACCP-like or HACCP-based inspection system. Then

another Risk Assessment Subcommittee meeting on listeria monocytogenese. This is a general risk assessment looking at all foods, sort of a relative assessment of which foods are highest risk in terms of listeria. And that will probably lead us within FSIS to a more refined assessment for our products.

And then on Friday, in plenary, those items that were discussed in subcommittee will come to the plenary session, and we will also introduce a discussion for the next meeting on bare-hand contact at retail, which is a fairly controversial issue in the Food Code, particularly.

If there are any questions, I'd be happy to answer them.

MS. MUCKLOW: What type of contact was that?

DR. WACHSMUTH: Bare hands.

MS. MUCKLOW: Bare hand.

DR. WACHSMUTH: It's when you have to wear gloves in serving or preparing food.

MR. BILLY: Dan?

DR. LaFONTAINE: Yeah. Kaye, you mentioned -- one of the things you were tackling was -- one of the things you mentioned was looking at HACCP and small plants as far as some of the major categories of risk. I didn't catch what you said.

DR. WACHSMUTH: No. This is this is a project

that the subcommittee has been working on now from a year or so. It's the identification of hazards expected to happen, right, in certain operations, very small operations for the different species.

DR. LaFONTAINE: That's very interesting and very pertinent as January 2000 comes.

DR. WACHSMUTH: Correct. That's why we will make every effort to finalize that this time if we can do it. They have been working on it for some time, and the Committee has changed. It's going to make it a little more difficult.

DR. LaFONTAINE: Then I guess my follow on committee to FSIS, if and when that's finalized, and I don't mean to put you on the spot, but how that's going to be communicated to the regulators and the industry if this expert committee is saying, here's some of the key risks that you need to be aware of, is what I'm hearing. That's what they are struggling with, all industry is.

DR. WACHSMUTH: Right. And there are packets of material that are being developed now for the very small plants within OPPDE, and someone may be able to comment on that better, but this will just be one part of that. This will be slipped into a larger guideline document for the very small plants.

DR. LaFONTAINE: I think we would all be very much

interested in some words on that today or tomorrow on the what the Office of Public Health is actually developing and when we can expect that.

MR. BILLY: Is there more you can add now?

DR. WACHSMUTH: Well, the Office of Public Health, per se, is not developing it. This will come from the advisory committee, a ranking of the different hazards for the different processes for slaughter --

DR. LaFONTAINE: I may use the wrong acronym, but within FSIS you mentioned that someone was doing this.

DR. WACHSMUTH: Right. In our HACCP Division within the Office of Policy and Program Development there is a whole series of -- well, there are a number of different efforts to develop packets of information, and there is one, HACCP guidelines, and this will just be the hazard-identification part of that. And maybe someone could come and discuss that.

MR. BILLY: What we're trying to do is to take the hazards and controls guide that we developed previously, update it with this type of information, and then we're focusing very specifically in very plain language kind of use in that guide to help the very small plants. And that's what will be a major component of that packet that we will make available to every single, very small plant. I think our target is the end of June or something like that.

DR. WACHSMUTH: Yes. Hopefully to have six months, to give folks six months to look at this.

MR. BILLY: Katie?

MS. HANIGAN: A question regarding this. It kind of ties in with the communication piece that I've put on further consideration, but once the hazards are identified and they come out in the report or in the packet, then are they going to be seen as mandatory CCPs for the small plants. And if the answer to that is no, then how is the Agency proposing to get that information out there and not have some districts and some in-house inspectors say that those are mandatory CCPs, how is that all going to mesh, because we're currently having those communication issues now in the field with the bigger plants?

The meganism we plan to use is a new procedure that is being finalize now focused on the circuit supervisors and providing them not only these packets, but a special set of instructions about how they are to be viewed and used. And we're looking to the circuit supervisors and holding them responsible for the interactions between the Agency and the very small plants with regard to HACCP implementation. And it will be made clear that these are, in fact, guidelines and that what a very small plant chooses to do needs to be based on their specific operation and what is applicable in that context.

And so we're turning very specifically to a delegated kind of approach with clear guidelines from the districts and headquarters in terms of interactions with the various small plants, and that process has actually already started.

MS. HANIGAN: Okay. Just a further clarification. Will that packet be sent to the very small plants so that they clearly understand what direction has gone to the circuit?

MR. BILLY: Yeah. That's what I meant earlier. It will be sent directly to every very small plant.

MS. HANIGAN: And I think, just as a recommendation, you know, the wording of some of those documents come out that says a prudent manufacturer would recognize these hazards. When we start seeing language like that coming across, it's almost interpreted as a mandatory. And I know it's difficult to write documents, because I write many of them for Farmland for our 12 plants, but the wording is very hard, and it gets a lot of interpretation out in the field.

MR. BILLY: And that's why we're focusing as much on the circuit supervisors and their interaction with the inspectors in charge and the other inspectors involved because they have to in a hands-on kind of way oversee this whole process of the third phase of HACCP implementation in

the very small plants. And we have very clear expectations in terms of how they approach that, and we're not relying just on the written word.

They are expected to have visited every small every single small plant, using a form to determine where they stand in the process of HACCP implementation, sizing up what is missing or what may be needed, and then repeating that in several cycles between now and next January 25th.

So there is quite a detailed strategy associated with that kind of interaction between the circuit supervisors, the inspectors they supervise and for the very small plants. Rosemary?

MS. MUCKLOW: I don't want to labor this too much. One of the problems that has arisen as we begin to look at ready-to-eat products and the sampling level in those very same, very small plants, because many of those very small plants make lots of different products, and suddenly they are having samples drawn for a lot of different products, and they are being sampled to death.

We submitted, one of my staff people did, earlier this week a recommendation to the Agency to revisit that sampling level before we put these people out of business and to look at them as classes of products, groupings. We hope you will look at that with some urgency because some of those firms are just so tied up with sampling now, and they

are very small. They don't produce much poundage, but they produce a wide variety of products, and, again, it's something that is very specific to the small plants who usually have a very short distribution chain.

The other thing, and this is mildly commercial, but we did make available to you recently a multiple organizational recommendation for GMPs, SOPs, and environmental sampling and testings, and we hope that you will help to get those out because they are written in what I call "plant-speak language." They are very basic, and they have got some broad support from the industry. So we hope you can find those useful.

MR. BILLY: Yes. I would like to acknowledge, in fact, that a number of industry trade organizations did get together and develop what appear to be some very useful guidelines in terms of addressing listeria. And we are looking at those very closely now, and as you are aware, there have been other similar submissions to us as well, and the work we've been doing internally, and that's all being molded together into an overall set the of recommendations that will be coming out of the Agency shortly.

MS. MUCKLOW: Dan may find those especially helpful. Have you found them yet the, Dan?

DR. LaFONTAINE: What was your question, Rosemary, specifically?

MS. MUCKLOW: Did you find those guidelines have you seen our guidelines?

DR. LaFONTAINE: I'm aware of them. We asked for them from your office.

MS. MUCKLOW: They are on the Web.

DR. LaFONTAINE: Okay. To answer your question, yes.

MR. BILLY: Collette?

MS. SCHULTZ KASTER: Well, I was going to make a point relative to what Katie tee said, and ask the question, with the circuit supervision, will there also be any kind of auditing function within the districts and between districts, perhaps with the HACCP coordinator, to ensure consistency between these implementations and interpretations of these hazards?

MR. BILLY: Perhaps what I should do is I'll look at the agenda and arrange for someone to come over that can talk about this a little more specifically. The answer to your question is yes, but we can provide more specific information on how that's going to work. Caroline?

MS. DEWAAL: Part of the goal of this meeting is to educate people from different segments. Rosemary, I just had a question for clarification. My understanding, and correct me if I'm wrong, of the HACCP rule is that the only mandatory sampling in that rule is in slaughter facilities.

And it's mandatory for generic E. coli.

So I'm confused by your statement that these small plants who were producing lots of different processed products are being sampled to death, my understanding of the rule is that there is no mandate for them to sample at all. Please correct me if I'm misstating anything.

MR. BILLY: Rosemary?

MS. MUCKLOW: The Agency has had a sampling program for ready-to-eat products because unlike raw products we are doing the generic E. coli testing, in the ready-to-eat products they are to be free of all pathogens. The Agency has a very comprehensive sampling program for listeria and salmonella.

MS. DEWAAL: Thank you for that clarification, Rosemary. My understanding of that sampling program, and I do not know if Kaye is the right person to answer that, how many thousands of samples are you doing a year on ready-to-eat product for listeria?

DR. WACHSMUTH: We have the resource right here, Dr. Havlik.

MR. BILLY: You need to speak into the microphone.

DR. HAVLIK: I have to do some thinking.

MR. BILLY: All right.

DR. HAVLIK: It's hard to -- I can't give you a number for listeria. I can give you a general number for

ready-to-eat products, and that would be around -- there is somewhere around, because it changes by the month, there is somewhere around 7,000 samples that are drawn.

MR. BILLY: Annually?

DR. HAVLIK: Yes.

MS. DEWAAL: And for how many pathogens or how many --

DR. HAVLIK: It depends. When we do ready-to-eat products we normally do -- we always do one, obviously, and sometimes do two, and it depends upon the product sometimes we'll do listeria because if listeria is there, then we don't have to do salmonella because there is already a problem.

In other cases we'll do salmonella because there is probably a very low risks of having listeria because the product was cooked in the package in which it is going to the consumer. In dry, semidry products we're looking for staph enorotoxin, and we do a very, very few canned products for clostridia.

The 0157 program runs as a separate -- that ground-beef program runs as a separate program.

MS. DEWAAL: I wouldn't just like to note at this point on the record that CSPI, joined by a number of other consumer organizations and public health organizations including the American Public Health Association, AARP, and

many other groups, have written to the secretary asking for him to not only continue the program for government sampling for listeria, which Dr. Havlik was just informing us about, but also requiring the ready-to-eat industry to do their own sampling for listeria.

Perhaps the reason that they feel like they are being sampled to death is, in fact, they don't know what the test results are going to look like because they are not checking their own products.

We think that this is a very reasonable approach to addressing some of the hazards that we've seen demonstrated by the recent out break from the Sarah Lee Company from the Bilmore plant in Michigan that resulted in over 20 deaths, including six miscarriages. I haven't seen the latest figures, but it's at least close to 100 illness. So I hope that we will hear back from the secretary soon.

And just to follow up, do you have any date for the release of your listeria recommendations at the meeting in January? You mentioned there would be short-term, medium-term, and long-term regulations and they would be out of the Agency within a month, and that was several months ago, so I'm just curious on an update on that.

MR. BILLY: We have developed our materials and approach, and they are currently under review, so our intent is to get them out as quickly as we can, but they have to go

through the appropriate processes for legal review and so forth. So that's under way. Phil?

DR. HAVLIK: If I might just add, looking at it from the laboratory standpoint, a laboratory-resource standpoint, listeria is a very difficult analysis. It takes us about six days from the time we get the sample in the laboratory to be able to say it's negative. And then if we have to go on and confirm, it can take a couple of more days.

We're probably going to publish a Commerce Business Daily request for information about a quick test for listeria because we're doing so many listeria now that's really having an impact on our throughput. So that's another consideration for doing listeria. It's a very labor-intensive analysis right now as compared to some of our others where we have some screening tests and where we can utilize some robotics to help us run a lot of these tests.

MR. MAMMINGA: Mike Mamminga. I just want to know when you, going back an issue -- we kind of get off the guidelines that you're going to send off to the very small plants, these will be made available to your state program people, et cetera.

MR. BILLY: Oh, yes, yeah. They will be made available in ample quantities to each of the HACCP

coordinators in the 50 states and through our system as well, so, yeah, that's our plan. Okay. Rosemary, and then Alice.

MS. MUCKLOW: I don't want to take us way down the wrong road, but testing methodology and rapid tests and so on is a very interesting subjects. There have been a lot of sessions. Testing is always a mystery, and it would be nice if this Committee could maybe add that to its to-do list of how we try to get a better understanding of what tests there are, how good they are, what the false-positive and false-negative, and the Agency's attitude to using rapid tests in conjunction and cooperation with the industry. And I think that would be a very helpful for us all to go through.

MR. BILLY: Thanks, Rosemary. Alice.

DR. HURLBERT: I'm going to jump back to the HACCP guidelines for a minute. The circuit supervisor is to be given the brochures and the information packets. Will they receive any training on any of the updates that are made to or on behalf of guide book? Will they sit down and walk through a hazard analysis?

MR. BILLY: I don't know the specific plan, so that's why I suggested that we get someone here that can tell you the specific approach. We'll follow up on that. Anyone else? Kaye, is there anything more you want to add?

DR. WACHSMUTH: No, except that you are all

invited to the meeting, the 26th through the 28th in which issue.

MR. BILLY: Next, we wanted to provide you a couple of updates. These are you want updates on issues that the Committee has spent a fair amount of time on. The first one is the interstate shipment of inspected product. Chris Church is with us two provide us an update and answer any questions you might have on that area. Chris?

MR. CHURCH: Good morning. The issue, as you will remember from last year, is under the current statutes the meat and poultry that is produced under state inspection programs is limited to distribution within that state. So last year the Agency presented a concept paper that outlined the steps and the statutory changes that would be needed that we were suggesting to create a seamless national inspection program that would allow for interstate shipment from the state-inspected plants.

I have brought copies of the concept paper, which I will leave. I know there are some new members who may not have seen the paper, and you may have lost your old ones. It has not been updated, but it is the concept paper that was presented here, and last year the committee endorsed the paper as a basis for legislation, so we have moved forward on that.

Just to recap the highlights of the concept paper,

a key element was, under current statutes state programs have to be at least equal to. That has caused controversy for the past 20 years as to what is "at least equal to." Our concept was, move beyond that language to a seamless national program where the states would be inspecting -- would be enforcing federal requirements. So that's one of the statutory requirements we were recommending.

The other elements of the concept were designed to strengthen the partnerships between the federal and state programs and also to ensure the integrity of a seamless national program. I won't go through all of the details again. I'll leave the concept paper there.

There have been a number of steps that have taken place over the past year since we have presented, and they have been key steps, necessary steps, and they are moving us along. First, this was an Agency concept. We have, in fact, gained over the course of the year the support of the secretary to proceed with the legislation based on the concept. We then have drafted the legislation.

The legislation that is drawn from the concept very much follows the concept. The draft legislation has then been put through Department clearance, and recently last month we briefed OMB on the legislation, the draft legislation that would be coming to OMB. And just recently the legislation has been forwarded for administrative

clearance at OMB.

So at this point we are hoping to hear back from OMB on their comments this month, and then we'll move forward on a strategy to have the bill introduced. It's an issue that we imagine will get bipartisan support. And we also imagine we will have state support, consumer support, industry support, and it may be one of the issues that we all actually live to see the day where there is interstate shipment. I know some people -- oh, excuse me -- are a little -- are understandably pessimistic, but I am cautiously optimistic that we will live to see the day of interstate shipment.

MR. BILLY: One of the questions that's raised and that was talked about in this Committee is the idea of permitting the export of state-inspected product. What's the status of that in terms of what's moving forward?

MR. CHURCH: As the concept paper mentioned, since the states will be enforcing federal requirements, the product produced under those states will be eligible for the federal seal. It will also be eligible to use the state seal. But as it will be product moving with federal seal, it will be eligible for export and included in other further processing for export. So as it stands now, that product would be eligible for exportation. Lee?

DR. JAN: This seems to be the big role block in

OMB. Is that an USDA OMB or --

MR. BILLY: It's the White House.

MR. CHURCH: This is the White House.

DR. JAN: The normal process is after it goes to Congress, then it goes to OMB.

MR:CHURCH: No. This is to get the administration's endorsement of the bill.

DR. WOTEKI: This is absolutely standard operating procedure for any legislative proposal that works its way from an agency through department clearance then through OMB for review and clearance.

DR. JAN: So had this been introduced by Congress or introduced in Congress without going from an agency, then it wouldn't have had this backlog, and OMB -- after Congress had enacted. Is that correct?

DR. WOTEKI: Legislation can be introduced by members that they bring forward from their constituencies representing their interests. If that law is passed and enacted, then the administration has the responsibility for carrying it out. If a proposal comes, though, from the administration. It has to gain the administration's approval.

And so this process that Chris had outlined of the development of the concept proposal then the development of the legislation and moving that forward through the

departmental and then through the Office of Management and Budget clearance procedure is standard procedure for when a legislative proposal arises from the administration.

DR. JAN: So if it goes through here, then, OMB, once it leaves OMB and goes finally to Congress, then Congress passes it, it's pretty much a done deal. It doesn't have to go back to OMB before the president signs it. It's got to go back again.

MS. WOTEKI: Correct.

MR. BILLY: Well, let me expand on that a little bit. There are presently several bills that have been introduced by members of Congress on the subject of interstate shipment.

Those bills, if, for example, they become the subject of a hearing, then the Office of Management and Budget will coordinate on behalf of the administration the development of a position on those bills.

And let's say they very widely, they have different components and approaches or whatever, and if there is an administration witness that testifies, then the administration witness would be speaking on behalf of the administration, and OMB would have coordinated the statement of the administration, the position of the administration with regard to those bills.

Now, if the bill that's now at OMB is concurred on

by OMB on behalf of the administration, then a process normally occurs where the administration consultation with members of Congress to find sponsors, someone that will introduce the bill on behalf of the administration.

And I think what Chris was referring to, there is an expectation that there should be pretty broad interest and support for that. And that administration bill would be added to the pile of bills on this subject area, and then it's up to Congress to decide how they will be addressed, whether there will be one or more hearings and so forth.

So, you know, at that point in time then it's in Congress's hands to enact a change in the law based on whatever input they choose to receive. I don't know if that helps you or not, or if anyone wants to add anything to that.

MS. FOREMAN: I was going to say, OMB gets it shot at the bill whether it comes from Congress or the administration. They have to decide if the administration is going to favor it or oppose it. So they get their grubby little hands on it sooner or later anyhow.

DR. JAN: Well, I knew that. My understanding is that they made recommendations to the president as far as to whether he should sign a veto, and that's the only reason I --

MS. FOREMAN: It's before the fact.

MR. BILLY: These are still bills under consideration by Congress.

MS. FOREMAN: And they answer to no one except God, and God doesn't live in the White House.

MR. BILLY: Okay.

DR. WOTEKI: One final note on that, though. I think it is important to understand as well that the coordinating role that OMB plays in the development of an administrative position actually reflects the fact that there may be multiple interests at stake beyond that of the department from which, in the case of the kind of bill that this is or the kind of legislation proposal that this is.

So at times there may be aspects that relate to taxation or treasury or other kinds of issues that go beyond what the Department of Agriculture is interested in. So OMB plays that role in clearance of major proposals because there may be multiple interests that need to be taken into account.

MR. BILLY: Okay. Rosemary? Terry?

MS. MUCKLOW: I'm encouraged by Chris Church's optimism and would also be relatively optimistic about this issue because this is the first time there has been broad support for something to address what has been a very complex issue. I would like to suggest that anybody in this room, whether they are at the other side of the yellow line.

Not get any ideas about hanging Christmas ornaments on this for their favorite issues because this fine bill that has been crafted with a lot of broad support would go down in flames, and it won't rise again for a long time. This is the best hope to do something in a great spirit of cooperation, and it would be very unfortunate if it gets enriched with undesirable ornaments.

MR. BILLY: Terry?

MR. BURKHARDT: I want to just ask, you know, part of the strategy with implementation or with the preparation of this bill was to coincide with the implementation of HACCP for the very small plants in the year 2000. Do you have any idea when the bill would be introduced, and is that still the goal of the administration, to make it effective by the year 2000?

MR. BILLY: The bill is premised on HACCP implementation. Given the time that has elapsed, there has been a little slippage in terms of target dates because, if you will recall, in the concept paper there is a process that occurs about review of state programs and other steps that have to occur, but it does have specific dates for opening the door for the states to notify whether they wish to pursue this, and in the review process and other things that occur, an ending dated as well in terms of the transformation of what now exists into this kind of

HACCP-based system that it provides for interstate shipment.

So it's consistent with that concept paper. That's the key message. The timing -- eventually if you assume that the appropriate committees in Congress will consider the bill, hold hearings. They will put dates into the bill based on input during the hearing process and based on the advise of the administration and others that are appropriate. So all that remains to be pinned down or finalized consistent with the legislative process. I guess that's the best way to answer that -- Chris?

MR. CHURCH: I guess one of the things, the integrity of the seamless program that we're anticipating, and one of the things is that a thorough review of the state programs prior to implementation. So the sooner the bill is passed, the sooner the reviews begin, the sooner we'll see interstate shipment, but dates are one of the things that are not in stone at this point.

MR. BILLY: Caroline?

MS. DEWAAL: Thank you, Tom. I want to go back to the question of OMB's role in approving the legislation. I have an easy question and a hard question. The easy question is, is it proposal remaining intact to the recommendations which the Advisory Committee made, or are you anticipating significant changes?

MR. CHURCH: The draft legislation is very true to

the concept paper. There are no surprises in the bill we sent and discussed with OMB.

MS. DEWAAL: Well, that's nice to hear. As one of the members of that subcommittee, and I'm sure the other people here who worked on it, so that's good to hear.

The harder question is this. Say in a hypothetical world we had two different food-safety agencies that were going down this road of looking at how to coordinate with state programs, and they seemed to be going down two different roads, one perhaps represented by the process this Committee went through and another represented by a very different process. Does OMB play a role in coordinating between those two competing plans? I think the question goes to the undersecretary.

MR. CHURCH: The hard question.

DR. WOTEKI: Yes. Well, clearly, OMB does play a role when there are policy conflicts, and the way that -- on this broader issue of federal, state, local regulatory agencies working interrelationships, the council that I spoke about before, the President's Food Safety Council, does have OMB represented at the policy level on the council as well as on the two task forces that I talked about.

So, you know, clearly where there are major policy differences among departments that have similar responsibilities, OMB frequently gets called on through its

role on the budget side for the adjudication of those policy difference and also in the clearance of initiatives like this bill.

Among the techniques that OMB uses when a bill would present itself or be presented to them is they send it around to all of the departments for review and comment. And then if in that process there are major difference that arise, then they usually convene a meeting, sometimes several meetings, to try to work those out and eventually will make a decision and make a recommendation.

MS. DEWAAL: As you know, but I'm not sure other people on the Committee know, there is a competing proposal for federal/state cooperation that is coming out of FDA and I don't know if Carol Tucker Foreman, who has now joined us, has any comments on it, but we are tremendously concerned that the ideas being presented by FDA have not gone through the type of vetting by the community of interest that this particular proposal has.

And we are very concerned that that proposal may come out prematurely without having gone through a full level of consultation with industry, consumer groups, and others. It apparently has been crafted mostly by the Agency and the states with no outside input formally at all.

MR. BILLY: Carol?

MS. FOREMAN: Yeah. I'm with Rosemary. I think

it is a terrific step forward that we have taken an issue that 25 years ago when I was at USDA was a problem, and it looks as though we have something that everybody can agree to.

It is also -- it was handled in exactly the way you would hope that your federal government would handle an issue, with a concept paper that went through several iterations that is tied logically to a change in the basic inspection system that got buy-in, discussion with and buy-in from the stakeholders represented in this Committee. And it's exactly what you would want to do, in that it contrasts vividly with the process at the Food and Drug Administration, which has had none of those aspects to it.

And I want members of the Committee to know that I have some concerns about whether what's happening at the FDA will slop over and have an impact on the rationality of the process that we have been pursuing with the Department on this. People are sure to say in the Congress once Bill gets up there, well, why do you have to have all of these nice little steps and protections? The other food safety agency isn't pursuing those.

Now, I have a question. How many bills have been introduced in Congress this year on this subject? Do you know, Chris?

MR. CHURCH: I don't know the exact number, but

there are at least two or three, and Congressman Thornberry of Texas just introduced one like, for instance, last week.

MS. FOREMAN: And Senator Hatch, has he reintroduced his bill?

MR. CHURCH: His bill has not been introduced.

MS. FOREMAN: Okay. Well, he had one in previous years.

MR. CHURCH: Right. There are some sort of standard bills that get introduced each Congress at some point.

MR. BILLY: Several of the key leaders in Congress are anxiously awaiting and expecting the administration's bill as a basis for pursuing this area and have signaled, you know, given an understanding of what the concept paper addresses, have signaled an interest in being a co-sponsor.

MS. FOREMAN: Some of those members have a rather substantial amount of influence with the administration because they chair important committees, so they might help move it through the process. Thanks.

MR. BILLY: Rosemary?

MS. MUCKLOW: Would it be helpful for us as a Committee to make a recommendation to the secretary that he give this an urgent push because of these other concerns? Would that be an appropriate action for this Committee to take?

MR. BILLY: Sure. Yes. Sure.

MS. MUCKLOW: Okay. Well, let's do that, ask him -- it's Frank Raines. Is he still at OMB? No. He's gone. Somebody else is there. Who?

DR. WOTEKI: Blue, Jacob Blue.

MS. MUCKLOW: I see. Let's ask him to call the directorate of OMB and get this on a fast track because there is some urgency to try to implement it, and I would so move.

MR. BILLY: Is that sort of a sense of the Committee, that we do that? Any other discussion about it?

MS. DEWAAL: Do we control the secretary's phone calls?

MR. BILLY: Rosemary, what you've said, as I heard it, was that you're focused specifically on the interstate shipment of meat and poultry products, and you are not addressing what other agencies may or may not be doing.

MS. MUCKLOW: I want to be there first.

MR. BILLY: Okay. I just wanted to be clear. Okay. Then we'll --

MS. DEWAAL: Well, could we entertain the concept of having the letter or the communication also mention that, you know, that OMB should perhaps look at look at making sure that other agencies' policies in this area are consistent with what USDA is recommending?

MS. FOREMAN: That's our view, not the secretary's.

MR. BILLY: Yes. Let me make a comment on that as the chairman of the Committee. Introducing that, in my opinion, will result in a significant delay of progress so if that's what the Committee wishes, that's fine, but I think it would be unavoidable. So I think --

MS. MUCKLOW: My motion is pure and simple. The simpler, the straighter, the purer, the faster, the better.

MR. BILLY: Okay. And I have a sense that that's supported by the Committee, so we'll follow up on that and note that appropriately and have the secretary follow up on that

DR. WOTEKI: And I might also note that since I am co-chairing the task force that is concerned with and charged with developing the long-range strategic plan that includes how we interrelate federal, state, and local responsibilities, that your concerns are noted.

MS. FOREMAN: Who is your co-chair?

DR. WOTEKI: Jane Haney.

MR. BILLY: Okay. Thank you, Chris. I'm going to move on.

The next issue update, which I think will be hopefully a pretty brief one -- we're a little bit behind schedule -- is an update on recall coordination, and this

was an issue that the Committee previously got into Bill Havlik is going to give us an update in terms of how the process works and so forth and is prepared to answer any questions, so Bill?

DR. HAVLIK: Yeah. I'll be very quick. As far as our liaison with FDA, we let FDA know whenever we do a recall, and they let us know whenever they do a recall. It's just a very formal system of going back and forth, faxing the information back and forth. The Agency can choose or not to choose to act upon the information.

If we have a product that involves both product from FSIS and product from FDA then FDA is asked to participate in the recall meeting. And products such as TV dinners, where we sample the meat product, and there may be some vegetables or some other product that FDA regulates, or it may be a product that FDA would have concerns about because of other products that are manufactured at the same facility that use similar processes, things like that.

We have about six contacts we make over at FDA on a regular basis. On all Class I recalls we have about 300 people we notify in states. It could be the state public-health officer, the epidemiology officer, the ag. department, whoever the state has indicated, and that's an automated system.

We just put the recall -- transferred the recall

notification file over to a computer, and the computer starts faxing automatically about 300-some-odd names. People can add their names to that by letting us know, or they can take their names off by letting us know. And that's about the way it works. If anybody has any questions, I would be glad to answer them.

MR. BILLY: Dan?

DR. LaFONTAINE: Yeah. Just some positive feedback. Speaking for one state, South Carolina, it's wonderful compared to what it used to be, because agriculture, health department, various epidemiologists, the Bureau of Food Protection, our organization, everybody is getting in simultaneously, and, you know, we all have the information that we need.

DR. HAVLIK: The only thing that we're working on that hopefully will get done in maybe about another year is to have self-maintenance so that if you are on it right now, then funded to get off it or add more names, you would just log on with your password and add more names so that we don't have to maintain the list. And we hope to get that in place in about a year.

MR. BILLY: Dan?

DR. LaFONTAINE: Yeah, and there is one thing I've noticed, and maybe it's been taken care of. I'm not sure. Sometimes there is additional recall -- 1199, for example.

I'm just pulling that off the top of my head. But then you get additional information, and it's hard to track it. Two things. Is this, in fact, totally new information buried in here somewhere? You need a system for 11-A or --

DR. HAVLIK: Right. I understand what you're saying.

DR. LaFONTAINE: And then also highlight what the change is, because I've literally had to read every sentence to figure out if there's additional items or what, so that does need refinement.

DR. HAVLIK: Yeah. We can take care of that.

MR. BILLY: Any other state representatives comment at all? Terry?

MR. BURKHARDT: I just would echo that. It's been very good. We get notifications regularly, and it's worked out well.

MR. BILLY: Okay. Rosemary and then, Nancy?

MS. MUCKLOW: You will be glad I'm not going to be here this afternoon. One of the new terms we've all learned of lately is exit strategies. I'd like the Agency to explain to us their exit strategy to get people off or close a recall. I haven't looked lately, but I think Hudson is still open.

It's almost two years' old now, and it's like a chancre sore asking for 25 million pounds when we think

there's probably eight or nine million pounds as a relative value there. We need a better exit strategy to close recalls. They shouldn't sit there looking for millions of pounds in meat when an awful lot less is available. It was the same with Colorado Box Beef and all of the screw up on that one. There was very little meat left. We do need a better exit strategy from the recall situation.

MR. BILLY: Let me say something, and then, Bill, you can add. By and large, the process that occurs to complete a recall rests with the company. There are procedures which they inform Agency that they believe that the product in question has been recovered, we, of course, have a monitoring system to independently verify that there has been an effective recall.

If there is a significant amount of product that has, in fact, been recovered, then it's the responsibility of the company to inform the Agency of how they plan to depose of the product. And in some instances those decisions are slow coming, and as a result, the recall is maintained on the list until such time as that process is completed and we can close it out.

So I understand your general concern, but you need to understand that there are instances where, for whatever reasons, we don't get follow up from the company that enables us to remove listed recall very quickly.

MS. MUCKLOW: The system is just a bit constipated. It needs to have a little diuretic to move it along.

MR. BILLY: Okay. Perhaps, Rosemary, in your role as the director of one of the trade associations, you could work with the others to develop some guidelines that would help the plants that are involved follow through in terms of their part of this, and we can certainly look at the our part and what we're doing.

MS. MUCKLOW: We'll be glad to the that. It's still has been very sluggish. And so maybe it needs a little more attention. We can all blame each other. It's a cooperate effort.

MR. BILLY: It sure is. Okay. Nancy?

MS. DONLEY: A question. The information that gets communicated to the states; does it include the -- I'm wondering how far -- to which level does it get down to as far as specifics? Does it identify specific retail out lets, or does it just get to the distributor level, or how far down does it actually go, or how detailed is the information?

DR. HAVLIK: We're prohibited from providing distribution information from a plant outside of the Agency because that's privileged information. So what we suggest is that if the state -- we'll tell a state that the product

has gone into their state, and it's up to their people then to contact the plant, and we provide that information, so they can find out from the plant where it was distributed in that state.

MS. DONLEY: I, just as kind of a follow-up comment, I would be interested to hear what some of the state people on this Committee have to say about this. I've had the opportunity to have some interaction with a couple of state health departments and got quite a sense of frustration from them that they have to, you know, literally go out and do the detective work themselves. It's a waste of time. It takes them time and energy to have to do that. I don't know what the solution here is.

I'd be interested to know why you're prohibited from doing that. I've also heard where some literally have just gone into their local areas, gone store to store to go meet with store managers, go look on the shelves themselves, and that seems to me a terrible waste of time and energy and resources.

MR. BILLY: Dan?

DR. LaFONTAINE: First of all, in many of the recalls there is detailed information about where it was distributed, and I think that's because the establishments voluntarily provide it.

MR. BILLY: That's correct.

DR. LaFONTAINE: I think most of the time they do, at least to their first destination --

MR. BILLY: Right.

DR. LaFONTAINE: -- with the various changes that are involved. So I guess my point is it's not 100-percent, but when I look at them, I'll have a real good feel if that product is, well, first, like you said, if it's distributed to the state or not, but also between us and the health department and Agriculture know where to look.

But then, Nancy, to your question, I guess I don't want to oversimplify it, but it will not work -- a recall system will not work if you try to drive it from the top only. It's a lot of hard work, and you just have to go out and start working with the chain stores and whatever are involved and work together to try to track it down to the Nth degree. There is no easy way, and it won't work. It will be impossible and probably inaccurate information if you try to have it all come from the top.

So they may not like it, but that's really what the real world is, is beating a path and finding out where all it's been distributed, because it goes a hundred different direction once it gets into these chain stores.

MS. DONLEY: Just as a follow up, I guess I can't really buy that because I think what it does is it doesn't give a level playing field or a level -- an equal level of

protection across the country. I want to live in an area where I've got some real person who is on top of things, has the time, energy, and resources to get out there, make the phone calls, or jump in the car, drive to the stores, and pull the things off the shelves by himself, if necessary.

But I guess that leads me to, though, is there any requirement that in the event of recalls, is there any onus on distributors in any sense of a legal way that they have to take it the next step and inform the establishment?

MR. BILLY: No. The entire recall process, at least for meat and poultry products, is voluntary, and it's voluntary from the plant that produced the product to their customer list, the distributors, to the secondary distributors, and on down the line.

I think some of you may have seen the presentation that Dale Allen made using one of their large slaughter plants as an example, and where they did, as I recall, what he characterized as sort of a mock recall involving a day's production. And I don't remember the numbers precisely, but one day's production from that slaughter plant when they triggered the mock recall, it was about four days later, their primary customer list was somewhere in the neighborhood of ninety to a hundred distributors.

Within four days that had been broadened out to about eight to 900 secondary and tertiary distributors from

one slaughter plant, one day's production. And under a recall we need the cooperation of all of those people to, as Dan characterized it, to ensure that there is an appropriate follow-up. And it is voluntary. Companies, whether they are districts or whatever, are normally very cooperate and respond in an appropriate way. It is the companies that pull the product.

That's the role, whether it's federal or state inspectors, we're out there auditing to see that, in fact, the product is off the shelves and that they have gotten the letters or the faxes, there is notification, there is action, that kind of thing. And we statistically sort of audit a recall to see if, in fact, there has been follow through, but it is a voluntary system. Dan?

DR. LaFONTAINE: I think it would be appropriate to mention on behalf of FSIS, and I don't see any representative compliance folks here or not, they have a standard protocol and policy of contacting in person or by phone at least 10 percent of the known primary and secondary distribution points. And so they can very rapidly -- they call it recall-effectiveness checks.

So within FSIS for FSIS-label products or produced products, I should say, products produced under FSIS's inspection, there is a system for checking the effectiveness, and if they find that no one has gotten the

word, then they can take appropriate action or the appropriate percentage.

MR. BILLY: Caroline?

MS. DEWAAL: I just have a fairly simple question. I'm confused, Dr. Havlik, at your statement that it's privileged information, and therefore, you can't release it to your state counter-part. Why would that -- it's not reachable by FOIA. I just don't understand legally why you can't release it to the states. It's not like you're releasing it to the general public in a press release. I'm wondering why you couldn't give specific distribution information to the states.

DR. HAVLIK: Because that's what has been ruled by our general counsel. I mean that's their interpretation of -- that information is considered to be production information, and that information, if it was released, could impact the business of the plant.

DR. WACHSMUTH: We could lose access to the information if we break the law, but we are trying to find ways to have better communication with the states now. We're explore several different ways.

DR. HAVLIK: We provide the states with as much possible information as we can. The other thing you have to remember is that when we go after distribution, it's really the compliance officers that get all of that information.

The plants have the information. The compliance office go in, and they will get the first level of distribution information from that plant.

That plant may or may not know the secondary and tertiary distribution, so then a compliance officer has to go to the secondary distribution and check all of those distribution lists and then would have to go through and check the tertiary distribution lists. This is a long-term process that is much easier dealt with by asking plants to please provide the information rather than seeking it out in a more -- in a different way.

MR. BILLY: There are, under the -- I don't remember the name of the Act specifically, but it's confidential business data, that type of thing. There are very specific provisions apply to federal employees, including civil and criminal penalties and imprisonment if it's demonstrated that you violated the law.

We don't have a mechanism whereby, as compared to the Food and Drug Administration, they have a provision in their law to "deputize" state officials, and through that process have all federal rules applied to them. If they are deputized, they are, in effect, a federal employee for that purpose. Not all states have the same protections in their laws, so there have been -- in fact, as I understand it, there have been a number of cases in this area, and people

have been penalized. So there are very specifically some important safeguards to protect business information.

As Dan pointed out, and I'll second, by and large, companies willingly provide the list, at least the initial list, and then it's that process of working it out and doing the necessary things to trace the product back out to wherever it end up. And good, voluntary cooperation is critical. Recalls are about protecting consumers, and it's real important that we maintain, given our current authorities and so forth, that we maintain appropriate balance so that when it's critically important that we get consumers to do something or stores to do something, they do it, and they do it in a full and effective way.

So I appreciate that there are those that feel that, well, this should be more done. As you're aware, the Department developed legislation in this area, but right now I think it's real important that in the context of the current system that we maintain the right balance in terms of working through this. Caroline and then Dale?

MS. DEWAAL: Thank you, Tom. If we hadn't gone through such a painful recall just a few months ago where product was not perhaps removed from the shelves as quickly as it should have been, where there were severe public-health consequences that resulted, perhaps we could sit back and look at this academically. However, I am

troubled, and I think the discussion today has been very good, with fact, you know, it sounds to me that recalls are as much about protecting businesses as it is about protecting consumers.

And one suggestion I might make, and it was a discussion during the subcommittee meetings on the interstate-shipment issue, the issue of a recall and how to strengthen the recall provisions through to the states to make sure that USDA had the recall authority it needed and the states needed that perhaps some deputizing of the states might be as a provision similar to what apparently FDA has, allowing it to give more information to the states.

I just think it's very troubling to see that USDA the Federal Agency, cannot transmit distribution information to the states, and I think that that's a water we could probably fix pretty easily, and there is even a legislative vehicle involving the states that it might be able to become part of, not as a Christmas-tree ornament, but as a rational approach as to how to address this problem.

MR. BILLY: Okay. Who is next? Dale.

DR. MORSE: First, just commenting, our observation is that there is a better method of notification. We hear a lot more rapidly of communication of recalls taking place. I think, as has been discussed, the flaw comes up in terms of when there is an outbreak, and

then we find that our food surveillance and control people feel that posting the recall appears after they hear about it in the press, number one, and, number two, is not having the distribution list in those settings.

Then we realize, like listeriosis case situation, where we found that there were delays in notification through the voluntary. We had one instance with the Meals on Wheels serving over 300 meals eight days after the recall, and they were notified, and then we tried to recover the meals before they were served, but most of them had already been distributed. Fortunately, people didn't get ill, but that sort of shows that the system doesn't work operationally when you have an outbreak or a pathogen.

So it's certainly clear that there are some organisms that are more virulent and a higher risk of causing illness in humans may be present in foods, certain subtypes of listeria may not be as much of a pathogen for humans, but when you have an outbreak, it's clear that you have to get that product off the shelf and away from consumers.

And there we have seen that there have been delays, that the system doesn't work, and that information is needed quickly by states and other individuals to help make sure that those products are recalled.

So, I guess, back to the status of the

legislation, I guess that didn't go anywhere in terms of giving authority for USDA to do recall.

MR. BILLY: That's correct. The administration's bill was not considered in the sense of hearings or any action by the previous Congress. So --

DR. WOTEKI: But it has been reintroduced in this session by Senator Harkin.

MR. BILLY: Right, and remains a priority in terms of the administration and the Department. Nancy?

MS. DONLEY: And I hope it makes it through, but in the interim, Dr. Havlik, do I understand this correctly? Does the Agency have the distribution information, but they just can't release it?

DR. HAVLIK: We have the information down to the -- certainly the primary level, the first level, and eventually several days later, as people get out and look at the other thing, we'll have it down to the secondary level. There have been a number of -- as Tom has indicated, there have been a number of cases where this has come up, so we have a fairly clear view of what our responsibilities is, and we cannot release the distribution information. We can act on the distribution information ourselves, but we cannot release the distribution information to other non-federal people.

MS. DONLEY: If you are specifically asked about

it, you are prohibited from answering or giving it?

DR. HAVLIK: You can give information out, but you can't give information out the in such a way that someone could take advantage of that information for their own personal benefit. If you ever see anything that we put out, you will find that there's never any plant lists. We always white out the plant names. We always white out the plant numbers. We always -- if we're giving a plant number, we usually white out the amount of product. You have to make sure that some body don't come back, and say, or somebody can say, well, "I know that 124 is now selling product to this person over here, and I've been trying to sell it, so I know they are buying products. I'm going to go after that person."

MS. DONLEY: I guess just as an as a final follow up, I just don't understand that this information is being sought by entities that are out to protect the public health and safety. It is public health departments that need this information, not on personal, for a personal reason, as you suggested, but for one that is providing a very critical and necessary protection for the public, and I'm no lawyer, so I don't understand how that fails to meet the letter of the law, but --

DR. HAVLIK: We provide as much information as we possibly can to the states.

MR. BILLY: Rosemary, and then I'm going to wrap this up.

MS. MUCKLOW: Okay. There are always imperfections in any system. The present recall system workers remarkably well. I have worked with companies that have had to undertake a recall, and I'm not here to cry for them. They have had a circumstance. They needed to get the product back. They work very closely with the compliance officers of the government. The product to be recalled is identified with great clarity.

All we would do would be to muddy up the news waves and the information waves if we started to say, and that hot dog was sold to Joe Blow, and Joe Blow sold it to -- you just get as much information out there, that nobody would pay any attention.

The critical issue is to get your hands around the product that is to be recalled, to get its name known, whatever name is on the label. That's what the Agency does right now, and it does it in cooperation with the company. I think it would be appropriate for us to try to improve that cooperation, but it is a cooperate effort. If the Agency were not to get cooperation in a recall, it has seizure authority under the law.

It can go and get an order of the court and seize the product, but it's a very unattractive alternative

because the Agency isn't in the market selling products. And how to access somebody's records becomes terribly complicated. The present system may not be perfect, but it works effectively to get your hands around the product.

Concerned about Dr. Morse's comment about 300 meals, I don't know if those were federally in the products or how they got distributed through the system. I'd be interested to talk to him later about that.

The present system gets their -- we could overload the system with information, and nobody would pay any attention to it.

MR. BILLY: I know there's -- I see a hand going up. I would suggest that the Committee consider this issue in terms of a list of issues. There is some more that we need to get through, and there is always room for more discussion, so I suggest that the Committee consider it in that context. I think it's been a good discussion. I appreciate the input from Bill.

I'm going to work with the Committee a minute now to talk about our schedule. It's about seven-minutes-to-twelve. We have a couple of options. One, Rosemary has requested as a Committee member currently and formerly, to have a brief opportunity to raise an issue before she has to leave. She as a conflict that was scheduled well before this meeting, and I think we

appreciate that and she had afford her that opportunity. She has to leave at lunchtime, so I'm not sure how long that might take, 10 or 15 minutes --

MS. MUCKLOW: It's not more than 10.

MR. BILLY: Okay. And we could do that and then break for lunch and then pick up the agenda with the strategic planning issue after a lunch break if you wish, or we could keep going and get started in an area, go until twelve-thirty or so, and then break for lunch so I'll bow to the wishes of the Committee. Carol?

MS. FOREMAN: Some of us have made some lunch-time appointments that are time restricted. I'm certainly in favor of giving Rosemary the opportunity to raise her issue before she has to leave.

MR. BILLY: Okay. Let's do that, and then we'll break for lunch, and then we'll resume after the lunch break.

MS. MUCKLOW: Tom, I'm sorry about that, but thank you very much for the opportunity. I am broken hearted not to be here to participate in the subcommittee this evening chaired by Carol Foreman on exemptions because exemptions is an issue that I heard about long before I ever knew Carol Tucker Foreman. I brought my niece when she was about nine years' old, and she is now 38, and that was the first hearing on the retail exemption.

We've studied this issue for three decades. We've had an ANPR. We've had Triangle Institute studies. We've done all kinds of interesting things, but the issue is in shambles, and the reason it is in shambles is not just this administration, but every prior administration since the Wholesome Meat Act has never put its hands around and dealt with the issue.

The issue is just fumbled along, and when the administration doesn't do rule making and doesn't carry out that rule making to its conclusion as it did very well, for instance, in developing the HACCP rule, we get other people who step in and do things that really screw it up royally, and that includes the Congress, where they developed exemptions for certain kinds of operations to sell pizza to the school lunch program and to develop the two-store rule and the DNW and all of those kinds of things, and the courts, in the current Honey Baked Ham case, where the are now dictating the terms of the retail exemption.

It's time that the administration decided to deal with this issue and do it through rule making, which is the vehicle that it is required to do under the Administrative Procedures Act.

A lot has changed since the 1967 exemptions were written. But there is nothing in the law that says that says you can't address it. We've talked it to death. I

doubt whether there is any new information this evening. The basic policy needs to be that the Agency needs to develop rule making with all of the massive amount of information that's buried somewhere in the bottom of the basement of the South Building, get it up and get it out, and do it with some speed and alacrity would be a highly commendable activity.

I'm sure the group this evening may have some further discussion on it, but the basic policies need to be determined. They should be based on food safety and what is the risk of public health if these exemptions occur. That should be the absolute clarion cry of developing retail or any other kind of an exemption policy. We shouldn't be saying that you can slaughter 5 chickens but not 10 chickens or that you can slaughter squab without inspection, but you've got to have chickens under it. There's just so many conflicts in the policy at this point because it truly is in shambles.

The word "shackles," I understand, is an Old English word and meant slaughterhouse. And so it's an appropriate word to use for this purpose. Thank you.

MR. BILLY: You're welcome. Any questions for Rosemary in terms of what she is talking about, since she has indicated she won't be around this afternoon?

MS. MUCKLOW: I'm truly sorry, Carol, not to be

there tonight.

MS. FOREMAN: We most certainly have your comments in mind, Rosemary.

MS. MUCKLOW: Thank you.

MS. DEWAAL: Are you coming back tomorrow, Rosemary?

MS. MUCKLOW: No. Sorry about that.

MR. BILLY: Any other questions? Okay. It's now noon. Let's basically until one-fifteen, and we'll resume at one-fifteen.

(Whereupon, at 12:00 p.m., a luncheon recess was taken.)

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

(1:15 p.m.)

MR. BILLY: Okay. Thank you very much, Mike. We talked about the idea of having someone come in that could talk about how this process of communication is intended to work with the circuit supervisors and so forth, particularly as it focuses on the very small plants but more generally as well. And our intention is to add an item to the Thursday agenda at eleven-thirty. And Bill Smith will be coming over and perhaps accompanied by some of the other appropriate people, to talk about who our plans are and provide an opportunity for some discussion.

So I just wanted to add that to the agenda. That's Thursday morning, 11:30 a.m., and it's on this issue of communication at the local level, the circuit supervisor, the inspector in charge, that kind of thing. I assume we still have some Committee members not here.

The other thing I wanted to point out, while Rosemary wanted an opportunity to address her concerns about exemptions, I think you will have noted that there is on the agenda this afternoon from three-thirty to four a specific item to address that, and there's materials under Tab 9 that deal with that issue and some of the past history that Rosemary referred to. She just wanted to have the other Committee members be aware of her concerns and her views

about that subject area.

Okay. We're going to get started now. We're going to pick up where we left off on the agenda, and the next item will be a briefing on the topic of our ongoing efforts to develop a new strategic plan and how we're approaching that and to introduce it to you so that over this meeting and subsequent meetings this Committee is fully engaged in that strategic planning process.

We have with us Mr. Charlie Danner, who is in charge of our planning area. He is a real expert in this area, and I'm sure you will enjoy hearing from him in terms of what we've developed to date and be in a position to answer your questions about the process as well. So Charlie.

MR. DANNER: Thank you. I handed out, or the staff handed out some papers here that didn't make it in your binder. One you see is the conceptual framework for risk-free meat, poultry and egg products, and then you have another piece that's burgundy in color, and then a third one that says conceptual framework questions in effect.

What I want to do is call your attention, though, to the conceptual framework itself, and I want to tell you a little bit about the background that led to its development and why it takes the form that it's in right now, and then I'll tell you about where it stands and what we intend to do

next.

Last summer, Tom suggested to me that it was time to start thinking about a new strategic plan, and it's interesting. I spoke to this Committee last year, and at that time briefed this strategic plan, which is the one that we're still using. And you will notice -- I don't know if you can see this, but it has a time horizon for 2002, so one could argue that we still have a current strategic plan.

But Tom pointed out, and when I thought about it, it was interesting to realize this strategic plan, which is a derivative of the HACCP pathogen reduction rule, has largely been implemented. In fact, in January of 2000, January of next year, yeah, in less than a year we will have implemented HACCP in very small plants, and most of the major provisions of the strategic plan that are in the works now for many years, we will be refining those and making other innovations, but it's time to develop another strategic plan.

Now there were other things going on as well. Dr. Woteki was interested in a process that would lead to budget formulation every year, one that looked at what we have done in the way of executing our plans for a particular year and then in critiquing that establishing initiatives that would be reflected in the new budgeted. And so we in the Agency prepared this -- back to the burgundy piece of paper here --

this annual program review, and if you look down to the calendar of events there, you will see it starts off with a strategic plan exercise.

We will do this, and we, in fact, ran this process this year, and while we will continue to run this every year. And we were starting pretty much from ground zero on starting a new strategic plan this year, each year we would kick the process off by reviewing the strategic plan and making any changes that we needed to make to it.

Now, there were a couple of other things that are sort of contextual information that led to this framework. In late August of last year the president issued Executive Order 13,100, which created the President's Food Safety Council. And one of the charges, among many others, was to create a National Food Safety Plan, and then in addition to that in the fall we knew that the National Academy was coming out with recommendations on food safety that also was going to recommend the development of a national food safety plan.

So with that, when we started our activity in September, it was with the understanding that there were going to be national plans, and we wanted to fit ourselves into those national plans, and, therefore, we started off by making some assumptions of what they might contain. We started, as I say, in late-September, and we started off

really making a vision statement.

I think it's rather interesting to tell you a little bit about that. Tom spent the first meeting talking about his philosophy of strategic intent or vision statements. We talked about how organizations can really push themselves ahead. In fact, we used the example of the United States in, I think it was 1962, that established a goal or a vision of landing a man on the moon by the end of the decade and how at that time that was regarded at technique impossible and yet it focused the nation's efforts and was accomplished.

And Tom, I have to say, had a lot of very interesting comments about vision statements, and I told you at the end of the meeting I wished I had recorded them because they would have made the a good articulate. But I did catch capture one comment you made at that time. You said something to the effect that organizations that have assumed leadership always have ambitions that are unrealistic. And so we began our process with creating a vision that was going to be unrealistic, that was going to be a real stretch for the organization, possibly something the organization was not out fitted currently to do.

And one other thing you said, and you might want to comment on this, is you said it also needs to pass the are-you-crazy test because if you read this vision, you know

you've got the right one when people react, are you crazy? And, in fact, I think the vision we created passes that test each time the people read it. But it also does this, and it became the food you eat is risk-free. Later we scaled that down to the products that we regulate.

But the food you eat is risk-free usually creates a reaction in people that you can't be serious; this is impossible. But the next thing it does, and this is typically, I think, of Americans, to start figuring out how to start evolves that problem, that possibly impossible problem. And the next thing that happens is people start saying, well, if you were going to do that, you would have to do A you would have to do B, and you would have to do C, and, of course, we're not going to do that, but you would have to do those things.

That's why this vision that we created, I think, is very important. It does pass the test, are-you-crazy test, and it does cause the organization to start thinking about making the stretches necessary here to break new ground in food safety.

Now, let me just go over to the conceptual framework for a second and call your attention to it. We intended this to be a full-blown strategic plan by now, but when we came up with that vision we realized that there were a lot of things that we were going to have to attend to that

really were outside of the authority or the scope of operation of FSIS. And there are still things that will have to be done by someone, but we put everything on the table.

We created what we thought were six goals that if they were achieved, would lead to a largely risk-free food supply. And I can show you the first one, for instance, here. By the way, we've packaged this with some explanatory material which says, in essence, what I'm telling you now. But the first goal is a technology and research goal, and a lot of work has to be done in that area.

We followed this same format that if you look on page four, you see that for the goal there are objectives identified. These are activities that we feel would have to be carried out to achieve that goal. And then we went one step further to try to describe what the outcome was.

In other words, if you were actually able to achieve the goal, what would the world look like? And that's what we were attempting to do with this outcome statement.

Now, we have not completed this. This document right now really applies to a lot of different organizations, and what we will do next as an Agency, and, in fact, what we're doing now is we're trying to take the parts that apply to us out of this. We will turn it into

another strategic plan like this which would meet our requirements under the law, under the Government Performance and Results Act. Our goals, our objectives, our performance measures would be packaged in this, but they would be derived from this conceptual framework.

Now you all are the first group that has seen this, and we're just now starting the outreach phase. We would like your comments on this. Generally, we would like to know if you think we have moved in the right direction, this is the way that food safety should be going, and I've also listed or given you some other questions to answer here. That was the last thing that I handed out.

These are just some ideas on how you might structure your comments, either individually as subcommittees or as a full committee. We don't intend to limit you to addressing these questions, but it would be a way to get started, and we would invite any comments that you have.

And once we have received your comments, and I'm going to begin distribution of the plan to our constituent mailing list which includes our employer originations very shortly and also distribute it to the VMO task force, which is in operation right now. We'll start putting those comments into our final strategic plan.

So I want to just wrap up by saying that I would

ask this Committee to look at the conceptual framework and address the questions and pass that information either to myself or through Mike Micchelli to me. And with that, I'll answer any questions. Ed?

MR. BILLY: Carol?

MS. FOREMAN: I want to make a comment, please. It doesn't pretend to be a question. I think you've met -- I'm just delighted by this -- I think you've met one of your requirements because I noticed that we got a comment from somebody in communications to the Department about this meeting, and it says: "In regard to Item 5 there clearly is no such thing as risk-free food, so what are you going to discuss?"

And I would say that when the Frenchman, de Tocquesville, came to the United States early in the 19th century, we wrote that, and it is one of my favorite lines, that he had never seen a people who were so persuaded of the ultimate perfectibility of mankind. And it strikes me that that's what you started out with here.

And I'm sure we're going to disagree a lot about the specifics of it, but how refreshing it is for an Agency to say, "So, what would we have to do to get to the perfect world?" instead of beginning with the assumption that we can't get there and we shouldn't even talk about it. So I couldn't be more delighted. I think this is what most

citizens think their government ought to be doing.

MR. BILLY: Thank you very much. Katie?

MS. HANIGAN: I just wonder what date he had in mind as far as the Committee getting comments back. Is this prior to November 2nd meeting?

MR. BILLY: We'll talk about that at the end of this discussion. I'll come back to that.

MR. DANNER: Let me add one thing. The planning horizon for this is 2006. I didn't mention that earlier. That's the centennial of FSIS.

MR. BILLY: Right. In the discussions that occurred -- I'd like to add a little bit to what Charlie presented and then come back to that question that Katie asked. This vision is obviously a vision that we would like to be true in 2006. Now, any one of you sitting here as you start to think about this, you can quickly identify a list of things that we don't have, we don't know, there is nothing in place to do things, et cetera. And all of that is good.

But in framing this, we tried to do it in a way where it's inclusive, because for this to be true, it will engage every responsible person in the farm-to-table continuum. It's not about -- it doesn't fall on the shoulders of one part of that continuum. You can take actions in terms of the production of animals or eggs.

You can obviously focus on slaughter and processing, distribution, and then the consumer, in terms of the proper procedures or the restaurant in terms of the proper procedures, for that part of the continuum. So it was -- it's thought of as a continuum and that each part of that continuum has a series of responsibilities that would work towards that vision being true.

And if you look at the goals, you will see that then the goals try to capture what we could think of in terms of the things that would have to happen, the research, the other things that would have to be done to try to achieve this vision by 2006.

And I'd like to highlight two or three examples of objectives that give you a sense in terms of the kind of thinking that we were trying to achieve. First, if you look under Goal 1, you will notice there that we talk about a national research and new technology infrastructure. Now, to say that argues that it doesn't exist right now, at least the kind of infrastructure that we're envisioning will be necessary to achieve this.

Now, FSIS, we don't do research. We're dependent on others for research, but it's clear to us that research is critical to achieving this kind of a vision, and research in a lot of different areas. So it is in that sense, then, that while in terms of this conceptual framework and what

we've developed, we've got to work effectively with the research community to achieve certain outcomes if we're going to approach this vision. That engages us. It's not those research people that are our partners, our team mates in this process, and that's a way of thinking about this.

Another point I want to make, and look under the first objective under "technology," the Agency has over the last three or four years held several conferences on new technology and encouraged the private sector to develop new technology for use in slaughter and processing plants or new methodology, rapid methods, et cetera, but it's been a piecemeal approach.

There is no continuity in terms of what we're trying to do. And not only that; we're not taking advantage of certain similar kinds of needs and how they were approached and learning from those experiences. If any of you that are familiar with the drive out to Dulles Airport, you will know that just before you get to Dulles there is this odd-shaped building that is a new technology center for computer development, software, and so forth, where government and the private sector can work together hand in hand to develop the tools.

New start-up companies can get space there, get support, and help in terms of developing whatever they are working on. There is cooperation. There is communication,

and so forth. That's what this objective number one is trying to capture. Now this doesn't exist. This is an idea.

But what we're saying is, if we're truly going to we're truly going to start to approach what it's going to take to make this vision a reality, we need something like this, and we need the help of Congress and the various parts of the administration, industry, all working together to make that become a reality, because it is something like that that is going to create these new breakthroughs that we'll need to begin to approach that kind of a vision

There is also a recognition, if you look at Goal 2, there is a recognition in the goal that it's not just something you can address nationally. Too much of our food, too much of the product, whether it's meat, poultry, egg products, or other food products, is imported, comes from different sources. And, again, if you're going to approach this, you need to look both nationally and internationally if you're going to approach addressing the risks, and that's what this goal is about.

So pursuing that on a national and an international level simultaneously is what you are going to need to do if you're going to be successful. There doesn't exist in many countries, even the rudimentary components of an infrastructure to do risk assessment, but we accept or

import foods from them, and I would argue what this is based on, the need to recognize to make this, again, a vision that could be possible, you need something like that and how you go about accomplishing it.

Another one is Goal 4, and it's designed to, again, capture all of those that have different parts of the responsibility, and it's interesting wording: "Ensure that all people who produce, process, handle, prepare, or come in contact with food, including consumers, shall and understand, accept, and take responsibility for food safety." It's an interesting wording in terms of what would have to be true, at least in the minds of those that pulled this together if you're going to approach this vision.

It doesn't stop anywhere; it's a broad responsibility. And now to make that goal, achieve that goal, then there are some very interesting objectives that have to be addressed, and, again, it's a more comprehensive approach.

So those are just some examples. There is a lot of thought that's gone into it, but there's a lot of good minds around this table and out the in the audience here that we would like to enlist your help in terms of further refining this, identifying things that we may have missed or not thought of, and through that process, continued to refine this and have it become something that week use to

achieve something along the lines of this vision statement. Are there any questions from the Committee? Any thoughts? Caroline?

MS. DEWAAL: Thank you, Tom. Caroline Smith, CSPI. First of all, I love this. This is a great beginning, I think, for the subcommittee to be working from. I would like to just mention something that I hope the subcommittee considers this evening, and that is the whole issue of technology approvals.

Right now we talk about multiple-hurdle approaches in preventing food poisoning in processing plants, but the reality is the multiple hurdles are in the Federal Government to getting new technologies approved for use in food processing. And while that approval process is vitally important to consumers, it is something that ensures that technologies are safe and make the food safer and not less safe. Nonetheless, the process really is quite difficult to go through.

We've watched technologies just take years and years simply to get through the administrative hurdles. Now, some people might suggest that a single food safety agency might resolve all of these issues, and that may not be the focus of this discussion, but I do think that under Goal 1 that that issue might be discussed more in terms of objectives.

MR. BILLY: Any other general comments? Okay. In terms of getting the Committee's input, it would seem like we could get perhaps some initial reaction as a result of the consideration of this by the subcommittee at this meeting and then set some sort of a deadline for Committee members to consider it further and perhaps provide us some written comment, say, by the end of the month or something like that, whatever you think would be appropriate.

This, again, is about getting your initial input, having some time to reflect. This is a pretty bold kind of thinking, so you need to think about it, get your arms around it, and I understand that. So I think something like, some initial reactions, and then setting a deadline. Does the end of the month sound reasonable? Dan?

DR. LaFONTAINE: We're a little confused. It's on the agenda tonight.

MR. BILLY: Yes, I know.

DR. LaFONTAINE: So are we going to -- but you're talking about comments by the end of the month, so I'm not sure which way we're headed.

MR. BILLY: Well, both. In other words, we've introduced it. You will be talking about it. You will have some initial reactions, but we just have a feeling that for a number of you beyond the initial reactions and whatever consensus you have, you may want to have an opportunity to

think about it some more and then provide further comment. We just wanted to provide for that, so that's the idea. Does that sound good to everyone? Does the end of the month sound all right? You provide the comments back into Mike and his staff, and then we'll pull those together and share them with everyone.

MR. DANNER: And comments on the objectives are particularly helpful to us, and if there is anything missing there from these goals, things that should be addressed or taken on.

MR. BILLY: Yes. Like Caroline identified something just now, and any other thoughts like that, those would be useful. Nancy?

MS. DONLEY: Just another point of clarification. Is this what we went through -- Charlie, I was in that five- year strategic plan. Is this --

MR. DANNER: This is going to replace the other one.

MS. DONLEY: That five-year strategic.

MR. DANNER: What I said earlier on I want to reiterate, that we had a very nice situation for the last few years. We had a rule, and we had a rule that really was our strategic plan, and so it's very easy for my staff to package that in the form of a strategic plan, and everything fit together because everything that we were doing was in

the rule, and so we had nice things to report on that showed the progress in achieving or objectives, and this is going to replace that.

This is the next big stretch beyond HACCP implementation, and much work will have to be done. You can think of it as maybe, in effect, writing a new rule, which is taking us to a whole new level of food safety activity.

MS. DONLEY: If I could, I'd just like to make one general comment because I remember the blue book very well that had it. And I think this is absolutely excellent because one of the problems I had -- I meant, there are some things in here I know I'm going to want to tinker with, but you have looked at this with a real -- put this together with very much a purist attitude and I want to really commend an Agency for doing that.

Nowhere in here do I see a quick, just flipping through, which I had a real problem with the previous five-year strategic plan, are trade implications in here. It's just you're really looking at this strictly from a safe-food perspective, and I want to commend you on that.

MR. DANNER: Well, you have to put politics aside when you're going for risk free.

MS. DONLEY: You didn't do that before, so this is very, very good.

MR. BILLY: Any other comments before we wrap this

up?

MS. DEWAAL: Can I just ask one more question? And I haven't been able to review every line, but do you talk anywhere in here on the inspection functions of the Agency?

MR. DANNER: It's contained in there, but, you know this is a rather global level. There is no real detail like that. I mean, inspection is one way. It's more in terms of risk management, risk assessment, risk management.

MR. BILLY: Goal free. There's quite a bit in there.

MR. DANNER: The detail will come later once we've settled on a specific set of objectives and teased out about that which we can undertake.

MS. DONLEY: And, Charlie, you said the comments on the objectives would be most helpful to you.

MR. DANNER: What I would like you to do is if you can find the time to do it is if you accept the motion that food can be risk-free and you accept that the goals that we've outlined here would accomplish that, then look at each goal and say, what are they trying to achieve there? What would you have to do? What specific activities would have to carry out to execute that goal?

And that's how we approached it. And I'm not sure we've got everything. For instance, if you want, you know, a technology in research capability in the country, there

are other things that we failed to mention in the objective lists. That's one useful way for you to approach this.

MR. BILLY: It's basically what's outlined here.

MR. DANNER: You can follow those questions, too.

MR. BILLY: In inviting the comments on the following. I think if you use that as a guide -- it's what Charlie just said -- and some other things. So this is what the guide to the Committee and the subcommittee, but it's also in terms of any further thoughts that any of you have as well. Katie?

MS. HANIGAN: I do appreciate comments being left open until the end of May because I myself am not on this subcommittee tonight and have not looked at the information and probably will not look at it until over the weekend, so I do appreciate the comments stay open on it.

MR. BILLY: Comments? Okay. Let's move on. Thanks, Charlie. The next item is to look at the qualifications of government and industry personnel who conduct HACCP tests. This discussion will be led by Jeanne Axtell, and there is material on this under Tab 6, I believe. So, Jeanne, the floor is yours.

MS. AXTELL: Thank you very much, Tom. At the last advisory committee meeting in November the topic of qualifications of FSIS inspectors and industry personnel in HACCP establishments was raised as an issue of interest for

today's meeting.

And as background to the Committee's deliberations, specific information had been requested by the Committee at that time about the in-plant field inspection work force profile and about the Agency's current thinking on changes that may be necessary to reshape the skills and qualifications of the inspection work force. So what I would like to do for just a few minutes --

(Pause.)

MS. AXTELL: All right. We've switched mikes. Just to back up, I'll start over, at the last advisory committee meeting in November the topic of qualifications of FSIS inspectors and industry personnel in HACCP establishments was raised as an issue of interest for today's meetings.

And as background, the Committee at that time requested some information about the in-plant field inspection work force profile and about the Agency's current thinking on changes that may be necessary to reshape the skills and qualifications of the inspection work force.

I would like to take just a few minutes up front to cover those background discussions that the Committee requested at its prior meeting before leading into the specific question and topic of interest.

In terms of the work force profile, there are two

summary-level charts that are behind Tab 6 and are also in the handout material for the audience that provide some background profile concerning the field inspection in-plant work force. The first chart profiles to two major occupations that are employed in in-plant positions: food inspectors and veterinary medical officers.

The data are current as of April 14th and represent employment by grade in those two occupations. And I think by the pie-chart arrangement you have a good sense of what the dispersion of employees is by grade.

The second chart profiles the occupational breakdown of circuit supervisors into the three major occupations that are there: Veterinary medical officers, food inspectors, and food technologists, and provides an employment count for district management. District staff, and enforcement position. So together these two charts would represent the in-plant circuit and district-level employment that presently is brought to bear on regulatory inspection and enforcement decision-making.

The Committee had also at the its last meetings asked for a bit of background discussion about some of the Agency's thinking on the work force of the future. In August of last year FSIS published a back-grounder entitled "Moving from a Plant-based Inspection Work Force to a Farm-to-table Consumer Safety Inspection Work Force."

The back-grounder profiled an overview of the Agency's thinking about changes that will be necessary to reshape the work force and deploy its resources differently, and the back-grounder also discussed in general the Agency's need to improve the skills and qualifications of the work force to take full advantage of those skills in meeting its goal to reduce food-borne illness and to provide appropriate regulatory oversight within its statutory authorities along the farm-to-table continuum.

Today, the 1863 food inspection work force is very highly specialized, jobs that discreetly identify technical inspection work based on the type of slaughter or processing operation, the type of product, the volume of production, the number of lines, the formulations used in product, and other factors that distinguish complexity of traditional, non-HACCP inspection.

In the future, with HACCP and beyond, we anticipate that inspection program personnel will expand the delivery of certain regulatory beyond the existing walls of slaughter and processing plants and that as a result FSIS will need an a more flexible, more highly educated work force that can be assigned at any time to any operation to perform inspection and to determine regulatory compliance of any industry operation.

The classification series that the agency has

identified as most closely meeting these requirements for the future is the 696. It's called a GS-696, consumer safety officer series. That is a professional series. It does have a positive education requirement.

In looking at several occupations before beginning to settle toward the 696 series, FSIS also wanted to find a way to assure that its current work force count nucleus for the transition to the future work force. We had already made commitments.

Both the Agency and the Department had made commitments to the work force that we employ, that every employee who wishes to have a job to continue to have a career with the agency would have one, but that more than likely that job that would be available would involve different duties and responsibilities and may require the employee to relocate and may require the employee to do some things on their own to meet the qualifications for work force of the future.

And to acquire this higher level of scientific and technical qualification the Agency has been developing plans to meet this capacity in two ways: By educating and retraining the existing work force and as a companion, recruiting and hiring employees who already possess those scientific skills and qualifications.

After HACCP was implemented in large plants in

January of 1998 several classification reviews were conducted at various locations around the country. These reviews were done of food-inspection jobs to determine how the introduction of HACCP and HACCP work procedures had affected the nature of the work performed by those employees. What was found from those reviews is the work was now sufficiently different that it was appropriate to consider classifying the work outside the food-inspector series into a different classification series.

And so as we began to look at alternative occupations for classifying jobs that we have in the plants today performing HACCP work, we wanted to consider the decision about what series to put these people in in light of the changes that we thought would be coming in the future and the skills and qualifications of the work force that we believed to be necessary in the future.

So, in effect, we are trying to meet two different objectives. The first objective is to find a series that most appropriately describe's the work now being performed by inspectors in HACCP plant and that would permit the Agency to distinguish the work of employees engaged in HACCP from the work of employees not engaged in HACCP duties.

And the second objective was to identify a classification series that would permit the existing work force by gaining necessary course work outside of their jobs

to prepare for and be able to transition for the long term into the 696, consumer safety officer series. And the series that we selected is called the consumer safety inspector, or the GS-1862.

Now, obviously, with the names being so similar, it sometimes is easy to confuse the consumer safety officer from the consumer safety inspector. The basic difference is the consumer safety officer series has a different set of qualifications requirements that come with it the need for a positive education requirement, whereas the 1872 consumer safety inspector series is basically a technician-level series like the food-inspector series is today.

Both the food inspector and consumer safety inspector series have comparable qualifications requirements. FSIS employees today who are food inspectors can qualify to be consumer safety inspectors and can be considered for promotion into those positions. The series itself would support the existing grade structure of off-line positions that FSIS currently employs in HACCP plants, and so we felt that it would be appropriate to look at the use of that series as a transition series as we move from a non-HACCP environment into HACCP environment and subsequently beyond.

The Agency is currently consulting with the National Joint Council of Food Inspection Locals over the

impacts associated with reclassification of those jobs involved in the performance of HACCP duties into the 1862 consumer safety inspector series.

The Agency has set a target date of July 1 to affect the reclassifications on those positions presently performing HACCP duties in large plants and in small plants, and we would expect that after HACCP implementation occurs in very small plants in January 2000 that inspection personnel covering those plants would also be reclassified as consumer safety inspectors.

That is the short-term plan. The longer term plan, again, is to move toward the more professional requirements and qualifications that would be part of the 696 consumer safety officer series. Again, that series has a positive education requirement, and the positions classified to that series will require the application and use of professional scientific judgment in regulatory work. In the handouts that you have there are some side-by-side comparisons that I think will facilitate the subcommittee and the Committee's deliberations.

One handout compares the Office of Personnel Management, the government-wide standards for qualifications for the food inspector, consumer safety inspector, and consumer safety officer series. The other handout is a side-by-side comparison of the classification series

distinctions between those three series, and that handout profiles difference in the nature of the work that would be conducted by persons who are employed in each of the three occupations.

MR. BILLY: That's the one that says qualifications comparison, and then in quotes "based on OPM qualification standards." The one you just referred to.

MS. AXTELL: That's correct. And then the one following it says "classification comparison, different OPM series." So the first one, the qualifications, is a comparison of the government standards for the qualifications in the three occupations. The second one are the government standards comparing the purpose or principally for which that occupation is established, how that is used.

The 696 series is a two-grade-interval series. That means that the grade-level or the grade-level structure for work that the occupation could begin at an entry level of GS-5 or 7 and proceed in two-grade intervals, 5, 9, 11. We are hopefully of being age to support the introduction of the consumer safety officer series, jobs that would go to GS-11 in the application of professional knowledge.

In the short term over the next few years we anticipate employing personnel in all three series. As I mentioned before, off-line HACCP work, jobs that are

performing HACCP tasks today in large, small, and very small plants, we see those as being classified as consumer safety inspectors.

We also are proposing under the HACCP-based inspection models project that the oversight and verification inspection activities in slaughter plants in those pilot tests and in the end distribution locations would also be classified as consumer safety inspectors. Because the model's project only pertains to those operations that slaughter certain target market classes of animals, there are other plants who do have production operations involving other market classes, and so we anticipate over the next several years to still be employing food inspectors principally engaged in slaughter-inspection activities in those operations.

We also are looking toward the introduction of the 696 series perhaps before the end of this fiscal year or early into the next fiscal year. The introduction of that series does require approval by both the Department and OPM, and there is still a great deal of developmental work going on within the Agency on how best to employ this kind of expertise in in-plant regulatory inspection work. And that is the focus for our initial introduction of the consumer safety officer series.

The question or the issue for consideration by the

Committee with respect to qualifications, as we introduce the consumer safety officer series, the 696 series, the professional series, there will be a need to develop very specific information to demonstrate how the OPM qualification standard may be applied to FSIS positions.

The standard, as you see from the handout, provides for qualifying individuals based on a very broad range of scientific, academic backgrounds, provided that those backgrounds are relevant to the positions being filled. The basic qualifications are that all applicants must have a degree with 30 semester hours of science course work, or in the absence of a degree 36 semester hours of science course work plus one year of specialized experience at the next lower grade.

FSIS several options regarding how liberally or how conservatively to evaluate the academic backgrounds of inspection personnel for internal placement -- these would be people that are already employed with the Agency today -- into the consumer safety officer series.

The options might range from crediting all types of scientific academic backgrounds that are permitted under the OPM standard to a more middle-ground approach which would be to attempt to identify those specialties and broad categories of course work that are most relevant to the work of the agency to the most narrow option, which would be

attempting to identify a very narrow, specific listing of academic course work that would be considered as qualifying.

Our thinking right now is that our best approach is to strike for the middle ground to look at identifying and crediting those specialties and broad categories of course work in order to provide sufficient candidates with education and experience that are closely associated with FSIS's professional and scientific needs. The Agency would very much benefit from the Committee's recommendations with respect to which particular disciplines and academic backgrounds that are outlined in the OPM standards should be credited.

Also, as I know there has been a lot of discussion, in the HACCP environment the need for background knowledge in statistics and in particular statistical process control is a very crucial part of being able to monitor and verify the adequacy of HACCP systems. And so a subset of this question is with respect to backgrounds in statistics should they also be credible as qualifying? Should they be a prerequisite, if you will, as qualifying experience, or can course work in statistics or statistical process control be acquired after employment or after placement, in-service placement into the 696 series?

I know that the Committee in its last meeting had also expressed interest in having some discussion about the

qualifications of industry personnel with respect to particularly to the models, the HACCP-based-inspection models project and the slaughter pilots, and with respect to that the Agency, FSIS, is not contemplating establishing any particular qualifications or training requirements beyond those that are already a part of Part 417.7, the HACCP rule itself.

Obviously, the subcommittee and the Committee may have some other thoughts about that, and we would certainly be interested in hearing those thoughts, but because, in our thinking right now, we anticipate that each plant who is a volunteer in that project may very likely approach the assumption of responsibilities in the slaughter-production arena differently, we think it would be very difficult to set prerequisite qualifications up front in the environment we're in now.

We believe there needs to be some latitude for industry to consider how best to design work that the arena, considering both procedures, production practices, the introduction of new technologies, all of which might cause a given plant or part of the industry to decide it needs a different set of training or qualifications requirements for it's employees than perhaps a plant in another location dealing with another species. I'd like to open it up for questions.

MR. BILLY: Now, the two questions that you've posed are in bold at the bottom of the first page under Tab 6.

MS. AXTELL: Yes.

MR. BILLY: So those are, in particular, questions that we would be interested in that Jeanne just outlined. Then obviously as you understand in general what we're working on, we have other thoughts and the separate issue of industry qualifications. I assume in that context you're talking about, for example, the people that would assume the sorting responsibility for carcasses on the slaughter line. If inspectors now have certain qualifications, should similar qualifications, as an example, be required or expected for plant personnel that would be doing, carrying out those functions?

MS. AXTELL: We are, just for the Committee's understanding, we are sharing the training materials that we use for basic slaughter-inspection training of all food-inspection personnel. We are sharing those materials with the plants that are a part of that pilot test project so that they have the benefit of that.

We are also looking at the possibility of making some arrangements to have some of the folks at our training center have some industry people in who are engaged in that project and share with them in a little more detail what the

training material is.

It is not an expectation of ours that the industry will necessarily adopt that material wholesale, but we believe that it at least is a starting point, and that material may be good working material for those plants in their consideration of how best to focus their energy.

MR. BILLY: Okay. Katie?

MS. HANIGAN: In the packet I received in the mail from Michael in preparation for this meeting I have a letter dated September 11th, from Dale Allen asking permission to have -- the title of the report is "FSIS Field Execution Task Force Report," and it was sent to me in preparation for this Committee meeting.

And clearly this report that was put together outlined seven areas that need to be addressed as far as FSIS personnel in the field, and my question to you, Tom, is the number-one area of concern here was qualifications, certifications of inspectors. But did this Committee in November decide that they did not want performance measurements put in place for inspectors or personnel of management brought out? Were the other issues brought up in this paper ruled as not significant for this Committee review?

MR. BILLY: Not that I'm aware of, no.

MS. AXTELL: No. I'm not sure that -- Mike can

correct me if I'm wrong, but I'm not sure that the Committee actually considered the report in any of their formal sessions. That was provided by Mr. Allen to the members of the Committee, but I don't believe the report itself was a specific topic of discussion. The issue that did surface during the Committee's meeting was the issue of qualification.

So the first of the issues that listed in that report was specifically identified as an issue to be taken up at this meeting, but we have not precluded consideration of the other issues should the Committee wish to consider that at some point in their agenda.

MS. HANIGAN: Okay. I guess I just find it difficult, and I'll be chairing that session tonight, as to how you can look at qualifications of inspectors or even professionals in our industry without having some type of a system put in for measuring of performance. And, you know, I'm going to ask the Committee again, then, to go back and look at this report that was supposed to have been presented to this Committee in November and consider all seven areas.

I think it's a key part as to the difficulties the industry and FSIS is having right now in the field. I don't think you can separate one area out of those seven that was presented in the November report.

MR. BILLY: Well, you know, I think that's -- in

one sense it's up to you, Katie, and the rest of the subcommittee and then the Committee as a whole. Often in these things you need to break these fairly complicated issues into component parts and use them sort of as building -- deal with one, then have that as the foundation for the next and so forth.

And the sense I had was that this was where the Committee was going to start and get an understanding of qualifications or the entry-level or the threshold-level before talking about performance. That's actual execution of the job. But if there is another way to do it that you feel confident that you can lead the subcommittee through and address some issues, that's fine.

MS. HANIGAN: Okay. Maybe I wrote down the wrong date. I wrote down a possible July '99 implementation date for some of this. Is that correct? Did I write that date down correctly?

MS. AXTELL: We have a target date of July '99 for reclassification of existing -- of positions involved in HACCP duties in large and small plants into the 162 consumer safety inspector series. Of necessity, assuming we do, in fact, meet that target date, once employees are employees are reclassified into that job it will also be incumbent upon us to change their performance standards, and so they will be measured against a different set of performance

standards than those that they are under today.

That's one of the features of being a government employee. If you're in a different employee, you're in a the different job series, you change grades, you get a different set of performance standards, but those standards and requirements are operating within government-wide requirements for personnel matters.

MS. HANIGAN: Well I would expect we'll have a very healthy conversation tonight regarding this. The only other concern I have is the wealth of information that has been presented by yourself, Jeanne, and by the gentleman right before you, I'd appreciate it if that information was mailed to us ahead of time because you sit in the meeting, and we have two hours tonight to discuss this, and another subcommittee has two hours to discuss a huge change in strategic planning.

We need to look at the documents ahead of time and come to this meeting prepared so that we don't spend the first half hour to 40 minutes of tonight's two hours trying to read the document and understand what it is. So I would appreciate prior to November's meeting if we could get all of the information forwarded to us ahead of time and have it clearly our responsibility to bring it with us.

MR. BILLY: Caroline and then Collette.

MS. DEWAAL: Just a question of clarification from

the chair. We have two hours tonight to discuss that issue plus the campylobacter issue in that subcommittee, so I don't mind discussing seven issues as long as we reserve an hour to discuss campylobacter as well.

MS. HANIGAN: But of that hour we will probably have to have a half-hour of coming up to speed as to where we are each hour. That's my point, Caroline. If we had the information to us ahead of time, we could hit two hours running. We're going to hit two hours with a half hour out of each hour coming up to speed here.

MR. BILLY: Okay. Collette?

MS. SCHULTZ KASTER: Could you reclarify on the officer versus inspector now that you've walked us all the way through the document? Just jump back to the very beginning again. What are the activities the inspector will be doing, HACCP-related duties, and what again will the officer be doing?

MS. AXTELL: Okay. Again, the reclassification of those inspection positions involved in the performance of HACCP duties to date would be reclassified as consumer safety inspectors. Their job would not change.

What we're saying that as a result of implementing HACCP we went after HACCP was implemented in large plants and looked at how the change in inspection procedures had affected the nature of the job, and we found that the job,

the way it was now being performed, was sufficiently different that it warranted being classified into a different occupational series.

And the one that right now our personnel community believes is the closest, most appropriate standard is consumer safety inspector series. That simply acknowledges that the work now being done today is different than the work being done in a non-HACCP plant by an inspector.

Now, the consumer safety officer has not yet been introduced. We are looking to potentially introduce that later this year. There is a lot of staff-development work going on with respect to the introduction of that series because if we're going to introduce employees possessing professional scientific knowledge and skills, of necessity that means a different work methodology than the work methodology being performed today because the work methodology today is basically a technician-level work methodology.

We basically have very defined procedures. We have centrally assigned schedules of work. We do data collection from those assigned schedules. We see that the work methodology for a consumer safety officer would be significantly different and would move more in the direction of that individual looking at a variety of data that was available and making appropriate determinations as to how

best to lay out a plan of inspection in that HACCP environment, meeting the same objectives of the current system but approaching it from the standpoint of making a professional judgment.

So we're still working on work methodology as well, but we would not envision being able to introduce that series without also introducing work methodology changes. And so for that reason our tentative thinking is that when we do introduce the consumer safety officer, because it is using those scientific methodologies, we would introduce it into the jobs that today we believe have the highest demand for the application of scientific professional judgment that would tend to be dealing with more sophisticated production processes, more sophisticated technologies in food production.

MS. SCHULTZ KASTER: So I think that kind of begging support for Katie's point of taking into account tonight all seven of these because it sounds like a pretty complex process that you that you've described. Clearly, it is, and if we want people that can help regulate campylobacter issues like that and we're going to have trained personnel, then we need to talk about communication and training of personnel management, performance measures, all of those things need to be addressed and interrelated.

MS. AXTELL: In part, and not necessarily to

defend the decision, and certainly, Katie, we will support you in however you and the subcommittee wish to proceed, we recognize that there was a lot to undertake in this discussion and that there were multiple topics to be assigned to the particular subcommittee.

We know that in particular we need some advice and guidance if sorting out the issue of academic disciplines because when you look at that OPM standards you can be an engineer and be a consumer safety officer. You can be a computer programmer and be a consumer safety officer.

And the question is, if the Agency is going to draw some choices about the academic backgrounds, let's have some dialogue about where those choices will give us the academic backgrounds most relevant to the work of the Agency. And we thought it would be a place to start knowing that the Committee may well want to continue discussion about this topic in future meetings.

MR. BILLY: Alice?

DR. HURLBERT: I'm going to roll a couple of things into this one question, Jeanne. First of all, I know that a lot of the HACCP model plants have sent people down to the training center and thought that it was super the interaction between the people there and the industry people there in learning, take the same course that the slaughter inspectors were taking. So from what I understand from the

guys in the pilot, that has worked really well, and I know they appreciate the Agency allowing that to happen.

MS. AXTELL: We appreciate the feedback.

DR. HURLBERT: Maybe just a few years ago we had a similar discussion like this on food technologists. What's described here and it's been several years for me now, so the brain is gone, what is the difference between the food technologist and what you've described with the consumer safety officer? Because if I remember right, it was 30 hours of science and inspectors currently in place could upgrade and everything, and we have the food technologists in place already.

Did the Committee review everything that happened when you went to the food technologists, and what was the outcome of that discussion? And before you answer, let me just give you all of that at once. The Australian pilot project where they talked about the training that they have given their employees with a two-year program, testing certification, the whole works, did this group look into that as well as any type of continuing education requirement that I know to be licensed you have to have so many CE units per year. Was there any thought given in this series that there should be continuing education, especially if we're looking at science and the changing technologies? That's a lot for one question.

MS.AXTELL: That's a lot for one question. Let me back up. We did look at a number of different occupations, including the food technologist, food scientist, food technologist series, which is a 1382 series. One of the things that we thought the consumer safety officer brought that the food technology series did not bring was the opportunity to consider an even broader spectrum of academic backgrounds. If you will notice, in the handout on the OPM qualifications it does not permit.

That series who have degrees in biological sciences, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields.

It did afford the opportunity to potentially broaden out the number of academic disciplines that could be considered and brought to bear on in-plant regulatory inspection work. It also would permit some consideration potentially in the future of how in other aspects of the Agency's work we might employ career safety officers, thereby providing an even broader career ladder or career options for the Agency as a whole. Again, it doesn't mean that we might not have food scientists, food technologists employed. All of them, all of those that did become qualified at that time would qualify for this 696 series.

Your subsequent question concerned --

DR. HURLBERT: Did you look at how --

MR. BILLY: Continuing education.

DR. HURLBERT: Continuing education and certification.

MS. AXTELL: Specifically, we have not looked at the Australian model because, and, you know, I may need to depend on some of our personnel folks to help out here. We have a different set of personnel guidelines that federal employees operate under in this country, and some of the certification, recertification kinds of requirements that might lead to removal from employment, there are just a different set of ground rules for the personnel rules that would be involved in that kind of activity.

Certainly, we do have a requirement for federal employees that there be performance standards. Employees are evaluated annually against those performance standards. If their performance is not up to par, the appropriate actions should and need to be taken with respect to attempting to correct any deficiencies and knowledge of execution that employees have, but it is a different system of government, a different system of personnel regulations that we are dealing with.

Now that is not to say that we could not at some point consider the acquisition and the maintenance of

certain types of skills as information that's credited for promotion if someone has to have the demonstrated skills and determined proficiency in those skills in order to be considered for advancement

MR. BILLY: Okay. Dan and then Nancy.

DR. LaFONTAINE: Dan LaFontaine, South Carolina Meat and Poultry Inspection. I'm going to try to make this brief because time is of essence. The issue of industry qualifications or minimum qualifications under HACCP-based inspection models project, that issue needs to be addressed. And now obviously we are not prepared to do it and we've got a full agenda, so to make a long story short, my suggestion to you, Mr. Chairman, is that we defer that to the next meeting, if appropriate, so that it can be a clear-cut topic and everyone will have their say.

One further comment: I would ask FSIS to make note of the Australian Meat Safety enhancement project, which FSIS, I guess, is still actively considering if you will buy into it. It has a lot of substance in it as far as what they are doing, and I'm not saying that we have to be a mirror image, but it would be, in my personal opinion, a serious mistake to not have at least some minimum qualifications if you're going to turn this whole arena of ante mortem and post mortem, the first line of responsibility, over to industry.

MR. BILLY: Thanks. Nancy?

MS. DONLEY: We're playing tag team here because Dan, I had two issues to cover, and he covered the first one beautifully, so thank you, Dan. I was just wondering if -- obviously there is going to be a price tag attached to this when you start changing grade levels, and what impact would it have on the number of inspectors? You have the pie charts here, the FSIS work force profile, and I assume that's as it exists under the current structure.

What will happen? Have you crunched the numbers to see what will happen by moving educational levels, grade levels up there, pay levels up, and what impact it will have on the size of the force?

MR. BILLY: I'd like to address that, and the answer is that it will depend on the level of support that we get in terms of budget requests. For example, in our current budget that's before Congress, in anticipation of moving to the 1682 and the 696 series, we have requested additional funding funds to cover greater salary costs.

We're on the front end of that budget process, and it remains to be seen what we ultimately get from it in terms of that kind of support. If in the end we move in this direction and there is not additional funds, then it will cause us to have fewer employees if we're going to pay significantly higher salaries to them.

So there are some trade-offs there that will have to get sorted out. But our current strategy is to, as we increase the scientific requirements of our employees consistent with the science-based HACCP approach to seek the funding support to achieve that, and that's the course we're currently on.

DR. DENTON: Jim Denton at the University of Arkansas. Alice already asked a couple of questions that I had in mind with regard to the food technology issue, but I would like to ask one follow-up question as a point of clarification.

I noticed that the degree portion of the qualifications requires 30 hours within these disciplines. My question is, on the combination that has the 30 semester hours plus the specialized experience with are we still talking about university-level training, or is it going to be training similar to what's at the FSIS Training Center?

MS. AXTELL: No. When we're looking at the qualifications issues we are looking at university-level training, college-level training.

DR. DENTON: Thank you.

MR. BILLY: I'd like to leave some of this to the subcommittee, so if there are further points of clarification or things he needs to get nailed down so he can have a fruitful discussion, let's clear those up, and

then we're going to move on.

DR. HURLBERT: To piggy-back on Dr. Denton, will the Agency -- are you considering budgeting any kind of money to help the inspectors that wish to gain their 30 hours, kind of like they did in the food technical so there will be some Agency assistance in gaining that?

MR. BILLY: Yes.

MS. AXTELL: Just so that everyone understand, we have nearly 600 employees in, nonveterinary employees, today in the work force that would qualify as consumer safety officers, and that's based on -- and we have more than that with degrees. These are based on people with the degrees in the qualifying disciplines. So there is a sizable proportion of the food inspection work force that could qualify, has the academic background today.

MR. BILLY: Okay. Katie, the last question.

MS. HANIGAN: I'll make it very quick. Just two points please. Okay? I have real concerns with the July implementation because even if we would go out and educate these people, there is absolutely no proof that they determine that they understands and can fulfill the job requirements.

And coming from a union environment, if you go through and reclassify people without actually having proof or demonstration that they can do the job functions, trying

to reclassify them to something lower perhaps becomes very difficult with a union, and I think we need to talk about it at length tonight about proof that they can carry out the job function.

MS. AXTELL: Okay. Can I just clarify one point? The reclassification actions in July are not to the consumer safety officer professional job.

MS. HANIGAN: And I understand.

MS. AXTELL: It is in recognition -- the work they are doing today is consumer safety inspector work. We're simply trying to bring their classification series in line with the work requirement. It's not saying the performance, the execution, but the work requirement that's out there today is most appropriately classified outside of the food inspection series.

MS. HANIGAN: And I do understand that, but I clearly think that there are some in the field that clearly do not understand their job function now as a consumer safety inspector. And then the last question, if you would, please, you stated that someone had gone out and reviewed in the field jobs and how the functions had changed since HACCP. How many jobs were reviewed, and who carried out the function of the review?

MS. AXTELL: The reviews were done by representatives from our Personnel Division who are charged

with the responsibility of determining the appropriate classification of jobs in our Agency, and they were the ones that essentially led the teams. We also in some cases had field inspection officials along and representatives of the union on those reviews, but the determinations coming out of it are personnel classification determinations.

MS. HANIGAN: Five jobs, 500? How many did they review?

MS. AXTELL: I believe it's approximately 100 and maybe a little more than that, and I can confirm that for the subcommittee before tonight's deliberations.

MS. HANIGAN: Thank you.

MR. BILLY: Okay. Thank you very much. The next item on the agenda is developments in the campylobacter program, and we have Dr. Gerri Ransom with us. She is going to lead this discussion. Again, under Tab 7 you will see materials that have been provided, and, Gerri.

DR. RANSOM: I was going to cover some campylobacter program developments for us today. Hopefully, everybody can see that. First, I was going to start out by talking about our campylobacter focus. Why a campylobacter focus? Well, we have our FSIS commitment to reduce food-borne disease. We're doing this in response to a significant public health concern, and our baseline studies have shown us that food animals contain campylobacter.

We've also got available information to help us. Campylobacter is a leading cause of gastroenteritis worldwide. Food Net data for 1996, 1997, and 1998 has shown us that campylobacter is the number-one food-borne-disease organism in the United States. There are substantial health care costs and lost productivity associated with campylobacteriosis. There is a high prevalence on raw poultry carcasses. We see between 70 and 90 percent in the literature, and infections are strongly associated with consumption and contact with contaminated poultry.

We've also got a heightened public awareness. Consumers are concerned about campylobacter contamination on chicken. And we have frequent news coverage that is keeping this issue in the forefront. Now, as far as our campylobacter program initiatives, we have some new testing programs for poultry. We're doing these programs to monitor the levels of campylobacter jejuna and coli in poultry.

We have some methods development going on through ARS Research, and our goal here is to develop a reliable and quantitative method that is less labor intensive and less expensive than our current methods. Our first new testing program that I wanted to talk about is our chicken-monitoring program for campylobacter. This program began in October 1998.

We are looking at all classes of raw whole chicken

carcasses. We're testing between 120 and 130 samples monthly, and we plan to run this program indefinitely to keep a handle on what's going on with campylobacter in poultry.

The second campylobacter testing program that we've just started up in January 1999 is our young-chicken baseline data collection program. This is a one-year study where we are intending to update the 1994-95 nationwide boiler chicken baseline as far as campylobacter. The data available from this program, we're going to have it in case we want to set the HACCP campylobacter performance standard for young chickens.

Now, as far as the campylobacter performance standard, I'm talking about a potential HACCP campylobacter performance standard for young chickens. FSIS management is committed to evaluating this concept.

Before I move on and show you some of our data, I wanted to talk a little bit about campylobacter methodology. Of course, this is going to be important to have a reliable, easy-to-use method that we can use in our testing programs as well as for us to look at a performance standard as far as being able to monitor whether a performance standard is being met. A good method is also going to be important for industry in order for them to take a look at how they are doing with the performance standard.

Now, the problem is that our current quantitative method for campylobacter, it's a most-probable-number enrichment procedure. It's labor intensive and not amenable to large-scale testing. It's also expensive. So as I said, ARS is doing research for us. We've worked collaboratively with them. We are working on a direct-plating method. This method is only verge of being released. We are almost finished.

We've been working for over a year. Part of this method, as I said, it's a direct-plating method. ARS has developed a new media called campy line augur. This media has a high selectivity for campylobacter, and it also makes campylobacter easier to see on the plating media, and it facilitates direct plating. We're hoping that this method will represent something that's going to simplify testing for campylobacter.

As soon as this method is released to us we will be evaluating it, and if we find that the method is equal to or better than our current method, we will be implementing it in our testing programs.

I brought today some of our data to take a look at. This is prevalence data. I've got some very preliminary data from our testing programs as well as our old broiler baseline prevalence data for campy. You can see on the broiler baseline we've got a prevalence of 88.2

percent. If you look at our monitoring program, our prevalence is coming in at 78.8 percent, and our baseline, we're seeing a 61.1 percent prevalence.

Now this is very preliminary data. The monitoring is only about six months' worth of data. The baseline is only about three months' worth of data. Also, we have not covered summer months here, so we don't know whether we're going to see an increase or not, so we really at this point cannot say that campylobacter is decreasing.

What we've got here is a hypothetical pass-fail status of establishments based on the current prevalence from our new programs. If you used a 78.8 percent prevalence or a 67.1 percent prevalence to set a campylobacter performance standard, similar to what we've got for our salmonella performance standard, what we're seeing is that 60 percent of the establishments would fail. Now this is based on very limited data.

Typically, for our performance standard for broilers we're looking at 51 data points. This is only looking at between one and five data points per establishment, so I do not know how much value we can put on looking at this table, but it gives us an idea that perhaps a performance standard based on prevalence may not be the thing we want.

I've got some quantitative data here in this table

for all three of our programs. If we look at MPN data, we have a range laid out all the way from 0.3 campylobacter per mill of rinse to greater than 30 campylobacter per mill of rinse. If we did something for a performance standard such as set a cut-off, maybe between greater than 30 at the very bottom, if we said we wanted a campylobacter performance standard based on a quantitative level of greater than 30, looking at the data that we see here, from the broiler baseline, the old baseline, 1994-95, what we would see is that 40 percent of the establishments would not meet this campylobacter performance standard.

If we look over towards the new programs, we will see that about 20 percent of the establishments would not be meeting a quantitative performance standard based on a cut-off of greater than 30. With the new programs we're seeing we have 80 percent of the establishments meeting the performance standard.

So we might want to look more closely at a quantitative performance standard based on a quantitative level.

To give you some more performance-standard considerations, and this should all be in your handouts. I'm sure this is pretty hard to see from the back. Looking at some of the things we thought about in choosing salmonella for an organism to use in the HACCP performance

standard, we can take a look at campylobacter as well. For instance, from the HACCP rule some of the original rationale we used, a common cause of food-borne disease, we can say yes for both campylobacter and salmonella.

As far as the organism colonizing a wide variety of animals and mammals and birds, again, we've got a yes for both organisms. Occurs at frequencies which permit changes to be detected and monitored in all species. For salmonella it was determined that, yes, this was appropriate. For campylobacter we have a high frequencies in poultry. It looks as if we maybe could use that for a performance standard. As far as current methodology available, salmonella fit there. For campylobacter, we hope soon that we're going to have a very reliable and simple method to run.

Your handout is incorrect on the next point, but it's correct up here on the slide. Interventions to reduce fecal contamination and other sources of salmonella also effective against other enteric pathogens. At the time we were looking at the HACCP rule we felt that interventions to reduce fee cal contamination and other sources of salmonella would also be effective against other enteric pathogens.

Now, if we look at the -- if we think back to the data I showed you, it does not appear that campylobacter is being drastically reduced. I'm sure everyone in this room

is familiar with our one-year HACCP data for broilers where we saw that the salmonella prevalence is running about 10 percent, and we originally had a prevalence of 20 percent.

So there we had -- it's looking to be a 50-percent decrease. We're not seeing that with campylobacter, so this laid a question in our mind as far as are these general interventions that we can use for salmonella and other enterics working for campylobacter?

We move on to the next point, performance standard is a verification tool of effective HACCP plans. It was decided that, yes, salmonella appropriate. We've thought about it in the Microbiology Division, and we thought campylobacter could also be appropriate here.

We've got some other conversations we can look at in choosing campylobacter as a performance standard organism. Usefulness of a qualitative versus a quantitative performance standard. For salmonella, a qualitative performance standard was acceptable. For campylobacter, we're not sure.

We've got work to do in looking at this. Significant seasonality effects on the prevalence from poultry. For salmonella it was determined that this wasn't going to be a problem in setting a performance standard. In campylobacter it may be, as we see the available literature shows us, campylobacter is much higher in July through

October in poultry.

Our current knowledge for justification of a safe or acceptable quantitative level. Well, because salmonella is a performance standard based on prevalence, this didn't apply. With campylobacter this is unknown. Things like risk assessments are going to help us. It may not totally answer this question, but at least we will have some guidance. And risk assessment for campylobacter is another thing the Agency is considering.

The next point: Significantly different physiologically, significantly different growth requirements than other enteric pathogens. For salmonella it's not that different than other enteric pathogens. For campylobacter we had to give that a yes. There are some qualities about campylobacter that are different than many other enterics, and we don't know if this is going to make it more difficult to control, and we also don't know if campylobacter's specifically controls are going to be effective against other enterics.

Okay. Looking at the next point, performance standard would encourage control measures and have a positive public health effect. We gave both organisms a yes. If you look at campylobacter, even if you're using a campylobacter-specific control that is not going to have any effect on other enterics, at least you're going to be

controlling campylobacter. So we had to give that a yes public health effect.

As far as severity of disease, we couldn't argue that both organisms were important enough to consider that a valid reason for a performance standard. On farm interventions, the last point, for salmonella some things exist: biosecurity, decreasing water activity, of litter, competitive exclusions. Some of these things have been worked on and found to be successful.

MS. HANIGAN: Excuse me. What does "GBS" mean?

DR. RANSOM: Guillaume-Barre Syndrome.

MS. HANIGAN: Okay. Thank you.

DR. RANSOM: As far as on-farm interventions for campylobacter none conclusively have been defined to date. We are very excited about an on going Agricultural Research Service study. They are conducting a study with industry looking at sources of campylobacter and salmonella in the broiler production area and assessing on-farm interventions is going to be a part of that.

Finally, in closing, I just wanted to mention a campylobacter performance standard for poultry should encourage specific and effective control measures. What this is going to do is prompt research on campy control in poultry. It's also going to prompt control measures to be put into practice. And if these control measures are found

effective, then we can't argue that this is going to have a positive public-health effect.

MR. BILLY: Okay. Again, we would like to provide an opportunity for questions, clarification, understanding of what's here as raw material for consideration by the subcommittee and then the Committee. So, Carol, do you want to start?

MS. FOREMAN: Yes. What other research activities are under way besides the ARS one that you mentioned? Is there anything looking for improved testing going on out in industry?

DR. RANSOM: I think there are a couple of recent commercial tests being talked about. I don't have the name offhand. I know there is an Aliza test being talked about for campylobacter. We are more intimately involved in the two ARS projects that I mentioned.

MS. FOREMAN: I won't be in this subcommittee tonight, but I think that it is a serious error and one that the Department has been getting away from to have the only source of reach on any method be through ARS. I would like to see the Department actively involved in encouraging the greatest amount of profit-making potential research out there on the part of people who might adapt other technologies and bring different kinds of thinking into this. Thanks.

MR. BILLY: Something that could occur at a new technology-development center, for example.

MS. FOREMAN: Yes, or something that just might happen because somebody else has got something that they think, gee, I could change mine a little bit and have a whole new sales area that I don't have now. That is just vital that we encourage that.

MR. BILLY: Katie and then Dan.

MS. HANIGAN: Just a point of clarification. I thought the Committee in November had moved the campylobacter to the Micro Committee that's scheduled now to meet in May, and I'm wondering if we've got the cart ahead of the horse here. Do we need to get some feedback from the Micro Committee as directed by this Committee in November? Can someone comment on that?

MR. BILLY: Sure. Kaye?

DR. WACHSMUTH: Well, we are poised to do that. I would like for someone from Policy to be here to explain exactly the timing of introducing it to this Committee before we do it. And I think it's to address some of the obvious up-front policy questions, the risk-management questions before we get into the scientific issues about the quantitative method and what's acceptable and what we can control and not. Tom might want to speak to that a little more.

MR. BILLY: I think that's the case. It's to begin the process of laying some ground work in terms of what some the issues are from a policy perspective so that this Committee is thinking about it. If it has any particular thoughts or guidance to the Micro Committee, then those kinds of thoughts should be identified and provided to the Micro Committee.

We will end up working in the right sequence. It's just it takes some time to work through this process. We thought that it would be useful to share with you the kinds of thinking and types of information requirements that would go into moving forward to setting some sort of a performance standard so you can get your arms around that. And then once we get the input from the Micro Committee, then having this on the agenda again for further deliberation by the Committee. Dan and then Caroline.

DR. LaFONTAINE: Two comments. First of all, I want to thank FSIS for an excellent paper and presentation here. There was some thought put into it, a chance to look at this from different angles, and quickly bring us up on the whole issue of methodologies. That's the type of thing that this Committee needs to deliberate.

In reference to your question, I made a visit to the FSIS Eastern Lab in December for a variety of reasons, just coordination, you might say, and visited with ARS and

with the cell that you have, not reach cell, but the emerging pathogens group. And my point that I'm leading up to is ARS clearly had the lead, but this was a very cooperative effort between them, FSIS folks. Ann and Jim, you might have to help me out. The Southeastern Poultry Cooperative. Is that the right title?

DR. DENTON: U.S. Poultry Association Research Group.

DR. LaFONTAINE: Yeah. Okay. So there was industry input, and they all are in the same campus there in Athens, so within a few miles of each other. So it's not what you were talking about. I realize that, but it wasn't just Federal Government in isolation working on this. They are very, very, very, very interested in this, and I'm not stealing anything from the poultry folks.

MS. FOREMAN: I want something that's got a financially vested interest in something that will find it quick and reliable.

DR. RANSOM: We did some work with the Naval Medical Research Group and also the University of Maryland working on the campylobacter method. This was a CLI method, colony-lift method, and it turned out not to be adaptable to large-scale testing, but we did do work on that, so we've worked with other groups.

DR. WACHSMUTH: What we did, to give you a little

history, is as soon as we got the '96 Food Net data news before the year was out we held a meeting at CDC of all of the federal agencies who might be doing reach in this area. It's hard for us to interact with, as you know, just directly with the industry without going through announcements and having proposals come in and things like that, but we talked to the Food and Drug Administration, NIH, CDC, all of the people in those arenas who were doing diagnostic development research.

MS. FOREMAN: Was that meeting open to the public?

DR. WACHSMUTH: No.

MS. FOREMAN: So if I'm out there with a business where I want to develop a fast test, I couldn't go to that meeting.

DR. WACHSMUTH: No.

DR. HAVLIK: I might mention one thing about that. First of all, ARS -- they are doing a fairly descent job for us, and they realized, which the private industry has not realized, that we're dealing with very low levels of micro organisms, and so we have to have an enrichment step. Most of the people -- I get at least three or four calls a week with somebody who has a really great test. The problem is that you end up having to go through a 24- or 48-hour enrichment and sometimes multiple transfers in order to be able to use their test.

The only reason that we haven't adopted this test yet is ARS is having a little bit of trouble getting the pH stabilized in the media, but once it gets stabilized, we're going to be able to do it, and it looks like it's going to work okay. You just take the rinse, take out a certain amount, put it on the plate, incubate it in a controlled atmosphere, and you can take the plate and put it in an automatic plate reading, and it's going to be automatable to the same extent our salmonella test is automatable.

MS. FOREMAN: Is there a document anywhere that states specifically what FSIS thinks would be basic and essential to a satisfactory test for campylobacter that is available to the public? I don't think you ought to have to spend 40 minutes explaining to somebody what you mean. I think there ought to be a piece of paper that is out there widely circulated so that anybody that's into this business knows what our requirements are.

MR. BILLY: All right. I'm going to shut this off. The point is made, and I understand it, and I think that's something we can follow up on. Jim?

DR. DENTON: I had a couple of quick questions here. One, with regard to the chicken monitoring program and also the baseline program, I understand that you said the prevalence may not be declining, but just looking at the this on the surface it raised a question in my mind with

regard to whether or not the seasonality effect has been accounted for. Are we trying to correlate this at all?

DR. RANSOM: Right. In the new programs we don't have the summer months data in yet since one began in January and one began in October, so it's possible the prevalence might go back up. We don't know what to predict at this point.

MR. BILLY: Okay.

DR. DENTON: I suspect that's probably what you're seeing. The other one is the comment about the methodology, and this is a general comment. I have faculty that are part of our research effort at the University of Arkansas as well as the faculty that are at Iowa State University working in the swine area that have spent a lot of time and effort looking at this particular organism, and I think the key is going to be a reliable method to isolated and quantify the organism.

It's very difficult to culture, and it's a very extensive procedure that we have to go through. With all of these factors working against it, I'm still a little bit amazed that it is a public health concern because it's awfully hard to grow.

MR. BILLY: Caroline.

MS. DEWAAL: I also want to commend the Agency for an excellent presentation. I have one question on Table 2.

It may be obvious, but I'd like to just get this out of the way. Current prevalence; are we dealing with the medium there?

DR. RANSOM: Can someone show me Table 2? Mine are out of order.

MS. DEWAAL: It's the establishments that would pass fail if it was based on the current prevalence.

DR. RANSOM: Okay, okay. What was your question?

MS. DEWAAL: Are we dealing with the median? And then my second question is, what's the universe of plants we're dealing with, because if we're dealing with the median, we should have 50 percent above 50 percent below.

DR. RANSOM: Okay. For the campylobacter monitoring program, which is looking at all classes of poultry, we're looking at about 204 establishments. For the campy baseline where we're looking at just the young chickens, we're looking at roughly 125 establishments, and, Bonnie, you made the table, so can you tell us -- Dr. Bonnie Rose sitting up front prepared this table for us, so can you explain how it was put together?

MR. BILLY: Use the microphone.

DR. ROSE: Okay. The current prevalence in that hypothetical table is just simply we calculated the prevalence for each of the establishments that has been

sampled so far, and then we took a simple average of that.

MS. DEWAAL: So it's the universe of pass and fail is the same universe of plants that were included in the studies you identified.

DR. ROSE: Yes.

MS. DEWAAL: Okay. So it's 204 plants for the top line and 124 for the second.

MS. ROSE: That is correct.

DR. WACHSMUTH: For poultry it's less a problem than it is for any other species because most of the poultry plants are large and it's a different -- it's a more uniform industry.

MS. DEWAAL: Okay. The other comment I just want to make while we're in a group before we break up into subcommittees, it really responds to Katie's issue of how this has been handled in previous meetings. This was first handled as a question on whether campylobacter should be considered as part of the inspection models project, and a recommendation came out of this Advisory Committee that campylobacter shouldn't be considered on the grounds that there was no baseline data.

Well, that was actually untrue because there was baseline data at the time, and you've got the baseline data here from July '94 to June '95 in which they did find an 88-percent prevalence, and we discovered that last fall

because then the turkey data came out again last fall which showed about a 90-percent prevalence for campylobacter.

So a recommendation came out of this advisory committee that was based really on an incomplete understanding of the data available. Now, we asked -- I know I raised it at the last meeting, and I also believe Dr. Dale Hancock raised it at the last meeting, the issue of what would be the -- could we reconsider that issue of the inclusions in the inspection models project?

And I appreciate this document because it shows that the Agency's thinking has moved forward substantially since we last met. But I also would like to have the full committee reconsider that recommendation, which was, again, based on some incomplete data that we had at the time.

MR. BILLY: Okay. Other comments? Nancy?

MS. DONLEY: Just a very quick question. It's Nancy Donley. Is there any way that this -- there seems to be a problem because of the high prevalence. Do we have data where we can instead look at it as more public health related and infectious dosage as perhaps --

DR. WACHSMUTH: Yes. This is what Gerri, I think, was referring to when she talked about a risk assessment. We don't know what the numbers mean on a bird, but we do know that some of the things that have affected the prevalence of salmonella have reduced the numbers of

campylobacter, even though they haven't eliminated them. The prevalence is about the same, but the numbers seem to be lower.

We also know from Food Net data that there has been a decline in salmonellosis as well as campylobacterosis. So if you look at the human disease, we may be having an effect, and it may be that we've used quantity rather than prevalence, but we have to look at that in a systematic way which would be a risk-assessment approach.

DR. RANSOM: If you do look closely at the quantitative table that I presented, it does look like a larger proportion of the samples were coming out at lower numbers if you closely look at that table, but you need to spend some time looking at it.

MR. BILLY: Collette?

MS. SCHULTZ KASTER: A point of clarification. Are we discussing this mainly relative to standards for poultry? And the reason I asked is as you go through your table of performance-standard considerations, that's very poultry based and that would need to be redone for other for other species because the assumptions there would not be correct for other species.

DR. RANSOM: Yeah. One reason I'm talking about chickens in particular, we're on the verge of the release of

the methodology for chicken. We've got two things. We've got the new chicken base lines under way, and also we're on the verge of getting methodology. If we start to consider other species, we're going to need other baselines and also methodology that's going to be applicable.

MR. BILLY: So I think a way to think about it, it's a starting point, but if the Committee is interested in looking at it more broadly, then you're welcome to do so, but there are, as pointed out, a whole series of factors that go into considering some sort of regulatory approach to dealing with campylobacter. Carol?

MS. FOREMAN: What would be the timing on a risk assessment, and is that likely to be a subject that the Micro Committee will discuss?

DR. WACHSMUTH: I am sure that someone on the Micro Committee will recommend that we do that. We're in the process of -- well, we have most of our resources right now dedicated to 157H7 in various cuts of meet and ground beef.

MR. BILLY: Most of our risk assessment resources.

DR. WACHSMUTH: Risk assessment resources. We could consider possibility of contracting some things to move this long faster, so we'll wait and see what the Micro Committee does recommend.

MS. FOREMAN: Do we want to predict how they will

deal with it, how they will sculpt their discussion?

DR. WACHSMUTH: I couldn't predict that.

MS. FOREMAN: Come on, Kaye.

DR. WACHSMUTH: Oh, there is no way.

MR. BILLY: There's a lot of new members of the Micro Committee. It's been enlarged. We have about 25 to 35, and so it would be interesting to see. We're all looking forward to that next meeting. Any other comments?

(No response.)

MR. BILLY: It is now ten-after-three. I'd like to take about a 20-minute break and resume again at three-thirty.

(Whereupon, at 3:15 p.m., a brief recess was taken.)

MR. BILLY: We're going to get started again. The next item on the agenda is briefing on a new topic, but one which the Committee expressed an interest in, which is the development of a concept paper on the mandatory inspection of all animal-flesh foods.

I should add as a little rejoinder on this that this agenda item has caught the attention of other agencies in town and raised some concern about what this is all about, so I'll just make that comment. Loren, do you want to introduce the subject?

MR. LANGE: Yes, and good afternoon. I was going

to start by covering what Tom mentioned and a couple of other things. At the top of this paper it says "Draft 1, April 1999," and that was intended for a purpose. The full Committee had recommended back in November that there be a concept paper on this issue of the mandatory inspection of all flesh foods, and I worked on this paper with just that sort of intent that it be sort of a paper that would be a starting point. As has been brought out, this paper was not shared with other regulatory agencies that have inspection programs. It wasn't even covered by our internal Office of General Counsel.

I prepared a couple of drafts. It was sent around to different staff people inside the Agency and to my boss sitting over here on the other end, and we did not prepare it as an Agency paper. It doesn't necessarily represent a finished FSIS product. It is a paper that is here as a starting point to facilitate the discussion that will occur in the future.

The approach I used was really to sort of read in detail all of the discussion that was conducted last November and try to capture it in this paper and add to it a little bit of information that sort of raises some other issues and sort of presents some material on our current sort of voluntary inspection program, which is at the end.

So, with that, I'll just sort of briefly sort of

flip through it and point out what I think are some sort of highlights of what is here. From the last proceedings I took this goal statement that was agreed to in the subcommittee, and that is to ensure that all flesh-foods, commercially slaughtered and/or processed for human consumption are federally or state inspected for safety and wholesome. And my former colleague in the audience from FDA noticed it says "federally inspected." It didn't say "FSIS has inspected."

I captured three principles from the material that sort of would guide discussion, I thought, and the first one being that the allocation of any inspection resources should be based on relative food safety risks presented by different animal-flesh foods. A second principle was that further discussion should probably operate under the guideline that we aren't going to have additional resources and sort of any change, any legislative change in the future should at least provide the flexibility that we can allocate our existing scarce resources based on sound risk-management decisions.

And, finally, a principle that the inspection systems that are designed and developed should be hazard based, science based, and public-health based.

The second item in here, which is on page two, and I'll just briefly point out, it's a discussion that just

sort of raises the issue that "animal" has to be defined, "flesh food" has to be defined, commercially "slaughtered" has to be defined. And if you look in the Webster's Dictionary, an animal is everything other than plant life and bacteria, so, yes, animals are insects, animals are seafood, animals are shell fish, and what is more the traditional food animals.

Again, I mentioned commercially slaughtered. We've always sort of, under both our existing meat and poultry inspection statutes we have this sort of, you know, exemption for the individual hunters, fishermen, they use the word "clammers" in there -- I don't know what the people are that go and dig for clams, but I guess they are clammers.

Section 3, the legislative approach, and there was a lot of discussion in the subcommittee last November, so I'll just briefly, you know, point out what the three approaches that have been at least mentioned, and there was a discussion of, well, we can amend the Meat and Poultry Inspection Acts. And then there was a lot of discussion that rather than amend these existing statutes, there was a lot of legislative change being considered. This is the time to really do a wholesale -- that's not the word I want, I guess, but anyway, a complete revision of, you know, the food inspection statute.

Staff inside FSIS said, well, you know, one way you can get around some of the issues of opening up the statutes is maybe you could attach on a third statute. I just through it in there for something to sort of facilitate discussion.

The Committee had sort of requested that the first concept paper sort of deal with, well, what would be the change that would be required, and I'll only mention briefly, you know, that our two statutes, the meat and poultry statutes, are very different in terms of our ability to, you know, expand the coverage.

The Poultry Products Inspection Act defines poultry as any domesticated bird. We have a regulation that says, yes, poultry is any domesticated bird, and we added a parenthetical in 1957 that that was chickens, turkeys, ducks, geese, and guineas.

I think, you know, there is certainly the possibility that one could expand the Poultry Act to include a lot more birds with a regulatory change rather than a statutory change. There is legislative history that would have to be considered, at least in debate on the Senate bill, which I think a year ago I covered front of the Committee that said they explicitly were not after commercially raised game birds at that time.

In contrast, if Federal Meat Inspection Act has a

specific list of types of animals that are covered. It's cattle, swine, sheep, goats, horses, mules, and other equine. That's far more limiting than the Poultry Act, so to add, you know, another type of animal to the Meat Act would clearly take a legislative change.

The next section of added in the concept paper was sort of the barriers to goal achievement, another topic that was debated considerably at the last meeting. Barriers -- obviously, changing statutes takes a lot of resources, inside government, outside of the government. There is a barrier of data.

You know, to support a legislative change, even legislative proposals have to deal with issues of public-health benefits versus cost. There is probably a lot of data that doesn't exist that would be needed to sort of develop the supporting documentation for, you know, any legislative change in the future.

The third barrier sort of related to the data issue, too, we have sort of preliminary data inside the Agency that says, well, a lot of states require, you know, flesh foods of certain sorts to already be inspected, and to sell certain products in certain jurisdictions they have to undergo some type of inspection.

And certainly I think we would have to overcome that barrier that some people might point out that, well, if

a lot of these products are already inspected, we're really talking about an economic issue, the economic issue being if you're one of the types of livestock or poultry that are covered by the Acts, the Government pays for the inspection. If you're one of the types of livestock or poultry that are not covered by the Acts, you know, you can get it provided, at least by the Federal Government, on a fee-for-service basis, $32.88 per hour.

So the third barrier is sort of, you know, making the case really that we have a public health issue here and not really an economic issue of who pays for the inspection.

One more section, and it gets back into another definition. The goal, as stated, says animal flesh foods should be under inspection. The goal hasn't defined how that inspection is to be done or whether it is to be of the nature of what is traditionally thought of as continuous inspection. All of the animals that are what we call today "nonamenable animals," if they are prepared for interstate commerce, they are subject today also to the Food, Drug and Cosmetic Act, and I point that out in there.

I noticed, in looking at sort of today, we have the voluntary inspection that covers reindeer and bison and antelope and stuff, and we have sort of the voluntary poultry inspection for quail and pheasants.

So I sort of noticed that the stuff we're

inspecting voluntarily today is certainly similar types of animals and poultry to what we do today, and when I sort of looked this up I saw that everything that we now call an exotic animal in the Meat Act that are meat animals are even-toed, horned ungulates, which means having hoofs. And for someone who learned their high-school biology from their high-school football coach, I'm at a disadvantage.

But, anyway, that's what they are. And the pheasants and quail are certainly more similar to our existing sort of birds that we slaughter than maybe certainly the rat-types, which have been in a lot of public debate in recent years.

Anyway, our people have pointed out, you know, that inspection would have to sort of consider the anatomy and physiology of different types of animals, and what we call exotic today would not be maybe exotic in the future.

I do point out that we do have a history of more exotic type of requests. We've had inquiries as to inspection for mountain lion, llama, alligators, armadillos, and nutria. And mostly in the past the Agency has sort of referred these sort of requests to the Food and Drug Administration or the National Marine Fishery Service where they would have the jurisdiction over these sort of other extra-exotic animals, if you will.

The history of armadillo, I thought, had an

interesting point. The request to have armadillo inspection, and it sort of -- and then someone noted the article actually that I found on the Internet many years later -- it was a National Geographic article, and it sort of pointed out that armadillos carry if bacteria that causes leprosy.

And if you talk to people in the Agency that remember this, yeah, boy, it just dropped immediately then. And then when I passed this out, people said, well, wait a minute, you know, yes, leprosy sort of has a history, and it sort of is a terrible disease, but what is the difference between a food animal like armadillo that has a bacteria that happens to cause leprosy versus the food animals today that have other bacteria that cause serious public health disease?

So, you know, people that can't reconstruct, it seems so obvious that when leprosy came up, well, that took care of that issue, but it doesn't necessarily, when you sort of rethink about it, other than the fact that leprosy has a history of being directly associated, I guess, with sin and misbehavior, and other food-borne illnesses do not have such is, I guess, colorful history.

Getting close to the end here, one of the last issues is the Poultry Act does have exemptions for small processors. I think that it's if you're within a state or

territory, you can do a thousand birds and the Act doesn't even apply. Under other conditions you can process up to 20,000 birds and be exempt from federal inspection.

So if the goal is all flesh-food animals, that's at least an issue would there be similar exemptions like this in any future considerations. The Meat Act does not have that. If you process one amenable species, one hog, one cattle, there is no limit on the number, even if it's distributed in interstate commerce.

The last thing that's in the paper, starting on about page 11, is sort of I added the stuff under our existing voluntary inspection programs that are under the Agriculture Marketing Act. I added a table on the last page that showed what we really do today is we provide inspection for, and it's decreasing for rabbits, again, the exotic animals, which are mostly bison and sort of the voluntary poultry, which are the migratory birds and game birds.

Most of that actually is quail, and I was able to sort of get to the fact that there is probably about a million dollars to a million and a quarter spent on the fees for conducting inspection under the Agriculture Marketing Act.

So, with that, I will open up for questions and, again, emphasize that I've tried to include information in here that people can use in tonight's discussion to sort of

further clarify some of the definitions and what the thinking is. Thank you.

MR. BILLY: Questions or clarifications? Comments?

MS. FOREMAN: Since there are no other comments, I might as well add one.

MR. BILLY: Okay.

MS. FOREMAN: Remember, in the words of the great Jim Hightower, the only thing that we find in the middle of the road are yellow lines and dead armadillos.

MR. LANGE: I will add to that, when you get on the Internet and try to find out something about armadillos, there must be defined a serious armadillo Web site is hard. It seems to be a creature that has, you know, road killus armadillos or something, and we love armadillos and stuff, but. I'm not an expert on searching the Web, but I did find that National Geographic article that I referenced in here.

MS. FOREMAN: I think the definition of armadillo processing factory is the yellow line in the middle of the road.

MR. BILLY: Okay. Any other questions or comments from anyone? Terry?

MR. BURKHARDT: I was just wondering, if you look at any data as far as of these exotics are being inspected under state inspection.

MR. LANGE: The paper points out, we really don't know that. FSIS does not collect the numbers. I do point out that it was just in there that we've heard that a lot of states require, but we don't have any estimate on the volume under state inspection, and we don't have an estimate for if there is for different exotics that are actually being consumed for human food without inspection. Our system is just -- that's not our business to collect that information.

MR. BURKHARDT: There are a considerable amount of those that are inspected under state inspection simply because they are smaller plants, they are a lot more adaptable to do it. I know in my particular state we do a lot of them.

MR. LANGE: I'll add real quickly to that, I think when I was here last year I had a draft paper that went to Congress on -- it was to be a cost/benefit paper for mandatory inspection of ratites. It went to the Hill. The Hill -- it's may paper so I hate to say that, but they weren't pleased with it.

And what we're in the process now of preparing back is what we think in time and money you it would take to really do a cost/benefit study. And one of the items in that paper is we would have to survey the states to find out, you know, what the volume of production under state inspection.

MR. BILLY: Dan?

DR. LaFONTAINE: Yes. Just kind of an introductory comment, we'll be talking about this this evening and, of course, report back tomorrow, but one of the reasons that this was brought up as an agenda item to begin with or proposed is it ties back to what Rosemary said this morning.

What we have going on is rule making by quality, and that is, I repeat the example of South Carolina where we have the largest quail slaughterhouse in the United States, over three million birds a year, and it was no inspection, and their market place was the whole U.S. and the great State of Texas finally said you're not coming in without some type of mark of inspection. So here we have attorney generals writing each other letters because this particular commercially raised and slaughtered food item, a bird, has no inspection.

So, enough said. I just wanted to kind of tie into the new members that this is one of the reasons this evolved is we've got a problem out there that's nipping at everybody's heels at the state level for sure that needs to be addressed.

MR. LANGE: This particular establishment is included in that voluntary poultry on page 13. It's a big chunk. They are paying, if I understand it, they are paying

for voluntary federal inspection.

DR. LaFONTAINE: No. It's all being done under state voluntary.

MR. LANGE: That's another one. Okay. There is a large quail plant that is -- inspection.

DR. LaFONTAINE: There are other quail plants, but this particular one is strictly a state-marked inspection.

MR. BILLY: Lee?

DR. JAN: I think this issue does need to be explored. But one of the things to kind of take -- your definition up front that you mentioned, you know, flesh foods and included insects and all of that and animals in the definition of all that. And we joke about armadillos, but nobody raises armadillos that I know of for food.

So I think when you look at the thing or talk and it, let me say, all animals raised for food or raised for purposes of food, dogs and cats, if people raise them for foods and want to slaughter, I think they need to be done under inspection. It doesn't sound like a great thing, but I wouldn't think that we would want to have dogs that are hit by a car to be then used for food. You would want to raise them for food, and you look at them like another livestock.

MR. BILLY: Caroline?

MS. DEWAAL: Just on that point, what is USDA's

position on fish farming?

MR. BILLY: We like to eat products from fish farms.

MS. DEWAAL: And do you inspect any of them? And how would this provision, in fact, govern that particular species? Because my point is, there are a lot of those areas of the food supply which are not currently under effective Federal Government regulation or even effective state regulation coordinated by the government.

MR. BILLY: We look forward to the input from the Committee in terms of this issue and questions of that nature.

DR. JAN: Caroline makes my point. Fish farms, they are raised for food, and they should be, I think, under inspection. And my thinking on that, and more than just send me the money, and I'll come by if I need to some years down the road like FDA may do.

What I'm talking about is if a company or an individual puts money into raising fish, and all they have to do is deliver them or take them to that thing and skin them and sell them and then may or may not have inspection or actual visual inspection more than paying a fee for a license, if they had a die-off of fish, if they got up there in the morning and they were all floating on top, there would be a big economic incentive to skin these things out

and sell the flesh if there is no visual inspection.

But it doesn't have to be that we take a temperature of every one. We've got organoleptic -- we have HACCP, and we've got other systems, and we customize the system to fit the species. And it may be HACCP plan that someone documents that the fish were alive when they were netted or whatever, but, you know, it takes away the ability to salvage an investment through selling it as food, and that would go for all species. And there's a lot of expertise out there now that can be salvaged for food without inspection because there is no requirement for it.

MR. LANGE: Just to follow up on that, I think traditionally inside the Agency, if I talk to people that work on inspection methods, the mind set has always been to sort of think, oh, someone has petitioned for a new animal. We have to think of how would we do post mortem and antemortem. In the future -- I mention in the paper -- maybe all we really need to think about is how we verify that industry sector's HACCP system.

MR. BILLY: All right. Good. Thank you, Loren. The next item on the agenda is exemptions from federal inspection. This is the item that Rosemary mentioned briefly. It's covered under Tab 9. We have Judy Riggins and Philip Dufler here. Judy.

MS. RIGGINS: I want to preface this by saying

that we at the last advisory committee meeting, Judy Nibrief gave you a side-by-side, which is in your package again, which lists all of the exemptions, if statutory citations, and then the citations from the CFR, so that you have a complete compilation of all of the exemptions that exist.

What we're going to present today is basically a response to your request that we do a white paper on exemptions. We weren't quite sure what the intent was of the group, so we've developed a paper that basically spells out how we view our approach, and we would like you to, in this evening's session, to give us some ideas. So I'll walk you through the paper.

Basically, the exemptions from the 1906 Meat Act provided for exemptions from retail stores and farm slaughter. And, of course, a debate on exemptions has gotten own throughout the century. But it should be noted that the majority of products, meat and poultry products, are not exempt. They are under jurisdiction of FSIS, and they are all subject to adulteration and misbranding provisions of the Act.

FSIS's plans this year do not include seeking elimination of all of the meat and poultry inspection exemptions. The Agency's plans are to use its resources to most effectively reduce the risk of food-borne illness associated with the consumption of meat and poultry. Our

highest priority, of course, has been the implementation of HACCP, and we plan to continue that.

Our microbial data collected from the 300 largest plants in 1998 indicate that the new inspection system has been very effective. And for the immediate future full implementation of HACCP will be our highest initiative and the best use of our inspection resources in protecting the public health.

Concurrently, our strategy includes taking steps that are from farm to table through each segment of the continuum of food from the farm-to-the-table.

Public-health risks can arise after meat and poultry products leave inspected facilities during transportation, storage, and at the retail level. And while there are certain exemptions from federal inspection for products in this sector and from other categories such as custom slaughter and very, very small poultry operations, is products are not exempt from adulteration and misbranding provisions.

FSIS recognizes that the current inspection system does not permit the Agency to allocate its resources according to the public health risk. Eliminating all exemptions would certainly force FSIS to reallocate its resources but not necessarily maximize the gains to public health, and perhaps it could result in requiring FSIS to

perform inspection tasks more appropriately performed by the state and the local authorities.

So we need to focus and exercise appropriately our jurisdiction over the products that leave the planted and to include the products and operations exempt from the provisions of the FMIA and the PPIA to best protect the public health. And we believe that we can best accomplish this by cooperation with the state and local authorities and other federal agencies, such as FDA.

Complying with the 1991 statute mandate from the Congress, we contracted with Research Triangle Institute to do a review of USDA's meat and poultry exemption policies, and a report was delivered to us in January of 1994.

The report had two major findings with respect to exemptions, first, that FSIS, policy in determining exemptions for individual products has been applied unevenly and inconsistently; and, second, that simple process is often conducted at retail establishments are not necessarily low risk. These processes include cutting, slicing, grinding, and repackaging of meat and poultry.

These findings, along with the reports' risk analysis, legislative analysis, and examination of the effects of exemption policies on the industry establishments and federal, state, and local regulators provide substantial valuable information that the agency has utilized to

continuously improve its exemption policies, but there is much to be learned about the food-safety risk that's posed by exempt products and meat and poultry products produced under exemptions from inspection compared to the risk posed by meat and poultry products produced under continuous inspection.

The best discussions on how to deal with exemptions will be made based on the full farm-to-table risk assessment that we are going to undergo as we make our way through HACCP implementation. Since the issuance of the report FSIS has taken several steps to eliminate unequal treatment. The Agency has instituted a review of its labeling approval process and has implemented a partially generic-label approval system, and we are also in the process of looking at expanding that generic-label approval system.

The agency has stated its intent to work with FDA or food standards to modernize the food standards and to basically evolve them into or develop them into guidelines for the industry. That will give more flexibility, allow for products that consumers want to have in the marketplace. We are working closely with FDA and the state agencies to ensure the adoption of a science-based standard at the retail level through the Food Code process, and last year Secretaries Shalala and Glickman sent letters to all

governors and to constituents and employees of USDA and HHS encouraging the adoption and the use of the Food Code.

We are continuing to work with the food industry as well as representatives of the state and local governments through the Conference of Food Protection and in other forums to encourage industry leaders and trade groups to endorse the Food Code and promote its adoption in all jurisdictions.

Major trade associations like the Food Marketing Institute, the National Restaurant Association, government groups like the National Association of the State Departments of Agriculture, and professional groups like the Association Food and Drug officials, and National Environmental Health Association and many others have had input and have endorsed the Food Code. This broad base of support has been instrumental in encouraging grassroots support and the adoption of the Food Code.

I believe Ralph Stafko reported to us that there are 15 states, I believe, that have adopted the Food Code to date. Okay.

In addition to improving and promoting the Food Code, we also want to provide assistance to states and local regulatory agencies through training and other means, and we do have an ongoing effort. Ralph Stafko has been leading that effort and is working with Caren Wilcox to make sure

that we are, in fact, using our money in a way that is efficient and effective for the states. And our hope is that the relationship that we are developing will lead to a much more comprehensive farm-to-table approach in the near future.

We are committed to working with the states and in our efforts to create a seamless meat and poultry inspection program, and we hope that when and if the interstate shipment bill passes that we will be ready to provide a seamless food-safety system throughout the United States using -- appropriately using federal resources and also state and local resources.

So it's clear that the federal agencies must work closely with the state and local agencies to address food-safety concerns, and we know that it's not going to be an easy process, but we are committed to working. And we basically want to find out what approach you believe we should take in addressing the issues that we know are emerging in the farm-to-table sector.

And we are looking at the possibility of performance standards for transportation, for warehousing, for cold storage, and we would like to have your ideas about how we can best use our resources based on our current statutory authorities and how we can work best with the states and with FDA and other sister agencies to make this

come about. Are there any questions?

MR. BILLY: One thought that occurs to me before we get to the questions. This item and the previous one on mandatory inspection of all animal-flesh foods, if you think about that in the context of our strategic objective, our strategic plan, the paper that we talked about earlier today sort of puts it into a perspective in terms of a direction to go in if, in fact, that's what your intent is.

You get a sense of what I'm saying; you can start from the specific issues within a certain legal/regulatory framework and look at it that way or talk about where you want to get to and then how you go about achieving that through the full integration of all of the resources that are available. So it's an interesting and different kind of approach for thinking about how you achieve a certain outcome in terms of food safety. Caroline, you wanted to ask a question.

MS. DEWAAL: Thank you, Tom. I have three quick comments. First, I think it's an important piece of this paper that you recognize that the current system doesn't allow you to allocate your resources in a hazard-based way. I think that's very significant. I also appreciate your support for the Food Code and promoting its further adoption by the states.

My question has to do with the big black hole of

government where somehow this advance notice of proposed rule making on transportation apparently fell, because we had several meetings and then submitted lengthy comments on an advanced notice of proposed rule making several years ago now dealing with transportation with your sister agency, the FDA and I'm just curious on giving your comments here what the status of that effort is.

MS. RIGGINS: It's ongoing. Part of the work that Ralph is doing now is gathering information --

MR. BILLY: You've got to move the microphone.

MS. RIGGINS: I'm sorry. The work that Ralph Stafko is doing now is gathering information that will inform us in going forward with the proposal. We felt that we needed more information to actually lay out a plan or a framework that would address all of the issues that were raised in the ANPR and in the comments that we received. And so we are continuing that.

It's a slow process because the sectors between -- well after the plant and before the grocery store are all very independent industries, and so Ralph has been out meeting with the truckers, meeting with those who make refrigeration equipment, those who actually house the food in warehouses and in cold storage. So he has had to address each sector separately, and he is gathering that information. So we haven't stopped doing the work, but it

is a longer term project than we originally anticipated.

MS. DEWAAL: I would agree with you it is a long, slow process. Would we anticipate that a proposed rule would come out with your sister agency, or are the two agencies working independently?

MR. DERFLER: We're working on our own regulation at this point. We're looking at developing a performance standard on handling in distribution, is the direction that we're looking.

MR. BILLY: Okay. Carol, and then Dan.

MS. FOREMAN: Do you know how many pounds of meat and poultry are processed in exempt situations now? Is that in the 1991 report?

MS. RIGGINS: We would have to get that information for you because I don't know off the top of my head.

MS. FOREMAN: Does anybody have any notion of what the percentage is? Are we talking two percent of the total?

MR. BILLY: I would be amazed if it's that much, but I don't know.

MS. FOREMAN: I have one other question. I continue to get reports, and Dan may be wanting to address it, of retail outlets, some of these superclub stores, grinding inspected meat and selling it at wholesale, a process that would be subject to inspection under most

circumstances. Have you got any notion about how widespread this is? Again, are we talking about --

MR. DERFLER: I'm not sure that we know how widespread that is. I know that our compliance officers are out and looking at this issue and trying to gain access to records and judging that.

MS. FOREMAN: And if you knew for a fact that somebody was doing this, is there action you can take against it, or is that an exempt activity?

MR. BILLY: There is action that we can take, and we are, in fact, in the process of doing that with several large companies.

MS. FOREMAN: So that's not really part of our consideration. I'm asking because I'm the chair of this subcommittee. Is this an issue that really is within our consideration tonight, in that it is really not an exempt activity?

MS. RIGGINS: The products are subjects to adulteration and misbranding provisions, so when we find an adulteration has occurred, we can take action, and we are taking action. So I'm not sure what --

MS. FOREMAN: But it is not illegal for them to be doing this.

MR. DERFLER: No. Grinding is listed in our regulation right now relating to retail if it's done in the

ordinary course of the retail trade and doesn't exceed certain amount levels.

MS. FOREMAN: What's the level? Do you remember? Is it in here?

MR. DERFLER: I don't think so.

MS. FOREMAN: And you don't have any data.

MR. BILLY: Forty thousand.

MS. FOREMAN: Forty thousand.

MR. BILLY: It's in that neighborhood

MS. FOREMAN: Forty thousand a year? Some of these people have to be doing 40,000 a month. No? Not that much?

MR. MAMMINGA: We're getting several issues here all intertwined with one another. When you talk about retail exemptions and what makes --

MS. FOREMAN: I'm not talking about the retail exemption.

MR. MAMMINGA: Then tell me what you're talking about, then.

MS. FOREMAN: I'm talking about actually stores, big ones, Sam's Club, for starters, that sell meat wholesale.

MR. MAMMINGA: Okay.

MS. FOREMAN: They are not under federal inspection.

MR. MAMMINGA: They are allowed to sell either a percentage ar a dollar amount on annual basis to other than household consumers, which by federal regulations are places that prepare meals -- hotels, restaurants, and institutions, the HRI trade. They are not allowed to process and package any sort of product for sale through another store.

For example, the Sam's Club supplying the local Piggly Wiggly with packaged meat. That is not permitted under these exemptions. The exemptions have to do with places that prepare meals, and it's a dollar amount that's set annually by USDA based on consumer price index for meat and poultry products.

MS. FOREMAN: And what is the --

MR. MAMMINGA: I think it's $38,900 worth of red meat. It's awful close to that, or $39,000 dollars for this calendar year, and it will be set, again, in August, and then there is another amount for poultry because there are two separate Acts. Or 20 percent of their retail sales.

So if you're a small corner grocery store in small-town Iowa and you sell a thousand dollars worth of retail meat a year, you've got $250 that you can send out to hotels, restaurants, and institutions.

Eighteen. All right. So it's the HRI exemption.

MR. MAMMINGA: And it is further limited to single-ingredient things that they process. They are not

allowed to make mixtures of things like sausages and species and extenders and binders and breaded and battered products and things like that. It's ground beef, ground pork, ground poultry, cut-up friers, steaks roasts, and chops, and that sort of thing that they are allowed to sell to other than household consumers where they prepare meals.

And in addition to the adulteration and misbranding provisions of the Act, the trichina control provisions of the Act apply to retail products by federal regulation.

So when you come into arena of what, for food-safety purposes, what may or may not affect or should affect these retail exemption, you also have to consider the fact that these simple processes of grinding beef are no longer considered quite so simple if you can do $40,000 of it a year and maybe cross 50 other businesses, place with people go to get their meals.

So I think it is an issue, a significant issue. It's not just the money or how much.

MS. FOREMAN: That's a lot of money, a lot of product.

MR. BILLY: Dan?

DR. LaFONTAINE: Let me add to the fire here, so to speak. I've brought the information memorandum from the Secretary of Agriculture that was generated as a result of

our previous discussion.

So I'm going to read a little bit out of context, but this is what the Committee, this Committee, put on the table a year ago: "Policy on Voluntary and Mandatory Inspection, Including Exemptions." And the first part of this is fresh foods, and I'll skip over that and go to the last few sentences. "In addition, the Committee recommends that current regulatory exemption for retail markets to sell to HRI with a specific dollar limit be limited. In other words, retail meat markets would not be authorized to what he will any meat or poultry products processed or further processed by that facility to another retail or food service establishment."

So that was the charter, as I see it, to FSIS to come back to us. And I'll just say it the way I feel: I think you missed the mark. I don't really see any substance on this particular issue.

The other thing I wanted to add before I yield the floor is $40,000, and this is primarily ground beef we're talking about, is, depending on the price, 20 ton per year. It could be less than that, 15 to 20 ton.

The number-one, what I consider legitimate complaint, from the folks they regulate, which is they are subject to the USDA regulations in our state, is I have pathogen reduction, I have salmonella testing, generic E.

coli testing -- of course, that applies only to carcasses, sanitation standard operating procedures, I'm coming under HACCP real soon. What about all of these folks that are putting out tons of ground beef to food services like I am? They consider it a very unlevel playing field. It's a food-safety issue for them, and it should be a food-safety issue for other folks that are selling it beyond their store boundaries for other commercial establishments.

MR. BILLY: Lee?

DR. JAN: The only exemptions it seems that we are talking about is HRI exemptions, but there are other exemptions of concern, and I don't know if we are supposed to address them at this subcommittee or not, but I certainly have problems with some of the exemptions for, for example, a bagel dog does not require inspection, but a product almost identical that's got a different name, "pig in a blanket," does require inspection. So we've got inconsistencies there that, I think, definitely need to be looked at, and I don't know how far we can go.

And also I really think that the Meat Act applies to all meat and provides an exemption for retail, and it wouldn't be, or I would like to see that changed that all meat is that is produced under the Wholesome Meat Act or those provisions, and at least when we go to HACCP move HACCP to those areas as well and the same considerations

that the inspected plants have, even though it's retail stores, and you mentioned Sam's.

But there are a lot of large markets that sell to the household consumers in more volume annually than some of the state-inspected and even some of the federally-inspected plants well through their wholesale districts.

So there is a lot more production, and if you saw "Nightline" or "Dateline" or one of those lines a couple of weeks ago, they had a pretty good program on ground beef and adulteration -- this was a species adulteration. They unfortunately moved into an area -- they shouldn't have listeria M in the raw ground product, but that he had real good points I think they made about, and I think it was, like, eight out of 10 stores had adulteration of the species, and so there needs to be regulation there, too.

MR. DERFLER: Well, I think, if I could, the issues are a little bit more complicated, I think, that we have to deal with. I mean, there was a recent court case in Honey Baked Ham, which I really don't want to talk about because I don't know that the Agency has made its decision on how it's going to proceed on that, but if you look in that case, the court there, just to talk in Meat Act terms, made a pretty strong distinction between Section 606 of the Act, which talks about the circumstances in which processors, et cetera, slaughterers or processing plants,

would be subjects to inspection and the circumstances in which they would not be, like under Section 624, which specifically talks about retail. At least in that decision that court panel drew a pretty strong distinction between the two of them.

So I mean, your last comment suggested that maybe that needs to change. If it does, it needs a sort of fundamental statutory changing that I think the Agency has to think about whether or not, given what it's trying to do in a lot of other areas, whether it can expend or has the political capital to address those sort of things. So we can talk about it more later, but I think that's a point for consideration.

MR. BILLY: Maybe one of the things that the Committee could do is picking up on what it recommended last year, get more specific, and in the various areas specifically say what you want addressed, and with the help and guidance of the staff, whether it's a legislative change or a regulatory change or, you know, given what we know, so that it's now not just a general recommendation; it's specific even to the extent of what is the highest priority, risk based or however you want to do it, that would address this broad area. I think that would be very helpful. Other comments on this? All right. Thanks very much.

We're going to be wrapping things up here in the

next 40 minutes. I'd like to take a little bit of time now to circle back to deal with subcommittee membership and to remind the Committee members to give us your issues, and then we're going to have a period for public comment, and we do have at least one speaker that's requested time to provide some comments to the Committee.

If you go to Tab 3, you will see here, again, the suggested makeup of the subcommittees, and I'm not sure if there was any negotiating going on during the course of the day in terms of changes or not, so that's the first question I wanted to ask.

MS. SCHULTZ KASTER: Successful or not successful?

MR. BILLY: Successful. All right. If one subcommittee finishes before another, you are absolutely welcome to join another subcommittee, and we encourage that, in fact. I don't know how likely that is, given off the meaty issues that we've identified, but keep that in mind. Caroline?

MS. DEWAAL: I would just like to note for the record that this Committee, despite your efforts to get additional consumer -- one conditional consumer public health representative, is still very heavily weighted to industry representation, and, in my estimation, every single subcommittee has two industry reps, at a minimum, so just a reminder to people that when the consumer reps need to leave

the room for a minute they shouldn't proceed with the agenda until people come back, the so-called "bathroom rule."

DR. LaFONTAINE: Mr. Billy.

MR. BILLY: Yes, Dan?

DR. LaFONTAINE: The gentleman from the American Public Health Association, I guess I just saw where he has gone to Congress, so that, I guess, eliminates him, so you're lost.

MR. BILLY: Back to square one.

MR. LaFONTAINE: I just wanted to note that they did try to add one, and I guess it didn't work out.

MR. BILLY: Okay. Also, a couple of pages back, we've identified the issues that are carry-over issues that were suggested by the Agency and issues that have been suggested by members of the Committee. Now, I understand, and I can offer some further explanation in terms of the suggestion by Katie Hanigan in terms of field execution task force -- it's not what I thought originally.

It is, in fact, talking about how we execute our daily operations and the importance of communication between the inspectors in charge and the circuit supervisors and on up the line and a concern about ensuring not only that that's happening and happening in an effective way but also a consistent way across the country.

So that's sort of a context for this. And as I

indicated, in part that will be addressed tomorrow, with an additional to the agenda at eleven-thirty tomorrow morning to talk about this area of communication, both as it relates to plants currently under HACCP and the very small plants that will be coming under HACCP next January.

And then, finally, there is a little further back a set of forms where you can add your suggestions in terms of additional issues, and we do want to receive that material from you, and that's sometime tonight.

MR. MICCHELLI: If you can, I need to have it tonight so I can compile the list and return the complete list back to you tomorrow morning.

MR. BILLY: So you don't have to be real elaborate. You can just come up here to give us a sense of what you're thinking about, and we encourage you to do that so we can get one composite list for purposes of setting some priorities tomorrow afternoon. Any questions again about that? It looks like everyone is all right. Okay.

I'd like to provide an opportunity for public comment. I'd like the commenters to please come up to the microphone. The first speaker is Dennis Sexhus, who is with the North American Bison Cooperative and would like to talk about the issue of mandatory inspection. Dennis?

MR. SEXHUS: Thank you very much. I appreciate coming here. I'm a Buffalo rancher from North Dakota. I

happen to be one of the 350 of us who built the slaughtering and processing plant in New Rockford, North Dakota, North American Bison Co-op. We're all producer/owners.

I don't get to town very often, and I will tell you this for what it's worth. I'm real impressed with the obvious talent and workings of this Committee today. You really -- I've sat here and listened to you all day, and you're all to be commended. I think you've certainly got your priorities right.

I'm only going to say a couple of things here. I came here from North Dakota because this is a very important issue to us bison ranchers. Just for your information, bison isn't exactly a fringe thing any more. I always am somewhat insulted because it always does get included with armadillos and rabbits and what not, but really several million pounds of buffalo meat is consumed each year.

It's probably the fastest growing segment of the livestock industry in North America. It's got a compound growth rate of over 20 percent a year. And just for your information, in the State of North Dakota it's second only to beef in terms of economic importance as a livestock enterprise. It has passed dairy, hogs, sheep, and all poultry, so it is no longer fringe.

There's two issues here really that bother us a lot. One is a basic issue of fairness. It's pretty

important to us ranchers living out in the Great Plains trying to make a living off the land. It's not easy. We start with a handicap against all other mates because of this nonamenable thing.

And I read the report, and I know it might be more complex than we see it to be, but the fact is that to me it's unconscionable to charge us ranchers $100,000 a year, which is roughly what we pay for voluntary federal inspection, when down the road the beef and pork people pay nothing.

That is absolutely wrong, and that has to be able to be corrected, I think, with all the talent on this Committee, to just sit down and say, look, it just makes sense here.

The Federal Government, on one hand, is trying to encourage alternate agriculture, we'll call it, some way that these farmers and ranchers can make a living, help them defray expenses of establishing things like bison farms ranches, and then we turn around and handcuff them with a fee like this, to me it absolutely makes no sense, and I feel you can tell I think quite strongly about it.

And the last issue is even more important, and that's the one on food safety. The people here -- I heard somebody -- I think it was the I don't think lady in back in red about the politics. This isn't politics. This is all

about food safety. That really impressed me a lot because it is.

You know, the bison industry cannot survive a Jack-in-the-Box or a Hudson Foods. Everybody in this room would just not eat bison any more if somebody dies from bison, God forbid. And there is uninspected product out there, and we live under that fear every day, that there is going to be an outbreak like that, and it's going to take our whole industry to our knees.

And it's hard to tell -- somebody mentioned earlier -- is the rabbit worth the chase, or however it was put. The cost benefit to me is, is the rabbit worth the chase? Boy, it is for all of us hundreds, and now thousands, of bison ranchers because this would take us out of business. We have to get that uninspected product out of the hands of consumers before it does damage that's going to be way beyond the amount of this cost that we're talking about here.

So that's my remarks on behalf of these 350 ranchers. I thank you. I hope you consider our position.

MR. BILLY: Hold up just a second. Are there any questions from the Committee?

MR. SEXHUS: Yes, ma'am?

MS. DONLEY: Do you do interstate shipments refuse your products, or is it primarily consumed in your state?

MR. SEXHUS: No. We are federally inspected, so we ship all over the United States. I think we ship into every state in the union, and we even ship to Europe because we happen to be EU approved, too.

MS. DONLEY: So is all of your product under voluntary -- is all bison under voluntary inspection now?

MR. SEXHUS: Yes, it is.

MS. DONLEY: So it's not uninspected product.

MR. SEXHUS: All of ours is under voluntary inspection, but bison does not have to be inspected.

MS. DONLEY: Right.

MR. SEXHUS: Some is under state inspection. Some is uninspected.

MS. DONLEY: Okay. But in your particular state you are all --

MR. SEXHUS: No. Just in our particular plant.

MS. DONLEY: Got you. Okay. Thank you.

MR. BILLY: Carol?

MS. FOREMAN: I have a question that I should know the answer to. I assume even though it's not under USDA inspection, it's subject to action if it's found to be adulterated, by FDA.

MR. BILLY: It's not wild game.

MS. FOREMAN: So the answer to my question is that we're not --

MR. BILLY: It's not so clear.

MS. FOREMAN: -- that adulterated bison meat might not be subject to anybody's seizure.

MR. BILLY: Well, if it didn't cross the state line, then it ties to the state. If it's in interstate commerce, that's an interesting question. I'm not sure where it would fall out. It's not under the Meat Act.

MS. FOREMAN: Well, I know.

MR. BILLY: So I don't think we could interpret that to be a poultry. It's a gray area. Thank you. I appreciate it.

Okay. The next speaker is Debra White, who is with the Food Marketing Institute, who would like to make a clarification in terms of the issue of species adulteration.

MR. DERFLER: No, wait. Bison is subject to the Food, Drug, and Cosmetic Act adulteration provisions. There is actually a case, a reported case, that went all the way up to the Supreme Court, Sodium Nitrite.

MR. BILLY: Okay. Thanks, Phil. Debra.

MS. WHITE: Yes. Debra White. I'm regulatory counsel for the for the Food Marketing Institute. One very quick clarification. One of the gentlemen at the table mentioned the "Dateline" program that ran a couple of weeks ago and mentioned that eight out of 10 of the samples had species adulteration. The number was actually eight out of

100 samples. I just wanted the record to reflect that. Thanks.

MR. BILLY: You're welcome. Anyone else? Okay.

MR. KAY: Yes I'm sorry I didn't sign up previously. I didn't get a chance.

MR. BILLY: That's all right. State your name and affiliation.

MR. KAY: Yeah. I'm Bret Kay with the National Consumers League, and I would like to give comments on behalf of the Safe Food Coalition, which is a coalition of public-health, consumer groups, and victims of food-borne illnesses.

And on behalf of the Safe Food Coalition I would like to talk -- microbial testing performance standards. I would like to request that FSIS and the USDA do require additional microbial testing in the Meat and Poultry HACCP and pathogen reduction program.

The latest food-poisoning outbreaks, specifically the listeria monocytogenese linked to the Sarah Lee hot dogs and other plants and the Luncheon Mates, which has caused 97 illnesses and 20 deaths so far, might have been avoided if the company has been required to test its fully cooked products for the harmful strain of listeria before the products were released to the public.

In the past few years USDA has modernized the meat

and poultry inspection system under the HACCP program, combining the performance and standards pathogen reduction sampling in the slaughter plants. Preliminary data released by FSIS has shown that the system has been effective in reducing salmonella rates for some meat and poultry products.

In addition, the government sampling for salmonella, the microbial testing for generic E. coli was also mandated, as you are aware.

The meat and poultry industries have most improved in those areas where the plants must meet measurable performance standards.

It is time to build upon the successes of these programs by strengthening the testing requirements and adding more public-health standards. I would feel that we need stronger standards to protect consumers from food-borne hazards and that so far USDA does have the toughest standards for listeria, a zero tolerance, which means that if it is found on meat and poultry products, they are subject to a recall.

While this USDA random searching for listeria has resulted in numerous recalls, which we commend certainly, contaminated meat and poultry products, the current outbreak demonstrates that random sampling simply doesn't identify all hazardous products.

And unlike slaughter plants, processing plants are not required to perform any microbial sampling to ensure the effectiveness of their HACCP systems. The Sarah Lee outbreak should provide the impetus to correct this serious deficiency in the HACCP and pathogen production program. Specifically, the Safe Food Coalition requests that all processing plants that produce hot dogs, cold cuts, luncheon meats, and other fully cooked, ready-to-eat meat or poultry products be required to test their products and their plants for listeria.

We feel that additional industry testing is not a substitute for testing by the government regulatory agencies, and we strongly support the continuation of the government sampling program for listeria. We certainly urge you to consider strengthening the program to include environmental sampling in plants and more end product, both at the plant and the retail outlets.

Second, we would urge that the Department add campylobacter testing to the HACCP monitoring program for poultry products. Campylobacter, as you know, is the number-one cause of bacterial food-borne illness, and it's present on the vast majority of poultry products. The baseline survey of turkeys, which represents, I guess, the most complete data that the government survey has done, has found that 90 percent of the turkeys tested in 1996-97 were

contaminated with campylobacter.

The baseline survey of broiler chickens conducted in 1994 and '95 found that 88 percent were contaminated with this bacterium. We realize that the data were collected before the new system before minimizing the hazards of meat and poultry started in the largest plants, and there is little evidence that campylobacter contamination has been reduced.

The best data available on campylobacter was from the tests conducted by Consumers Union on the 1,200 chickens and reported in the October 1998 issue of Consumer Reports magazine. The percentage of chickens contaminated with campylobacter actually seemed to increase between October 1997 and May and June of 1998, while the prevalence of the salmonella did, in fact, decline while it is premature to draw any firm conclusions from these data, it is clear that campylobacter must be carefully monitored to access the HACCP effectiveness.

In closing, I would like to just thank you for FSIS's leadership in food safety and working on this and promoting the pathogen reduction, but we urge that there be more of it done, especially for listeria and the campylobacter issue.

MR. BILLY: Thank you very much. Are there any questions or comments? Okay. We're going to finish a

little early, which is good. It will give you a chance to get some food and rest a little bit before you work hard this evening in terms of a lot of important issues.

Don't forget to give your suggestions on other issues to Mike or one of the staff people so that we can compile all of that for tomorrow. I'd like to thank the Committee very much. I'd like to thank all of you in the audience for your attention and participation. Thank you.

MR. MICCHELLI: I have one slight change to the agenda. Instead of meeting in the Monroe Room tonight, it will be in the Lincoln Room. That's the Resource Allocation Standing Subcommittee. It's in the Lincoln Room, not the Monroe Room. I will put a sign up there as well, so if you follow the agenda, you will end up in the wrong place. They are all on the third floor. Thank you.

(Whereupon, at 4:42 p.m., the hearing was adjourned, to be reconvened at 8:30 a.m. on May 6, 1999.)

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